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Change Notice: Any information related to Prostate-Specific Antigen (PSA) in the following guideline may have been revised in the American Urological Association's (AUA) *PSA Best Practice Statement: 2009 Update.* In the case of any discrepency in recommendations between guidelines pertaining to PSA, please refer to the AUA's *PSA Best Practice Statement: 2009 Update* for the latest AUA recommendation regarding PSA testing.

Erectile Dysfunction

Erectile Dysfunction Guideline Update Panel

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The Management of Erectile Dysfunction: An Update

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In July 2005, the U.S. Food and Drug Administration notified healthcare professionals of updated labeling for Cialis, Levitra and Viagra to reflect a small number of post-marketing reports of sudden vision loss, attributed to NAION (non arteritic ischemic optic neuropathy), a condition where blood flow is blocked to the optic nerve. FDA advises patients to stop taking these medicines and call a doctor or healthcare provider right away if they experience sudden or decreased vision loss in one or both eyes. At this time, it is not possible to determine whether these oral medicines for erectile dysfunction were the cause of the loss of eyesight or whether the problem is related to other factors such as high blood pressure or diabetes, or to a combination of these problems.

Chapter 1: Diagnosis and Treatment Guideline

Chapter 2: Methodology

Chapter 3: Detailed Outcomes Analyses of Treatments for Erectile Dysfunction

Chapter 1: AUA Guideline on the Management of Erectile Dysfunction: Diagnosis and Treatment Recommendations

Introduction

In 1996, the Erectile Dysfunction Clinical Guideline Panel published the *Report on the Treatment of Organic Erectile Dysfunction* (the 1996 *Report*), an evidence-based guideline for the diagnosis and treatment of erectile dysfunction (ED).[1] Since that time, impotence, more precisely termed "erectile dysfunction," has received increasing attention because of the availability of new treatments approved by the U.S. Food and Drug Administration (FDA). In addition, the overall quality of clinical research and the methods of measuring outcomes have improved substantially. The 1996 analysis was based mainly on the outcomes of clinical series. The randomized, controlled trial has now become the norm.

An Erectile Dysfunction Guideline Update Panel (the Panel) was appointed by the American Urological Association (AUA) Practice Guidelines Committee in the year 2000 to update the existing document. Using a consensus-based approach, the Panel concluded that (1) *informed patient decision making* should remain the standard; (2) no new evidence has suggested that the guideline statements on the diagnostic evaluation should be changed; (3) a psychologic overlay frequently exists in patients with ED; and (4) endocrine disorders are an important consideration in the etiology of ED. Although sex therapy and the diagnosis and treatment of endocrine disorders are important management issues, the Panel agreed that these issues were beyond the scope of the guideline and would, therefore, not be discussed.

The Panel's major focus was to use an evidence-based approach to develop a guideline for the ED treatment modalities that had become available in the United States after publication of the 1996 *Report*. Guideline statements from the 1996 *Report* on previously available therapeutic

modalities were either revised or brought forward unchanged depending on the existing evidence.

All guideline statements were graded according to the degree of flexibility in clinical application: standard, recommendation, or option, with standard being the least flexible and option being the most flexible (Table 1). Grading is based on two characteristics: knowledge of the health outcomes of the alternative intervention and preference for the intervention.

Table 1. Grades of Guideline Statements Based on Levels of Flexibility of Application

Grade	Knowledge of Health Outcomes of the Alternative Interventions	Preference for Intervention
Standard	Sufficiently well known to permit meaningful decisions	Virtual unanimity
Recommendation	Sufficiently well known to permit meaningful decisions	An appreciable but not unanimous majority agrees
Option	Not sufficiently well known to permit meaningful decisions	Unknown or equivocal

The Panel believed that the patient, with physician guidance, must make his own decision in selecting treatment. Outcome estimates derived from review and meta-analysis of evidence provide physicians and patients with scientifically based information to assist them in making appropriate treatment decisions. Thus, a second Panel objective was to determine whether or not there was sufficient evidence for outcomes (both benefits and risks) to be estimated.

Definitions

The National Institutes of Health (NIH) Consensus Development Conference on Impotence (December 7-9, 1992) defined impotence as "male erectile dysfunction, that is, the inability to achieve or maintain an erection sufficient for satisfactory sexual performance."[2] ED is the more

precise term, especially given the fact that sexual desire and the ability to have an orgasm and ejaculate may well be intact despite the inability to achieve or maintain an erection. The recommendations and findings of the Panel were based upon the management of an Index Patient that represents the most prevalent presentation of this disorder since management may vary in atypical patients. ***The Index Patient for this document is defined as a man with no evidence of hypogonadism or hyperprolactinemia who develops, after a well-established period of normal erectile function, ED that is primarily organic in nature.*** This definition is a slightly modified version of the definition used to develop the 1996 *Report.*

Methodology

The Panel's task was to prepare a guideline on therapies for ED that became available after the publication of the 1996 *Report* and to revise those portions that required updating so that patients and physicians could participate in a scientifically based, informed decision-making process. In addition to ED, the Panel elected to address three topics relevant to erection, Peyronie's disease, priapism, and premature ejaculation. Guidelines for priapism and premature ejaculation are currently available: http://www.auanet.org/guidelines/priapism.cfm; http://www.auanet.org/guidelines/pe.cfm.

In the year 2000, MEDLINE® searches of English-language references on human subjects were initiated for each of the four topics. Search strategies ranged from very general to very specific. Citations identified through subsequent targeted searches, such as those specifically focused on individual treatments, and through Panel member suggestions also were added to the database. The ED portion of the searches spanned the years from 1994, when the final literature search for the 1996 *Report* was completed, to February 2004. The Panel continued to scrutinize key references that were identified up until the peer-review process.

Panel chairmen reviewed each citation title and abstract. Papers that presented outcomes data resulting from the evaluation of ED therapies were winnowed from the other publications. Sufficient new evidence was available to update the recommendations for many of the treatments discussed in the 1996 *Report* on ED. The initial plan was to conduct a full review, data extraction, and meta-analysis of the FDA-approved oral agents and alprostadil intra-urethral suppositories. Because of data limitations, varying types of analyses were undertaken for the other treatment modalities.

Data from 112 articles selected by the chairmen were extracted and recorded on a data extraction form. The Panel determined that although there were many different outcome measures used in the studies, only a limited number would be considered adequate for this review: the International Index of Erectile Function (IIEF) (including the erectile function and intercourse satisfaction domains as well as questions 3 and 4 individually) (Appendix 1-A;[3,4]) and the specific measures "ability to have intercourse," “return to normal," and erection grade of 4 or 5 (on a five-point scale). The extracted data were entered into a database, and evidence tables were generated and reviewed by the Panel. Twenty-seven papers were rejected for lack of relevant data or inadequate quality. Of the accepted articles, nine reported the results of two or more trials that were extracted as separate studies. A detailed meta-analysis of study outcomes was attempted. Difficulties were encountered in developing outcome estimates for all therapies because of study inconsistencies in patient selection and outcome measures, the lack of sufficient data, and the reporting of adjusted results. Given these problems with the data, the Panel ultimately decided that meta-analysis was inappropriate.

The Panel performed focused reviews and analyses of the surgical therapies, implantable devices, and vascular surgery. Each topic was assigned to a Panel member for review and

development of evidence tables or reports. The review of implantable devices was restricted to the question of mechanical failure/replacement rates. The review of arterial vascular surgical therapy focused on an Index Patient which differed from the standard Index Patient defined for other treatments. A special review of herbal therapies was performed later in the guideline process since few citations on herbal therapies were initially extracted. The search for herbal therapies included non-English language journals with abstracts written in English. Of the articles on herbal therapies that were identified, only three were randomized controlled trials using objective outcome criteria. The sections on vacuum constriction devices and intracavernous vasoactive drug injection were not updated as no new evidence was found that materially affected the recommendations for these treatments. The Panel also decided against reviewing the data on testosterone as it was beyond the scope of the guideline, and on apomorphine, which was not approved for use in the United States.

As in the 1996 *Report*, the Panel generated guideline statements based on the strength of the evidence and the expected amount of variation in patient preferences for treatments. In some cases, guideline statements were supported solely by the Panel's expert opinion and are designated as such in the text. The Panel also outlined suggestions for future clinical research priorities.

This guideline was drafted, reviewed by the Panel and by 80 peer reviewers, and finally approved by the Practice Guidelines Committee and the Board of Directors of the AUA. A full description of the methodology is presented in Chapter 2.

Diagnostic Evaluation of Erectile Dysfunction

The Panel unanimously agreed that the present update should reflect current practices in the diagnostic evaluation of a new patient with ED. As in the 1996 *Report*, the discussion is based

solely on Panel opinion and is handled similarly herein. The Panel did not conduct a rigorous systematic review of the literature; therefore, the following discussion is not intended to be all-inclusive or limiting with regard to assessment of individual patients.

The typical initial evaluation of a man complaining of ED is conducted in person and includes sexual, medical, and psychosocial histories as well as laboratory tests thorough enough to identify comorbid conditions that may predispose the patient to ED and that may contraindicate certain therapies. History may reveal causes or comorbidities such as cardiovascular disease (including hypertension, atherosclerosis, or hyperlipidemia), diabetes mellitus, depression, and alcoholism. Related dysfunctions such as premature ejaculation, increased latency time associated with age, and psychosexual relationship problems may also be uncovered. Most importantly, a history can reveal specific contraindications for drug therapy. Additional risk factors include smoking, pelvic, perineal, or penile trauma or surgery, neurologic disease, endocrinopathy, obesity, pelvic radiation therapy, Peyronie's disease, and prescription or recreational drug use. Other critical elements are alterations of sexual desire, ejaculation, and orgasm, presence of genital pain, and lifestyle factors, such as sexual orientation, presence of spouse or partner, and quality of the relationship with the partner. Finally, a history of the partner's sexual function may be helpful. Attention is given to defining the problem, clearly distinguishing ED from complaints about ejaculation and/or orgasm, and establishing the chronology and severity of symptoms. An assessment of patient/partner needs and expectations of therapy is equally important.

A focused physical examination evaluating the abdomen, penis, testicles, secondary sexual characteristics and lower extremity pulses is usually performed. Established patients with a new complaint of ED typically are not re-examined. According to the AUA Prostate-specific Antigen

(PSA) Best Practice Policy on early detection of prostate cancer, both digital rectal examination of the prostate and serum PSA measurement should be offered annually in all men over 40 with an estimated life expectancy of more than 10 years.[5] Prostate-specific antigen measurement and rectal examination may assume additional significance when considering the use of testosterone in the management of male sexual dysfunctions. Additional testing, such as testosterone level measurement, vascular and/or neurological assessment, and monitoring of nocturnal erections, may be indicated in select patients.

Initial Management and Discussion of Treatment Options With Patients

Recommended Therapies and Patient Information

Standard: The management of erectile dysfunction begins with the identification of organic comorbidities and psychosexual dysfunctions; both should be appropriately treated or their care triaged. The currently available therapies that should be considered for the treatment of erectile dysfunction include the following: oral phosphodiesterase type 5 [PDE5] inhibitors, intra-urethral alprostadil, intracavernous vasoactive drug injection, vacuum constriction devices, and penile prosthesis implantation. These appropriate treatment options should be applied in a stepwise fashion with increasing invasiveness and risk balanced against the likelihood of efficacy.

[Based on review of data and Panel consensus.]

Currently employed medical interventions for the management of ED include oral therapies that target the penis through phosphodiesterase type 5 (PDE5) inhibition and intrapenile therapies (intra-urethral suppositories and intracavernous injections). The vacuum constriction device is a noninvasive mechanical device. Surgical therapies include implantation of prosthetic devices and vascular surgeries. Psychosexual therapy may be useful in combination with both

medical and surgical treatment for men with ED. For some patients, brief education, support, and reassurance may be sufficient to restore sexual function and for others, referral for more specialized and intensive counseling may be necessary.[6] Endocrine therapy for hypogonadism, hyperprolactinemia, and thyroid disorders is an appropriate intervention for patients with a definite endocrinopathy. The literature on the management of ED in patients with psychosexual etiology or endocrinopathies, though, was not examined by the Panel and will not be reviewed in this guideline. This guideline, except where otherwise noted, is directed at the management of the Index Patient defined earlier in the document.

Standard: The patient and, when possible, his partner should be informed of the relevant treatment options and their associated risks and benefits. The choice of treatment should be made jointly by the physician, patient, and partner, when possible, taking into consideration patient preferences and expectations and the experience and judgment of the physician.

[Based on Panel consensus.]

Erectile Dysfunction and Comorbidities

Modifying Risk Factors for Erectile Dysfunction

Erectile function is the result of a complex interplay between vascular, neurologic, hormonal, and psychologic factors. The attainment and maintenance of a firm erection requires good arterial inflow of blood as well as efficient reduction of venous outflow. Risk factors and disease processes that affect the function of the arterial or venous systems would therefore be expected to have a negative impact on erectile function. Since the risk of developing ED is increased in the presence of diabetes, heart disease, and hypertension, it is logical to conclude that optimal management of these diseases may prevent the development of ED.[7,8,9] It is also logical to

assume that lifestyle modifications to improve vascular function such as avoiding smoking, maintaining ideal body weight and engaging in regular exercise might either prevent or reverse ED, however, only minimal data exists today to support this supposition.[10,11]

Managing Erectile Dysfunction in the Presence of Cardiovascular Disease

Cardiovascular disease and ED may share a common etiology when endothelial dysfunction and atherosclerosis affect both coronary arteries and penile vasculature.[12] Consequently, patients with ED frequently have concurrent cardiovascular disease.[13] Treatment of ED in patients with cardiovascular disease is complicated by a small increase in the risk of myocardial infarction (MI) related to sexual activity in these patients independent of the method of treatment. Sexual activity increases physical exertion levels to 3 to 4 METS (1 MET is the amount of energy used at the resting state associated with oxygen consumption of approximately 3.5 mL/kg/min), and sympathetic activation during sexual activity may increase blood pressure and heart rate more than other types of exercise.[14] Together, these factors result in a 2.5-fold (95% CI, 1.7-3.7) greater relative risk of nonfatal MI following sexual activity in healthy men than during noncoital activities and a 2.9-fold (95% CI, 1.3-6.5) greater risk in men with a history of MI.[14] Even with this effect, however, the absolute risk of MI during and for 2 hours following sexual activity is extremely low — only 20 chances per million per hour in post-MI patients and even less in men without a history of MI.[15] The major risk factors associated with cardiovascular disease are age, hypertension, diabetes mellitus, obesity, smoking, dyslipidemia, and sedentary lifestyle. Patients with three or more of these risk factors[16] are considered to be at increased risk for MI during sexual activity.

Guidelines for managing ED in patients with cardiovascular disease developed by the Princeton Consensus Panel[14] recommend assigning patients to one of three risk levels (high,

intermediate, and low) based on their cardiovascular risk factors. High-risk patients are defined as those with unstable or refractory angina; uncontrolled hypertension; congestive heart failure (CHF; New York Heart Association class III, IV); MI or a cardiovascular accident within the previous 2 weeks; high-risk arrhythmias; hypertrophic obstructive and other cardiomyopathies; or moderate-to-severe valvular disease. The document states that patients at high risk should not receive treatment for sexual dysfunction until their cardiac condition has stabilized. Patients at low risk may be considered for all first-line therapies. The majority of patients treated for ED are in the low-risk category defined as those who have asymptomatic coronary artery disease and less than three risk factors for coronary artery disease (excluding gender); controlled hypertension; mild, stable angina; a successful coronary revascularization; uncomplicated past MI; mild valvular disease; or CHF (left ventricular dysfunction and/or New York Heart Association class I). Patients whose risk is indeterminate should undergo further evaluation by a cardiologist before receiving therapies for sexual dysfunction.

Treatment Guideline Statements

The nonsurgical therapies for ED considered for review by the Panel include the PDE5 inhibitors, sildenafil, tadalafil, and vardenafil; alprostadil intra-urethral suppositories; intracavernous injection with alprostadil, papaverine, or phentolamine or combinations; vacuum constriction devices; trazodone; and herbal therapies including yohimbine. Chapter 3 provides the results of the evidence-based, outcomes analyses of the noninvasive therapies to the extent that the outcomes evidence was available. The following practice guideline statements are specific to the nonsurgical therapies.

Phosphodiesterase Type 5 (PDE5) Inhibitors

Standard: Oral phosphodiesterase type 5 inhibitors, unless contraindicated, should be offered as a first-line of therapy for erectile dysfunction.

[Based on review of data and Panel consensus.]

Sildenafil, tadalafil, and vardenafil are potent, reversible, competitive inhibitors of PDE5. At this time, there is insufficient evidence to support the superiority of one agent over the others. While a comparison of the efficacy and side effects of the PDE5 inhibitors would be very useful for clinicians and patients, such a comparison cannot be done with the presently available data. At the time of our final literature search, studies directly comparing these drugs had not been published. Attempts at developing a comparative outcomes table based on meta-analysis also failed for two reasons. First, studies evaluating vardenafil and tadalafil excluded subjects who did not respond to sildenafil. This specific difference from the sildenafil clinical trials made comparisons invalid. Second, because many of the studies identified through the original literature search used mathematical models to compensate for patient variability in age, race, smoking status, and baseline function, e.g.,[17,18,19,20,21] these data could not be used for valid meta-analysis. Although authors of previously published evidence-based reviews[22,23] had obtained raw data directly from study investigators for meta-analytic purposes, the Panel believed that even if the raw data were obtained, useful comparisons still could not be made due to the incomparable patient populations.

Differences in pharmacokinetic and adverse event profiles do exist. Sildenafil and vardenafil have very similar pharmacokinetic profiles with a time to achieve maximum serum levels (T_{max}) of approximately 1 hour and a serum half-life of approximately 4 hours. In contrast, tadalafil has a T_{max} of approximately 2 hours and a half-life of approximately 18 hours. All three drugs are

metabolized by the liver so the dosage should be adjusted in those patients with altered hepatic function due to disease or medication, especially those that affect cytochrome P450. The side effect profiles of the three drugs are very similar. All three medications have side effects due to peripheral vasodilation such as facial flushing, nasal congestion, headache, and dyspepsia. Both sildenafil and vardenafil, but not tadalafil, have some cross-reactivity with PDE6 and thus may produce visual side effects. Tadalafil exhibits some cross-reactivity with PDE11, but there are no known side effects due to PDE11 inhibition at this time. Back pain has been reported in a limited number of patients, especially those taking tadalafil, and the pathophysiology of this adverse effect is unknown. A mild prolongation of the QT interval has been observed with vardenafil. The FDA-approved product labeling for vardenafil recommends that caution be used when prescribing vardenafil in patients with a known history of QT prolongation or in patients who are receiving agents that prolong the QT interval.

The management of men with ED is often complicated by the concomitant use of antihypertensive and/or lower urinary tract symptom (LUTS) pharmacotherapies. Studies investigating the epidemiology of and risk factors for ED have clearly identified hypertension as a risk for ED and have recently suggested a statistical relationship between ED and LUTS, independent of aging.[13,7,24] When considering PDE5 inhibitors for the management of ED, physicians should be aware that even healthy volunteers may experience mild transient systemic vasodilation; this effect may be aggravated by alpha-blocking therapies. All three medications interact to some degree with alpha blockers, a class of drugs used primarily for the treatment of LUTS in men and, less commonly, for hypertension (for Product Labeling see: http://www.fda.gov/cder/foi/label/1998/viagralabel2.pdf; http://www.fda.gov/cder/foi/label/2003/021368lbl.pdf;

http://www.fda.gov/cder/foi/label/2005/021400s004lbl.pdf). All dosages of vardenafil and tadalafil as well as sildenafil at the 50mg and 100 mg doses should be administered with caution in patients taking alpha blocker medications (see respective PI's for details).

Standard: Phosphodiesterase type 5 inhibitors are contraindicated in patients who are taking organic nitrates.

[Based on review of the Food and Drug Administration approved product labeling and Panel consensus.]

PDE5 inhibitors potentiate the hypotensive effects of organic nitrates and nitrites such as amyl nitrite,[12,25] and therefore their concomitant use is contraindicated (for Product Labeling see: http://www.fda.gov/cder/foi/label/1998/viagralabel2.pdf; http://www.fda.gov/cder/foi/label/2003/021368lbl.pdf; http://www.fda.gov/cder/foi/label/2005/021400s004lbl.pdf). Commonly prescribed nitrates are listed in Appendix 1-B. In an emergent setting (e.g., for presumed MI or ischemia), especially when clinicians are unfamiliar with a patient's drug history, careful questioning may aid in avoiding these combinations. Although a safe time interval between the use of nitrates and PDE5 inhibitors has not been definitively determined, a suggested time interval for nitrate administration during a medical emergency (under close medical supervision and patient monitoring) in patients who have received sildenafil is 24 hours[26] and for tadalafil is 48 hours[27] (http://www.fda.gov/cder/foi/label/2003/021368lbl.pdf). A suggested time interval has not been published for vardenafil, but additional blood pressure and heart rate changes were not detected when vardenafil was dosed 24 hours before nitrate administration (http://www.fda.gov/cder/foi/label/2003/021400lbl.pdf).

Recommendation: The monitoring of patients receiving continuing phosphodiesterase type 5 inhibitor therapy should include a periodic follow-up of efficacy, side effects, and any significant change in health status including medications.

[Based on Panel consensus.]

A patient's medical status and medication use change over time. Thus, it is important to follow-up with each patient to ascertain whether the medication is still effective and that their cardiovascular health has not changed significantly. Typically, this is done at the time of prescription renewal.

Recommendation: Prior to proceeding to other therapies, patients reporting failure of phosphodiesterase type 5 (PDE5) inhibitor therapy should be evaluated to determine whether the trial of PDE5 inhibition was adequate.

[Based on Panel consensus.]

PDE5 inhibitor therapy is not efficacious in all ED patients. However, failure to respond may be due to one or more potentially modifiable factors such as hormonal abnormalities, food or drug interactions, timing and frequency of dosing, lack of adequate sexual stimulation, heavy alcohol use, and the patient's relationship with his partner.[28,29,30] After re-education and counseling, which includes information on patient and partner expectations, proper drug administration, and titration to maximum dosing, evidence has shown that sildenafil therapy becomes successful in some men who were not previously responders.[28,29]

Recommendation: Patients who have failed a trial with phosphodiesterase type 5 (PDE5) inhibitor therapy should be informed of the benefits and risks of other therapies, including the use of a different PDE5 inhibitor, alprostadil intra-urethral suppositories, intracavernous drug injection, vacuum constriction devices, and penile prostheses.

[Based on Panel consensus.]

Once an adequate trial has been completed with one drug and all modifiable risk factors have been addressed, the patient may be treated with a different PDE5 inhibitor or proceed with other, more invasive therapies for ED. Currently, there are not sufficient data to counsel patients on the likelihood of success with a different PDE5 inhibitor if they failed an "adequate" trial with one drug. Still, there are data to support the very realistic chance that more invasive therapies will be successful.

Alprostadil Intra-urethral Suppositories

Standard: The initial trial dose of alprostadil intra-urethral suppositories should be administered under healthcare provider supervision due to the risk of syncope.

[Based on review of the Food and Drug Administration-approved product labeling and Panel consensus.]

Alprostadil, a synthetic vasodilator identical to PGE_1, has been formulated for transurethral delivery as a suppository for the treatment of ED. Despite the significantly greater efficacy of alprostadil intra-urethral suppositories in producing erections when compared to placebo in randomized controlled trials,[31] their use has produced less successful results in postmarketing studies.[32,33] Because hypotension has been reported to occur in approximately 3% of patients after the first dose,[31] it is recommended that the first dose be administered under supervision of a healthcare provider. The efficacy of alprostadil suppositories in combination with other treatment modalities recently has been evaluated. Studies assessing the combination of alprostadil suppositories with either a penile constriction device or oral PDE5 inhibitors have shown increased efficacy over alprostadil alone.[34,35]

Although not as effective, alprostadil intra-urethral suppositories are a less invasive treatment option than penile injection and may be considered for select patients such as men who are either not candidates for or have failed therapy with oral PDE5 inhibitors. The combination of intra-

urethral alprostadil suppositories with other pharmacotherapies or a penile constriction device holds some promise, but additional studies are needed to assess dosing, efficacy, and safety.

Intracavernous Vasoactive Drug Injection Therapy

Intracavernous injection therapy is the most effective nonsurgical treatment for ED; however, it is invasive and has the highest potential for priapism among ED treatments. Alprostadil (PGE_1), papaverine, and phentolamine are the most widely used vasoactive drugs for injection therapy. As monotherapy, alprostadil is the most popular vasoactive agent; however, combination therapy with the other vasoactive drugs (bimix and trimix) can either increase efficacy or reduce side effects. The advantage of monotherapy with either papaverine or alprostadil is that they are readily available at most pharmacies whereas bimix and trimix are only available from pharmacies that offer compounding services. Physician preference guides the initial choice of therapy. Final choice is based on efficacy, side effects, and cost.

Because the Panel believed that the new body of evidence on the efficacy and safety of intracavernous therapy would not substantially change the outcome estimates of the *1996 Report,* the literature on this topic was not reviewed. The co-administration of oral PDE5 inhibitors and intracavernous injection therapy has not been adequately evaluated at this time.

Standard: The initial trial dose of intracavernous injection therapy should be administered under healthcare provider supervision.

[Based on Panel consensus.]

A healthcare provider should be present to instruct patients on the proper technique of intracavernous drug administration, to determine an effective dose, and to monitor patients for side effects, especially prolonged erection. Education of the patient is particularly important to minimize frustration and to decrease the probability of untoward side effects. Effective training

and periodic follow-up will likely decrease the occurrence of improper injection and treatment failure. When appropriate, the patient should be able to adjust within specific bounds the total dose of medication injected to match the specific situation for which it is used. Vasoactive drug injection therapy should not be used more than once in a 24-hour period.

Standard: Physicians who prescribe intracavernous injection therapy should (1) inform patients of the potential occurrence of prolonged erections, (2) have a plan for the urgent treatment of prolonged erections and (3) inform the patient of the plan.

(See AUA guideline on priapism: http://www.auanet.org/guidelines/priapism.cfm)

[Based on Panel consensus.]

Priapism is defined as a prolonged erection lasting greater than four hours. It is important that patients be advised that erections that last 4 hours after an intracavernous injection be reported promptly to the healthcare professional who prescribed intracavernous injection therapy or his surrogate. Priapism should be treated as rapidly as possible to avoid adverse sequelae including corporal tissue damage. The prolonged erections and priapism associated with injection therapy are often readily reversed with nonsurgical measures when intervention occurs early. Thus, it is imperative for the physician to both have a plan in place to manage this complication and to communicate to the patient the seriousness of this complication and the need for rapid intervention.

Vacuum Constriction Devices

Recommendation: Only vacuum constriction devices containing a vacuum limiter should be used whether purchased over-the-counter or procured with a prescription.

[Based on Panel consensus.]

Vacuum constriction devices are often effective, low-cost treatment options for select patients with ED. These devices are available without a prescription. Vacuum limiters avoid injury to the penis by preventing extremely high negative pressures. Because no new evidence on efficacy or safety was found on review of the literature, the Panel decided not to include a detailed discussion of the data in this guideline update. Low patient acceptability limits the application or use of this therapy.

Treatment Modalities With Limited Data

Trazodone

Recommendation: The use of trazodone in the treatment of erectile dysfunction is not recommended.

[Based on review of the data and Panel consensus.]

Trazodone hydrochloride is an oral antidepressant agent with anxiolytic and sedative/hypnotic effects. The mechanism by which trazodone exerts its effect on erectile function may be related to its antagonism of alpha$_2$-adrenergic receptors. In penile vascular and corporal smooth muscle, this may relax the tissues and enhance arterial inflow, producing an erection.[36] Results of a limited number of randomized, placebo-controlled, clinical trials of trazodone evaluating its efficacy and safety in the treatment of ED have been published. Although trazodone appeared to have greater efficacy than placebo in some trials, differences in pooled results were not statistically significant.[36]

Testosterone

Recommendation: Testosterone therapy is not indicated for the treatment of erectile dysfunction in the patient with a normal serum testosterone level.

[Based on Panel consensus.]

Outcome measures used in studies to date are insufficient to evaluate testosterone's efficacy in the treatment of ED in men who have normal serum testosterone levels.[37]

Yohimbine

Recommendation: Yohimbine is not recommended for the treatment of erectile dysfunction.

[Based on review of the data and Panel consensus.]

Yohimbine is an indole alkaloid with a chemical similarity to reserpine. It frequently has been prescribed as an oral treatment for ED prior to the advent of the PDE5 inhibitors. Among its properties is a selective inhibition of alpha$_2$-adrenergic receptors. In humans, yohimbine can cause elevations of blood pressure and heart rate, increased motor activity, irritability, and tremor. [38]

The drug was grandfathered by the FDA in 1976, bypassing controlled trials to demonstrate efficacy in treating ED. Although yohimbine increases sexual motivation in rats, [39] this enhanced libido effect has not been confirmed in humans. There has only been one small study[40] published to date that used acceptable efficacy outcome measures; thus, conclusions about efficacy and safety cannot be made.

Other Herbal Therapies

Recommendation: Herbal therapies are not recommended for the treatment of erectile dysfunction.

[Based on review of the data and Panel consensus.]

Despite the fact that herbal therapies are used extensively worldwide for the treatment of ED,[41] the mechanisms of action, effectiveness, and safety of these agents have not been documented in repeated, randomized clinical trials with independent data monitoring. The literature review of herbal therapies, excluding yohimbine, found three randomized controlled

trials. In only one of these studies did results show benefits that reached statistical significance. The results of this one small randomized controlled trial[42] have suggested that Korean red ginseng may be an effective treatment for ED. Clinical efficacy of Korean red ginseng remains to be validated by larger trials. Based on this insufficiency of data, the Panel cannot make recommendations for the use of herbal therapies.

The lack of regulation for the manufacture and distribution of herbal therapies has permitted disparities in the raw materials used, in variations in manufacturing procedures, and in poor identification of the potentially active agent. Product potency and quality both within and between brands are inconsistent.[43] In addition, one study found deliberate contamination of some herbal products with therapeutic levels of PDE5 inhibitors[44] (U.S. Food and Drug Administration: www.fda.gov/bbs/topics/Answers /2003 /ANS01235.html).

Topical Therapies

Alternative routes of administration of vasoactive drugs for the treatment of ED that are less threatening than injection therapy have been explored. Agents that are approved by the FDA for other indications or other routes of administration, including alprostadil, organic nitrates, minoxidil, papaverine, and yohimbine, have been tested via topical administration to the glans penis or penile shaft. Although these therapies are not currently approved by the FDA, they may be available through compounding pharmacies. A specific literature search was not conducted on this topic due to the lack of both FDA approval and widespread application. Based upon the limited studies available and expert consensus, there does not appear to be significant efficacy beyond that observed with intraurethral administration of alprostadil.

Surgical Therapies

Penile Prosthesis Implantation

Standard: The patient considering prosthesis implantation and, when possible, his partner should be informed of the following: types of prostheses available; possibility and consequences of infection and erosion, mechanical failure, and resulting reoperation; differences from the normal flaccid and erect penis, including penile shortening; and potential reduction of the effectiveness of other therapies if the device is subsequently removed.

[Based on Panel consensus.]

Penile prostheses can be divided into two general types: malleable or noninflatable and inflatable. Noninflatable devices are also commonly referred to as semirigid rod prostheses. The Panel discussion on penile prosthetic implantation was limited to inflatable penile prostheses because recent design changes have improved mechanical reliability. Inflatable penile prostheses provide the recipient with closer to normal flaccidity and erection, but in addition to mechanical failure, they are associated with complications such as pump displacement and auto-inflation. Although design modifications have lowered the 5-year mechanical failure rate of inflatable prostheses to the range of 6% to 16% depending on the type of device, limited information concerning the failure rate beyond 5 years is available.

Infection is a devastating complication of any prosthetic surgery. Currently available inflatable prostheses have been modified in an attempt to reduce the risk of infection. One available device has an antibiotic coating consisting of rifampin and minocycline (American Medical Systems, Minnetonka, MN) and the other has a hydrophilic coating (Mentor Corporation, Santa Barbara, CA). A recently published industry-sponsored study[45] demonstrates a statistically significant reduction of infection rate using the antibiotic-coated device from

1.61% to 0.68% at 180 days. A similar study has been published evaluating the efficacy of a hydrophilic-coated device that is immersed in an antibiotic pre-operatively. At 1-year follow-up, the infection rate for non-coated prosthesis was 2.07% compared to 1.06% for the same prosthesis with hydrophilic coating.[46] Additional data are needed to confirm these initial findings.

Another design modification recently introduced by the Mentor Corporation was the addition of a lockout valve to prevent autoinflation. A study comparing the occurrence of autoinflation in 160 men implanted with the modified Mentor Alpha-1 prosthesis with that in 339 historical controls implanted with the Mentor Alpha-1 prosthesis with no lockout valve found rates of 1.3% and 11%, respectively.[47]

Noninflatable penile prostheses remain legitimate alternatives to inflatable devices with the advantages of lower cost, better mechanical reliability despite the design improvements of the inflatable devices, and ease of use by the patient. Patient education about inflation and deflation techniques is not necessary.

The preliminary literature review found that only evidence on failure rates for inflatables might have yielded changes in the outcome estimates or recommendations of the 1996 *Report.* Hence, these were the only outcomes that were reviewed and updated by the Panel. However, on a more detailed review of the relevant articles, the Panel decided to re-affirm the content of the 1996 guideline. The Panel stresses, though, that it is important for the patient to understand that prosthesis implantation likely will reduce the efficacy of subsequent therapies should they be needed.

Questions often arise concerning the safety of performing magnetic resonance imaging (MRI) in patients with a penile prosthesis. MRI may be utilized to evaluate the status of a penile

implant or may be performed for other indications in a patient who has a penile prosthesis.[48] MRI is contraindicated in patients with a ferromagnetic implant because of the risks associated with movement, dislodgement, induction of electrical current, excessive heating and/or misinterpretation artifacts. An ex-vivo MRI study of nine different types of penile prosthetics found that only the OmniPhase (Dacomed, Minneapolis, MN) device had movement/deflection in an MRI at a field strength of 1.5 Tesla. No movement/deflections were noted with the 3-piece inflatable devices, and MRI has been safely used in this patient population.[49] The OmniPhase prosthesis is no longer marketed. Similarly, the Duraphase prosthesis, previously manufactured by Endocare, is not MRI compatible. Currently in the United States, however, no manufacturer produces penile implants that have MRI contraindications.

Standard: Prosthetic surgery should not be performed in the presence of systemic, cutaneous, or urinary tract infection.

[Based on Panel consensus.]

Preoperative preparation of the implant recipient is directed primarily at reducing the risk of infection. The recipient should be free of urinary tract infection, and he should have no infections elsewhere in the body that might result in bacterial seeding during the healing phase. There should be no dermatitis, wounds, or other cutaneous lesions in the operative area. While better control of diabetes mellitus may reduce risk of infection, the literature fails to demonstrate a consistent benefit.[50,51]

Standard: Antibiotics providing Gram-negative and Gram-positive coverage should be administered preoperatively.

[Based on Panel consensus.]

Based on studies with other surgical procedures and implantable devices, broad-spectrum antibiotics providing both Gram-negative and Gram-positive coverage are administered prophylactically to promote implant survival.[52,53,54] Frequently used agents include aminoglycosides, vancomycin, cephalosporins, and fluoroquinolones. These antibiotics are administered before the incision is made and usually are continued for 24 to 48 hours postoperatively.

The operative area is shaved immediately prior to surgery. If shaving is done earlier, small cuts in the skin may become infected. After the patient is shaved, a thorough skin preparation is performed. Penile prosthesis implantation is usually performed using general, spinal, or epidural anesthesia but has been performed under local anesthesia.[55,56]

Vascular Surgery

Penile Venous Reconstructive Surgery

Recommendation: Surgeries performed with the intent to limit the venous outflow of the penis are not recommended.

[Based on review of the data and Panel consensus.]

Since the publication of the 1992 NIH Consensus Statement and subsequently the 1996 *Report,* there has been no new substantial evidence to support a routine surgical approach in the management of veno-occlusive ED. While the hemodynamics of veno-occlusive ED are recognized, it is difficult to distinguish functional abnormalities (smooth muscle dysfunction) from anatomical defects (tunical abnormality). It also is difficult to determine what percentage of ED is due to veno-occlusive ED independent of general arterial hypofunction, how to accurately diagnose this condition, how often arterial insufficiency coexists, and whether or not there exists a subset of patients with this disorder who would benefit from surgical intervention. Currently, there is no evidence from randomized controlled trials documenting a standardized

approach to diagnosis or the efficacy of treatment for veno-occlusive ED. This lack of new evidence suggests that no changes in the previous guideline statement are warranted.

Penile Arterial Reconstructive Surgery

Surgical intervention for the management of vasculogenic ED has been performed by a variety of procedures for the past 30 years. The efficacy of this surgery remains unproven and controversial, largely because the selection criteria, outcome measurements, and microsurgical techniques have not been objective or standardized. One of the goals of the present Panel was to determine whether there is any objective evidence of efficacy for arterial reconstructive surgery in a subgroup of patients that is likely to respond. The Panel assumed that the patient who is likely to benefit from arterial reconstructive surgery is an otherwise healthy man 55 years old or younger with recently acquired ED due to focal arterial occlusive disease. Therefore, a new Index Patient (Arterial Occlusive Disease Index Patient) definition was created specifically to evaluate the efficacy of the treatment of arterial occlusive disease. The reason for including the criteria of recently acquired onset and the absence of other risk factors such as smoking, diabetes, or others in this definition was to eliminate patients with either diffuse vascular disease or cavernous myopathy due to chronic ischemia.

Initially, 31 papers on penile vascular surgery were identified. After careful review, 27 papers were rejected because they failed to meet the criteria for the Arterial Occlusive Disease Index Patient. A majority of the rejected papers also were excluded for lack of objective outcome criteria. The detailed process of extracting relevant data from the remaining four papers was completed.

While the 31 reports on penile arterial surgery contain hundreds of patients, the four studies that were extracted had only 50 patients that met the criteria. Of these 50, 42 patients had an anastomosis of the inferior epigastric artery to the dorsal penile artery (dorsal artery

arterialization) and eight had an anastomosis of the inferior epigastric artery to the dorsal penile vein (dorsal vein arterialization). Satisfactory outcome, measured by objective criteria, occurred in 36% to 91% of patients.

The Panel consensus is that a patient population of 50 is too small to determine whether arterial reconstructive surgery is efficacious or not. To demonstrate that penile arterial reconstructive surgery is efficacious, a large study of hundreds of patients who meet the demographic, selection, surgical, and outcome criteria of the Arterial Occlusive Disease Index Patient is needed. Such a study should focus on men who meet the criteria listed above, who have failed medical therapy, and who are followed with objective measures of sexual function. In the absence of a control arm for a surgical study, an objective method to document the patency of the vascular anastomosis would help to confirm that a positive functional outcome is due to a physiological response. The following option applies to the Arterial Occlusive Disease Index Patient.

Option: Arterial reconstructive surgery is a treatment option only in healthy individuals with recently acquired erectile dysfunction secondary to a focal arterial occlusion and in the absence of any evidence of generalized vascular disease.

[Based on review of the data and Panel consensus.]

Future Research

Many of the future research needs outlined in the 1996 *Report* have been addressed in the past 8 years. The development of the PDE5 inhibitors has answered the requirement for an oral therapy that has broad-based usage with minimal side effects. While new and better designed studies, i.e., prospective, randomized controlled trials, have allowed fresh insight into the

treatment of ED, drawbacks of the methodologies employed have been identified. Despite these advances, however, many of the issues raised still remain controversial while other knowledge gaps have arisen.

In order to develop new and more effective agents for treatment, research is needed in the areas of pathophysiology, natural history, and epidemiology. Specifically, the Panel recognizes that data concerning the role of hypogonadism in ED are seriously lacking, as are the proportion of men with ED and the prevalence of bothersomeness in men and their partners before and after treatment. The prevalence and severity of ED in men with specific risk factors, such as those with hypertension, hyperlipidemia, diabetes, and smoking, should be identified and compared.

Although diagnostic testing was not evaluated in the guideline, after review of the published clinical trials, the Panel noted that new, clinically applicable instruments are needed to diagnose ED and to assess treatment satisfaction. In addition, a clinically applicable test of neurological function of the corpora cavernosa should be developed. The best measure of venous-occlusive dysfunction must also be determined. Since the advent of oral pharmacotherapy, there has been a shift in the evaluation paradigm for ED away from the objective (evidence-based) toward the subjective (historical) that has impeded our appreciation of the clinical impact of veno-occlusive dysfunction. Evidence-based criteria are needed in order to categorize patients to arterial or venous etiologies.

The therapeutic armamentarium has changed considerably since 1996, and the PDE5 inhibitors are enjoying widespread use. However, many questions still remain unanswered regarding these and other therapeutic modalities:

- Outcomes of oral PDE5 inhibitors should be characterized/stratified based on serum testosterone levels.

- Additional research also is needed to characterize, in greater detail, the adverse events associated with the use of ED therapies such as their duration.
- Effect of lifestyle modification on PDE5 inhibitor use should be clarified.
- The cohort of patients who should not be sexually active with or without PDE5 inhibitors should be identified.
- PDE11 is present in the anterior pituitary and the testes. While studies, to date, have demonstrated no effect on spermatogenesis when PDE5 inhibitors are administered daily for 6 months in healthy individuals, further assessment of the effect of PDE5 inhibitors that cross react with PDE11 in patients with abnormal spermatogenesis is needed.
- The applicability of PDE5 inhibitors after radical prostatectomy needs to be characterized.
- Whether vasoactive intracavernous therapy will cause improvement in spontaneous erectile function needs to be clarified.
- The role of testosterone therapy in men with sexual dysfunction with low, borderline normal, and normal testosterone levels should be better defined.
- Additional randomized controlled trials of various herbal therapies are needed.
- Additional prospective patient-partner satisfaction studies are needed using standardized questionnaires both pre- and post-penile prostheses implantation.
- The role of prophylactic antibiotics in penile prostheses implantation and the use of impregnated prostheses needs to be studied further.
- The efficacy and safety of combining pharmacotherapies and/or mechanical therapies such as oral and intrapenile vasoconstrictive therapies, PDE5 inhibitors and prostheses, or vacuum constriction and vasoconstriction devices should be explored.

- Additional research also is needed to evaluate the efficacy and safety of arterial reconstruction in the treatment of ED.
- No randomized controlled trial to date has addressed the particular efficacy of drugs in the management of veno-occlusive ED or defined those patients thought to have veno-occlusive dysfunction who would benefit from surgical application.
- Cost-effectiveness analyses of the fixed and unfixed costs involved with the various ED treatment modalities need to be undertaken.

Despite the increasing number of properly planned and executed randomized controlled clinical trials in the literature, extraction of data for comparison and meta-analysis remains a challenge. Drawbacks of the methodologies employed have been identified. The Panel now recognizes a need for standardized inclusion and exclusion criteria, as well as outcome measures to be incorporated in future study designs:

- Patients enrolled in these studies have varied in their disease severity and duration, etiology, success with other treatments, and in-office success with therapy. If outcomes are not stratified by patient characteristics, both study and guideline results are biased. A crossover design also may compensate for variation in patient characteristics. While statistically adjusting results can be a useful way to overcome patient differences, reporting results stratified by those characteristics can be more useful for later patient/physician decision making.
- Although the IIEF provides a uniform measure, not all studies use the IIEF and many of those that do report only limited and variable subsets of the IIEF. Many studies still use other measures as well. A standardized measure of patient-partner satisfaction beyond

the IIEF could be developed, for example, in the case of penile prosthesis implantation or in general an instrument to measure sexual desire.

The Panel noted that future research in penile prosthesis implantation should always express survival using Kaplan-Meier methods and include data on the numbers of patients censored.

- Data presentation that facilitates meta-analysis:

  Measures of variance (standard error, standard deviation, confidence interval) are needed to perform meta-analysis on continuous or discrete outcome measures. Change from baseline, mean change, and/or percentage change are frequently the most meaningful outcome measures particularly when patients vary with regard to baseline values. In addition, measures of variance of change and percentage of change are needed to meta-analyze change data.

  While presentation of results adjusted for patient variables compensates for patient differences, meta-analysis is possible only if adjustments are identical. Because investigators do not report details of the adjustment process, raw data should be made available.

  When previously reported study outcomes are regrouped or reanalyzed in a subsequent publication, the investigator should indicate such so that patients will not be counted more than once in a meta-analysis.

Because direct comparisons of the therapies via meta-analyses are not possible with the available data, comparative trials still are required. Trial design should use comparable doses and not use titration-to-response, which can be biased by the available doses. If data presentation

among studies is compatible, one-on-one comparisons for all agents may not be required to produce valid conclusions.

Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

RAPID COMMUNICATION

ELSEVIER

THE INTERNATIONAL INDEX OF ERECTILE FUNCTION (IIEF): A MULTIDIMENSIONAL SCALE FOR ASSESSMENT OF ERECTILE DYSFUNCTION

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ABSTRACT

Objectives. To develop a brief, reliable, self-administered measure of erectile function that is cross-culturally valid and psychometrically sound, with the sensitivity and specificity for detecting treatment-related changes in patients with erectile dysfunction.

Methods. Relevant domains of sexual function across various cultures were identified via a literature search of existing questionnaires and interviews of male patients with erectile dysfunction and of their partners. An initial questionnaire was administered to patients with erectile dysfunction, with results reviewed by an international panel of experts. Following linguistic validation in 10 languages, the final 15-item questionnaire, the International Index of Erectile Function (IIEF), was examined for sensitivity, specificity, reliability (internal consistency and test-retest repeatability), and construct (concurrent, convergent, and discriminant) validity.

Results. A principal components analysis identified five factors (that is, erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction) with eigenvalues greater than 1.0. A high degree of internal consistency was observed for each of the five domains and for the total scale (Cronbach's alpha values of 0.73 and higher and 0.91 and higher, respectively) in the populations studied. Test-retest repeatability correlation coefficients for the five domain scores were highly significant. The IIEF demonstrated adequate construct validity, and all five domains showed a high degree of sensitivity and specificity to the effects of treatment. Significant (P values = 0.0001) changes between baseline and post-treatment scores were observed across all five domains in the treatment responder cohort, but not in the treatment nonresponder cohort.

Conclusions. The IIEF addresses the relevant domains of male sexual function (that is, erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction), is psychometrically sound, and has been linguistically validated in 10 languages. This questionnaire is readily self-administered in research or clinical settings. The IIEF demonstrates the sensitivity and specificity for detecting treatment-related changes in patients with erectile dysfunction. UROLOGY **49:** 822–830, 1997.

Erectile dysfunction (ED), defined by a National Institutes of Health (NIH) Consensus Development Conference as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance,[1] is estimated to affect as many as 30 million men in the United States.[2] The problem is strongly age-related, with an approximately twofold to threefold increase in the prevalence of moderate-to-severe ED between the ages of 40 and 70 years.[2] A variety of medical, psychologic, and lifestyle factors have been implicated in the etiology of ED,[2–4] which impacts negatively on self-esteem, quality of life, and interpersonal relationships.[1]

Although laboratory-based diagnostic procedures are available, it has been proposed that sexual function is best assessed in a naturalistic setting with patient self-report techniques.[5,6] For this purpose, multidimensional instruments are more

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Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

sensitive than unidimensional scales in the evaluation of treatment outcomes, and they are more psychometrically valid.[7] Multidimensional scales also provide greater potential for use in a clinical setting. Self-report methods are preferable to patient interview techniques, particularly in multicenter, multinational clinical trials.

Existing self-report measures of male sexual function[8–11] have several limitations, including excessive length or complexity, unacceptable patient burden, an overly narrow or restrictive focus, and inadequate psychometric, cultural, or linguistic validation. None of the current measures has been demonstrated to have adequate discriminant validity or to provide sufficient sensitivity in evaluating treatment outcomes in multinational clinical trials. Additionally, factor analytic methods were not used in the development of existing measures. Despite these limitations, self-report measures provide essential data on male sexual function in both research and clinical settings.[5] A strong recommendation of the NIH Consensus Conference was to develop better and more reliable methods for assessing the symptoms of ED and relevant treatment outcomes.[1]

The objective of the present research was to develop a brief and reliable measure of erectile function that is culturally, linguistically, and psychometrically valid. State-of-the-art methods for questionnaire development were used, and a multidimensional measure was designed to provide sensitive and specific outcome assessments in clinical trials of ED. Finally, the goal was to develop a self-administered questionnaire that would be suitable for use by clinicians and researchers, one that would be minimally burdensome to patients.

METHODS

Phase 1: Item Selection

Using multiple sources, relevant domains of male sexual function were identified across various cultures. A comprehensive review of the literature was conducted, and existing questionnaire instruments were evaluated. Detailed interviews of male patients with ED (n = 37) and their partners (n = 7) were also conducted in five countries. In this phase, four dimensions of male sexual function were identified: erectile function, orgasmic function, sexual desire, and sexual satisfaction. In a phase II trial of 351 patients with ED, an initial version of the questionnaire was administered and found to have a high degree of internal consistency among items (Cronbach's alpha statistic[12] greater than 0.85) and excellent treatment sensitivity ($P < 0.01$).[13] An exploratory factor analysis was performed that indicated a robust factor structure.[13,14] The results were reviewed by an international panel of experts who made recommendations for item modification and the development of additional items.

Phase 2: Cultural and Linguistic Evaluation

Pilot testing of the instrument was conducted in 14 men with ED in the United Kingdom. All patients completed the International Index of Erectile Function (IIEF) questionnaire in less than 15 minutes and reported little or no difficulty in comprehending the items. Linguistic validation of the instrument was conducted in 10 languages (Danish, Dutch, English [American, Australian, and British], Finnish, French, German, Italian, Norwegian, Spanish, and Swedish)* in 12 countries by the MAPI Research Institute in Lyon, France. This process included forward and back translations of the items and comprehensive testing of the final item pool. International harmonization techniques were used to ensure cross-cultural equivalence of the items in the targeted languages.

Phase 3: Reliability, Construct Validity, and Treatment Responsiveness

The final 15-item questionnaire (see Appendix) was administered in a large-scale clinical trial of patients with ED (study A), a comparison group of functional, age-matched volunteers (study B), and a clinical validation study that included both patients with ED and normal volunteers (study C). The designs of the studies and subject characteristics are summarized in Table I. Each study protocol was approved by the institutional review board at the participating site. All participants in the studies gave written informed consent. Men aged 18 years or older with a clinical diagnosis of ED of broad-spectrum etiology and of at least 6 months' duration (studies A and C) or normal volunteers (studies B and C) were eligible for enrollment. Patients with penile anatomic defects, uncontrolled major medical illnesses or psychologic disorders, or known drug or alcohol dependence were excluded from the studies.

Study A. This study consisted of a 2 to 4-week run-in phase, followed by a 12-week, double-blind, placebo-controlled phase in which 111 patients with ED of broad-spectrum etiology were randomized to receive either placebo or 25 mg (one capsule) of sildenafil (VIAGRA; Pfizer Inc.). Sildenafil is an oral medication that is being evaluated for the treatment of ED.[15,16] The placebo or sildenafil dose could be increased to 50 mg (two capsules) and then to 100 mg (four capsules) if a patient's response was suboptimal. The IIEF was self-administered at the screening visit (week −4 or −2), at the end of the run-in phase (week 0), and at the end of 2, 4, 8, and 12 weeks of double-blind treatment. A global efficacy question ("Did the treatment improve your erections?") was asked at the end of the double-blind treatment phase. The sensitivity, specificity, and reliability (internal consistency and test-retest repeatability) of the 15-item questionnaire were determined as follows. Each patient was designated as a "responder" or "nonresponder," based on his response to the end-of-treatment global efficacy question. Within each cohort, the mean and median baseline-to-end point changes in response values for each question were calculated. The sensitivity of the IIEF was assessed by evaluating the clinical relevance and statistical significance of the changes in the responder cohort. Specificity was assessed in the same manner in the nonresponder cohort. Internal consistency was evaluated by calculating Cronbach's alpha statistic on the item domains and the total scale.[12]

Study B. This study assessed the response to the IIEF questionnaire in 109 male volunteers (controls) without any history of male ED. These volunteers were age-matched to the patients randomized in study A (Table I). The IIEF was self-administered, with the results in these controls compared with those obtained in men with ED in study A using be-

** Additional validation studies of other languages (for example, Arabic, Chinese, Mandarin, and Portuguese, among others) in Asia and Latin America are ongoing.*

Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

TABLE I. ***Study designs and baseline characteristics of individuals enrolled in validation studies***

Study Design	Study A (Patients with ED)	Study B (Controls)	Study C	
			Patients with ED	Controls
Treatments	Sildenafil (25, 50, or 100 mg) or placebo	None	None	
Duration of study	12 weeks	1 day	4 weeks	
Timing of IIEF self-administration	Week −4 or −2, 0, 2, 4, 8, and 12	Day 1	Week 0 and 4	
Other relevant assessments	Global efficacy question: final visit		Clinical interview: Week 0 and 4 Locke-Wallace Scale: Week 0 Marlowe-Crowne Scale: Week 0	
Patient characteristics				
n	111	109	37	21
Mean age, yr (range)	56 (29–89)	55 (29–76)	53 (29–71)	58 (37–76)
Mean duration of ED, yr (range)	4.61 (1–37)	—	5.9 (1–18)	—
Primary etiology*				
Organic	21%	—	14%	—
Psychogenic	40%	—	49%	—
Mixed	37%	—	38%	—
Unknown	3%	—	0%	—

KEY: ED = erectile dysfunction; IIEF = International Index of Erectile Function.
** Percentages do not total 100 due to rounding.*

tween-groups discriminant analysis (analysis of covariance controlling for age) and post hoc comparison of group differences on individual items.

Study C. This 4-week study evaluated the construct validity and test-retest repeatability of the IIEF in 37 patients with male ED and in 21 age-matched controls (Table I). The IIEF was self-administered at week 0 and week 4. In this study, blinded clinical interviews of patients were conducted at week 0 to evaluate the convergent validity of the measure (that is, concordance with an independent method of assessment). In addition, patients completed measures of marital satisfaction (Locke-Wallace scale[17]) and social desirability (Marlowe-Crowne scale[18]) to assess divergent validity (that is, separateness from overlapping or related constructs) at week 0. Test-retest reliability of the total and individual item scores of the IIEF were assessed by calculating the Pearson product-moment correlation coefficient[19] for each group (patients and controls). Internal consistency was evaluated using the Kuder-Richardson formula. Discriminant validity was assessed using repeated-measures analysis of variance, with subject group as the between-groups variable, time (week 0 and week 4) as the repeated-measures factor, and study measure as the outcome variable.

RESULTS

Factor Analysis and Domain Scoring

A principal components analysis (with varimax rotation) was performed to investigate the factor structure of the final 15-item questionnaire (see Appendix). Five factors with eigenvalues† greater than 1.0 were identified (Table II). Final item selection for each factor was based on a combination of statistical and clinical considerations.[20] Based on results of the confirmatory factor analysis, together with clinical interviews and expert panel consultation, the responses to individual items of the questionnaire were assigned to five separate domains of sexual function: (1) erectile function, (2) orgasmic function, (3) sexual desire, (4) intercourse satisfaction, and (5) overall satisfaction. Domain scores were computed by summing the scores for individual items in each domain. The system of domain scoring and resulting interdomain correlations are presented in Table III.

Scale Reliability

Two separate aspects of scale reliability were evaluated, namely, internal consistency and test-retest repeatability. Internal consistency (Cronbach's alpha) was computed separately for the five domains and for all items combined in each of the three test samples. Responses in the erectile and orgasmic function domains were highly consistent, with alpha values greater than 0.90 (Table IV). A satisfactory degree of consistency also was observed for items in the other domains (alpha values greater than 0.70) and for the total scale (alpha values greater than 0.90) in each of the test samples.

Test-retest repeatability was assessed in study C by computing correlations between the domain scores and total scale scores at baseline and week

† *Eigenvalue is a statistical measure of the relative explanatory power of individual factors in a factor analysis.*

TABLE II. ***Principal components analysis with varimax rotation of 15 questions of International Index of Erectile Function: factor loadings****

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
1. Erection frequency	**0.77**	0.03	0.31	0.17	−0.05
2. Erection firmness	**0.92**	0.12	0.20	0.08	0.04
3. Penetration ability	**0.89**	0.16	0.15	0.06	0.14
4. Maintenance frequency	**0.82**	0.26	0.13	−0.02	0.22
5. Maintenance ability	**0.68**	0.39	0.09	0.07	0.41
6. Intercourse frequency	0.10	−0.02	0.11	0.34	**0.79**
7. Intercourse satisfaction	0.61	0.28	0.31	−0.13	**0.48**
8. Intercourse enjoyment	0.53	0.39	0.18	0.01	**0.53**
9. Ejaculation frequency	0.26	0.20	**0.89**	0.10	0.13
10. Orgasm frequency	0.23	0.25	**0.87**	0.18	0.12
11. Desire frequency	0.06	−0.01	0.15	**0.88**	0.16
12. Desire level	0.04	0.26	0.07	**0.87**	0.08
13. Overall satisfaction	0.29	**0.76**	0.28	0.15	−0.01
14. Relationship satisfaction	0.18	**0.83**	0.21	0.14	0.13
15. Erection confidence	**0.65**	0.53	0.01	0.01	0.07
Eigenvalue	4.72	2.22	2.03	1.81	1.47

* *Items with the highest loadings within each factor are boldfaced.*

4 visits. As shown in Table IV, test-retest repeatability was relatively high for the erectile function ($r = 0.84$) and intercourse satisfaction ($r = 0.81$) domains, as well as for the total scale scores ($r = 0.82$). Moderately high correlations were observed for the other domains (r values of 0.64 to 0.77).

Discriminant Validity

Discriminant validity, or the ability of the IIEF scale to discriminate reliably between clinical and nonclinical populations, was assessed by comparing the responses from patients with ED with those from controls in two studies. As shown in Table V, highly significant differences were observed between the the patients with ED and age-matched controls for most domains. Differences between domain scores between these two groups were greatest for the erectile function domain ($P \leq 0.0001$), followed by intercourse satisfaction ($P \leq 0.001$) and overall satisfaction ($P \leq 0.001$). The least degree of difference between patients and controls was seen for the sexual desire domain, with results failing to reach statistical significance in study C. This result is not surprising because all patients were recruited for a clinical trial of ED and were excluded for concomitant sexual disorders, such as hypoactive sexual desire.

Convergent and Divergent Validity

To demonstrate construct validity of a new measure, it is important to show that scale scores are positively correlated with independent measures of the same or similar domains (convergent validity). Conversely, there should be minimal association with measures that do not directly assess the domains in question (divergent validity). In study C, domain scores were compared with blinded, independent clinician ratings of sexual functioning and with scales that measure marital adjustment (Locke-Wallace) and social desirability (Marlowe-Crowne). Significant positive correlations were observed between independent clinician ratings and subscale scores for all five domains (Table VI). In contrast, none of the correlations between domain scores and measures of marital adjustment or social desirability reached statistical significance.

Sensitivity and Specificity

To evaluate the sensitivity of the IIEF, a comparison was made between mean pretreatment and post-treatment domain scores of patients who were self-rated as treatment responders in study A. Specificity was assessed by comparing the pretreatment and post-treatment domain scores in patients rated as nonresponders in the same study. Patients were defined as responders or nonresponders based on their response to the end-of-treatment global efficacy question. All five domains of the IIEF demonstrated a high degree of sensitivity and specificity to the effects of treatment (Table VII). Although the magnitude of change was greatest for the erectile function domain, significant changes were observed across all five domains in the treatment responder group. The lowest magnitude of change was noted for the sexual desire domain. In contrast, none of the comparisons in the treatment nonresponder group approached significance (P values of 0.11 to 0.79).

Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

TABLE III. *IIEF domain scoring and intercorrelations*

Domain	Items	Domain Scoring: Score Range	Minimum Score	Maximum Score
EF	1, 2, 3, 4, 5, 15	0 (or 1)–5	1	30
OF	9, 10	0–5	0	10
SD	11, 12	1–5	2	10
IS	6, 7, 8	0–5	0	15
OS	13, 14	1–5	2	10

	Domain Intercorrelations: EF	OF	SD	IS	OS
EF	1.00				
OF	0.55	1.00			
SD	0.30	0.39	1.00		
IS	0.76	0.47	0.35	1.00	
OS	0.60	0.53	0.37	0.53	1.00

Key: EF = erectile function; IIEF = International Index of Erectile Function; IS = intercourse satisfaction; OF = orgasmic function; OS = overall satisfaction; SD = sexual desire.

COMMENT

A 15-item, self-administered questionnaire scale was developed for the assessment of erectile function. This instrument (the IIEF) was developed in several stages, including initial pretesting with selected patient groups and expert panel consultants, followed by an intensive linguistic validation process. Based on a principal components analysis with varimax rotation, five factors or response domains were identified: (1) erectile function, (2) orgasmic function, (3) sexual desire, (4) intercourse satisfaction, and (5) overall satisfaction. The highest degree of positive correlation was between erectile function and intercourse satisfaction (r = 0.76), with two items (items 7 and 8) showing positive loadings on both factors. This is not surprising because a primary outcome of ED for most patients is the inability to achieve satisfactory sexual intercourse.[1]

Psychometric validation of the final instrument was addressed in three major areas: (1) test reliability, (2) construct validity, and (3) treatment responsiveness. Adequate performance in each of these areas should be demonstrated before a new scale is accepted for general research or clinical use.[21–23] For the IIEF, analyses were performed in each of these areas in two separate samples of patients with ED and age-matched controls. Overall, the IIEF was shown to have strong internal consistency, measured in terms of both the total scale and individual domain scores, and adequate test-retest repeatability. Although some variation in the degree of internal consistency was noted between samples, all of the values obtained were greater than 0.70 and more than half were greater than 0.90. Test-retest repeatability correlation coefficients ranged from 0.64 to 0.84, and all were highly significant.

Construct validity (that is, whether the instrument actually measures what it was designed to assess) is normally accomplished by experimental testing of a priori questions or hypotheses, such as: (1) Will the test reliably differentiate between clinical patients and age-matched controls? (discriminant validity); (2) Can a positive association be shown with alternative measures of the same construct or domains? (convergent validity); and (3) Are the results influenced by related, but conceptually independent, variables? (divergent validity). In the present study, adequate construct validity was established in each of these three areas. Discriminant validity was demonstrated by a comparison of baseline scores between patients and controls. In the larger sample (studies A and B), between-group differences were highly significant (P values ≤ 0.01) for all five domains. In the smaller sample (study C), differences between groups were significant (P values ≤ 0.01) for all domains, with the exception of sexual desire (P = 0.72). In this study, patients and controls were closely matched on sexual desire, perhaps reflecting a high level of sexual motivation in patients seeking treatment in a clinical trial of ED. Tests of convergent and divergent validity were similarly confirmatory. First, a significant positive association was shown with independent clinician ratings for each of the major response domains. As expected, the highest correlation was observed for the domain of erectile function (r = 0.73). This association might have been even higher, except for the fact that clinician interview ratings took

Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

TABLE IV. *IIEF domain characteristics: reliability*

	Internal Consistency*			Test-Retest Repeatability†
	Study A	Study B	Study C	Study C
All items	0.91	0.96	0.91	0.82
Erectile function	0.92	0.96	0.93	0.84
Orgasmic function	0.92	0.99	0.93	0.64
Sexual desire	0.77	0.82	0.91	0.71
Intercourse satisfaction	0.73	0.87	0.88	0.81
Overall satisfaction	0.74	0.87	0.86	0.77

Key: IIEF = International Index of Erectile Function.
** Cronbach's alpha.*
† Pearson product-moment correlation coefficient.

TABLE V. *IIEF domain characteristics: discriminant validity*

	Study A and Study B			Study C		
	Patients	Controls		Patients	Controls	
Domain	Mean ± SD	Mean ± SD	*P* Value*	Mean ± SD	Mean ± SD	*P* Value*
Erectile function	10.7 ± 6.5	25.8 ± 7.6	≤0.0001	13.5 ± 8.1	26.9 ± 5.3	≤0.0001
Orgasmic function	5.3 ± 3.2	8.8 ± 2.9	≤0.001	7.3 ± 3.5	9.5 ± 2.2	≤0.01
Sexual desire	6.3 ± 1.9	7.0 ± 1.8	≤0.01	7.2 ± 1.5	7.0 ± 1.9	0.72
Intercourse satisfaction	5.5 ± 3.0	10.6 ± 3.9	≤0.001	6.0 ± 4.5	10.8 ± 4.8	≤0.0003
Overall satisfaction	4.4 ± 2.3	8.6 ± 1.7	≤0.001	5.5 ± 2.4	9.0 ± 1.6	≤0.0001

Key: IIEF = International Index of Erectile Function.
** P values assessed using repeat-measures, between-groups analysis of variance method.*

TABLE VI. *IIEF domain characteristics: convergent and divergent validity*

	Validation Measure (Study C)					
	Clinical Interview		Marital Adjustment (Locke-Wallace)		Social Desirability (Marlowe-Crowne)	
Domain	Pearson *r*	*P* Value	Pearson *r*	*P* Value	Pearson *r*	*P* Value
Erectile function	0.75	<0.0001	−0.08	0.62	−0.07	0.63
Orgasmic function	0.51	<0.001	−0.21	0.23	−0.13	0.45
Sexual desire	0.61	<0.0001	0.16	0.36	0.24	0.15
Intercourse satisfaction	0.45	<0.005	−0.05	0.89	−0.02	0.78
Overall satisfaction	0.63	<0.001	0.31	0.07	0.17	0.31

Key: IIEF = International Index of Erectile Function.

into account both past history and current sexual performance ratings, whereas the questionnaire assessed only the latter. Second, measures of social desirability and marital adjustment were not significantly correlated with any IIEF domain scores. This suggests that IIEF scores are highly independent of social desirability and marital adjustment influences.

A final area of test validation concerns treatment responsiveness, or the sensitivity and specificity of the instrument, which was evaluated by comparing the change between baseline and end point scores in treatment responders and nonresponders (study A). A high degree of sensitivity and specificity was demonstrated for each of the domains of the IIEF. For the responder group, highly significant changes between baseline and end point scores were observed in each domain. The mean change in scores was highest for the erectile function domain and lowest for the sexual desire domain. These results are not surprising because the study drug, sildenafil, is an agent with a peripheral site of action and proerectile effects.[15,16] Treatment response specificity was demonstrated by the relative lack of change between baseline and end point scores in the nonresponder group. Taken together, these findings indicate that the IIEF is a highly sensitive and specific instrument for de-

TABLE VII. *IIEF domain characteristics: sensitivity and specificity (study A)*

Domain	n	Mean Change*	SEM	*t* Statistic	*P* Value
Treatment responders					
Erectile function	50	12.80	1.2	10.6	≤0.0001
Orgasmic function	50	3.44	0.5	6.4	≤0.0001
Sexual desire	49	1.12	0.3	4.5	≤0.0001
Intercourse satisfaction	48	4.63	0.6	8.4	≤0.0001
Overall satisfaction	49	3.47	0.4	8.4	≤0.0001
Treatment nonresponders					
Erectile function	42	0.88	0.8	1.07	0.67
Orgasmic function	42	0.70	0.6	1.25	0.36
Sexual desire	42	−0.52	0.3	−1.55	0.32
Intercourse satisfaction	42	0.10	0.4	0.27	0.79
Overall satisfaction	42	0.57	0.3	1.65	0.11

KEY: *IIEF = International Index of Erectile Function.*
* *Mean difference between pretreatment score and post-treatment scores.*

tecting changes in erectile function in response to treatment.

Other advantages of this new scale are worth noting. First, all of the major aspects of the NIH definition are addressed by individual items in the erectile function domain. A patient's ability to achieve or maintain an erection sufficient for intercourse are addressed separately (items 3 and 4, respectively), as is the degree of satisfaction achieved (item 7). The IIEF also addresses the ability to achieve erections independent of intercourse (items 1 and 2). Furthermore, the psychologic dimension of erectile confidence is assessed (item 15), which has been shown to be related to treatment outcome in other contexts.[24] Finally, the brevity and ease of comprehension of the measure provide important practical advantages. For example, the IIEF may be ideally suited for use in studies assessing the prevalence of ED in different countries.

Limitations of the instrument are the sole focus on current sexual functioning, the superficial assessment of nonerectile components of sexual response, and the limited assessment of the partner relationship. Although the IIEF provides a broad measure of sexual function across five domains, it should be viewed as an adjunct to, rather than a substitute for, a detailed sexual history. The IIEF was designed as an assessment measure for ED, and it is not intended for use as a primary measure of premature ejaculation or hypoactive sexual desire. Finally, the IIEF has not been evaluated in long-term follow-up studies or in the patient subpopulations that were excluded from the clinical trials described, such as those with anatomic deformities (for example, Peyronie's disease). Thus, further studies would be needed to determine whether this instrument is valid in these instances.

CONCLUSIONS

The IIEF, a 15-item questionnaire, has been developed and validated as a brief and reliable self-administered scale for assessing erectile function. This instrument is psychometrically sound and easy to administer in research and clinical settings. The IIEF currently is available in 10 languages for use in multinational clinical trials, and it demonstrates adequate sensitivity and specificity for detecting treatment-related changes in erectile function in patients with ED.

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Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

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APPENDIX

Individual items of International Index of Erectile Function Questionnaire and response options (US version)

Question*	Response Options
Q1: How often were you able to get an erection during sexual activity?	0 = No sexual activity 1 = Almost never/never
Q2: When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
Q3: When you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?	0 = Did not attempt intercourse 1 = Almost never/never
Q4: During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
Q5: During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	0 = Did not attempt intercourse 1 = Extremely difficult 2 = Very difficult 3 = Difficult 4 = Slightly difficult 5 = Not difficult
Q6: How many times have you attempted sexual intercourse?	0 = No attempts 1 = One to two attempts 2 = Three to four attempts 3 = Five to six attempts 4 = Seven to ten attempts 5 = Eleven+ attempts
Q7: When you attempted sexual intercourse, how often was it satisfactory for you?	0 = Did not attempt intercourse 1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always

Appendix 1-A: The International Index of Erectile Dysfunction (IIEF) Validation Study (Rosen 1997)

Q8: How much have you enjoyed sexual intercourse?	0 = No intercourse 1 = No enjoyment 2 = Not very enjoyable 3 = Fairly enjoyable 4 = Highly enjoyable 5 = Very highly enjoyable
Q9: When you had sexual stimulation or intercourse, how often did you ejaculate? **Q10**: When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?	0 = No sexual stimulation/intercourse 1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
Q11: How often have you felt sexual desire?	1 = Almost never/never 2 = A few times (much less than half the time) 3 = Sometimes (about half the time) 4 = Most times (much more than half the time) 5 = Almost always/always
Q12: How would you rate your level of sexual desire?	1 = Very low/none at all 2 = Low 3 = Moderate 4 = High 5 = Very high
Q13: How satisfied have you been with your overall sex life? **Q14**: How satisfied have you been with your sexual relationship with your partner?	1 = Very dissatisfied 2 = Moderately dissatisfied 3 = About equally satisfied and dissatisfied 4 = Moderately satisfied 5 = Very satisfied
Q15: How do you rate your confidence that you could get and keep an erection?	1 = Very low 2 = Low 3 = Moderate 4 = High 5 = Very high

* *All questions are preceded by the phrase "Over the past 4 weeks."*

1-B Commonly Used Nitrates/Nitrites

Commonly Used Nitrates/Nitrites

Generic Name	Trade Name*
Amyl nitrite	Various
Erythrityl tetranitrate	Cardilate
Isosorbide dinitrate	Dilatrate & Dilatrate SR Iso-Bid Iso-D Isotrate Isordil Onset-5 Sorbide-10 Sorbitrate & Sorbitrate SR
Isosorbide mononitrate	Imdur Ismo Monoket
Nitroglycerine	Deponit (transdermal) Minitran Transdermal System Nitrek Nitro-Bid Nitrocin (sustained release) Nitrocine Nitrocot Nitroderm (transdermal) Nitrodisc (transdermal) Nitro-Dur Nitrogard Nitroglyn Nitrolingual Spray Nitrol Ointment (Appli-Kit) Nitrong Nitropar Nitrostat Nitro-Time Transderm-Nitro Transdermal NTG Tridil
Pentaerythritol tetranitrate	Cartrax Duotrate Miltrate & Miltrate 10 Papavatral Pennate Penta Cap #1 Pentrate Pentritol Peritrate Tetrate-30
Sodium nitroprusside	Nitropress

*This list is not all inclusive.

Chapter 2: Methodology

Introduction

As mentioned in Chapter 1, this guideline is an update of the 1996 *Report on the Treatment of Organic Erectile Dysfunction*, originally developed by the Erectile Dysfunction Clinical Guideline Panel (Appendix 2-A), in which the primary goal was to develop outcomes tables comparing the available treatments for erectile dysfunction (ED) in a defined Index Patient. All available literature on the diagnosis and treatment of ED was reviewed and where possible meta-analyzed to develop outcomes tables. Guideline statements for each treatment were based on these tables.

The initial purpose of revisiting the 1996 *Report* was to revise the outcomes tables, particularly to include treatments that were not available when the *1996 Report* was in development. However, as will be explained below, the actual result of this update is somewhat different. First, the new 2004 Panel (Appendix 2-B) elected to address three other topics related to erection- Peyronie's disease, priapism, and premature ejaculation - in addition to ED. Second, the Panel determined that not all treatments for ED required updating. Third, upon review of the evidence, it was determined that generation the of outcomes tables was not possible with the available evidence, although the development of guideline statements was feasible based on the extant evidence.

Search, Categorization of Results, and Designation of Topics for Review

The 1996 *Report* was based on data from 1882 citations. In the year 2000, several MEDLINE® searches were initiated to support an update of the 1996 *Report* and guidelines on the new topics, with search strategies that ranged from very general to very specific. In all cases,

searches were restricted to English language references on human subjects. The initial general search topics included impotence, Peyronie's disease, priapism, and premature ejaculation. Citations found through subsequent targeted searches, such as those specifically focused on individual treatments, also were added to the database. Final searches included articles published through early 2004. When all searches were completed, a total of 7151 citations had been included in the database.

After each search was performed, the Panel chairmen reviewed the captured citations and their abstracts for relevance. Citations were considered relevant for further consideration when selected by at least one chairman. If both chairmen believed a citation was irrelevant, further review was not conducted. Except for some of these targeted searches that were reviewed by specific Panel members, the results of each subsequent search were reviewed by the chairmen.

The initial winnowing process yielded 1021 articles that were subjected to a preliminary review and extraction. Nine residents and fellows from the Cleveland Clinic and the Johns Hopkins Medical Center were trained as data extractors. The purpose of this initial extraction process was to determine the nature and potential utility of the citations and not to actually extract the data. The required information was recorded on an article review form and entered into a database. Initially, all preliminary extractions were double-reviewed. American Urological Association (AUA) staff and consultants also performed quality spot checks. Statistics on the data compiled for the four proposed topics were prepared for Panel review.

The Panel met to decide how to proceed with each of the four topics. After reviewing the database, the Panel determined that there was insufficient evidence to support a useful guideline on Peyronie's disease. While there was little evidence of sufficient quality for addressing the management of priapism, the Panel believed that there was a clear need for a review of the

available literature. The guideline for priapism was undertaken and released in 2003. The guideline for the pharmacologic treatment of premature ejaculation released a year later included a full review of the literature but did not include a meta-analysis due to the lack of meta-analyzable data.

The Panel determined that there was sufficient new evidence to update the recommendations for the majority of treatments discussed in the 1996 *Report* on ED. The initial plan was to conduct a full review, data extraction, and meta-analysis of the U.S. Food and Drug Administration (FDA)-approved oral agents and for intra-urethral prostaglandins. The Panel also decided to perform focused reviews of specific surgical therapies: implantable devices and vascular bypass and repair. The review of implantable devices was restricted to the question of mechanical failure/replacement rates. The review of arterial vascular surgical therapy focused on an Index Patient who differed from the standard Index Patient defined for other treatments. A special review of herbal therapies was performed later in the guideline process since few citations on herbal therapies were initially extracted. The sections on vacuum constriction devices and intracavernous vasoactive drug injection were not updated as no new evidence was found that materially affected the recommendations for these treatments. The Panel also decided against reviewing the data on testosterone as it was beyond the scope of the guideline, and on apomorphine since it was not approved for use in the United States.

Methods of Evidence Review and Analysis

FDA-approved Oral Agents and Intra-urethral Alprostadil Suppositories

Methods of Review

Evidence concerning FDA-approved oral agents and intra-urethral alprostadil suppositories was extracted from the 112 articles deemed relevant using a predesigned data extraction form

(Appendix 2-C) by both newly trained and previously employed residents and fellows from the Cleveland Clinic. Double extraction was performed initially followed by quality checks on approximately 10% of the remaining extractions. Twenty-seven papers were rejected for lack of relevant data or inadequate quality. Of the accepted articles (Appendices 2-D and 2-E), nine reported the results of two or more trials that were extracted as separate studies. Data were entered into a Microsoft Access® database that was used to produce evidence tables for review by the Panel. For meta-analysis of suitable data, the FAST*PRO® meta-analysis program was used. Most of these analyses were later discarded as fatally flawed. (The results of these analyses are detailed below.) The Panel determined that although there were many different outcome measures used in the studies, only a limited number would be considered adequate for this review. These outcomes included the International Index of Erectile Function **(**IIEF) erectile function and intercourse satisfaction domains and questions 3 and 4 (Appendix 1-A). The measures "ability to have intercourse" and "return to normal" also were used in a number of studies as well as an "erection grade" of 4 or 5 on a five-point scale for intra-urethral alprostadil suppositories. Adverse event data were categorized under major headings (Appendix 2-F) designated by the Panel after a review of the extracted data.

Limitations of the Data

For the FDA-approved therapies, analysis of efficacy outcomes data was complicated by problems with the extracted data. Perhaps the most noteworthy problem was the lack of standardization of outcome measures for ED. In the extraction database, 345 different outcome measures (excluding IIEF measures) had been recorded. Some of these differences were solely a function of terminology, so the Panel attempted to group the measures that were essentially similar. This exercise resulted in 52 grouped measures with 86 measures considered ungroupable. In addition to these outcomes, the 15 questions of the IIEF are divided into five

domains and an overall score. Although the erectile function domain and questions 3 and 4 were the most commonly reported, some studies reported other domains and combinations of questions.

In addition to wide variability of outcome measures used in the trials, the following limitations were identified:

1. Although the ideal outcome measure would have been the change in a measure of erectile function from pretreatment values, very few studies reported a measure of variance (standard deviation, standard error, or confidence intervals) of change data, which is a necessary component for a meta-analysis.

2. Many of the sildenafil studies were published as abstracts only; the Panel elected not to include abstracts because the data presented were incomplete.

3. Studies evaluating the efficacy and safety of vardenafil and tadalafil excluded men who did not respond to sildenafil. Thus, comparing results with those of the sildenafil studies was impossible as patients were not preselected using the same criteria.

4. Because many of the studies identified through the original literature search used mathematical models to compensate for patient variability in age, race, smoking status, and baseline function (e.g., [17,18,19,20,21]), these data could not be used for valid meta-analysis. Although authors of previously published evidence-based reviews[22,23] had obtained raw data directly from study investigators for meta-analytic purposes, the Panel believed that even if the raw data were obtained, useful comparisons still could not be made due to the incomparable patient populations.

5. Many of the sildenafil publications appeared to reanalyze data that had been published previously, but these redundancies were difficult to confirm.

6. No direct comparisons of phosphodiesterase type 5 (PDE5) inhibitors had been published during the data acquisition phase of the guideline process.

7. Studies evaluating the use of alprostadil intra-urethral suppositories used a preselection design. Only patients who had a positive response to therapy in the office setting were randomized for the "at home" trials.

8. Only one controlled trial evaluating the use of yohimbine used outcome measures accepted by the Panel.

9. The majority of publications did not include adverse event data. Thus, the Panel elected to review the adverse event data reported in the product labeling, which included much larger patient populations than those extracted from the published data.

10. An extant meta-analysis failed to show efficacy for trazodone[36] and no additional studies showing positive results were found. As a result, the Panel elected not to perform an analysis of this agent.

Other Treatments

Separate analyses were conducted for surgical and herbal therapies. Rather than using external data extractors, each topic was reviewed by one or more Panel members who extracted the data from articles directly into evidence tables. These tables were reviewed by the entire Panel prior to the generation of recommendations.

Guideline Generation, Writing, and Review

After the evidence was extracted and tabulated, the Panel met several times, both face-to-face and by teleconference, to review the data. Based on the data review and subsequent identification of the data limitations detailed above, meta-analysis was not deemed to be appropriate except for the intra-urethral alprostadil suppositories. Even meta-analyzed intra-urethral therapy data were

not considered applicable for inclusion in an outcomes table because the patient inclusion criteria biased the results. Thus, the Panel decided to present the results separately for each treatment. The Panel also determined that for the PDE5 inhibitors, the previously published meta-analyses and data from the FDA-approved product labeling could be used as an alternative to detailed reanalysis of the unadjusted data.

The Panel developed guideline statements based on the limited data. As in the previous guideline, the present guideline statements were graded with respect to the degree of flexibility in application. Although the terminology has changed slightly, the current three levels are essentially the same as in the previous guideline. A "standard" has the least flexibility as a treatment policy, a "recommendation" has significantly more flexibility, and an "option" is even more flexible. These three levels of flexibility are defined as follows:

1. **Standard**: A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well-known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. **Recommendation**: A guideline statement is a recommendation if (1) the health outcomes of the alternative intervention are sufficiently well-known to permit meaningful decisions and (2) an appreciable but not unanimous majority agrees on which intervention is preferred.
3. **Option**: A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well-known to permit meaningful decisions or (2) preferences are unknown or equivocal.

In addition to the flexibility ratings, all guideline statements now include an explanation of the evidentiary basis for the statement. Thus, if a guideline statement is based on expert opinion, it will so state.

This text of the report was developed as a group process with Panel members and consultants writing various sections. The editor was responsible for unifying the sections and incorporating the changes into the multiple drafts. The Panel reviewed each draft and the proposed changes. Several drafts of the guideline were distributed before final Panel approval.

After Panel approval, a draft underwent peer review by 80 individuals, including members of the Practice Guidelines Committee, the AUA Board of Directors, and external experts in the management of ED. Peer reviewers' comments were entered into a database that the Panel subsequently met to review. The Guideline was modified where the Panel deemed necessary in response to these comments. A final version of the report was generated and the Panel voted for approval. This version was then forwarded in turn for approval of the Practice Guidelines Committee and the AUA Board of Directors.

This Guideline is published on the AUA website and the first chapter is reprinted in the *Journal of Urology*. The recommendations are published annually in a pocket guide. The guideline is expected to be updated when the Practice Guidelines Committee determines that additional treatments or evidence about existing treatments warrants a revision.

Appendix 2-A: Erectile Dysfunction Clinical Guideline Panel Members and Consultants

(1996)

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Appendix 2-C: Data Extraction Form

American Urological Association, Inc.
ED Guidelines Panel

Reference # _____

Erectile Dysfunction

COVER Sheets – Medical Therapies

Citation:

Extractor: _____ **Date**: _____

____ **ACCEPTED** and Extracted

____ **REJECTED** and not Extracted
(If REJECTED, please complete sections 1, 4, 6, 7)

Article REJECTED due to (check all that apply):
___ No data
___ Not dealing with ED
___ Treatments not available or not current
___ Doesn't deal with treatment:
___ Basic Science ___ Epidemiology ___ Other
___ Other reason for exclusion:
specify: _____
___ Does not meet extraction criteria

1. Study Design: _____

2. Study: Total Patients enrolled: _____ **(N)**
Location: _____ (City, State, Country)
___ Check if multi-center/location

3. Group Definitions:
(use Group Nos. >= 90 for Placebo or Control arms)

Group No.	Patients (N)	Definition

4. Comments:

American Urological Association, Inc. Reference # _____
ED Guidelines Panel

Erectile Dysfunction

GROUPS and TREATMENTS – Medical Therapies

Group Number: _____
(use >= 90 for Placebo or Control)

1. Group Characteristics

Number of Patients in this Group: _____ (**N**)

Age (years): Min _____ Max _____ Mean _____ Median _____

Duration of ED (years): Min _____ Max _____ Mean _____ Median _____

Other patient characteristics that distinguish this group (_____)

Type of ED (this group only):	✔	%	x
Organic			
Psychogenic, define:			
Mixed			
Other, define:			

Related Conditions (this group only):	✔	%	x
Diabetes			
Hypogonadism			
Hyperprolactinemia			
Immunosuppressed			
Neurogenic			
Post prostatectomy			
Non nerve-sparing prostatectomy			
Unilateral nerve-sparing prostatectomy			
Bilateral nerve-sparing prostatectomy			
Post radiation therapy			
Post-priapism			
Peyronie's (secondary to)			
Spinal cord injury			
Trauma			
Vascular (arterial)			
Vascular (venous)			
Vascular (mixed or unspecified)			
Other, define:			
Other, define:			

2. Treatments

		Dosing Info				
	Titrate	**Min**	**Max**	**Fixed**	**%**	**x**
Sildenafil	☐					
Vardenafil	☐					
Tadalafil (Cialis)	☐					
Intra-urethral Prostaglandin (Muse)	☐					
Trazadone	☐					
Yohimbine	☐					
Placebo	☐					
Other, specify:	☐					

American Urological Association, Inc. Reference # _____
ED Guidelines Panel

Erectile Dysfunction

GROUPS and TREATMENTS – Medical Therapies

Comments:

American Urological Association, Inc.
ED Guidelines Panel

Reference # _____

Erectile Dysfunction

ADVERSE EVENTS – Medical Therapies

Group Number: _____
(use >= 90 for Placebo or Control)

3. Adverse Events

Overall number of patients for whom A/E's are reported: _____

Adverse Events	%	x	y
Bruising			
Cardiac			
Dermatitis			
Device mechanical failure			
Dizziness			
Edema			
Erosion			
Fibrosis			
Flu Syndrome			
Flushing			
GI symptoms			
Glans hyperemia			
Headache			
Hematoma			
Hypotension/syncope			
Impeded ejaculation			
Ischemic tissue loss			
Infection			
Myalgia			
Pain - Back			
Pain - Urethral			
Pain – Other or unspecified _____			
Painful Erection			
Penile curvature			
Penile edema			
Petechiae			
Priapism			
Rhinitis			
Sensory loss			
Urethral Bleeding			
Urethritis			
Visual disturbance/Abnormal Vision			

Other Side effects: _____	%	x	y
Other Side effects: _____			
Other Side effects: _____			
Other Side effects: _____			

Comments:

American Urological Association, Inc. Reference # _____
ED Guidelines Panel

Erectile Dysfunction

OUTCOMES and Other Efficacy Measures – Medical Therapies

Group Number: _____
(use >= 90 for Placebo or Control)

4. Outcomes

Time Point: _____ (weeks)

Dropped Out / Lost to Follow-up

	%	x	y
Lost to Follow-up			
Discontinuation of Therapy due to treatment related adverse events			
due to insufficient response			
for other reasons			

Overall number of patients for whom outcomes are reported: _____

	%	x	y
Ability to have intercourse			
Patient satisfaction			
Partner satisfaction			
Other measure of erection: _____			
Compliance: _____			
Durability of response: _____			
Other: _____			
Other: _____			
Other: _____			

Other Efficacy Measure:

Time Point: _____ (weeks)

Define: _____

Number of patients: _____ Range of points: _____ to _____ Time Period: _____

	Mean	Med	Min	Max	SE	SD	____	% CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

Comments:

American Urological Association, Inc. Reference # _____
ED Guidelines Panel

Erectile Dysfunction

IIEF Scores – Medical Therapies

Group Number: _____
(use >= 90 for Placebo or Control)

5. IIEF Scores
(use multiples of this page, as needed)

Time Point: _____ (weeks)

Number of patients: _____ Range of points: _____ to _____

Questions: Q1: ____ (0-5) Q2: ____(0-5) Q3: ____(0-5) Q4: ____(0-5) Q5: ____(0-5)
Q6: ____(0-5) Q7: ____(0-5) Q8: ____(0-5) Q9: ____(0-5) Q10: ____(0-5)
Q11: ____(1-5) Q12: ____(1-5) Q13: ____(1-5) Q14: ____(1-5) Q15: ____(1-5)

All Domains/Questions : ____

Domains:	EF: ____	OF: ____	SD: ____	IS: ____	OS: ____
Point range:	(1 – 30)	(0 – 10)	(2 – 10)	(0 – 15)	(2 – 10)
Questions in domain:	(1,2,3,4,5,15)	(9,10)	(11,12)	(6,7,8)	(13,14)

	Mean	Med	Min	Max	SE	SD	____	% CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

Time Point: _____ (weeks)

Number of patients: _____ Range of points: _____ to _____

Questions: Q1: ____ (0-5) Q2: ____(0-5) Q3: ____(0-5) Q4: ____(0-5) Q5: ____(0-5)
Q6: ____(0-5) Q7: ____(0-5) Q8: ____(0-5) Q9: ____(0-5) Q10: ____(0-5)
Q11: ____(1-5) Q12: ____(1-5) Q13: ____(1-5) Q14: ____(1-5) Q15: ____(1-5)

All Domains/Questions : ____

Domains:	EF: ____	OF: ____	SD: ____	IS: ____	OS: ____
Point range:	(1 – 30)	(0 – 10)	(2 – 10)	(0 – 15)	(2 – 10)
Questions in domain:	(1,2,3,4,5,15)	(9,10)	(11,12)	(6,7,8)	(13,14)

	Mean	Med	Min	Max	SE	SD	____	% CI
Baseline:								
at Follow-up:								
Change in score (number of points):								
Change in score (percentage):								

	%	x	y		Points		%
Patients improved overall:							
Patients improved:				by		by threshold	
Patients improved:				by		by threshold	

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Total number of articles from all journals: 85

Appendix 2-F: Categories of Adverse events

American Urological Association, Erectile Dysfunction Guidelines Panel

Complications and Adverse Events Groupings

Abdominal
Abdominal

Abnormal EKG
Abnormal EKG

Adverse Events NS
Adverse Events
Adverse Events - Mild
Adverse Events - Moderate
Adverse Events - Severe
Adverse Events NS

Allergy
Allergy

Appendicitis
Appendicitis

Back Pain/Myalgia
Back Pain
Myalgia

Body as Whole
Body as Whole

Cardiovascular
Cardiac
Hypertension
Hypertensive crisis
incr. art. pressure
Palpitations
Tachycardia

Chest pain
Chest pain

Chills
Chills

Conjunctivitis
Conjunctivitis

Cough
Cough

Death
Death

Decreased sexual desire
Decreased sexual desire

Dermatitis
Dermatitis

Diarrhea
Diarrhea

Disturbed Sleep
Disturbed Sleep
Insomnia

Drowsiness
Drowsiness
Sleepiness
Somnolence

Dry mouth
Dry mouth

Ear Disorders
Ear Disorders

Elevated neutrophil count
Elevated neutrophil count

Facial edema
Facial edema

Fatigue
Asthenia
Fatigue

Fibrosis
Fibrosis

Flu Syndrome
Flu Syndrome

Flushing
Flushing
Sweating

Genital/Penile Pain

Ache, pulling or burning in penis or groin
Discomfort &/or scrotal/perineal
Genital/Penile Pain
Scrotal pain
Testicular pain

GI Symptoms

Dyspepsia
Epigastralgia
GI Symptoms

Glossitis

Glossitis

Headache

Headache
Headaches - mild

Hematological changes

Hematological changes

Hypoesthesia

Hypoesthesia

Hypotensive

Dizziness
Hypotension/Syncope
Syncope

Inf. liimb paresthesia

Inf. liimb paresthesia

Infection

Infection

Kidney Stones

Kidney Stones

Lab abnormality

Lab abnormality

lab test changes incl. liver

lab test changes incl. liver and creatinine

Lack of energy

Lack of energy

Malaise
- Malaise

MI
- MI

MI/death
- MI/death

Musculoskeleteral overall
- Musculoskeletal, not myalgia
- Musculoskeleteral overall

Nausea
- Nausea

Nervous System
- Nervous
- Nervous System

Paesthesia
- Paesthesia

Perspiration
- Perspiration

Pharyngitis
- Pharyngitis

Prolonged erection
- Priapism
- Prolonged erection

Rash
- Rash

Rectal Disorder
- Rectal Disorder

Respiratory
- Respiratory
- Respiratory Overall
- Respiratory tract disorder
- Respiratory tract infection

Rhinitis

Nasal Congestion
Rhinitis
Sinusitis

Skin and appendages

Skin and appendages overall

Special Senses

Special senses adverse event
Special senses overall

Stomatitis

Stomatitis

Transient arm paresthesia

Transient arm paresthesia

Unintentional incomplete

Unintentional incomplete sexual arousal

Urethral Pain

Dysuria
Irritation
minor urethral trauma
Urethral Bleeding
Urethral Pain
Urethritis

Urethral Stricture

Urethral Stricture

Urinary Frequency

Frequent urination
Incr. urinary freq.
Urinary frequency

Urticaria

Urticaria

Vaginal burning (partner)

Vaginal burning (partner)

Visual

Blue Color Vision

Visual

Chapter 3: Detailed Outcomes Analyses of Treatments for Erectile Dysfunction

Introduction

This chapter provides a detailed discussion of the outcomes analyses of the potential benefits and risks of treatments for patients with erectile dysfunction (ED). As described in Chapter 1, the Erectile Dysfunction Clinical Guideline Panel (the Panel) analyzed evidence extracted from the literature on the following treatments: the phosphodiesterase type 5 (PDE5) inhibitors, alprostadil intra-urethral suppositories, penile prosthesis implants, vascular surgeries, herbal therapies including yohimbine, and trazodone. Data published on injection therapies and vacuum constriction devices did not warrant close examination or change from the initial guideline, and the outcomes tables from the *1996 Report on the Treatment of Organic Erectile Dysfunction* (the *1996 Report)* should be used as a reference for these treatments (www.auanet.org).

Methods underlying analyses related to each therapy are detailed in Chapter 2. For most treatments, methodologies and outcome measures varied considerably across studies, making analyses of outcomes data difficult and precluding the combining of data for meta-analysis.

Efficacy Outcomes Analyses — Noninvasive Therapies

Phosphodiesterase Type 5 Inhibitors (PDE5)

Phosphodiesterases play a key role in the physiology of erection since they hydrolyze both cGMP and cAMP, the second messengers in the intracellular cascade of smooth muscle relaxation. PDE5 appears to be the dominant isoform in the corpus cavernosum. Selective inhibition of PDE5 prevents breakdown of cGMP, thus promoting corpus cavernosum smooth muscle relaxation potentiating erection during sexual stimulation. Specific PDE5 inhibitors, such

as sildenafil, tadalafil, and vardenafil, enhance intracellular levels of cGMP to improve erection. These drugs are distinctly different from intra-urethral or injectable vasoactive therapies for ED: they are orally active and strategically penile specific since they require sexual stimulation to work.[57,58,59]

Although comparisons of the efficacy of the PDE5 inhibitors would be very useful to clinicians and patients, studies directly comparing these drugs had not been published at the time the literature search supporting this guideline was completed. Attempts at developing a comparative outcomes table based on meta-analysis also failed for two reasons. First, studies evaluating vardenafil and tadalafil excluded subjects who did not respond to sildenafil. This specific difference from the sildenafil clinical trials made comparisons invalid. Second, because many of the studies identified through the original literature search used mathematical models to compensate for patient variability in age, race, smoking status, and baseline function (e.g.,[17,18,19,20,21]), these data could not be used for valid meta-analysis. Although authors of previously published evidence-based reviews[22,23] had obtained raw data directly from study investigators for meta-analytic purposes, the Panel believed that even if the raw data were obtained, useful comparisons still could not be made due to the incomparable patient populations.

With these caveats, details of the meta-analytic process are described below and the supporting evidence is presented in Appendices 3-A to 3-D. As described in Chapter 2, meta-analyses of randomized controlled trial data alone were performed in addition to meta-analyses of all clinical series data, including each treatment arm of the randomized controlled trials.

Sildenafil

In the initial literature search, several published systematic reviews and meta-analyses of sildenafil were identified.[22,23,60,61,62] A few of these reviews took steps to address the analytic problems recognized by the Panel. The authors of the two Veterans Administration (VA) studies,[22,23] for example, obtained and used unadjusted data for their meta-analyses. The Panel decided to obtain and assess unadjusted data only if the results were expected to be different from those previously published. To make this determination, the findings for the International Index of Erectile Function (IIEF) questions 3 (ability to penetrate) and 4 (ability to maintain) which were used in both VA studies and in the Panel's review, were compared (Table 3.1).[22,23] Mean differences between patients receiving sildenafil and placebo for IIEF question 3 were 1.40 and 1.50 in the studies published by Wilt et al (1999)[23] and Fink et al (2002),[22] respectively, compared with 1.58 for the present analysis; parallel differences for IIEF question 4 were 1.50, 1.50, and 1.48, respectively. Because findings using adjusted and unadjusted data were similar, the Panel did not believe that obtaining and reanalyzing the unadjusted data would significantly contribute to the literature assessment.

Table 3.1. Comparison of Sildenafil Meta-analyses[22,23]

Outcome Measure	AUA Difference: Sildenafil and Placebo	Wilt et al (1999)* Difference: Sildenafil and Placebo	Fink et al (2002)* Difference: Sildenafil and Placebo
IIEF Question 3 (ability to penetrate)	1.58	1.40	1.50
IIEF Question 4 (ability to maintain)	1.48	1.50	1.50

AUA = American Urological Association; IIEF = International Index of Erectile Function.
*Calculated value.

Overall, the Panel's review identified six randomized controlled trials reporting acceptable data for the outcome "able to have intercourse" that included 1179 men who were followed for 12 weeks. Including any reported dose, the difference from placebo at follow-up ranged from 36% to 76%. For the IIEF erectile function domain, the difference from placebo at follow-up (typically 12 weeks) ranged from 3.70 to 11.00 in eight studies of 1744 patients overall. For the IIEF intercourse satisfaction domain, the difference between sildenafil and placebo at follow-up ranged from 1.40 to 4.00 in seven studies involving 1607 patients. For IIEF question 3, the reported difference between sildenafil and placebo at follow-up ranged from 1.08 to 1.60 in 3612 patients evaluated in 14 studies. For IIEF question 4, the reported difference between sildenafil and placebo at follow-up ranged from 0.97 to 1.90 in 3474 patients evaluated in 14 studies.

The Panel performed a second broader analysis that included the active treatment arms from randomized controlled trials as well as all clinical series of sildenafil that reported the outcome measures reviewed by the Panel. In these studies, the percent of sildenafil patients "able to have intercourse" at follow-up ranged from 55% to 89%. The IIEF erectile function domain scores ranged from 14.00 to 27.10 while the intercourse satisfaction domain scores ranged from 7.00 to 11.04. The IIEF question 3 scores ranged from a low of 2.40 to a high of 4.40, and question 4 scores ranged from 2.40 to 4.20. The number of studies included varied from six to 20 depending on the outcome. Some of the variability in the results of the outcome measurements may be explained by variability in the patients at baseline. Baseline IIEF erectile function domain scores ranged from 9.30 to 17.80 in those studies reporting baseline data. For the intercourse satisfaction domain, baseline scores ranged from 4.90 to 7.40. For questions 3 and 4 of the IIEF, the baseline ranges were 1.60 to 3.20 and 1.30 to 2.90, respectively.

Tadalafil

Although tadalafil is commercially available in doses of 5 mg, 10 mg, and 20 mg only, the literature review found that seven different tadalafil doses were evaluated in four randomized clinical trials. For 42 patients receiving the 20 mg dose, the difference from placebo at follow-up was 11% for the outcome "able to have intercourse." For the 35 evaluated patients, differences from placebo at follow-up were 4.60 for the IIEF erectile function domain, 1.30 for the intercourse satisfaction domain, 1.00 for IIEF question 3, and 0.70 for IIEF question 4.

In the 44 patients evaluated using the outcome "able to have intercourse" who received the 5 mg dose, the difference from placebo at follow-up was 16%. In the 37 patients who were evaluated using IIEF measures, differences from placebo at follow-up were 8.20 for the erectile function domain, 2.50 for the intercourse satisfaction domain, 1.70 for question 3, and 1.30 for question 4.

A total of 175 patients received a 10 mg dose of tadalafil in three studies. Differences from placebo at follow-up ranged from 25% to 42% for the outcome "able to have intercourse." In an additional study of 36 patients that used IIEF outcome measures, differences from placebo at follow-up were 8.90 for the erectile function domain, 3.00 for the intercourse satisfaction domain, 1.80 for question 3, and 1.60 for question 4.

When the 20 mg dose was evaluated in a study of 72 patients, the difference from placebo at follow-up was 36% for the outcome "able to have intercourse."

A total of 101 patients received the 25 mg dose of tadalafil in two studies. The differences from placebo at follow-up ranged from 37% to 39% for the outcome "able to have intercourse." In an additional study in which the IIEF was used as the outcome measure in 36 patients, differences from placebo at follow-up were 9.50 for the erectile function domain, 3.40 for the intercourse satisfaction domain, 1.70 for question 3, and 1.60 for question 4.

Both the 50 mg and 100 mg doses were evaluated in 59 patients included in a single study. Differences of tadalafil from placebo at follow-up were 53% and 47%, respectively, for the outcome "able to have intercourse."

Analyses of data for individual arms of the four randomized controlled trials were performed. For patients receiving 2 mg, 5 mg, 10 mg, 20 mg, 25 mg, 50 mg, or 100 mg doses of tadalafil, between 45% and 93% of patients were “able to have intercourse” at follow-up with some apparent dose-response relationship. In one study, those treated with 2 mg, 5 mg, 10 mg, or 25 mg doses reported IIEF erectile function domain scores at follow-up ranging from 19.30 to 24.20, intercourse satisfaction domain scores ranging from 8.70 to 10.80, and scores on questions 3 and 4 ranging from 3.50 to 4.20 and from 3.10 to 4.00, respectively. Baseline data were reported in one study in which the 2 mg, 5 mg, 10 mg, and 25 mg doses were evaluated. Baseline erectile function domain scores ranged from 14.90 to 15.80 across dosage groups. For questions 3 and 4 of the IIEF, baseline ranges were 2.80 to 3.10 and 2.30 to 2.50, respectively.

Vardenafil

Three doses of vardenafil, 5 mg, 10 mg, and 20 mg, were evaluated in two randomized clinical trials. For 146 patients receiving the 5 mg dose, the difference from placebo at follow-up was 35% for the outcome “able to have intercourse.” Using IIEF outcome measures, differences from placebo at follow-up were 5.30 for the erectile function domain, 1.70 for the intercourse satisfaction domain, and 1.00 for both questions 3 and 4. In the second study, in which “return to normal” was used as an outcome measure, the difference from placebo at follow-up was 16% in the 205 patients evaluated.

In 140 patients receiving the 10 mg dose, the difference from placebo at follow-up was 31% for the outcome “able to have intercourse.” Using IIEF outcome measures in these patients, differences from placebo at follow-up were 6.50 for the erectile function domain, 2.30 for the

intercourse satisfaction domain, and 1.20 and 1.10 for questions 3 and 4, respectively. In the second study, the difference from placebo at follow-up was 30% for the measure "return to normal."

In 147 patients who received the 20 mg dose, the difference from placebo at follow-up was 39% for the outcome "able to have intercourse." Using IIEF outcome measures in the same patients, differences from placebo at follow-up were 7.20 for the erectile function domain, 2.40 for the intercourse satisfaction domain, and 1.30 for both questions 3 and 4. The difference from placebo at follow-up for the measure of "return to normal" for the 197 patients in the second study was 33%.

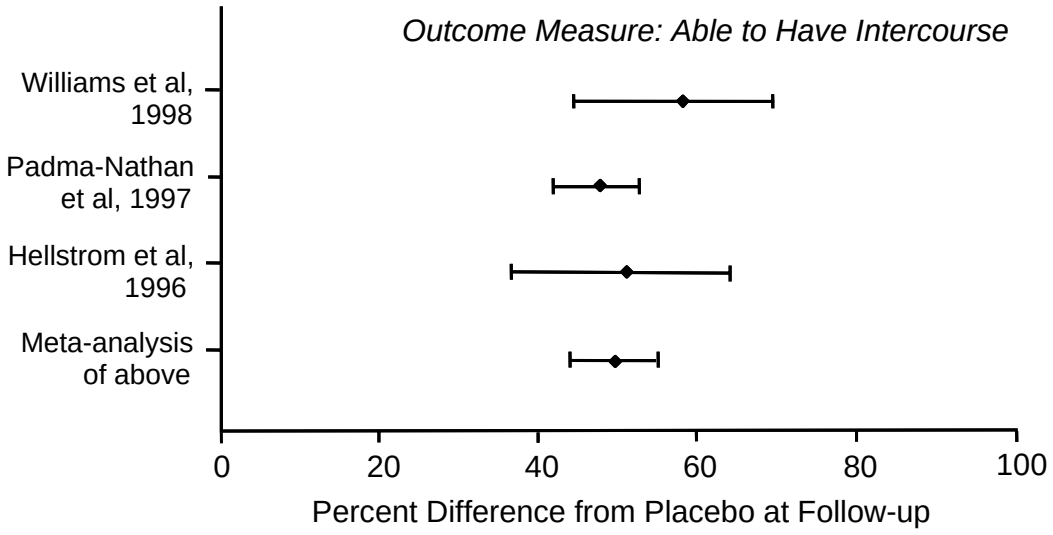
Assessing the single arms of the two randomized controlled trials of the three vardenafil doses, the percent of patients "able to have intercourse" at follow-up ranged from 58% to 66%. Erectile function domain scores on the IIEF ranged from 20.90 to 22.80, intercourse satisfaction domain scores ranged from 10.00 to 10.70, and scores for questions 3 and 4 ranged from 3.70 to 4.00 and from 3.50 to 3.80, respectively. Baseline data were reported in one study of 5 mg, 10 mg, and 20 mg doses. For the outcome "able to have intercourse," baseline scores ranged from 12.30 to 14.20. Baseline IIEF erectile function domain scores ranged from 13.80 to 14.20 while intercourse satisfaction domain scores ranged from 7.10 to 7.30 across the dosage groups. For questions 3 and 4 of the IIEF, the baseline scores ranged from 2.40 to 2.60, respectively, and were 2.10 for both questions across doses.

Alprostadil Intra-urethral Suppositories

Alprostadil is a synthetic vasodilator identical to prostaglandin (PG) E_1, an endogenous PG synthesized in the smooth muscle of the corpus cavernosum. PGE_1 has a dual mechanism of action causing the intracellular accumulation of second-messenger cAMP and directly inhibiting the release of noradrenaline by adrenergic nerves.[63]

An exception to the other treatments, the efficacy of alprostadil intra-urethral suppositories was evaluated in three randomized controlled trials using the same outcome measure — the ability to have intercourse (Appendices 3-A to 3-D). The results of the meta-analyses of outcomes data from these trials are presented in Figure 3.1. [31,64,65] Overall, the studies included 1268 men who were followed for 2 weeks to 3 months. Including all trials, the median percent difference from placebo at follow-up was 49% (95% CI, 43% to 54%). In one study of 68 patients, the Erection Assessment Scale (EAS) also was used as an outcome measure; the median percent difference from placebo for an EAS score ≥4 was 44% (95% CI, 30% to 56%). In these trials, the patient response to alprostadil was confirmed in the office setting prior to being randomized, a factor that biased patient selection.

Figure 3.1. Median percent difference from placebo at follow-up reported in randomized controlled trials of alprostadil intra-urethral suppositories for the treatment of erectile dysfunction. [31, 64,65,]



Herbal Therapies

The literature review of herbal therapies, excluding yohimbine, found three randomized controlled trials. In only one of these studies did results show benefits that reached statistical significance. Based on the insufficiency of data, the Panel could not make recommendations in favor of the use of herbal therapies.

A double-blind, placebo-controlled, crossover study included 45 patients and compared 8 weeks of treatment with placebo to 8 weeks of therapy with the herbal agent Korean red ginseng 900 mg three times a day.[42] The baseline IIEF erectile function domain score was 10.60 ± 7.41; after 8 weeks, the domain score in the placebo group was 11.24 ± 6.94 and 15.02 ± 8.18 in the group treated with Korean red ginseng (P <0.05). Scores for question 3 of the IIEF (ability to penetrate) were 1.8 at baseline; after 8 weeks, scores were 2.06 in the placebo group and 2.7 in the active treatment group (P <0.01). Parallel scores for question 4 of the IIEF (ability to maintain) were 1.78, 1.92, and 2.83, respectively (P <0.01). The Rigiscan scores for percent tip rigidity were 34.21 ± 33.11 at baseline; after 8 weeks, scores were 40.42 ± 30.21 in the placebo group and 44.51 ± 28.84 in patients receiving Korean red ginseng (P <0.05). Differences between the placebo and Korean red ginseng were not statistically significant with respect to percent base rigidity, base circumference, tip circumference, or penile hemodynamics, including end diastolic and peak systolic blood flow velocity. Although the efficacy of Korean red ginseng remains to be validated by larger studies, these findings suggest that this herbal therapy may be an effective treatment for ED.

Another randomized controlled trial of Korean red ginseng[66] included 90 patients, 81 of whom had psychogenic ED. Thirty patients were randomized to each of three groups: placebo,

Korean red ginseng 1800 mg daily, and trazodone 25 mg at bedtime. Outcome measures reflected responses of participants and their partners to questions (apparently verbal rather than written) posed by investigators, serum testosterone levels, and an uncommon measure of penile hemodynamics, radioisotope audiovisual penograms. There were no statistically significant differences among groups in objective parameters of testosterone or penile hemodynamics. Compared to those receiving placebo or trazodone, however, patients treated with Korean red ginseng showed statistically significant increases in scores on subjective parameters, including the quality of morning erections, erection rigidity, libido, patient satisfaction, and "end result." The Panel considered this study to provide weak support at best for the efficacy of Korean red ginseng given the subjective nature of reported improvements, the psychogenic etiology of the ED of most included patients, and the uncommon technique used for measuring penile hemodynamics.

The third randomized controlled study that used objective outcome criteria to evaluate herbal therapies was an evaluation of L-arginine published in 1999.[67] The authors describe subjective improvement in sexual function (as reported in patients' sexual activity diaries) in nine of 29 patients (31%) taking 5 grams daily of L-arginine and in two of 17 patients (12%) taking placebo. No improvement was seen in any objective parameter, including the O'Leary Brief Male Sexual Function Inventory (a questionnaire designed for the study), or in ultrasonic penile hemodynamics measuring peak systolic velocity and end diastolic velocity. Because differences between L-arginine and placebo were small and found only in patients' subjective reporting, the Panel did not believe that this study provides objective evidence to support the efficacy of L-arginine.

Yohimbine

Although 14 randomized controlled trials were found in the literature review, only one small study[40] met the outcomes inclusion criteria described in Chapter 2. The relevant evidence identified by the Panel is presented in Appendices 3-A to 3-D. Forty-five patients underwent a three-way, 2-week crossover study comparing placebo to yohimbine alone and to yohimbine plus arginine in the treatment of ED. The primary endpoint, the change in the erectile function domain score of the IIEF, did not show a statistically or clinically significant difference between yohimbine and placebo treatment. Based on these data, the Panel could not draw conclusions about the efficacy of yohimbine in the treatment of ED. Larger studies are needed to evaluate efficacy.

Trazodone

Examination of the literature published since the 1996 *Report* on the use of trazodone for the treatment of ED found few new studies supporting its efficacy (Appendices 3-A to 3-D). A meta-analysis of evidence published by Fink and associates[36] was based on a MEDLINE® and Cochrane Library search. The authors found six trials involving 396 men that met their eligibility criteria of a randomized controlled trial of at least 7 days' duration with clinically relevant outcomes. Two trials used the outcome measure "able to achieve intercourse" whereas the others used either a study-specific sexual function questionnaire or subjective patient assessment of overall treatment response. The treatment duration in these studies ranged from 4 to 13 weeks. Although trazodone appeared to have greater efficacy than placebo in some trials, differences in pooled results were not statistically significant. In addition, subgroup analyses suggested that patient population, dose, and trial methodology potentially may have influenced the results.[36]

Efficacy Outcomes Analyses — Surgical Therapies

Penile Prosthesis Implantation

A review of the penile prosthesis literature published following the cutoff date for the 1996 *Report* included both noninflatable (malleable) and two- and three-piece inflatable types. Although advances in penile prosthesis design had increased the duration of device survival, only five studies of noninflatable penile prosthesis implantation were identified as relevant. Because noninflatable prostheses had few design changes since the 1996 *Report* was prepared, the Panel decided not to undertake an update of the evidence for these devices. The Panel did review the literature on the use of three-piece inflatable prostheses (devices having paired cylinders, a scrotal pump, and an abdominal fluid reservoir) because design improvements were made almost exclusively in these devices.

The literature published subsequent to that reviewed for development of the 1996 *Report* was surveyed to identify articles on the use of three-piece inflatable penile prostheses where proportions of devices remaining free of mechanical failure were expressed as Kaplan-Meier estimates. Eight such studies were found (Table 3.2 [45,68,69,70,71,72,73,74]).

Table 3.2. Inflatable Penile Prostheses and Mechanical Failure: Summary of Studies Published after Those Included in the 1996 *Report* Analysis[45,68,69,70,71,72,73,74]

Reference	Number of Patients	Follow-up in Months: Range (Mean)	Data Pre- or Postmodification	% of Devices Free of Mechanical Failure*
AMS 700CX/CXM (not modified)				
Choi et al (2001)	273	6 - 100 (49)	NA	90.4
Carson et al (2000)	372	38 - 134 (57)	NA	86.2
Montorsi et al (2000)	90	(60)	NA	93.1
Daitch et al (1997)	111	1 - 112 (47.2)	NA	90.8
Dubocq et al (1998)	103	(66 across 3 groups)	NA	83.9†
AMS Ultrex (modified 1993)				
Montorsi et al (2000)	110	(58)	Both	79.4
Dubocq et al (1998)	103	(66 across 3 groups)	Both	84.2†
Milbank et al (2002)	85	<1 - 136 (75)	Pre-1993	64.7
Milbank et al (2002)	52	<1 - 92 (46)	Post-1993	93.7
Mentor Alpha-1 (modified 1992)				
Goldstein et al (1997)	434	<1 - 44 (22)	Both	85‡
Dubocq et al (1998)	117	(66 across 3 groups)	Both	95.7†
Wilson et al (1999)	410	Not specified	Pre-1992	75.3
Wilson et al (1999)	971	Not specified	Post-1992	92.6

NA = not applicable.
*Kaplan-Meier survival estimates; 5-year estimates unless otherwise noted.
†63-month estimate.
‡Three-year estimate.

Five studies with a total of 949 implant recipients evaluated the AMS 700CX/CXM® prosthesis (American Medical Systems, Minnetonka, Minnesota). Kaplan-Meier estimates of proportions of devices free of mechanical failure ranged from 83.9% (63 months) to 93.1% (5

years). There have been no significant design improvements in the AMS 700CX/CXM® device since it was introduced in 1987.

The AMS Ultrex® prosthesis (American Medical Systems, Minnetonka, Minnesota) has cylinders that provide both girth and length expansion. The device was introduced in 1990, and the cylinders were modified in 1993. Results are available from two studie[69,71] that included 213 implant recipients who received either pre- or postmodification devices. Kaplan-Meier estimates of proportions of devices free of mechanical failure were 79.4% (5 years) and 84.2% (63 months). One study[72] evaluated device survival before and after the 1993 cylinder modification; at 5 years, proportions of devices free of mechanical failure were estimated to be 64.7% (N = 85) for premodification devices and 93.7% (N = 52) for postmodification devices.

The Mentor Alpha-1® prosthesis (Mentor, Santa Barbara, California) was introduced in 1989, and a pump design modification was made in November 1992. Two studies[71,73] with a total of 551 implant recipients assessed rates of mechanical failure in both pre- and postmodification devices. Kaplan-Meier estimates of proportions of devices free of mechanical failure were 85% at 3 years and 95.7% at 63 months. A study by Wilson et al (1999) [74] assessed device survival before and after the November 1992 design modification; estimates of proportions of devices free of mechanical failure at five years were 75.3% (N = 410) for those manufactured before the 1992 modification and 92.6% (N = 971) for those manufactured after the modification.

Vascular Surgeries

Treatment of vasculogenic ED by penile arterial revascularization has been performed using a variety of microvascular procedures for the past 30 years. The efficacy of this surgery is unproven and controversial largely because, in most reported studies, selection and outcome criteria have not been objective and because a variety of surgical techniques has been used.

Penile Venous Reconstructive Surgery

Since the publication of the 1992 National Institutes of Health Consensus Statement[2] and subsequently the 1996 *Report,* sufficient evidence to support a routine surgical approach in the management of veno-occlusive ED has not been published.

Penile Arterial Reconstructive Surgery

The English-language literature from 1966 to 2003 was searched for reports of penile vascular surgery. Articles that reported penile arterial surgery on the Arterial Occlusive Disease Index Patient (Table 3.3) and that contained clear selection criteria, descriptions of surgical technique, and outcomes data as outlined were chosen to undergo a process of data extraction and analysis.

Table 3.3. Penile Arterial Surgery: Criteria for Article Selection

Patient age	55 years or less
Exclusion criteria	Diabetes mellitus, cigarette smoking
Length of follow-up	12-month minimum
Inclusion criteria	Normal serum testosterone Failed pharmacologic erection test or documentation of organicity by either abnormal nocturnal penile tumescence or abnormal blood flow studies (duplex Doppler ultrasonography or dynamic infusion cavernosometry) Abnormal penile arteriogram Artery-to-artery or artery-to-dorsal vein anastomosis used in surgical technique Objective follow-up data reported by either duplex Doppler ultrasonography, penile arteriogram, or validated outcome questionnaire

While the 31 reports on penile arterial surgery contained hundreds of patients, only four articles met the Panel's criteria for acceptance as defined in Chapter 2 and Table 3.3. These four papers report the outcomes for a total of only 50 patients. Of the 50 patients, 42 had an

anastomosis of the inferior epigastric artery to the dorsal penile artery (dorsal artery arterialization) and eight had an anastomosis of the inferior epigastric artery to the dorsal penile vein (dorsal vein arterialization; Table 3.4).[75,76,77,78]

Table 3.4. Penile Arterial Reconstructive Surgery: Summary of Studies Published Subsequent to the 1996 *Report* Literature Analysis[75,76,77,78]

Reference	Type of Surgery	Number of Patients	Months of Follow-up Overall: Range (Mean)	Success Rate % (N)	Success Criteria
Ang and Lim (1997)	Dorsal vein	6	8 to 37 (20)	66 (4)	NPT, Doppler
DePalma et al (1995)	Dorsal artery	11	12 to 48	60% (7)	Doppler
Grasso et al (1992)	Dorsal artery	22	1 y for all	68 (15)	NPT
				36 (8)	Doppler
Jarow and DeFranzo (1996)	Mixed	11	12 to 84 (50)	91 (10)	Doppler; DUS

DUS = duplex ultrasonography; NPT = nocturnal penile tumescence.

The total of 50 patients with reported outcomes is too small to determine whether arterial reconstructive surgery is or is not efficacious.

Complications/Adverse Events Analyses

Complication and adverse event data were extractable for the PDE5 inhibitors, alprostadil intra-urethral suppositories, and yohimbine. PDE5 inhibitor adverse event data were sorted by both treatment and dose. When these results were compared with the types and frequencies of events reported in the approved product labeling and with the results of other meta-analyses and reviews of the literature, minimal differences between sildenafil, vardenafil, and tadalafil were identified (Tables 3.5 to 3.7) Thus, to avoid duplication of efforts, the Panel decided that a meta-analysis of the complication and adverse event data was not warranted.

Table 3.5. Comparison of the Results of the AUA Analysis (by All Doses and Dosage Level) of Sildenafil Adverse Events With Other Published Data[22,62]

Adverse Event by All Doses	AUA Analysis		Product Insert (N = 734)	VA Analysis		Fink et al (2002)[22] Flex Dose only (N = 3780)	Morales et al (1998)[62] (N = 734)
	No. of Patients	Rate (%)	Rate (%)	No. of Patients	Rate (%)	Rate (%)	Rate (%)
Headache	3776	16.4	16	627	18	11	16
Flushing	3644	13.6	10			12	10
GI symptoms/dyspepsia	3568	7.3	7			5	7
Hypotensive/dizziness	930*	5.4	2†				2
Rhinitis/nasal congestion	1794	5.0	4				4
Visual/abnormal vision	3268	3.9	3	615	4	3	3
Rash	124	3.2	2				2
Diarrhea	14	0.0	3				3
Urinary tract infection (UTI)	Not analyzed		3				3
Other (flushing, dyspepsia, rhinitis, UTI)				491	33		

Adverse Event by Dosage Level	AUA Analysis (25 mg)		AUA Analysis (50 mg)		AUA Analysis (100 mg)	
	No. of Patients	Rate (%)	No. of Patients	Rate (%)	No. of Patients	Rate (%)
Headache	347	18.4	400	20.0	274	22.6
Flushing	315	11.4	340	22.4	234	19.7
GI symptoms/dyspepsia	335	5.7	388	8.8	274	13.9
Hypotensive/dizziness*	12	0.0	27	3.7		
Rhinitis/nasal congestion	102	1.0	134	4.5	147	10.2
Visual/abnormal vision	230	0.9	259	2.7	234	10.3

AUA = American Urological Association; GI = gastrointestinal; VA = Veterans Administration.
* Hypotensive includes dizziness and hypotension/syncope.
† Product insert reported dizziness only.

Table 3.6. Comparison of the Results of the AUA Analysis (by All Doses and Dosage Level) of Vardenafil Adverse Events With the Product Labeling Data

Adverse Event by All Doses	AUA Analysis No. of Patients	AUA Analysis Rate (%)	Product Insert (N = 2203) Rate (%)
Headache	1545	13.5	15
Rhinitis	1357	11.7	9
Flushing	1377	9.8	11
GI symptoms/dyspepsia	1018	3.6	4
Flu syndrome	580	3.1	3
Hypotensive/dizziness	41	2.4	2
Nausea	188	1.1	2
Sinusitis	Not analyzed		3

Adverse Event by Dosage Level	AUA Analysis (5 mg) Patients	AUA Analysis (5 mg) Rate (%)	AUA Analysis (10 mg) Patients	AUA Analysis (10 mg) Rate (%)	AUA Analysis (20 mg) Patients	AUA Analysis (20 mg) Rate (%)
Headache	340	8.5	513	15.4	504	15.9
Flushing	340	7.1	492	10.2	504	11.1
GI symptoms/dyspepsia	340	0.9	340	3.5	338	6.5
Rhinitis/nasal congestion	340	10.0	513	9.4	504	15.3
Visual/abnormal vision	193	0.0	199	0.0	188	0.0

AUA = American Urological Association; GI=gastrointestinal.

Table 3.7. Comparison of the Results of the AUA Analysis (by All Doses and Dosage Level) of Tadalafil Adverse Events With the Product Labeling Data

	AUA Analysis (All Doses)		Product Insert (All Doses) (N = 724)	AUA Analysis (5 mg)		Product Insert (5 mg) (N = 151)
Adverse Event	**Patients**	**Rate (%)**	**Rate (%)**	**Patients**	**Rate (%)**	**Rate (%)**
Headache	1439	13.4	14.5	188	9.6	11
GI symptoms/dyspepsia	1439	9.0	12.3	188	5.3	4
Back pain	1264	5.2	6.5	188	2.7	3
Myalgia	1295	4.4	5.7	151	1.3	1
Rhinitis/nasal congestion	804	5.0	4.3	151	4.0	2
Flushing	1196	3.6	4.1	151	2.6	2

	AUA Analysis (10 mg)		Product Insert (10 mg) (N = 394)	AUA Analysis (20 mg)		Product Insert (20 mg) (N = 635)
Adverse Event	**Patients**	**Rate (%)**	**Rate (%)**	**Patients**	**Rate (%)**	**Rate (%)**
Headache	430	11.4	11	505	14.7	15
GI symptoms/dyspepsia	430	8.6	8	505	11.9	10
Back pain	430	5.3	5	330	7.6	6
Myalgia	394	4.8	4	505	5.3	3
Rhinitis/nasal congestion	321	5.6	3	258	4.7	3
Flushing	394	3.3	3	433	5.5	3

AUA = American Urological Association; GI = gastrointestinal.

Appendix 3A - Accepted Article Summaries
Studies Including Apomorphine

750054 Lammers, P. I., Rubio-Aurioles, E., Castell, R., Castaneda, J., Ponce de Leon, R., Hurley, D., Lipezker, M., Loehr, L. A., Lowrey, F.. Combination therapy for erectile dysfunction: a randomized, double blind, unblinded active-controlled, cross-over study of the pharmacodynamics and safety of combined oral formulations of apomorphine hydrochloride, phentolamine mesylate and papaverine hyd. 2002

Pts: 43 Controlled Trial: Randomized, partially blinded, crossover study Mexico Ext: AJM

Grp: 1	PM and APO	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 1.1	Group 1 + Prior sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 1.2	Group 1 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 2	PM and PAP	age:	duration:	Pts: 43
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 2.1	Group 2 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 2.2	Group 2 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 3	Tri combo	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx: 40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	
Grp: 3.1	Group 3 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	
Grp: 3.2	Group 3 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	
Grp: 4	Sildenafil	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx: sildenafil 100	
Grp: 4.1	Group 4 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: sildenafil 100	
Grp: 4.2	Group 4 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: sildenafil 100	

795501 Von Keitz, A. T., Stroberg, P., Bukofzer, S., Mallard, N., Hibberd, M.. A European multicentre study to evaluate the tolerability of apomorphine sublingual administered in a forced dose-escalation regimen in patients with erectile dysfunction. 2002

Pts: 507 Controlled Trial: randomized, double blind Europe Ext: AJM

Grp: 1	Apomorphine	age: 55(22,70)	duration:	Pts: 254
	Pt. Desc: diabetes 10%, hypogonadism 0%, neurogenic 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: Apomorphine [2,4]	
	Discontinued: /33/ Discont. AE: /12/			
Grp: 1.1	Apomorphine 2 mg only	age:	duration:	Pts: 254
	Pt. Desc:		Rx: Apomorphine 2	
Grp: 1.2	Apomorphine 2-3 mg	age:	duration:	Pts: 234
	Pt. Desc:		Rx: Apomorphine [2,3]	
Grp: 1.3	Apomorphine 2-4 mg	age:	duration:	Pts: 221
	Pt. Desc:		Rx: Apomorphine [2,4]	
Grp: 90	Placebo	age: 54.6(22,70)	duration:	Pts: 253
	Pt. Desc: diabetes 8%, hypogonadism 0%, neurogenic 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: Placebo [2,4]	
	Discontinued: /33/ Discont. AE: /4/			
Grp: 90.1	Placebo 2 mg	age:	duration:	Pts: 253
	Pt. Desc:		Rx: Placebo 2	

Grp: 90.2	Placebo 2-3 mg	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [2,3]	
Grp: 90.3	Placebo 2-4 mg	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [2,4]	

795500991 Dula, E., Bukofzer, S., Perdok, R., George, M.. Double-blind, crossover comparison of 3 mg apomorphine SL with placebo and with 4 mg apomorphine SL in male erectile dysfunction. 2001

Pts: 194 Controlled Trial: Randomized, double blinded, crossover, controlled 25 centers in the US Ext: AJM

Grp: 1	Apomorphine 3 mg	age: 56.7(27,72)	duration: (0.25,)	Pts: 194
	Pt. Desc: diabetes 15%,		Rx: Apomorphine 3	
Grp: 1.1	Apomorphine - mild ED	age:	duration:	Pts: 45
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.2	Apomorphine - moderate ED	age:	duration:	Pts: 46
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.3	Apomorphine - severe ED	age:	duration:	Pts: 49
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.4	Apomorphine CAD	age:	duration:	Pts: 14
	Pt. Desc: Coronary artery disease 100%,		Rx: Apomorphine 3	
Grp: 1.5	Apomorphine BPH	age:	duration:	Pts: 44
	Pt. Desc: BPH 100%,		Rx: Apomorphine 3	
Grp: 1.6	Apomorphine HTN	age:	duration:	Pts: 74
	Pt. Desc: HTN 100%,		Rx: Apomorphine 3	
Grp: 1.7	Apomorphine DM	age:	duration:	Pts: 27
	Pt. Desc: diabetes 100%,		Rx: Apomorphine 3	
Grp: 90	Placebo	age: 56.7(27,72)	duration: (0.25,)	Pts: 194
	Pt. Desc: diabetes 15%,		Rx: Placebo 3	
Grp: 90.1	Placebo - mild ED	age:	duration:	Pts: 45
	Pt. Desc:		Rx: Placebo 3	
Grp: 90.2	Placebo - moderate ED	age:	duration:	Pts: 46
	Pt. Desc:		Rx: Placebo 3	
Grp: 90.3	Placebo - severe ED	age:	duration:	Pts: 49
	Pt. Desc:		Rx: Placebo 3	
Grp: 90.4	Placebo CAD	age:	duration:	Pts: 14
	Pt. Desc: Coronary artery disease 100%,		Rx: Placebo 3	
Grp: 90.5	Placebo BPH	age:	duration:	Pts: 44
	Pt. Desc: BPH 100%,		Rx: Placebo 3	
Grp: 90.6	Placebo HTN	age:	duration:	Pts: 74
	Pt. Desc: HTN 100%,		Rx: Placebo 3	
Grp: 90.7	Placebo DM	age:	duration:	Pts: 27
	Pt. Desc: diabetes 100%,		Rx: Placebo 3	

795500992 Dula, E., Bukofzer, S., Perdok, R., George, M.. Double-blind, crossover comparison of 3 mg apomorphine SL with placebo and with 4 mg apomorphine SL in male erectile dysfunction. 2001

Pts: 102 Controlled Trial: Randomized, double blinded, crossover 25 centers in the US Ext: AJM

Grp: 1	Apomorphine 3 mg	age: 56.6(32,71)	duration: (0.25,)	Pts: 102
	Pt. Desc: diabetes 12%,		Rx: Apomorphine 3	
Grp: 1.1	Apomorphine 3 mg mild ED	age:	duration:	Pts: 16
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.2	Apomorphine 3 mg moderate ED	age:	duration:	Pts: 28
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.3	Apomorphine 3 mg severe ED	age:	duration:	Pts: 25
	Pt. Desc:		Rx: Apomorphine 3	
Grp: 1.4	Apomorphine 3 mg CAD	age:	duration:	Pts: 10
	Pt. Desc: Coronary Artery Disease 100%,		Rx: Apomorphine 3	

Grp: 1.5	Apomorphine 3 mg BPH	age:	duration:	Pts: 16
	Pt. Desc: BPH 100%,		Rx: Apomorphine 3	
Grp: 1.6	Apomorphine 3 mg HTN	age:	duration:	Pts: 24
	Pt. Desc: HTN 100%,		Rx: Apomorphine 3	
Grp: 1.7	Apomorphine 3 mg DM	age:	duration:	Pts: 8
	Pt. Desc: diabetes 100%,		Rx: Apomorphine 3	
Grp: 2	Apomorphine 4 mg	age: 56.6(32,71)	duration: (0.25,)	Pts: 102
	Pt. Desc: diabetes 12%,		Rx: Apomorphine 4	
Grp: 2.1	Apomorphine 4 mg mild ED	age:	duration:	Pts: 16
	Pt. Desc:		Rx: Apomorphine 4	
Grp: 2.2	Apomorphine 4 mg moderate ED	age:	duration:	Pts: 28
	Pt. Desc:		Rx: Apomorphine 4	
Grp: 2.3	Apomorphine 4 mg severe ED	age:	duration:	Pts: 25
	Pt. Desc:		Rx: Apomorphine 4	
Grp: 2.4	Apomorphine 4 mg CAD	age:	duration:	Pts: 10
	Pt. Desc: Coronary Artery Disease 100%,		Rx: Apomorphine 4	
Grp: 2.5	Apomorphine 4 mg BPH	age:	duration:	Pts: 16
	Pt. Desc: BPH 100%,		Rx: Apomorphine 4	
Grp: 2.6	Apomorphine 4 mg HTN	age:	duration:	Pts: 24
	Pt. Desc: HTN 100%,		Rx: Apomorphine 4	
Grp: 2.7	Apomorphine 4 mg DM	age:	duration:	Pts: 8
	Pt. Desc: diabetes 100%,		Rx: Apomorphine 4	

Appendix 3A - Accepted Article Summaries
Studies Including MUSE

10035 Shabsigh, R., Padma-Nathan, H., Gittleman, M., McMurray, J., Kaufman, J., Goldstein, I.. Intracavernous alprostadil alfadex is more efficacious, better tolerated, and preferred over intraurethral alprostadil plus optional actis: a comparative, randomized, crossover, multicenter study. 2000

Pts: 111 Controlled Trial: crossover unblinded United States Ext: DSS

Grp: 0	All patients	age: 59.2(30,79)	duration: 4.5(0.5,)	Pts: 111
	Pt. Desc: no endocrine disorders or penile fibrosis 100%,		Rx:	
Grp: 1	ICI alprostadil in office	age:	duration:	Pts: 95
	Pt. Desc:		Rx: ICI alprostadil [,40]T	
	Discont. other: /16/111			
Grp: 1.1	ICI alprostadil at home	age:	duration:	Pts: 68
	Pt. Desc:		Rx: ICI alprostadil [,40]	
	Discont. other: /27/95			
Grp: 2	Intraurethral alprostadil in office	age:	duration:	Pts: 95
	Pt. Desc:		Rx: MUSE [,1000]T	
	Discont. other: /16/111			
Grp: 2.1	Intraurethral alprostadil at home	age:	duration:	Pts: 69
	Pt. Desc:		Rx: MUSE [,1000]	
	Discont. other: /27/95			

10184 Shokeir, A. A., Alserafi, M. A., Mutabagani, H.. Intracavernosal versus intraurethral alprostadil: a prospective randomized study. 1999

Pts: 60 Controlled Trial Saudi Arabia Ext: AJM

Grp: 1	Intracavernosal PGE1	age: 55(18,)	duration: 3(0.25,)	Pts: 30
	Pt. Desc: organic 100%, diabetes 50%, trauma 10%, vascular mixed or unspec. 30%, "other organic causes" 10%,		Rx: intracavernous PGE1 20	
	Lost: /6/ Discontinued: /20/ Discont. AE: /9/ Discont. other: /5/			
Grp: 2	MUSE	age: 56(18,)	duration: 3.2(0.25,)	Pts: 30
	Pt. Desc: diabetes 60%, trauma 10%, vascular mixed or unspec. 20%, "other organic causes" 10%,		Rx: MUSE 100	
	Lost: /5/ Discontinued: /5/			

10519 Porst, H.. Transurethral alprostadil with MUSE (medicated urethral system for erection) vs intracavernous alprostadil--a comparative study in 103 patients with erectile dysfunction. 1997

Pts: 103 Controlled Trial: controlled tiral; crossover Hamburg, Germany Ext: AJM

Grp: 1	MUSE	age: 51.7	duration: (0.5,)	Pts: 103
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 2	Intracavernous Alprostadil	age: 51.7	duration: (0.5,)	Pts: 103
	Pt. Desc:		Rx: Alprostadil intracavernous [5,40]T	

10527 Werthman, P., Rajfer, J.. MUSE therapy: preliminary clinical observations. 1997

Pts: 100 Case Series/Report UCLA, California Ext: Meet

Grp: 0	All patients	age: (25,86)	duration:	Pts: 100
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 1	125mg muse	age:	duration:	Pts: 100
	Pt. Desc:		Rx: MUSE 125	
Grp: 2	250mg muse	age:	duration:	Pts: 39
	Pt. Desc:		Rx: MUSE 250	
Grp: 3	500mg muse	age:	duration:	Pts: 61
	Pt. Desc:		Rx: MUSE 500	
Grp: 4	1000mg muse	age:	duration:	Pts: 34
	Pt. Desc:		Rx: MUSE 1000	

10644 Padma-Nathan, H., Hellstrom, W. J., Kaiser, F. E., Labasky, R. F., Lue, T. F., Nolten, W. E., Norwood, P. C., Peterson, C. A., Shabsigh, R., Tam, P. Y.. Treatment of men with erectile dysfunction with transurethral alprostadil. Medicated Urethral System for Erection (MUSE) Study Group. 1997

Pts: 1511 Controlled Trial: randomized double-blinded MUSE Study Group Ext: JT

Grp: 1	All patients in office testing	age: 61(27,88)	duration: 4.25(0.25,44)	Pts: 1511
	Pt. Desc: diabetes 29%, vascular mixed or unspec. 29%, surgery or trauma 30%, alcohol, tobacco, neurologic, or side effects of drugs 21%,		Rx: MUSE [125,1000]T	
Grp: 1.1	Pts receiving 125 mcg alprostadil in office	age:	duration:	Pts: 1490
	Pt. Desc:		Rx: MUSE 125	
Grp: 1.2	Pts receiving 250mcg alprostadil in office	age:	duration:	Pts: 1492
	Pt. Desc:		Rx: MUSE 250	
Grp: 1.3	Pts receiving 500mcg alprostadil in office	age:	duration:	Pts: 1117
	Pt. Desc:		Rx: MUSE 500	
Grp: 1.4	Pts receiving 1000mcg alprostadil in office	age:	duration:	Pts: 1140
	Pt. Desc:		Rx: MUSE 1000	
Grp: 20	All patients in at home phase	age: 61.5(30,84)	duration: 4.04(0.25,44)	Pts: 996
	Pt. Desc:		Rx:	
	Lost: /23/ Discont. AE: /15/ Discont. Insuff. resp.: /13/ Discont. other: /72/			
Grp: 21	Patients using alprostadil at home	age: 62(38,84)	duration: 4(0.25,44)	Pts: 485
	Pt. Desc: diabetes 19%, vascular arterial 29%, surgery or trauma 32%, alcohol, tobacco, neurologic or drug side effect 21%,		Rx: MUSE [125,1000]T	
Grp: 21.1	Men who reported intercourse at least once	age:	duration:	Pts: 299
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 21.11	Men age >=70	age: (70,)	duration:	Pts:
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 21.2	Pts with vascular disease as cause	age:	duration:	Pts: 140
	Pt. Desc: vascular arterial 100%,		Rx: MUSE [125,1000]T	
Grp: 21.3	Pts with diabetes as cause	age:	duration:	Pts: 91
	Pt. Desc: diabetes 100%,		Rx: MUSE [125,1000]T	
Grp: 21.4	Pts with surgery/trauma as cause	age:	duration:	Pts: 154
	Pt. Desc: surgery or trauma 100%,		Rx: MUSE [125,1000]T	
Grp: 21.5	Pts with other cause	age:	duration:	Pts: 100
	Pt. Desc: alcohol, tobacco, neurologic, or drug side effect 100%,		Rx: MUSE [125,1000]T	
Grp: 21.5	Pts with other cause	age:	duration:	Pts: 100
	Pt. Desc: alcohol, tobacco, neurologic, or drug side effect 100%,		Rx: MUSE [125,1000]T	
Grp: 21.6	Men age < 55	age: (,54)	duration:	Pts:
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 21.7	Men age 55-59	age: (55,59)	duration:	Pts:
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 21.8	Men age 60-64	age: (60,64)	duration:	Pts:
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 21.9	Men age 65-69	age: (65,69)	duration:	Pts:
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 29	Patients using placebo at home	age: 61(30,83)	duration: 4.08(0.25,30)	Pts: 511
	Pt. Desc: diabetes 19%, vascular arterial 28%, surgery or trauma 31%, alcohol, tobacco, neurologic, or drug side effect 21%,		Rx: Placebo [125,1000]T	
Grp: 29	Patients using placebo at home	age: 61(30,83)	duration: 4.08(0.25,30)	Pts: 511
	Pt. Desc: diabetes 19%, vascular arterial 28%, surgery or trauma 31%, alcohol, tobacco, neurologic, or drug side effect 21%,		Rx: Placebo [125,1000]T	
Grp: 29.1	Pts with vascular disease cause	age:	duration:	Pts: 145
	Pt. Desc: vascular arterial 100%,		Rx: Placebo [125,1000]T	
Grp: 29.2	Pts with diabetes cause	age:	duration:	Pts: 98
	Pt. Desc: diabetes 100%,		Rx: Placebo [125,1000]T	

Grp: 29.3	Pts with surgery/trauma cause	age:	duration:	Pts: 159
	Pt. Desc: surgery or trauma 100%,		Rx: Placebo [125,1000]T	
Grp: 29.4	Pts with other cause	age:	duration:	Pts: 109
	Pt. Desc: alcohol, tobacco, neurological, or drug side effect 100%,		Rx: Placebo [125,1000]T	
Grp: 29.5	Men age <55	age: (,54)	duration:	Pts:
	Pt. Desc:		Rx: Placebo [125,1000]T	
Grp: 29.6	Men age 55-59	age: (55,59)	duration:	Pts:
	Pt. Desc:		Rx: Placebo [125,1000]T	
Grp: 29.7	Men age 60--64	age: (60,64)	duration:	Pts:
	Pt. Desc:		Rx: Placebo [125,1000]T	
Grp: 29.8	Men age 65-69	age: (65,69)	duration:	Pts:
	Pt. Desc:		Rx: Placebo [125,1000]T	
Grp: 29.9	Men age >=70	age: (70,)	duration:	Pts:
	Pt. Desc:		Rx: Placebo [125,1000]T	

10672 Hellstrom, W. J., Bennett, A. H., Gesundheit, N., Kaiser, F. E., Lue, T. F., Padma-Nathan, H., Peterson, C. A., Tam, P. Y., Todd, L. K., Varady, J. C., Place, V. A.. A double-blind, placebo-controlled evaluation of the erectile response to transurethral alprostadil. 1996

Pts: 68 Controlled Trial: crossover US (unclear location) Ext: JT

Grp: 1	all patients on Muse	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, tobacco, ETOH, prescription drugs 12%, surgery or trauma 26%,		Rx: MUSE [125,1000]	
Grp: 1.1	125 mcg dose	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, tobacco, ETOH, prescription drugs 12%, surgery or trauma 26%,		Rx: MUSE 125	
Grp: 1.2	250 mcg dose	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, tobacco, ETOH, prescription drugs 12%, surgery or trauma 26%,		Rx: MUSE 250	
Grp: 1.3	500 mcg dose	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, tobacco, ETOH, prescription drugs 12%, surgery or trauma 26%,		Rx: MUSE 500	
Grp: 1.4	1000 mcg dose	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, tobacco, ETOH, prescription drugs 12%, surgery or trauma 26%,		Rx: MUSE 1000	
Grp: 1.5	pts with vascular disease as cause	age:	duration:	Pts: 32
	Pt. Desc: vascular arterial 100%,		Rx: MUSE [125,1000]	
Grp: 1.6	pts with surgery/trauma as cause	age:	duration:	Pts: 18
	Pt. Desc: surgery/trauma 100%,		Rx: MUSE [125,1000]	
Grp: 1.7	pts with other causes (ETOH,diabetes, age, tobacco, or drug side effects)	age:	duration:	Pts: 18
	Pt. Desc: diabetes 56%, ETOH, tobacco, prescription drug side effects 44%,		Rx: MUSE [125,1000]	
Grp: 90	All patients on placebo	age: 58.6(26.8,76.4)	duration: 3.4	Pts: 68
	Pt. Desc: diabetes 15%, vascular arterial 47%, surgery/trauma 26%, ETOH, tobacco, prescription drug SE 12%,		Rx: Placebo	
Grp: 90.1	pts with vasuclar disease as cause	age:	duration:	Pts: 32
	Pt. Desc: vascular arterial 100%,		Rx: Placebo	
Grp: 90.2	pts with surgery/trauma as cause	age:	duration:	Pts: 18
	Pt. Desc: surgery/trauma 100%,		Rx: Placebo	
Grp: 90.3	pts with other causes (ETOH,diabetes, age, tobacco, or drug side effects)	age:	duration:	Pts: 18
	Pt. Desc: diabetes 56%, ETOH, tobacco, prescription drug side effects 44%,		Rx: Placebo	

701003 Guay, A. T., Perez, J. B., Velasquez, E., Newton, R. A., Jacobson, J. P.. Clinical experience with intraurethral alprostadil (MUSE) in the treatment of men with erectile dysfunction. A retrospective study. Medicated urethral system for erection. 2000

Pts: 270 Case Series: Retrospective Peabody, Massachusetts Ext: AJM

Grp: 0	All patients on MUSE	age: 60[61](27,81)	duration:	Pts: 270
	Pt. Desc:		Rx: MUSE [125,1000]T	
	Lost: 6.7%// Discontinued: 8.1%//			
Grp: 1	Organic ED	age:	duration:	Pts: 175
	Pt. Desc: organic 100%,		Rx: MUSE	
Grp: 2	Mixed ED	age:	duration:	Pts: 39
	Pt. Desc: mixed 100%,		Rx: MUSE	
Grp: 3	Psychologic ED	age:	duration:	Pts: 15
	Pt. Desc: psychogenic 100%,		Rx: MUSE	
Grp: 4	Prostatectomy, suprapubic	age:	duration:	Pts: 9
	Pt. Desc: post-prostatectomy 100%,		Rx: MUSE	
Grp: 5	Fibrosis	age:	duration:	Pts: 17
	Pt. Desc: Fibrosis, define 100%,		Rx: MUSE	
Grp: 6	Hypertension	age:	duration:	Pts: 111
	Pt. Desc: Hypertension 100%,		Rx: MUSE	
Grp: 6	Hypertension	age:	duration:	Pts: 111
	Pt. Desc: Hypertension 100%,		Rx: MUSE	
Grp: 7	Diabetes	age:	duration:	Pts: 65
	Pt. Desc: diabetes 100%,		Rx: MUSE	
Grp: 8	TURP	age:	duration:	Pts: 10
	Pt. Desc: Transurethral resection of the prostate 100%,		Rx: MUSE	
Grp: 9	Alcohol	age:	duration:	Pts: 7
	Pt. Desc: Alcohol abuse 100%,		Rx: MUSE	
Grp: 10	Tobacco	age:	duration:	Pts: 24
	Pt. Desc: Tobacco abuse 100%,		Rx: MUSE	
Grp: 11	Multiple meds	age:	duration:	Pts: 72
	Pt. Desc: Multiple medications 100%,		Rx: MUSE	
Grp: 12	Bi/tri mix injection	age:	duration:	Pts: 27
	Pt. Desc: Injection therapy - bi or tri mix 100%,		Rx: MUSE	
Grp: 13	Alprostadil injection	age:	duration:	Pts: 47
	Pt. Desc: Injection therapy - alprostadil 100%,		Rx: MUSE	
Grp: 14	Men age 30-49	age: (30,49)	duration:	Pts: 32
	Pt. Desc:		Rx: MUSE	
Grp: 15	Men age 50-59	age: (50,59)	duration:	Pts: 69
	Pt. Desc:		Rx: MUSE	
Grp: 16	Men age 60-69	age: (60,69)	duration:	Pts: 86
	Pt. Desc:		Rx: MUSE	
Grp: 17	Men age 70-79	age: (70,79)	duration:	Pts: 40
	Pt. Desc:		Rx: MUSE	
Grp: 18	Patients who failed because of side effects	age:	duration:	Pts: 39
	Pt. Desc:		Rx: MUSE	
Grp: 19	Patients who responded	age:	duration:	Pts: 128
	Pt. Desc:		Rx: MUSE	

701004 Kim, S. C., Ahn, T. Y., Choi, H. K., Choi, N. G., Chung, T. G., Chung, W. S., Hwang, T. K., Hyun, J. S., Jung, G. W., Kim, C. I., Kim, J. J., Kim, S. W., Lee, C. H., Lee, K. S., Lee, W. H., Min, K. S., Moon, K. H., Paic, J. S., Park, K.. Multicenter study of the treatment of erectile dysfunction with transurethral alprostadil (MUSE) in Korea. 2000

Pts: 334 Case Series: Uncontrolled trial Korea Ext: AJM

Grp: 1	All patients in the in-clinic study	age: 50.6(19,79)	duration: 3.01(0.25,30)	Pts: 334
	Pt. Desc: organic 70%, psychogenic 30%, diabetes 16%,		Rx: MUSE [250,1000]T	
	Lost: /35/ Discont. AE: /27/ Discont. Insuff. resp.: /34/ Discont. other: /17/			
Grp: 1.1	Psychogenic	age:	duration:	Pts: 100
	Pt. Desc: psychogenic 100%,		Rx: MUSE	

Grp: 1.2	Organic	age:	duration:	Pts: 234
	Pt. Desc: organic 100%,		Rx: MUSE	
Grp: 1.21	Organic--diabetes	age:	duration:	Pts: 54
	Pt. Desc: organic 100%, diabetes 100%,		Rx: MUSE	
Grp: 1.22	Organic--HTN	age:	duration:	Pts: 53
	Pt. Desc: organic 100%, Hypertension 100%,		Rx: MUSE	
Grp: 1.22	Organic--HTN	age:	duration:	Pts: 53
	Pt. Desc: organic 100%, Hypertension 100%,		Rx: MUSE	
Grp: 1.23	Organic--trauma/surgery	age:	duration:	Pts: 22
	Pt. Desc: organic 100%, Trauma or surgery 100%,		Rx: MUSE	
Grp: 1.24	Organic--other	age:	duration:	Pts: 231
	Pt. Desc: organic 100%, Other organic 100%,		Rx: MUSE	
Grp: 2	Responders who continued to at home phase	age: 51.1(24,79)	duration: 2.96(0.25,30)	Pts: 228
	Pt. Desc: organic 68%, psychogenic 32%, diabetes 13%, Hypertension 15%, 'Trauma or surgery 7%,		Rx: MUSE [250,1000]T	
	Lost: /6/ Discont. AE: /14/ Discont. Insuff. resp.: /34/ Discont. other: /4/			
Grp: 2	Responders who continued to at home phase	age: 51.1(24,79)	duration: 2.96(0.25,30)	Pts: 228
	Pt. Desc: organic 68%, psychogenic 32%, diabetes 13%, Hypertension 15%, 'Trauma or surgery 7%,		Rx: MUSE [250,1000]T	
	Lost: /6/ Discont. AE: /14/ Discont. Insuff. resp.: /34/ Discont. other: /4/			
Grp: 2.1	Psychogenic	age:	duration:	Pts: 72
	Pt. Desc: psychogenic 100%,		Rx: MUSE	
Grp: 2.2	Organic	age:	duration:	Pts: 156
	Pt. Desc: organic 100%,		Rx: MUSE	
Grp: 2.21	Organic--diabetes	age:	duration:	Pts: 30
	Pt. Desc: organic 100%, diabetes 100%,		Rx: MUSE	
Grp: 2.22	Organic--HTN	age:	duration:	Pts: 35
	Pt. Desc: organic 100%, Hypertension 100%,		Rx: MUSE	
Grp: 2.22	Organic--HTN	age:	duration:	Pts: 35
	Pt. Desc: organic 100%, Hypertension 100%,		Rx: MUSE	
Grp: 2.23	Organic trauma/surgery	age:	duration:	Pts: 17
	Pt. Desc: organic 100%, Trauma or surgery 100%,		Rx: MUSE	
Grp: 2.24	Organic--other	age:	duration:	Pts: 165
	Pt. Desc: organic 100%, Other organic 100%,		Rx: MUSE	
Grp: 2.3	Phase II 250mg	age:	duration:	Pts: 86
	Pt. Desc:		Rx: MUSE 250	
Grp: 2.4	Phase II 500 mg	age:	duration:	Pts: 64
	Pt. Desc:		Rx: MUSE 500	
Grp: 2.5	Phase II 1000 mg	age:	duration:	Pts: 78
	Pt. Desc:		Rx: MUSE 1000	

755000 Kongkanand, A., Ratana-Olarn, K., Wuddhikarn, S., Luengwattanakit, S., Tantiwong, A., Ruengdilokrat, S., Opanuraks, J., Sripalakit, S.. Evaluation of transurethal alprostadil for safety and efficacy in men with erectile dysfunction. 2002

Pts: 90 Case Series/Report Bangkok, Thailand Ext: HSB

Grp: 1	Patients given MUSE trial in office	age: (18,)	duration: (0.5,)	Pts: 90
	Pt. Desc:		Rx: MUSE T	
	Discontinued: /12/ Discont. other: /12/			
Grp: 1.1	Patients succeeding in office trial given MUSE at home	age:	duration:	Pts: 59
	Pt. Desc:		Rx: MUSE [500,1000]T	
	Lost: /8/			

796111 Khan, M. A., Raistrick, M., Mikhailidis, D. P., Morgan, R. J.. MUSE: clinical experience. 2002

Pts: 100 Case Series UK Ext: PMF

Grp: 1	Patients who underwent a trial of MUSE in the clinic	age: 56(46,73)	duration:	Pts: 100
	Pt. Desc: organic 64%, psychogenic 36%, Discont. Insuff. resp.: 65%/65/100		Rx: MUSE [250,1000]	
Grp: 1	Patients who underwent a trial of MUSE in the clinic	age: 56(46,73)	duration:	Pts: 100
	Pt. Desc: organic 64%, psychogenic 36%, Discont. Insuff. resp.: 57%/20/35		Rx: MUSE [250,1000]	
Grp: 1.1	Patients with Organic ED	age:	duration:	Pts: 64
	Pt. Desc: organic 100%,		Rx: MUSE [250,1000]	
Grp: 1.11	Patients with Organic ED and Diabetes mellitus	age:	duration:	Pts: 22
	Pt. Desc: organic 100%, diabetes 100%,		Rx: MUSE [250,1000]	
Grp: 1.12	Patients with Organic ED and vasculogenic cause of ED	age:	duration:	Pts: 20
	Pt. Desc: organic 100%, vascular mixed or unspec. 100%,		Rx: MUSE [250,1000]	
Grp: 1.13	Patients with Organic ED and mixed causes of ED (vasculogenic and neurogenic)	age:	duration:	Pts: 16
	Pt. Desc: organic 100%, Mixed vasculogenic and neurogenic 100%,		Rx: MUSE [250,1000]	
Grp: 1.14	Patients with Organic ED, post prostatectomy	age:	duration:	Pts: 6
	Pt. Desc: organic 100%, post-prostatectomy 100%,		Rx: MUSE [250,1000]	
Grp: 1.2	Patients with Psychogenic ED	age:	duration:	Pts: 36
	Pt. Desc: psychogenic 100%,		Rx: MUSE [250,1000]	

10297991 Williams, G., Abbou, C. C., Amar, E. T., Desvaux, P., Flam, T. A., Lycklama, a. Nijeholt GA//Lynch, S. F., Morgan, R. J., Muller, S. C., Porst, H., Pryor, J. P., Ryan, P., Witzsch, U. K., Hall, M. M., Place, V. A., Spivack, A. P., Todd, L. The effect of transurethral alprostadil on the quality of life of men with erectile dysfunction, and their partners. MUSE Study Group. 1998

Pts: 249 Other: Open label, uncontrolled — Europe — Ext: AJM

Grp: 0	All patients	age: 56.5(25,78)	duration: 4.86(0.25,53)	Pts: 249
	Pt. Desc: organic 100%, diabetes 22%, vascular mixed or unspec. 40%,		Rx: MUSE [125,1000]T	

10297992 Williams, G., Abbou, C. C., Amar, E. T., Desvaux, P., Flam, T. A., Lycklama, a. Nijeholt GA//Lynch, S. F., Morgan, R. J., Muller, S. C., Porst, H., Pryor, J. P., Ryan, P., Witzsch, U. K., Hall, M. M., Place, V. A., Spivack, A. P., Todd, L. The effect of transurethral alprostadil on the quality of life of men with erectile dysfunction, and their partners. MUSE Study Group. 1998

Pts: 159 Controlled Trial — Europe — Ext: AJM

Grp: 0	All patients	age: 57.3(25,78)	duration: 5.125(0.25,53)	Pts: 159
	Pt. Desc: organic 100%, diabetes 23%, vascular mixed or unspec. 47%, Lost: /12/ Discontinued: /42/ Discont. AE: /4/ Discont. Insuff. resp.: /3/ Discont. other: /23/		Rx:	
Grp: 1	MUSE	age:	duration:	Pts: 81
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 90	Placebo	age:	duration:	Pts: 78
	Pt. Desc: organic 100%,		Rx: Placebo	

10396991 Williams, G., Abbou, C. C., Amar, E. T., Desvaux, P., Flam, T. A., Lycklama, a. Nijeholt GA//Lynch, S. F., Morgan, R. J., Muller, S. C., Porst, H., Pryor, J. P., Ryan, P., Witzsch, U. K., Hall, M. M., Place, V. A., Spivack, A. P., Gesundh. Efficacy and safety of transurethral alprostadil therapy in men with erectile dysfunction. MUSE Study Group. 1998

Pts: 249 Other: Data escalation, not blinded, not controlled — London, UK/13 centers in Europe — Ext: AJM

Grp: 0	All pts - dose escalation	age: 56.3(25,78)	duration: 4.9(0.25,53.7)	Pts: 249
	Pt. Desc: organic 100%, diabetes 17%, trauma 23%, vascular mixed or unspec. 30%,		Rx: MUSE [125,1000]T	

10396992 Williams, G., Abbou, C. C., Amar, E. T., Desvaux, P., Flam, T. A., Lycklama, a. Nijeholt GA//Lynch, S. F., Morgan, R. J., Muller, S. C., Porst, H., Pryor, J. P., Ryan, P., Witzsch, U. K., Hall, M. M., Place, V. A., Spivack, A. P., Gesundh. Efficacy and safety of transurethral alprostadil therapy in men with erectile dysfunction. MUSE Study Group. 1998

Pts: 159 Controlled Trial: randomized — London, UK/13 centers in Europe — Ext:

Grp: 0	All pts	age: 57.3(25,78)	duration: 5.12(0.25,53.7)	Pts: 159
	Pt. Desc: organic 100%,		Rx:	
	Lost: /12/ Discontinued: /42/ Discont. AE: /4/ Discont. Insuff. resp.: /3/ Discont. other: /23/			
Grp: 1	Alprostadil	age: 57.3(25,78)	duration: 5(0.25,53.7)	Pts: 78
	Pt. Desc: organic 100%, diabetes 18%, trauma 24%, vascular mixed or unspec. 33%,		Rx: MUSE [125,1000]	
	Discontinued: /25/			
Grp: 1.1	Pts with at least one erection in the trial	age:	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.11	Alprostadil + duration <24 months	age:	duration: (0.25,2)	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.12	Alprostadil + duration 24-48 months	age:	duration: (2,4)	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.13	Alprostadil + duration >48 months	age:	duration: (4,)	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.14	Alprostadil--pts with partial tumescense pre-study	age:	duration:	Pts: 37
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.15	Alprostadil--pts without partial tumescense pre-study	age:	duration:	Pts: 41
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.16	Alprostadil--pts attempted previous tx	age:	duration:	Pts: 40
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.17	Alprostadil--pts didn't attempt previous tx	age:	duration:	Pts: 38
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.2	Alprostadil + vascular disease	age:	duration:	Pts: 26
	Pt. Desc: organic 100%, vascular mixed or unspec. 100%,		Rx: MUSE [125,1000]	
Grp: 1.3	Alprostadil + DM	age:	duration:	Pts: 14
	Pt. Desc: organic 100%, diabetes 100%,		Rx: MUSE [125,1000]	
Grp: 1.4	Alprostadil + surgery trauma	age:	duration:	Pts: 19
	Pt. Desc: organic 100%, trauma 100%,		Rx: MUSE [125,1000]	
Grp: 1.5	Alprostadil + other etiology	age:	duration:	Pts: 19
	Pt. Desc: organic 100%, "Other organic causes" 100%,		Rx: MUSE [125,1000]	
Grp: 1.6	Alprostadil + age <55	age: (,55)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.7	Alprostadil + age 55-59	age: (55,59)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.8	Alprostadil + age 60-64	age: (60,64)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 1.9	Alprostadil + age > or=65	age: (65,)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: MUSE [125,1000]	
Grp: 90	Placebo	age: 57.3(26,77)	duration: 5.3(0.33,34.8)	Pts: 81
	Pt. Desc: organic 100%, diabetes 15%, trauma 21%, vascular mixed or unspec. 41%,		Rx: Placebo [125,1000]	
	Discontinued: /17/			
Grp: 90.1	Placebo + ED duration <24 months	age:	duration: (0.25,2)	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.11	Placebo + ED duration 24-48 months	age:	duration: (2,4)	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.12	Placebo + ED duration >48 months	age:	duration: (4,)	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.13	Placebo + partial tumescense pre-study	age:	duration:	Pts: 43
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	

Grp: 90.14	Placebo + no partial tumescense pre-study	age:	duration:	Pts: 38
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.15	Placebo + prior treatment	age:	duration:	Pts: 44
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.16	Placebo + no prior treatment	age:	duration:	Pts: 37
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.2	Placebo + vascular disease	age:	duration:	Pts: 33
	Pt. Desc: organic 100%, vascular mixed or unspec. 100%,		Rx: Placebo [125,1000]	
Grp: 90.3	Placebo + DM	age:	duration:	Pts: 12
	Pt. Desc: organic 100%, diabetes 100%,		Rx: Placebo [125,1000]	
Grp: 90.4	Placebo + surgery/trauma	age:	duration:	Pts: 17
	Pt. Desc: organic 100%, trauma 100%,		Rx: Placebo [125,1000]	
Grp: 90.5	Placebo + other organic etiology	age:	duration:	Pts: 19
	Pt. Desc: organic 100%, "Other organic causes" 100%,		Rx: Placebo [125,1000]	
Grp: 90.6	Placeb + age <55	age: (,55)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.7	Placebo + age 55-59	age: (55,59)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.8	Placebo + age 60-64	age: (60,64)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	
Grp: 90.9	Placebo + age > or =65	age: (65,)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: Placebo [125,1000]	

10035 Shabsigh, R., Padma-Nathan, H., Gittleman, M., McMurray, J., Kaufman, J., Goldstein, I.. Intracavernous alprostadil alfadex is more efficacious, better tolerated, and preferred over intraurethral alprostadil plus optional actis: a comparative, randomized, crossover, multicenter study. 2000

Pts: 111 Controlled Trial: crossover unblinded United States Ext: DSS

Grp: 0	All patients	age: 59.2(30,79)	duration: 4.5(0.5,)	Pts: 111
	Pt. Desc: no endocrine disorders or penile fibrosis 100%,		Rx:	
Grp: 1	ICI alprostadil in office	age:	duration:	Pts: 95
	Pt. Desc:		Rx: ICI alprostadil [,40]T	
	Discont. other: /16/111			
Grp: 1.1	ICI alprostadil at home	age:	duration:	Pts: 68
	Pt. Desc:		Rx: ICI alprostadil [,40]	
	Discont. other: /27/95			
Grp: 2	Intraurethral alprostadil in office	age:	duration:	Pts: 95
	Pt. Desc:		Rx: MUSE [,1000]T	
	Discont. other: /16/111			
Grp: 2.1	Intraurethral alprostadil at home	age:	duration:	Pts: 69
	Pt. Desc:		Rx: MUSE [,1000]	
	Discont. other: /27/95			

10184 Shokeir, A. A., Alserafi, M. A., Mutabagani, H.. Intracavernosal versus intraurethral alprostadil: a prospective randomized study. 1999

Pts: 60 Controlled Trial Saudi Arabia Ext: AJM

Grp: 1	Intracavernosal PGE1	age: 55(18,)	duration: 3(0.25,)	Pts: 30
	Pt. Desc: organic 100%, diabetes 50%, trauma 10%, vascular mixed or unspec. 30%, "other organic causes" 10%,		Rx: intracavernous PGE1 20	
	Lost: /6/ Discontinued: /20/ Discont. AE: /9/ Discont. other: /5/			
Grp: 2	MUSE	age: 56(18,)	duration: 3.2(0.25,)	Pts: 30
	Pt. Desc: diabetes 60%, trauma 10%, vascular mixed or unspec. 20%, "other organic causes" 10%,		Rx: MUSE 100	
	Lost: /5/ Discontinued: /5/			

10237 Reiter, W. J., Pycha, A., Schatzl, G., Pokorny, A., Gruber, D. M., Huber, J. C., Marberger, M.. Dehydroepiandrosterone in the treatment of erectile dysfunction: a prospective, double-blind, randomized, placebo-controlled study. 1999

Pts: 40 Controlled Trial: Propsective, randomized, placebo-controlled Vienna, Austria Ext: AJM

Grp: 1	DHEA	age: 56.6(43,68)	duration: (0.5,)	Pts: 20
	Pt. Desc: diabetes 0%, neurogenic 0%, post-prostatectomy 0%,		Rx: DHEA 50	
	Discont. Insuff. resp.: /3/			
Grp: 90	Placebo	age: 56.4(41,69)	duration: (0.5,)	Pts: 20
	Pt. Desc: diabetes 0%, neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo 50	
	Discont. Insuff. resp.: /6/ Discont. other: /1/			

10519 Porst, H.. Transurethral alprostadil with MUSE (medicated urethral system for erection) vs intracavernous alprostadil--a comparative study in 103 patients with erectile dysfunction. 1997

Pts: 103 Controlled Trial: controlled tiral; crossover Hamburg, Germany Ext: AJM

Grp: 1	MUSE	age: 51.7	duration: (0.5,)	Pts: 103
	Pt. Desc:		Rx: MUSE [125,1000]T	
Grp: 2	Intracavernous Alprostadil	age: 51.7	duration: (0.5,)	Pts: 103
	Pt. Desc:		Rx: Alprostadil intracavernous [5,40]T	

10780 Aydin, S., Odabas, O., Ercan, M., Kara, H., Agargun, M. Y.. Efficacy of testosterone, trazodone and hypnotic suggestion in the treatment of non-organic male sexual dysfunction. 1996

Pts: 79 Controlled Trial: Randomized Turkey Ext: AJM

Grp: 1	testosterone	age: 38.7(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.1	testostersone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	

Grp: 1.2	testosterone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.3	testosterone age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.4	testosterone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Testosterone 120	
Grp: 2	trazodone	age: 39.5(21,)	duration:	Pts: 21
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.1	trazodone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.2	trazodone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.3	trazodone age 41-50	age: (41,50)	duration:	Pts: 7
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.4	trazodone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 3	hypnosis	age: 34.2(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: hypnosis	
Grp: 3.1	hypnosis age 21-30	age: (21,30)	duration:	Pts: 10
	Pt. Desc:		Rx: hypnosis	
Grp: 3.2	hypnosis age 31-40	age: (31,40)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.3	hypnosis age 41-50	age: (41,50)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.4	hypnosis age 51+	age: (51,)	duration:	Pts: 2
	Pt. Desc:		Rx: hypnosis	
Grp: 90	placebo	age: 39.1(21,)	duration:	Pts: 18
	Pt. Desc:		Rx: Placebo	
Grp: 90.1	placebo age 21-30	age: (21,30)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	placebo age 31-40	age: (31,40)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	placebo age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	placebo age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	

700015 Eardley, I., Morgan, R., Dinsmore, W., Yates, P., Boolell, M.. Efficacy and safety of sildenafil citrate in the treatment of men with mild to moderate erectile dysfunction. 2001

Pts: 44 Controlled Trial: Randomized, placebo controlled, crossover trial UK Ext: AJM

Grp: 1	Sildenafil	age: 53(33,69)	duration: 2.9(0.5,10)	Pts: 44
	Pt. Desc:		Rx: sildenafil [25,75]T	
	Discontinued: /4/			
Grp: 2	Sildenafil then placebo	age: 53(33,69)	duration: 2.8(0.5,10)	Pts: 24
	Pt. Desc:		Rx: seldenafil followed by placebo	
Grp: 3	Placebo then sildenafil	age: 53(36,69)	duration: 3.1(0.5,10)	Pts: 20
	Pt. Desc:		Rx: Placebo followed by sildenafil	
Grp: 90	Placebo	age: 53(33,69)	duration: 2.9(0.5,10)	Pts: 44
	Pt. Desc:		Rx: Placebo [25,75]T	
	Discontinued: /4/			

704145 Sobotka, J. J.. An evaluation of Afrodex in the management of male impotency: a double- blind crossover study. 1969

Pts: 50 Controlled Trial: Placebo controlled, crossover Phoenix, Arizona Ext: AJM

Grp: 1	All patients on Afrodex	age: 51.82(22,73)	duration: 1.18(0.5,3)	Pts: 50
	Pt. Desc: psychogenic 22%, diabetes 4%,		Rx: Afrodex T	
Grp: 1.1	Afrodex 1st	age: 53.25(26,73)	duration: 1.16(0.5,3)	Pts: 28
	Pt. Desc: psychogenic 21%,		Rx: Afrodex T	
Grp: 1.2	Afrodex 2nd	age: 50(22,71)	duration: 1.2(0.5,3)	Pts: 22
	Pt. Desc: psychogenic 23%, diabetes 5%,		Rx: Afrodex T	
Grp: 90	All patients on placebo	age: 51.82(22,73)	duration: 1.18(0.5,3)	Pts: 50
	Pt. Desc: psychogenic 22%,		Rx: Placebo T	
Grp: 90.1	Placebo 1st	age: 50(22,71)	duration: 1.2(0.5,3)	Pts: 22
	Pt. Desc: psychogenic 23%, diabetes 5%,		Rx: Placebo T	
Grp: 90.2	Placebo 2nd	age: 53.25(26,73)	duration: 1.16(0.5,3)	Pts: 28
	Pt. Desc: psychogenic 21%, diabetes 4%,		Rx: Placebo	

705006 Kurt, U., Ozkardes, H., Altug, U., Germiyanoglu, C., Gurdal, M., Erol, D.. The efficacy of anti-serotoninergic agents in the treatment of erectile dysfunction. 1994

Pts: 100 Controlled Trial: placebo controlled, randomized trial Ankara, Turkey Ext: AJM

Grp: 0	All patients	age: 47(23,68)	duration: (0.5,)	Pts: 100
	Pt. Desc: psychogenic 100%,		Rx:	
	Lost: /5/ Discont. AE: /4/ Discont. other: /6/			
Grp: 1	Trazodone	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: trazodone 50	
	Discont. AE: /2/			
Grp: 2	Ketanserin	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Ketanserin 20	
	Discont. AE: /0/			
Grp: 3	Mianserin	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Mianserin 10	
	Discont. AE: /2/			
Grp: 90	Placebo	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Placebo T	

750054 Lammers, P. I., Rubio-Aurioles, E., Castell, R., Castaneda, J., Ponce de Leon, R., Hurley, D., Lipezker, M., Loehr, L. A., Lowrey, F.. Combination therapy for erectile dysfunction: a randomized, double blind, unblinded active-controlled, cross-over study of the pharmacodynamics and safety of combined oral formulations of apomorphine hydrochloride, phentolamine mesylate and papaverine hyd. 2002

Pts: 43 Controlled Trial: Randomized, partially blinded, crossover study Mexico Ext: AJM

Grp: 1	PM and APO	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 1.1	Group 1 + Prior sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 1.2	Group 1 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: 40mg phentolamine + 6 mg apomorphine 40	
Grp: 2	PM and PAP	age:	duration:	Pts: 43
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 2.1	Group 2 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 2.2	Group 2 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx: 40 mg phentolamine + 150mg papaverine 40	
Grp: 3	Tri combo	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx: 40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	

Grp: 3.1	Group 3 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx:	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40
Grp: 3.2	Group 3 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx:	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40
Grp: 4	Sildenafil	age: (40,75)	duration: (0.5,)	Pts: 43
	Pt. Desc: post-prostatectomy 0%,		Rx:	sildenafil 100
Grp: 4.1	Group 4 + Prior Sildenafil use	age:	duration:	Pts: 7
	Pt. Desc:		Rx:	sildenafil 100
Grp: 4.2	Group 4 - Prior Sildenafil use	age:	duration:	Pts: 29
	Pt. Desc:		Rx:	sildenafil 100

790779 Gomaa, A., Eissa, M., El-Gebaley, A.. The effect of topically applied vasoactive agents and testosterone versus testosterone in the treatment of erectile dysfunction in aged men with low sexual interest. 2001

Pts: 42 Controlled Trial: Randomized, double blind, crossover trial Assiut, Egypt Ext: AJM

Grp: 1	Testosterone cream	age: 54(41,67)	duration: (0.33,6)	Pts: 42
	Pt. Desc: organic 55%, psychogenic 45%, hypogonadism 100%, neurogenic 12%, post-prostatectomy 0%, vascular mixed or unspec. 43%,		Rx:	0.8% testosterone cream 2
Grp: 1.1	Psychogenic patients on testosterone cream	age:	duration:	Pts: 19
	Pt. Desc:		Rx:	0.8% testosterone cream 2
Grp: 1.2	Vasculogenic patients on testosterone cream	age:	duration:	Pts: 18
	Pt. Desc:		Rx:	0.8% testosterone cream 2
Grp: 1.3	Neurogenic patients on testosterone cream	age:	duration:	Pts: 5
	Pt. Desc:		Rx:	0.8% testosterone cream 2
Grp: 2	Polypharmacy cream	age: 54(41,67)	duration: (0.33,6)	Pts: 42
	Pt. Desc: organic 55%, psychogenic 45%, hypogonadism 100%, neurogenic 12%, post-prostatectomy 0%, vascular mixed or unspec. 43%,		Rx:	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2
Grp: 2.1	Psychogenic patients on polypharmacy cream	age:	duration:	Pts: 19
	Pt. Desc:		Rx:	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2
Grp: 2.2	Vasculogenic patients on polypharmacy cream	age:	duration:	Pts: 18
	Pt. Desc:		Rx:	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2
Grp: 2.3	Neurogenic patients on polypharmacy cream	age:	duration:	Pts: 5
	Pt. Desc:		Rx:	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2
Grp: 3	Testosterone cream then polypharmacy cream	age:	duration:	Pts: 21
	Pt. Desc:		Rx:	testosterone followed by polypharmacy cream
Grp: 4	Polypharmacy cream then testosterone cream	age:	duration:	Pts: 21
	Pt. Desc:		Rx:	poplypharmacy cream followed by testosterone

796089 Lebret, T., Herve, J. M., Gorny, P., Worcel, M., Botto, H.. Efficacy and safety of a novel combination of L-arginine glutamate and yohimbine hydrochloride: a new oral therapy for erectile dysfunction. 2002

Pts: 48 Controlled Trial France Ext: PMF

Grp: 1	Results for Yohimbine Hydrochloride alone (YP)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx:	yohimbine 6

Discont. AE: /0/48 Discont. other: /3/48

Grp: 1.1	Results for Yohimbine Hydrochloride alone with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: yohimbine 6	
Grp: 1.2	Results for Yohimbine Hydrochloride alone with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: post-prostatectomy 0%, non nerve sparing 0%,		Rx: yohimbine 6	
Grp: 2	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride (AY)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
	Discont. AE: /0/48 Discont. other: /3/48			
Grp: 2.1	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: post-prostatectomy 0%, non nerve sparing 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
Grp: 2.2	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
Grp: 90	Results for Placebo (PP)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	
	Discont. AE: /0/48 Discont. other: /3/48			
Grp: 90.1	Results for Placebo with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	
Grp: 90.2	Results for Placebo with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	

10021 Eardley, I., Brooks, J., Yates, P. K., Ellis, P., Boolell, M.. Sildenafil citrate (VIAGRA): an oral treatment for erectile function with activity for up to four hours' duration. 1999

Pts: 16 Controlled Trial — Kent, UK — Ext: AJM

Grp: 1	Sildenafil with VSS p 2-3	age: 57(35,68)	duration: 1.9(0.25,8)	Pts: 16
	Pt. Desc: No known organic cause 100%,		Rx: sildenafil 100	
Grp: 2	Sildenafil with VSS p 4-5	age: 57(35,68)	duration: 1.9(0.25,8)	Pts: 16
	Pt. Desc: No known organic cause 100%,		Rx: sildenafil 100	
Grp: 90	Placebo with VSS p 2-3	age: 57(35,68)	duration: 1.9(0.25,8)	Pts: 16
	Pt. Desc: No known organic cause 100%,		Rx: Placebo 100	
Grp: 91	Placebo with VSS p 4-5.	age: 57(35,68)	duration: 1.9(0.25,8)	Pts: 16
	Pt. Desc: No known organic cause 100%,		Rx: Placebo 100	

10023 Hartmann, U., Meuleman, E. J., Cuzin, B., Emrich, H. M., Declercq, G. A., Bailey, M. J., Maytom, M. C., Smith, M. D., Osterloh, I. H.. Sildenafil citrate (VIAGRA): analysis of preferred doses in a European, six-month, double-blind, placebo-controlled, flexible dose-escalation study in patients with erectile dysfunction. Multicentre Study Group. 1999

Pts: 315 Controlled Trial: randomized — Europe — Ext: Meet

Grp: 1	Sildenafil	age: 55(18,)	duration: 5(0.5,)	Pts: 159
	Pt. Desc:		Rx: sildenafil [25,100]T	
	Discont. AE: 5%/8/159 Discont. Insuff. resp.: 8%/13/159			
Grp: 90	Placebo	age: 54(18,)	duration: 5(0.5,)	Pts: 156
	Pt. Desc:		Rx: Placebo [25,100]T	
	Discont. AE: 3%/5/156 Discont. Insuff. resp.: 35%/54/156			

10024 Giuliano, F., Hultling, C., el Masry, W. S., Luchner, E., Stien, R., Maytom, M. C., Orr, M., Smith, M. D., Osterloh, I. H.. Sildenafil citrate (VIAGRA): a novel oral treatment for erectile dysfunction caused by traumatic spinal cord injury. 1999

Pts: 178 Controlled Trial — Europe — Ext: AJM

Grp: 1	Sildenafil	age: (19,63)	duration: (0.7,38)	Pts: 178
	Pt. Desc: spinal cord injury 100%,		Rx: sildenafil [25,100]T	
	Discont. AE: /3/			
Grp: 90	Placebo	age: (19,63)	duration: (0.7,38)	Pts: 178
	Pt. Desc: spinal cord injury 100%,		Rx: Placebo [25,100]T	
	Lost: /3/ Discont. AE: /1/			

10026 Shabsigh, R.. Efficacy of sildenafil citrate (VIAGRA) is not affected by aetiology of erectile dysfunction. 1999

Pts: 329 Controlled Trial — New York — Ext: AJM

Grp: 0	All patients	age:	duration:	Pts: 329
	Pt. Desc: organic 59%, psychogenic 15%, mixed 26%,		Rx:	
Grp: 1	All patients getting Sildenafil	age:	duration:	Pts: 163
	Pt. Desc:		Rx: sildenafil [25,100]T	
	Lost: /25/			
Grp: 1.1	Organic patients getting Sildenafil	age:	duration:	Pts: 81
	Pt. Desc: organic 100%,		Rx: sildenafil [25,100]T	
Grp: 1.2	Psychogenic patients getting Sildenafil	age:	duration:	Pts: 19
	Pt. Desc: psychogenic 100%,		Rx: sildenafil [25,100]T	
Grp: 1.3	Mixed	age:	duration:	Pts: 38
	Pt. Desc: mixed 100%,		Rx: sildenafil [25,100]T	
Grp: 90	Al placebo patients	age:	duration:	Pts: 166
	Pt. Desc:		Rx: Placebo [25,100]T	
	Lost: /28/			
Grp: 90.1	Placebo organic patients	age:	duration:	Pts: 90
	Pt. Desc: organic 100%,		Rx: Placebo [25,100]T	
Grp: 90.2	Placebo psychogenic patients	age:	duration:	Pts: 24
	Pt. Desc: psychogenic 100%,		Rx: Placebo [25,100]T	
Grp: 90.3	Placebo mixed patients	age:	duration:	Pts: 24
	Pt. Desc: mixed 100%,		Rx: Placebo [25,100]T	

10028 Padma-Nathan, H.. Oral sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction: assessment of erections hard enough for sexual intercourse. 1999

Pts: Controlled Trial: 532 — California, USA — Ext: AJM

Grp: 0	All patients	age: 58(20,87)	duration: 3.2	Pts: 532
	Pt. Desc: organic 77%, psychogenic 9%, mixed 13%,		Rx:	
Grp: 1	25 mg sildenafil	age:	duration:	Pts: 102
	Pt. Desc:		Rx: sildenafil 25	
Grp: 2	50 mg sildenafil	age:	duration:	Pts: 107
	Pt. Desc:		Rx: sildenafil 50	
	Discont. AE: /1/			
Grp: 3	100 mg sildenafil	age:	duration:	Pts: 107
	Pt. Desc:		Rx: sildenafil 100	
	Discont. AE: /2/			
Grp: 90	placebo	age:	duration:	Pts: 216
	Pt. Desc:		Rx: Placebo 25	
	Discont. AE: /1/			

10029 Feldman, R., Meuleman, E. J., Steers, W.. Sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction: analysis of two flexible dose-escalation studies. Sildenafil Study Group. 1999

Pts: 644 Controlled Trial — WV, CT, Netherlands — Ext: AJM

Grp: 0	All patients	age:	duration: 5(0.5,35)	Pts: 644
	Pt. Desc:		Rx:	
Grp: 1	All patients on Sildenafil	age:	duration:	Pts: 322
	Pt. Desc:		Rx: sildenafil	
	Discont. AE: /6/			
Grp: 90	Placebo (all patients on placebo)	age:	duration:	Pts: 322
	Pt. Desc:		Rx: Placebo	
	Discont. AE: /2/			

10031 Young, J.. Sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction: a 12-week, flexible-dose study to assess efficacy and safety. 1999

Pts: 329 Controlled Trial — Laguna Hills, California — Ext: AJM

Grp: 0	All patients	age: (18,)	duration: (0.5,)	Pts: 329
	Pt. Desc:		Rx:	
Grp: 1	Sildenafil	age: (18,)	duration: (0.5,)	Pts: 163
	Pt. Desc:		Rx: sildenafil [25,100]T	
	Discontinued: /9/ Discont. AE: /2/			
Grp: 90	Placebo	age: (18,)	duration: (0.5,)	Pts: 166
	Pt. Desc:		Rx: Placebo [25,100]T	
	Discontinued: /13/ Discont. AE: /2/			

10062 Virag, R.. Indications and early results of sildenafil (Viagra) in erectile dysfunction. 1999

Pts: 177 Case Series/Report — Paris, France — Ext: Meet

Grp: 0	enitre cohort of enrolled patients - sildenafil	age: [56.48](22,85)	duration:	Pts: 177
	Pt. Desc:		Rx: sildenafil [50,100]T	
	Lost: /8/177 Discont. AE: /3/177 Discont. other: /12/177			
Grp: 1	Pts with coronary disease	age:	duration:	Pts: 4
	Pt. Desc: coronary heart disease 100%,		Rx: sildenafil [50,100]T	
Grp: 2	other cardiac conditions	age:	duration:	Pts: 2
	Pt. Desc: other cardiac: cardiomyopathy, WPW, arrhythmia 100%,		Rx: sildenafil [50,100]T	
Grp: 3	lower limb arteritis	age:	duration:	Pts: 1
	Pt. Desc: lower limb arteritis 100%,		Rx: sildenafil [50,100]T	
Grp: 4	diabetes	age:	duration:	Pts: 2
	Pt. Desc:		Rx: sildenafil [50,100]T	

Grp: 5	hypertension	age:	duration:	Pts: 24
	Pt. Desc: hypertension 100%,		Rx: sildenafil [50,100]T	
Grp: 5	hypertension	age:	duration:	Pts: 24
	Pt. Desc: hypertension 100%,		Rx: sildenafil [50,100]T	
Grp: 6	>20 cigarettes/day	age:	duration:	Pts: 15
	Pt. Desc: >20 cigarettes/day 100%,		Rx: sildenafil [50,100]T	
Grp: 7	high cholesterol	age:	duration:	Pts: 17
	Pt. Desc:		Rx: sildenafil [50,100]T	
Grp: 8	pelvic cancer	age:	duration:	Pts: 8
	Pt. Desc: post-prostatectomy 88%, rectal amputation 12%,		Rx: sildenafil [50,100]T	
Grp: 9	neurologic disorder	age:	duration:	Pts: 7
	Pt. Desc: neurologic disorder 100%,		Rx: sildenafil [50,100]T	
Grp: 10	fully rigid with ICI	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [50,100]T	
Grp: 11	not fully rigid with ICI	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [50,100]T	
Grp: 12	major cavernous leak	age:	duration:	Pts: 24
	Pt. Desc: major cavernous leak 100%,		Rx: sildenafil [50,100]T	

10103 Lowentritt, B. H., Scardino, P. T., Miles, B. J., Orejuela, F. J., Schatte, E. C., Slawin, K. M., Elliott, S. P., Kim, E. D.. Sildenafil citrate after radical retropubic prostatectomy. 1999

Pts: 84 Case Series/Report Houston, Texas Ext: Meet

Grp: 0	Post prostatectomy wilth sildenafil	age: 62(47,76)	duration: 2.1(0.3,9.5)	Pts: 84
	Pt. Desc: post-prostatectomy 100%, non nerve sparing 13%, unilateral nerve sparing 27%, bilateral nerve sparing 60%,		Rx: sildenafil [50,200]T	
	Discont. AE: /1/84			
Grp: 1	bilateral nerve sparing prostatectomy	age:	duration:	Pts: 50
	Pt. Desc: bilateral nerve sparing 100%,		Rx: sildenafil	
Grp: 2	unilateral nerve sparing prostatectomy	age:	duration:	Pts: 23
	Pt. Desc: unilateral nerve sparing 100%,		Rx: sildenafil	
Grp: 3	no nerve sparing prostatectomy	age:	duration:	Pts: 11
	Pt. Desc: non nerve sparing 100%,		Rx: sildenafil	

10161 Palmer, J. S., Kaplan, W. E., Firlit, C. F.. Erectile dysfunction in spina bifida is treatable. 1999

Pts: 8 Controlled Trial: Cross-over Chicago, Illinois Ext: DSS

Grp: 0	All spina bifida patients	age: (19,35)	duration:	Pts: 8
	Pt. Desc: organic 100%, neurogenic 100%,		Rx: Placebo [25,50]sildenafil [25,50]	
	Lost: 0%// Discontinued: 0%//			
Grp: 1	25 mg Sildenafil	age: (19,35)	duration:	Pts: 8
	Pt. Desc: organic 100%, neurogenic 100%,		Rx: sildenafil 25	
Grp: 2	50 mg Sildenafil	age: (19,35)	duration:	Pts: 8
	Pt. Desc: organic 100%, neurogenic 100%,		Rx: sildenafil 50	
Grp: 90	25 mg placebo	age: (19,35)	duration:	Pts: 8
	Pt. Desc: organic 100%, neurogenic 100%,		Rx: Placebo 25	
Grp: 91	50 mg placebo	age: (19,35)	duration:	Pts: 8
	Pt. Desc: organic 100%, neurogenic 100%,		Rx: Placebo 50	

10169 Giuliano, F., Hultling, C., El Masry, W. S., Smith, M. D., Osterloh, I. H., Orr, M., Maytom, M.. Randomized trial of sildenafil for the treatment of erectile dysfunction in spinal cord injury. Sildenafil Study Group. 1999

Pts: 183 Controlled Trial: Double blinded randomized placebo-controlled Sildenafil Study Group, France Ext: DSS

Grp: 1	Patients receiving sldenafil with spinal cord injury	age: 38(19,63)	duration: 11(0.7,38)	Pts: 178
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: sildenafil [25,100]T	
	Discontinued: 3%/6/175 Discont. AE: 2%/3/175 Discont. Insuff. resp.: /0/ Discont. other: 2%/3/175			

Grp: 1.3	Patients with complete spinal cord transection (ASIA category A)	age:	duration:	Pts: 95
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: sildenafil [25,100]T	
Grp: 1.4	Patients SCI ASIA Category B,C,D and unknown	age:	duration:	Pts: 83
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: sildenafil [25,100]T	
Grp: 1.5	Patients with residual erectile function at baseline	age:	duration:	Pts: 143
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: sildenafil [25,100]T	
Grp: 1.6	Patients with no residual function at baseline	age:	duration:	Pts: 25
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: sildenafil [25,100]T	
Grp: 90	Patients receiving placebo with spinal cord injury	age: 38(19,63)	duration: 11(0.7,38)	Pts: 128
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: Placebo [25,100]T	
	Discontinued: 2%/4/174 Discont. AE: 1%/1/174 Discont. other: /3/174			
Grp: 90.3	Placebo, ASIA A	age:	duration:	Pts: 95
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: Placebo [25,100]T	
Grp: 90.4	Placebo, ASIA B,C,D,E and unknown	age:	duration:	Pts: 83
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: Placebo [25,100]T	
Grp: 90.5	Placebo, with residual erectile function at baseline	age:	duration:	Pts: 143
	Pt. Desc: organic 100%, spinal cord injury 100%,		Rx: Placebo [25,100]T	

10223 Dinsmore, W. W., Hodges, M., Hargreaves, C., Osterloh, I. H., Smith, M. D., Rosen, R. C.. Sildenafil citrate (Viagra) in erectile dysfunction: near normalization in men with broad-spectrum erectile dysfunction compared with age- matched healthy control subjects. 1999

Pts: 111 Controlled Trial: Randomized, placebo controlled UK Ext: AJM

Grp: 1	Sildenafil	age: 56(30,78)	duration: 3.7(0.6,15)	Pts: 57
	Pt. Desc: organic 21%, psychogenic 40%, mixed 39%, diabetes 12%,		Rx: sildenafil [25,100]T	
	Discontinued: /3/ Discont. AE: /0/ Discont. Insuff. resp.: /1/			
Grp: 90	Placebo	age: 55(29,89)	duration: 5.4(0.5,37)	Pts: 54
	Pt. Desc: organic 20%, psychogenic 39%, mixed 37%,"other/unknown" 4%, diabetes 7%,		Rx: Placebo [25,100]T	
	Discontinued: /11/ Discont. Insuff. resp.: /1/			

10252 Maytom, M. C., Derry, F. A., Dinsmore, W. W., Glass, C. A., Smith, M. D., Orr, M., Osterloh, I. H.. A two-part pilot study of sildenafil (VIAGRA) in men with erectile dysfunction caused by spinal cord injury. 1999

Pts: 27 Controlled Trial: double blind randomized crossover 2 stage UK Ext: JT

Grp: 1	All patients all phase - sildenafil-all have spinal cord injury	age: 33(21,49)	duration: 7.27(0.8,24)	Pts: 26
	Pt. Desc: spinal cord injury 100%,		Rx: sildenafil 50	
Grp: 1.1	Phase 1 in office sildenafil	age: 33(21,49)	duration: 7.27(0.8,24)	Pts: 26
	Pt. Desc: spinal cord injury 100%,		Rx: sildenafil 50	
	Lost: /1/			
Grp: 1.2	Phase 2 at home sildenafil-randomized subset	age: 32(21,49)	duration: 6.7(0.8,24)	Pts: 13
	Pt. Desc: spinal cord injury 100%,		Rx: sildenafil 50	
Grp: 1.21	Subset with incomplete spinal cord injuries	age:	duration:	Pts: 5
	Pt. Desc: trauma 100%,		Rx: sildenafil 50	
Grp: 1.22	Subset with complete spinal cord injuries	age:	duration:	Pts: 7
	Pt. Desc:		Rx: sildenafil 50	
Grp: 90	All patients all phases - placebo - all with spinal cord injury	age: 37(21,49)	duration: 7.3(0.8,24)	Pts: 26
	Pt. Desc: spinal cord injury 100%,		Rx: Placebo 50	
Grp: 90.1	Phase 1 - in office - placebo	age: 37(21,49)	duration: 7.3(0.8,24)	Pts: 26
	Pt. Desc: spinal cord injury 100%,		Rx: Placebo 50	
	Lost: /1/			

Grp: 90.2 Phase 2 at hoome placebo - randomized subset age: 34(22,47) duration: 7.8(1,23) Pts: 14
Pt. Desc: spinal cord injury 100%, Rx: Placebo 50

10263 Rendell, M. S., Rajfer, J., Wicker, P. A., Smith, M. D.. Sildenafil for treatment of erectile dysfunction in men with diabetes: a randomized controlled trial. Sildenafil Diabetes Study Group. 1999

Pts: 268 Controlled Trial: Randomized US Ext: AJM

Grp: 1 Sildenafil age: 57(33,76) duration: 5.3(0.6,22) Pts: 136
Pt. Desc: organic 95%, mixed 5%, diabetes 100%, Type I DM 16%, Type II DM 84%, Rx: sildenafil [25,100]T
Lost: /1/ Discontinued: /5/ Discont. AE: /1/ Discont. Insuff. resp.: /1/ Discont. other: /2/

Grp: 1.1 Sildenafil age 18-49 age: (33,49) duration: Pts: 29
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.11 Sildenafil Type I DM age: duration: Pts: 20
Pt. Desc: Type I DM 100%, Rx: sildenafil [25,100]T

Grp: 1.12 Sildenafil Type II DM age: duration: Pts: 111
Pt. Desc: Type 2 DM 100%, Rx: sildenafil [25,100]T

Grp: 1.2 Sildenafil age 50-64 age: (50,64) duration: Pts: 62
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.3 Sildenafil age > or = 65 age: (65,76) duration: Pts: 40
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.4 Sildenafil ED 0-3 years age: duration: (0.6,3) Pts: 51
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.5 Sildenafil ED 3-6 years age: duration: (3,6) Pts: 34
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.6 Sildenafil ED >6 years age: duration: (7,22) Pts: 46
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.7 Sildenafil Diabetes 0-6 years age: duration: Pts: 39
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.8 Sildenafil Diabetes 6-12 years age: duration: Pts: 39
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 1.9 Sildenafil Diabetes >12 years age: duration: Pts: 53
Pt. Desc: diabetes 100%, Rx: sildenafil [25,100]T

Grp: 90 Placebo age: 57(27,79) duration: 5.8(1,24) Pts: 132
Pt. Desc: organic 96%, mixed 4%, diabetes 100%, Type I DM 21%, Type II DM 79%, Rx: Placebo [25,100]T
Lost: /0/ Discontinued: /11/ Discont. AE: /1/ Discont. Insuff. resp.: /1/ Discont. other: /9/

Grp: 90.1 Placebo age 18-49 years age: (27,49) duration: Pts: 27
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.11 Placebo Type I DM age: duration: Pts: 26
Pt. Desc: Type I DM 100%, Rx: Placebo [25,100]T

Grp: 90.12 Placebo Type II DM age: duration: Pts: 100
Pt. Desc: Type 2 DM 100%, Rx: Placebo [25,100]T

Grp: 90.2 Placebo age 50-64 years age: (50,64) duration: Pts: 70
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.3 Placebo age > or = 65 years age: (65,79) duration: Pts: 29
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.4 Placebo ED 0-3 years age: duration: (1,3) Pts: 36
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.5 Placebo ED 4-6 years age: duration: (3,6) Pts: 49
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.6 Placebo ED >6 years age: duration: (7,24) Pts: 41
Pt. Desc: diabetes 100%, Rx: Placebo [25,100]T

Grp: 90.7	Placebo Diabetes 0-6 years	age:	duration:	Pts: 41
	Pt. Desc: diabetes 100%,		Rx: Placebo [25,100]T	
Grp: 90.8	Placebo Diabetes 6-12 years	age:	duration:	Pts: 40
	Pt. Desc: diabetes 100%,		Rx: Placebo [25,100]T	
Grp: 90.9	Placebo Diabetes >12 years	age:	duration:	Pts: 45
	Pt. Desc: diabetes 100%,		Rx: Placebo [25,100]T	

10338 Price, D. E., Gingell, J. C., Gepi-Attee, S., Wareham, K., Yates, P., Boolell, M.. Sildenafil: study of a novel oral treatment for erectile dysfunction in diabetic men. 1998

Pts: 21 Controlled Trial: randomized blinded cross-over Sandwich, UK Ext: Meet

Grp: 0	all patients	age: 51(42,65)	duration: 3(1,14)	Pts: 21
	Pt. Desc: diabetes 100%,		Rx:	
Grp: 1	25 mg sildenafil	age:	duration:	Pts: 20
	Pt. Desc: diabetes 100%,		Rx: sildenafil	
	Discont. other: /1/21			
Grp: 2	50 mg sildenafil	age:	duration:	Pts: 21
	Pt. Desc: diabetes 100%,		Rx: sildenafil	
	Lost: /0/			
Grp: 90	placebo	age:	duration:	Pts: 21
	Pt. Desc: diabetes 100%,		Rx: Placebo	
	Lost: /0/			

10409 Morales, A., Gingell, C., Collins, M., Wicker, P. A., Osterloh, I. H.. Clinical safety of oral sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction. 1998

Pts: Meta-analysis: 6473 Kingston, Ontario, Canada Ext: AJM

Grp: 0	All patients in placebo controlled trials.	age: (18,87)	duration: 5	Pts: 4274
	Pt. Desc:		Rx:	
Grp: 1	PRN flexible dose Sildenafil	age:	duration:	Pts: 734
	Pt. Desc:		Rx: sildenafil [25,100]T	
	Discont. AE: 2.5%//			
Grp: 2	PRN fixed dose. All doses sildenafil.	age:	duration:	Pts: 1606
	Pt. Desc:		Rx: sildenafil	
Grp: 2.1	PRN fixed sildenafil 25.	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil 25	
	Discont. AE: 0.6%//			
Grp: 2.2	PRN fixed sildenafil 50.	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil 50	
	Discont. AE: 0.4%//			
Grp: 2.3	PRN fixed sildenafil 100.	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil 100	
	Discont. AE: 1.2%//			
Grp: 3	Open label sildenafil.	age:	duration:	Pts: 2199
	Pt. Desc:		Rx: sildenafil	
	Discontinued: 10%// Discont. AE: 2%// Discont. Insuff. resp.: 4%//			
Grp: 4	All placebo/controlled patients on sildenafil.	age:	duration:	Pts: 2722
	Pt. Desc:		Rx: sildenafil	
Grp: 90	PRN flexible dose placebo	age:	duration:	Pts: 725
	Pt. Desc:		Rx: Placebo [25,100]T	
	Discont. AE: 2.3%//			
Grp: 91	PRN fixed dose placebo.	age:	duration:	Pts: 607
	Pt. Desc:		Rx: Placebo	
Grp: 92	All placebo/controlled patients on placebo.	age:	duration:	Pts: 1552
	Pt. Desc:		Rx: Placebo	

10622 Mulhall, J.. Sildenafil: a novel effective oral therapy for male erectile dysfunction. 1997

Pts: 12 Letter Sandwich, UK Ext: AJM

Grp: 0	All patients	age: 47.9	duration: (1.5,10)	Pts: 12
	Pt. Desc:		Rx:	
Grp: 1	50mg sildenafil	age:	duration:	Pts: 12
	Pt. Desc:		Rx: sildenafil 50	
Grp: 90	Placebo	age:	duration:	Pts: 12
	Pt. Desc:		Rx: Placebo	

10708 Boolell, M., Gepi-Attee, S., Gingell, J. C., Allen, M. J.. Sildenafil, a novel effective oral therapy for male erectile dysfunction. 1996

Pts: 12 Controlled Trial: randomized, double blind, crossover Sandwich, UK Ext: JT

Grp: 1	Sildenafil	age: 47.9(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: sildenafil 25	
Grp: 90	Placebo	age: 47.9(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: Placebo 25	

10730 Boolell, M., Allen, M. J., Ballard, S. A., Gepi-Attee, S., Muirhead, G. J., Naylor, A. M., Osterloh, I. H., Gingell, C.. Sildenafil: an orally active type 5 cyclic GMP-specific phosphodiesterase inhibitor for the treatment of penile erectile dysfunction. 1996

Pts: 12 Controlled Trial Bristol, UK Ext: AJM

Grp: 1	Sildenafil 10 mg	age: 48(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: sildenafil 10	
	Discont. AE: /0/			
Grp: 2	Sildenafil 25mg	age: 48(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: sildenafil 25	
	Discont. AE: /0/			
Grp: 3	Sildenafil 50 mg	age: 48(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: sildenafil 50	
	Discont. AE: /0/			
Grp: 90	Placebo	age: 48(36,63)	duration: 3.4(1.5,10)	Pts: 12
	Pt. Desc:		Rx: Placebo 50[,10]	
	Discont. AE: /0/			

104993 Feldman R. Sildenafil in the treatment of erectile dysfunction: efficacy in patients taking concomitant antihypertensive therapy.. 1998

Pts: 3413 Controlled Trial Waterbury, CT Ext: AJM

Grp: 0	All patients	age: 56	duration:	Pts: 3413
	Pt. Desc:		Rx:	
Grp: 1	On antihypertensives + sildenafil	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [5,100]	
Grp: 2	No antihypertensives + sildenafil	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [5,100]	
Grp: 90	On antihypertensives + placebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [5,100]	
Grp: 91	No antihypertensives + palcebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [5,100]	

105033 Padma-Nathan H. Efficacy and safety of oral sildenafil in the treatment of erectile dysfunction: a double-blind, placebo-controlled study of 329 patients.. 1998

Pts: 329 Controlled Trial: randomized US Ext: Meet

Grp: 1	Sildenafil	age: 60(26,79)	duration: 5(0.5,26)	Pts: 163
	Pt. Desc: organic 55%, psychogenic 14%, mixed 31%, diabetes 8%, post-prostatectomy 9%, hypertension 24%, hyperlipidemia 15%,		Rx: sildenafil [25,100]T	
	Lost: /3/163 Discont. AE: /1/163 Discont. Insuff. resp.: /1/163 Discont. other: /4/163			

Grp: 1 Sildenafil age: 60(26,79) duration: 5(0.5,26) Pts: 163
Pt. Desc: organic 55%, psychogenic 14%, mixed 31%, diabetes 8%, post-prostatectomy 9%, hypertension 24%, hyperlipidemia 15%, Rx: sildenafil [25,100]T
Lost: /3/163 Discont. AE: /1/163 Discont. Insuff. resp.: /1/163 Discont. other: /4/163

Grp: 90 Placebo age: 59(31,81) duration: 4.7(0.6,26) Pts: 166
Pt. Desc: organic 63%, psychogenic 16%, mixed 22%, diabetes 11%, post-prostatectomy 11%, hypertension 28%, hyperlipidaemia 15%, Rx: Placebo [25,100]T
Lost: /2/166 Discont. AE: /1/166 Discont. Insuff. resp.: /3/166 Discont. other: /7/166

Grp: 90 Placebo age: 59(31,81) duration: 4.7(0.6,26) Pts: 166
Pt. Desc: organic 63%, psychogenic 16%, mixed 22%, diabetes 11%, post-prostatectomy 11%, hypertension 28%, hyperlipidaemia 15%, Rx: Placebo [25,100]T
Lost: /2/166 Discont. AE: /1/166 Discont. Insuff. resp.: /3/166 Discont. other: /7/166

105100 Montorsi F, McDermott TED, Morgan R, Olsson A, Schultz A, Kirkeby HJ, Osterloh IH.. Efficacy and safety of fixed-dose oral sildenafil in the treatment of erectile dysfunction of various etiologies.. 1999
Pts: 514 Controlled Trial: double blind rct Ireland; UK; Norway; Denmark Ext: HSB

Grp: 1 25mg sildenafil age: 55(19,74) duration: 4.5(0.5,30) Pts: 128
Pt. Desc: organic 28%, psychogenic 28%, mixed 44%, diabetes 8%, GU procedures (turp or rp) 14%, GU disease (e.g. bph) 2%, Rx: sildenafil 25
Discont. AE: /0/

Grp: 2 50mg sildenafil age: 57(30,76) duration: 4.6(0.5,40) Pts: 132
Pt. Desc: organic 36%, psychogenic 23%, mixed 41%, diabetes 10%, GU procedures (turp or rp) 14%, GU disease (e.g. bph) 5%, Rx: sildenafil 50
Discont. AE: /1/

Grp: 3 100mg sildenafil age: 56(25,79) duration: 5(0.5,30) Pts: 127
Pt. Desc: organic 35%, psychogenic 25%, mixed 39%, diabetes 7%, GU procedures (turp or rp) 12%, GU disease (e.g. bph) 10%, Rx: sildenafil 100
Discont. AE: /5/

Grp: 90 placebo age: 55(20,77) duration: 5(0.6,30) Pts: 127
Pt. Desc: organic 29%, psychogenic 24%, mixed 46%, diabetes 10%, GU procedures (turp or rp) 19%, GU disease (e.g. bph) 4%, Rx: Placebo
Discont. AE: /1/

200110 Prieto Castro, R. M., Anglada Curado, F. J., Regueiro Lopez, J. C., Leva Vallejo, M. E., Molina Sanchez, J., Saceda Lopez, J. L., Requena Tapia, M. J.. Treatment with sildenafil citrate in renal transplant patients with erectile dysfunction. 2001
Pts: 50 Case Series/Report Spain Ext: AJM

Grp: 1 All patients in the study age: 54 duration: Pts: 50
Pt. Desc: Rx: sildenafil [25,100]T
Discontinued: /6/

200300 Lewis, R., Bennett, C. J., Borkon, W. D., Boykin, W. H., Althof, S. E., Stecher, V. J., Siegel, R. L.. Patient and partner satisfaction with Viagra (sildenafil citrate) treatment as determined by the Erectile Dysfunction Inventory of Treatment Satisfaction Questionnaire. 2001
Pts: 247 Controlled Trial: randomized, placebo controlled trial US Ext: AJM

Grp: 1 Sildenafil age: 58(33,77) duration: 3.9(0.44,17.1) Pts: 124
Pt. Desc: organic 82%, psychogenic 3%, mixed 15%, diabetes 21%, Rx: sildenafil [25,100]T
Discontinued: /7/ Discont. AE: /2/ Discont. Insuff. resp.: /2/

Grp: 90 Placebo age: 60(31,81) duration: 3.6(0.6,13.6) Pts: 123
Pt. Desc: organic 80%, psychogenic 5%, mixed 15%, diabetes 19%, Rx: Placebo [25,100]T
Discontinued: /12/ Discont. AE: /0/ Discont. Insuff. resp.: /8/

700002 Incrocci, L., Koper, P. C., Hop, W. C., Slob, A. K.. Sildenafil citrate (Viagra) and erectile dysfunction following external beam radiotherapy for prostate cancer: a randomized, double-blind, placebo-controlled, cross-over study. 2001
Pts: 60 Controlled Trial: Randomized, placebo controlled crossover study Rotterdam, Netherlands Ext: AJM

Grp: 1	Sildenafil	age: 68(56,79)	duration: (,4.6)	Pts: 60
	Pt. Desc: diabetes 5%, post-radiation 100%,		Rx: sildenafil [25,100]T	
	Discont. AE: /0/			
Grp: 90	Placebo	age: 68(56,79)	duration: (,4.6)	Pts: 60
	Pt. Desc: diabetes 5%, post-radiation 100%,		Rx: Placebo [25,100]T	
	Discont. AE: /0/			

700003 Boulton, A. J., Selam, J. L., Sweeney, M., Ziegler, D.. Sildenafil citrate for the treatment of erectile dysfunction in men with Type II diabetes mellitus. 2001

Pts: 219 Controlled Trial: Placebo controlled, randomized trial Europe Ext: AJM

Grp: 1	Sildenafil	age: 58.2(38,80)	duration: 4.6(0.4,21)	Pts: 110
	Pt. Desc: organic 64%, psychogenic 4%, mixed 32%, diabetes 100%,		Rx: sildenafil [25,100]T	
	Discont. AE: 1.8%//			
Grp: 1.1	HbAIC <8.3% + Sildenafil	age:	duration:	Pts: 57
	Pt. Desc:		Rx: sildenafil	
Grp: 1.2	HbAIC >8.3% + Sildenafil	age:	duration:	Pts: 53
	Pt. Desc:		Rx: sildenafil	
Grp: 1.3	No diabetic complications + Sildenafil	age:	duration:	Pts: 47
	Pt. Desc:		Rx: sildenafil	
Grp: 1.4	At least one diabetic complication + Sildenafil	age:	duration:	Pts: 63
	Pt. Desc:		Rx: sildenafil	
Grp: 90	Placebo	age:	duration:	Pts: 109
	Pt. Desc:		Rx: Placebo [25,100]T	
	Discont. AE: 1.8%//			
Grp: 90.1	HbAIC <8.3 + Placebo	age:	duration:	Pts: 53
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	HbAIC >8.3 + Placebo	age:	duration:	Pts: 56
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	No diabetic complications + placebo	age:	duration:	Pts: 34
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	At least one diabetic complication + placebo	age:	duration:	Pts: 75
	Pt. Desc:		Rx: Placebo	

700006 Seidman, S. N., Roose, S. P., Menza, M. A., Shabsigh, R., Rosen, R. C.. Treatment of erectile dysfunction in men with depressive symptoms: results of a placebo-controlled trial with sildenafil citrate. 2001

Pts: 152 Controlled Trial: Randomized, double blind, placebo controlled US Ext: AJM

Grp: 1	Sildenafil	age: 56.7(27,76)	duration: 6.1(0.3,33)	Pts: 74
	Pt. Desc: Depression 100%,		Rx: sildenafil [25,100]T	
Grp: 90	Placebo	age: 55.2(25,81)	duration: 5.4(0.6,23)	Pts: 78
	Pt. Desc: Depression 100%,		Rx: Placebo [25,100]T	

700008 Hussain, I. F., Brady, C. M., Swinn, M. J., Mathias, C. J., Fowler, C. J.. Treatment of erectile dysfunction with sildenafil citrate (Viagra) in parkinsonism due to Parkinson's disease or multiple system atrophy with observations on orthostatic hypotension. 2001

Pts: 24 Controlled Trial: Randomized, placebo controlled, crossover trial Ext: AJM

Grp: 1	Sildenafil	age: (46,68)	duration: (1,7.5)	Pts: 24
	Pt. Desc:		Rx: sildenafil [25,100]T	
Grp: 1.1	Parkinson's Disease	age: [61](48,68)	duration: 4.5(1,6)	Pts: 12
	Pt. Desc: Parkinson's Disease 100%,		Rx: sildenafil	
	Discont. other: /2/			
Grp: 1.2	Multiple system atrophy	age: [54](46,61)	duration: [4.75](2,7.5)	Pts: 12
	Pt. Desc: Multiple system atrophy 100%,		Rx: sildenafil	
Grp: 1.3	Parkinson's Disease and Sildenafil	age:	duration:	Pts: 12
	Pt. Desc:		Rx: sildenafil	
Grp: 90	Placebo	age: (46,68)	duration: (1,7.5)	Pts: 24
	Pt. Desc:		Rx: Placebo [25,100]T	

Grp: 90.1 Multiple system atrophy and placebo age: duration: Pts: 12
Pt. Desc: Rx: Placebo

700009 Chen, K. K., Hsieh, J. T., Huang, S. T., Jiaan, D. B., Lin, J. S., Wang, C. J.. ASSESS-3: a randomised, double-blind, flexible-dose clinical trial of the efficacy and safety of oral sildenafil in the treatment of men with erectile dysfunction in Taiwan. 2001

Pts: 237 Controlled Trial: Randomized, placebo controlled Taiwan Ext: AJM

Grp: 1 Sildenafil age: 60.7(28,80) duration: 4 Pts: 119
Pt. Desc: organic 81%, psychogenic 9%, mixed 10%, diabetes 22%, Rx: sildenafil [25,100]T
Discont. AE: /1/ Discont. Insuff. resp.: /1/ Discont. other: /8/

Grp: 90 Placebo age: 60.2(26,78) duration: 4 Pts: 117
Pt. Desc: organic 83%, psychogenic 8%, mixed 9%, diabetes 25%, Rx: Placebo [25,100]T
Discont. AE: /1/ Discont. Insuff. resp.: /1/ Discont. other: /4/

700015 Eardley, I., Morgan, R., Dinsmore, W., Yates, P., Boolell, M.. Efficacy and safety of sildenafil citrate in the treatment of men with mild to moderate erectile dysfunction. 2001

Pts: 44 Controlled Trial: Randomized, placebo controlled, crossover trial UK Ext: AJM

Grp: 1 Sildenafil age: 53(33,69) duration: 2.9(0.5,10) Pts: 44
Pt. Desc: Rx: sildenafil [25,75]T
Discontinued: /4/

Grp: 2 Sildenafil then placebo age: 53(33,69) duration: 2.8(0.5,10) Pts: 24
Pt. Desc: Rx: seldenafil followed by placebo

Grp: 3 Placebo then sildenafil age: 53(36,69) duration: 3.1(0.5,10) Pts: 20
Pt. Desc: Rx: Placebo followed by sildenafil

Grp: 90 Placebo age: 53(33,69) duration: 2.9(0.5,10) Pts: 44
Pt. Desc: Rx: Placebo [25,75]T
Discontinued: /4/

700016 Olsson, A. M., Speakman, M. J., Dinsmore, W. W., Giuliano, F., Gingell, C., Maytom, M., Smith, M. D., Osterloh, I.. Sildenafil citrate (Viagra) is effective and well tolerated for treating erectile dysfunction of psychogenic or mixed aetiology. 2000

Pts: 351 Controlled Trial: Placebo controlled, randomized, double blind Europe Ext: AJM

Grp: 1 10 mg sildenafil age: 52(28,70) duration: 4.7(0.4,30) Pts: 90
Pt. Desc: organic 1%, psychogenic 59%, mixed 40%, Rx: sildenafil 10
Lost: /1/ Discontinued: /7/ Discont. AE: /1/ Discont. Insuff. resp.: /1/ Discont. other: /4/

Grp: 2 25 mg sildenafil age: 53(24,70) duration: 4.5(0.3,23) Pts: 85
Pt. Desc: organic 1%, psychogenic 61%, mixed 38%, Rx: sildenafil 25
Lost: /1/ Discontinued: /7/ Discont. AE: /4/ Discont. Insuff. resp.: /2/ Discont. other: /0/

Grp: 3 50 mg sildenafil age: 52(26,69) duration: 4.5(0.4,30) Pts: 81
Pt. Desc: organic 0%, psychogenic 59%, mixed 41%, Rx: sildenafil 50
Lost: /0/ Discontinued: /11/ Discont. AE: /5/ Discont. Insuff. resp.: /1/ Discont. other: /5/

Grp: 4 Psychogenic patients on 10 mg sildenafil age: duration: Pts: 53
Pt. Desc: Rx: sildenafil 10

Grp: 5 Mixed etiology patients on 10mg sildenafil age: duration: Pts: 36
Pt. Desc: Rx: sildenafil 10

Grp: 6 Psychogenic patients on 25 mg sildenafil age: duration: Pts: 52
Pt. Desc: Rx: sildenafil 25

Grp: 7 Mixed etiology pts on 25 mg sildenafil age: duration: Pts: 32
Pt. Desc: Rx: sildenafil 25

Grp: 8 Psychogenic patients on 50 mg sildenafil age: duration: Pts: 48
Pt. Desc: Rx: sildenafil 50

Grp: 9 Mixed etiology patients on 50 mg sildenafil age: duration: Pts: 33
Pt. Desc: Rx: sildenafil 50

Grp: 90 Placebo age: 53(26,70) duration: 4.3(0.2,40) Pts: 95
Pt. Desc: organic 0%, psychogenic 54%, mixed 46%, Rx: Placebo 999
Lost: /4/ Discontinued: /9/ Discont. AE: /4/ Discont. Insuff. resp.: /0/ Discont. other: /1/

Grp: 91 Psychogenic patients on placebo age: duration: Pts: 51
Pt. Desc: Rx: Placebo

Grp: 92 Mixed etiology patients on placebo age: duration: Pts: 44
Pt. Desc: Rx: Placebo

700018 Meuleman, E., Cuzin, B., Opsomer, R. J., Hartmann, U., Bailey, M. J., Maytom, M. C., Smith, M. D., Osterloh, I. H.. A dose-escalation study to assess the efficacy and safety of sildenafil citrate in men with erectile dysfunction. 2001
Pts: 315 Controlled Trial: randomized double blind dose escalation Europe (Belgium,France,Germany, UK,Netherlands) Ext: Meet

Grp: 1 Entire sildenafil group age: 55(24,77) duration: 4.75(1,35) Pts: 159
Pt. Desc: organic 29%, psychogenic 31%, mixed 38%, diabetes 16%, hypertension 21%, ischaemic heart disease 21%, Rx: sildenafil [25,100]T
Discontinued: /35/ Discont. AE: /5/ Discont. Insuff. resp.: /13/ Discont. other: /17/

Grp: 1 Entire sildenafil group age: 55(24,77) duration: 4.75(1,35) Pts: 159
Pt. Desc: organic 29%, psychogenic 31%, mixed 38%, diabetes 16%, hypertension 21%, ischaemic heart disease 21%, Rx: sildenafil [25,100]T

Grp: 1 Entire sildenafil group age: 55(24,77) duration: 4.75(1,35) Pts: 159
Pt. Desc: organic 29%, psychogenic 31%, mixed 38%, diabetes 16%, hypertension 21%, ischaemic heart disease 21%, Rx: sildenafil [25,100]T
Discontinued: /35/ Discont. AE: /5/ Discont. Insuff. resp.: /13/ Discont. other: /17/

Grp: 1 Entire sildenafil group age: 55(24,77) duration: 4.75(1,35) Pts: 159
Pt. Desc: organic 29%, psychogenic 31%, mixed 38%, diabetes 16%, hypertension 21%, ischaemic heart disease 21%, Rx: sildenafil [25,100]T

Grp: 1.1 organic impotence-sildenafil age: duration: Pts: 46
Pt. Desc: organic 100%, Rx: sildenafil [25,100]T

Grp: 1.2 psychogenic impotence - sildenafil age: duration: Pts: 50
Pt. Desc: psychogenic 100%, Rx: sildenafil [25,100]T

Grp: 1.3 mixed impotence - sildenafil age: duration: Pts: 60
Pt. Desc: mixed 100%, Rx: sildenafil [25,100]T

Grp: 90 entire placebo group age: 54(23,82) duration: 5.05(1,27) Pts: 156
Pt. Desc: organic 29%, psychogenic 32%, mixed 35%,undefined 2%, diabetes 15%, hypertension 19%, ischaemic heart disease 6%, Rx: Placebo [25,100]T
Discontinued: /77/ Discont. AE: /1/ Discont. Insuff. resp.: /54/ Discont. other: /22/

Grp: 90 entire placebo group age: 54(23,82) duration: 5.05(1,27) Pts: 156
Pt. Desc: organic 29%, psychogenic 32%, mixed 35%,undefined 2%, diabetes 15%, hypertension 19%, ischaemic heart disease 6%, Rx: Placebo [25,100]T

Grp: 90 entire placebo group age: 54(23,82) duration: 5.05(1,27) Pts: 156
Pt. Desc: organic 29%, psychogenic 32%, mixed 35%,undefined 2%, diabetes 15%, hypertension 19%, ischaemic heart disease 6%, Rx: Placebo [25,100]T

Grp: 90 entire placebo group age: 54(23,82) duration: 5.05(1,27) Pts: 156
Pt. Desc: organic 29%, psychogenic 32%, mixed 35%,undefined 2%, diabetes 15%, hypertension 19%, ischaemic heart disease 6%, Rx: Placebo [25,100]T
Discontinued: /77/ Discont. AE: /1/ Discont. Insuff. resp.: /54/ Discont. other: /22/

Grp: 90.1 organic impotence - placebo age: duration: Pts: 46
Pt. Desc: organic 100%, Rx: Placebo [25,100]T

Grp: 90.2 psychogenic impotence - placibo age: duration: Pts: 50
Pt. Desc: psychogenic 100%, Rx: Placebo [25,100]T

Grp: 90.3 mixed impotence - placebo age: duration: Pts: 54
Pt. Desc: mixed 2%, Rx: Placebo [25,100]T

700020 Tan, H. M., Moh, C. L., Mendoza, J. B., Gana, T., Albano, G. J., de la Cruz, R., Chye, P. L., Sam, C. C.. Asian sildenafil efficacy and safety study (ASSESS-1): a double-blind, placebo-controlled, flexible-dose study of oral sildenafil in Malaysian, Singaporean, and Filipino men with erectile dysfunction. The Assess-1 Study Group. 2000

Pts: 254 Controlled Trial | Singapore, Philippines, Malaysia | Ext: AJM

Grp: 1	Slidenafil	age: 52.1(31,78)	duration: 3.6	Pts: 127
	Pt. Desc: organic 65%, psychogenic 12%, mixed 24%, diabetes 38%, Hypertension 22%, Visual disturbance 17%,		Rx: sildenafil [25,100]T	
Grp: 1	Slidenafil	age: 52.1(31,78)	duration: 3.6	Pts: 127
	Pt. Desc: organic 65%, psychogenic 12%, mixed 24%, diabetes 38%, Hypertension 22%, Visual disturbance 17%,		Rx: sildenafil [25,100]T	
Grp: 90	Placebo	age: 50.8(26,70)	duration: 3.6	Pts: 127
	Pt. Desc: organic 61%, psychogenic 14%, mixed 24%, diabetes 34%, Hypertension 26%, Visual disturbance 20%,		Rx: Placebo [25,100]T	
Grp: 90	Placebo	age: 50.8(26,70)	duration: 3.6	Pts: 127
	Pt. Desc: organic 61%, psychogenic 14%, mixed 24%, diabetes 34%, Hypertension 26%, Visual disturbance 20%,		Rx: Placebo [25,100]T	

700023 Palmer, J. S., Kaplan, W. E., Firlit, C. F.. Erectile dysfunction in patients with spina bifida is a treatable condition. 2000

Pts: 17 Controlled Trial: Randomized, controlled, crossover trial | Chicago | Ext: AJM

Grp: 0	All patients	age: (19,35)	duration:	Pts: 17
	Pt. Desc: neurogenic 100%,		Rx:	
	Lost: /2/			
Grp: 1	25 mg sildenafil	age: (19,35)	duration:	Pts: 17
	Pt. Desc: neurogenic 100%,		Rx: sildenafil 25	
Grp: 2	50 mg sildenafil	age: (19,35)	duration:	Pts: 17
	Pt. Desc: neurogenic 100%,		Rx: sildenafil 50	
Grp: 3	All patients getting sildenafil	age:	duration:	Pts: 17
	Pt. Desc:		Rx: sildenafil	
Grp: 90	25 mg placebo = placebo #1	age: (19,35)	duration:	Pts: 17
	Pt. Desc: neurogenic 100%,		Rx: Placebo 25	
Grp: 91	50 mg placebo = placebo #2	age: (19,35)	duration:	Pts: 17
	Pt. Desc: neurogenic 100%,		Rx: Placebo 50	
Grp: 92	All patients getting placebo	age:	duration:	Pts: 17
	Pt. Desc:		Rx: Placebo	

700025 Hultling, C., Giuliano, F., Quirk, F., Pena, B., Mishra, A., Smith, M. D.. Quality of life in patients with spinal cord injury receiving Viagra (sildenafil citrate) for the treatment of erectile dysfunction. 2000

Pts: 178 Controlled Trial: Randomized controlled trila | Europe | Ext: AJM

Grp: 1	Sildenafil	age: 38(18,63)	duration: 11	Pts: 178
	Pt. Desc: spinal cord injury 100%,		Rx: sildenafil [25,100]T	
	Discontinued: 3.4%//			
Grp: 90	Placebo	age: 38(18,63)	duration: 11	Pts: 178
	Pt. Desc: spinal cord injury 100%,		Rx: Placebo [25,100]T	
	Discontinued: 2.3%//			

750019 Lindsey, I., George, B., Kettlewell, M., Mortensen, N.. Randomized, double-blind, placebo-controlled trial of sildenafil (Viagra) for erectile dysfunction after rectal excision for cancer and inflammatory bowel disease. 2002

Pts: 34 Controlled Trial: Randomized, placebo controlled, partial crossover | Oxford, UK | Ext: AJM

Grp: 0	All patients	age: [58.7]	duration:	Pts: 32
	Pt. Desc: Post-proctectomy for rectal cancer 38%, Post-proctectomy for inflammatory bowel disease 62%,		Rx:	
	Lost: /0/ Discont. AE: /0/			
Grp: 1	Sildenafil	age: [59.5]	duration:	Pts: 14
	Pt. Desc:		Rx: sildenafil [25,100]T	

Grp: 2	Unblinded crossover from placebo to sildenafil	age:	duration:	Pts: 10
	Pt. Desc:		Rx: sildenafil T	
Grp: 3	All pts receiving sildenafil (before and after crossover) s/p rectal cancer resection	age:	duration:	Pts: 9
	Pt. Desc: s/p rectal resection for rectal cancer 100%,		Rx: sildenafil	
Grp: 4	All pts receiving sildenafil (before and after crossover) with IBD	age:	duration:	Pts: 15
	Pt. Desc: s/p rectal resection for inflammatory bowel disease 100%,		Rx: sildenafil	
Grp: 5	All pts receiving sildenafil (before and after crossover) with partial ED	age:	duration:	Pts: 11
	Pt. Desc:		Rx: sildenafil	
Grp: 6	All pts receiving sildenafil (before and after crossover) with complete ED	age:	duration:	Pts: 13
	Pt. Desc:		Rx: sildenafil	
Grp: 90	Placebo	age: [58.7]	duration:	Pts: 18
	Pt. Desc:		Rx: Placebo [25,100]T	
Grp: 90.1	Control subgroup who will eventually unblind and crossover	age:	duration:	Pts: 10
	Pt. Desc:		Rx: Placebo	

750035 Dundar, M., Kocak, I., Dundar, S. O., Erol, H.. Evaluation of side effects of sildenafil in group of young healthy volunteers. 2001

Pts: 40 Other: Side effect study Aydin, Turkey Ext: AJM

Grp: 1	Sildenafil	age: 26.8(20,38)	duration:	Pts: 20
	Pt. Desc:		Rx: sildenafil 50	
Grp: 90	Placebo	age: 25.7(21,36)	duration:	Pts: 20
	Pt. Desc:		Rx: Placebo 50	

750205 Wagner, G., Montorsi, F., Auerbach, S., Collins, M.. Sildenafil citrate (VIAGRA) improves erectile function in elderly patients with erectile dysfunction: a subgroup analysis. 2001

Pts: 482 Meta-analysis Ext: AJM

Grp: 1	Elderly ED pts in "broad spectrum etiology group" + sildenafil	age: 70(65,87)	duration: 4(0.5,20)	Pts: 253
	Pt. Desc: organic 66%, psychogenic 6%, mixed 27%,Unknown 0%, diabetes 7%, hypogonadism 0%, spinal cord injury 0%,		Rx: sildenafil [25,100]	
Grp: 2	Elderly ED pts with diabetes-focused group + sildenafil	age: 69(65,76)	duration: 6(0.6,11)	Pts: 40
	Pt. Desc: organic 93%, psychogenic 0%, mixed 8%, diabetes 100%, hypogonadism 0%, spinal cord injury 0%,		Rx: sildenafil [25,100]T	
Grp: 3	All patients on sildenafil (group 1 and 2)	age:	duration:	Pts: 293
	Pt. Desc:		Rx: sildenafil	
	Discontinued: 3%// Discont. AE: 1%//			
Grp: 90	Elderly ED pts in "broad spectrum etiology group" on placebo	age: 69(65,82)	duration: 4(0.5,27)	Pts: 158
	Pt. Desc: organic 71%, psychogenic 6%, mixed 22%,Unknown 1%, diabetes 9%, hypogonadism 0%, spinal cord injury 0%,		Rx: Placebo [25,100]	
Grp: 91	Elderly ED pts with diabetes-focused group on placebo	age: 69(65,79)	duration: 7(1,24)	Pts: 31
	Pt. Desc: organic 97%, psychogenic 0%, mixed 3%, diabetes 100%, hypogonadism 0%, spinal cord injury 0%,		Rx: Placebo [25,100]T	
Grp: 92	All patients on placebo (group 90 and 91)	age:	duration:	Pts: 189
	Pt. Desc:		Rx: Placebo	
	Discontinued: 3%// Discont. AE: 1%//			

796021 Young, J. M., Bennett, C., Gilhooly, P., Wessells, H., Ramos, D. E.. Efficacy and safety of sildenafil citrate (Viagra) in black and Hispanic American men. 2002

Pts: 441 Controlled Trial: double blind RCT, opt. crossover, open label ext. Ext: HSB

Grp: 1	Black patients on sildenafil	age: 53(25,73)	duration: 4(0.3,33)	Pts: 124
	Pt. Desc: organic 56%, psychogenic 13%, mixed 31%, diabetes 27%, mild to moderate Ed 61%, severe ED 31%,		Rx: sildenafil [25,100]T	
	Discont. AE: /0/			
Grp: 1	Black patients on sildenafil	age: 53(25,73)	duration: 4(0.3,33)	Pts: 124
	Pt. Desc: organic 56%, psychogenic 13%, mixed 31%, diabetes 27%, mild to moderate Ed 61%, severe ED 31%,		Rx: sildenafil [25,100]T	
	Discont. AE: /0/			
Grp: 2	Hispanic patients on sildenafil	age: 55(31,84)	duration: 4.1(0.2,43)	Pts: 98
	Pt. Desc: organic 66%, psychogenic 10%, mixed 23%, diabetes 35%, severe ED 46%, mild-moderate ED 39%,		Rx: sildenafil [25,100]T	
	Discont. AE: /1/			
Grp: 2	Hispanic patients on sildenafil	age: 55(31,84)	duration: 4.1(0.2,43)	Pts: 98
	Pt. Desc: organic 66%, psychogenic 10%, mixed 23%, diabetes 35%, severe ED 46%, mild-moderate ED 39%,		Rx: sildenafil [25,100]T	
	Discont. AE: /1/			
Grp: 3	mild moderate ED on sildenafil	age:	duration:	Pts: 146
	Pt. Desc: mild-moderate ED 100%,		Rx: sildenafil [25,100]T	
Grp: 4	severe ED on sildenafil	age:	duration:	Pts: 76
	Pt. Desc: severe ED 100%,		Rx: sildenafil [25,100]T	
Grp: 4	severe ED on sildenafil	age:	duration:	Pts: 76
	Pt. Desc: severe ED 100%,		Rx: sildenafil [25,100]T	
Grp: 5	zero risk factors on sildenafil	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [25,100]T	
Grp: 6	1 risk factor on sildenafil	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [25,100]T	
Grp: 7	2 or more risk factors on sildenafil	age:	duration:	Pts:
	Pt. Desc:		Rx: sildenafil [25,100]T	
Grp: 90	Black patients on placebo	age: 54(23,81)	duration: 5.2(0.3,30)	Pts: 122
	Pt. Desc: organic 54%, psychogenic 13%, mixed 33%, diabetes 30%, mild-moderate ED 60%, severe ED 29%,		Rx: Placebo [25,100]T	
	Discont. AE: /0/			
Grp: 90	Black patients on placebo	age: 54(23,81)	duration: 5.2(0.3,30)	Pts: 122
	Pt. Desc: organic 54%, psychogenic 13%, mixed 33%, diabetes 30%, mild-moderate ED 60%, severe ED 29%,		Rx: Placebo [25,100]T	
	Discont. AE: /0/			
Grp: 91	hispanic patients on placebo	age: 53(22,75)	duration: 3.2(0.2,20)	Pts: 97
	Pt. Desc: organic 60%, psychogenic 11%, mixed 29%, diabetes 41%, mild-moderate ED 62%, severe ED 26%,		Rx: Placebo [25,100]T	
	Discont. AE: /0/			
Grp: 91	hispanic patients on placebo	age: 53(22,75)	duration: 3.2(0.2,20)	Pts: 97
	Pt. Desc: organic 60%, psychogenic 11%, mixed 29%, diabetes 41%, mild-moderate ED 62%, severe ED 26%,		Rx: Placebo [25,100]T	
	Discont. AE: /0/			
Grp: 92	mild moderate ED on placebo	age:	duration:	Pts: 133
	Pt. Desc: Mild to moderate ED 100%,		Rx: Placebo [25,100]T	
Grp: 93	severe ED on placebo	age:	duration:	Pts: 61
	Pt. Desc: severe ED 100%,		Rx: Placebo [25,100]T	
Grp: 93	severe ED on placebo	age:	duration:	Pts: 61
	Pt. Desc: severe ED 100%,		Rx: Placebo [25,100]T	
Grp: 94	zero risk factors on placebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [25,100]T	
Grp: 95	1 risk factor on placebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [25,100]T	
Grp: 96	2 or more risk factors on placebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [25,100]T	

796055 Bocchi, E. A., Guimaraes, G., Mocelin, A., Bacal, F., Bellotti, G., Ramires, J. F.. Sildenafil effects on exercise, neurohormonal activation, and erectile dysfunction in congestive heart failure: a double-blind, placebo- controlled, randomized study followed by a prospective treatment for erectile dysfunction. 2002

Pts: 24 Controlled Trial: RCT followed by open label extention brazil Ext: HSB

Grp: 1	Sildenafil-pts with CHF	age: 50	duration: 24	Pts: 24
	Pt. Desc: CHF 100%,		Rx: sildenafil	
Grp: 90	Placebo-pts with CHF	age: 50	duration: 24	Pts: 24
	Pt. Desc: chf 100%,		Rx: Placebo	

796061 Gomez, F., Davila, H., Costa, A., Acuna, A., Wadskier, L. A., Plua, P.. Efficacy and safety of oral sildenafil citrate (Viagra) in the treatment of male erectile dysfunction in Colombia, Ecuador, and Venezuela: a double-blind, multicenter, placebo-controlled study. 2002

Pts: 24 Controlled Trial: double blind RCT colombia, ecuador and venezuela Ext: HSB

Grp: 1	Sildenafil	age: 57.8(24,77)	duration: 3(0.5,11.5)	Pts: 76
	Pt. Desc: organic 63%, psychogenic 13%, mixed 24%, diabetes 17%, prior surgery 28%, hypertension 33%,		Rx: sildenafil [50,100]T	
	Lost: /4/ Discont. AE: /1/ Discont. Insuff. resp.: /0/ Discont. other: /7/			
Grp: 1	Sildenafil	age: 57.8(24,77)	duration: 3(0.5,11.5)	Pts: 76
	Pt. Desc: organic 63%, psychogenic 13%, mixed 24%, diabetes 17%, prior surgery 28%, hypertension 33%,		Rx: sildenafil [50,100]T	
	Lost: /4/ Discont. AE: /1/ Discont. Insuff. resp.: /0/ Discont. other: /7/			
Grp: 90	placebo	age: 55.3(22,76)	duration: 3(0.4,10.5)	Pts: 82
	Pt. Desc: organic 54%, psychogenic 20%, mixed 27%, diabetes 21%, prior urogenital surgery 23%, hypertension 21%,		Rx: Placebo [50,100]T	
	Lost: /3/ Discont. AE: /0/ Discont. Insuff. resp.: /1/ Discont. other: /6/			
Grp: 90	placebo	age: 55.3(22,76)	duration: 3(0.4,10.5)	Pts: 82
	Pt. Desc: organic 54%, psychogenic 20%, mixed 27%, diabetes 21%, prior urogenital surgery 23%, hypertension 21%,		Rx: Placebo [50,100]T	
	Lost: /3/ Discont. AE: /0/ Discont. Insuff. resp.: /1/ Discont. other: /6/			

796062 Becher, E., Tejada Noriega, A., Gomez, R., Decia, R.. Sildenafil citrate (Viagra) in the treatment of men with erectile dysfunction in southern Latin America: a double-blind, randomized, placebo-controlled, parallel-group, multicenter, flexible-dose escalation study. 2002

Pts: 146 Controlled Trial: RCT-double blind Southern Latin America Ext: HSB

Grp: 0	All patients who entered active phase	age:	duration:	Pts: 143
	Pt. Desc: organic 39%, psychogenic 44%, mixed 16%,		Rx:	
Grp: 1	Patients taking sildenafil	age: 57.2	duration: 3.5(0.5,22.4)	Pts: 72
	Pt. Desc: diabetes 17%, post-prostatectomy 3%, post TURP 8%,		Rx: sildenafil [25,100]T	
	Discontinued: /7/ Discont. AE: /0/			
Grp: 90	Patients taking placebo	age: 56.7	duration: 2.6(0.5,20.5)	Pts: 71
	Pt. Desc: diabetes 18%, post-prostatectomy 7%, post TURP 8%,		Rx: Placebo [25,100]T	
	Discontinued: /6/ Discont. AE: /0/			

796063 Glina, S., Bertero, E., Claro, J., Damiao, R., Faria, G., Fregonesi, A., Jaspersen, J., Mendoza, A., Mattos, D. Jr//Rocha, L. C., Sotomayor, M., Teloken, C., Ureta, S., Zonana, E., Ugarte, F.. Efficacy and safety of flexible-dose oral sildenafil citrate (Viagra) in the treatment of erectile dysfunction in Brazilian and Mexican men. 2002

Pts: 245 Controlled Trial: RCT double blind Brazil and Mexico Ext: HSB

Grp: 1	sildenafil	age: 58(28,85)	duration: 3.7(0.5,25.6)	Pts: 124
	Pt. Desc: organic 41%, psychogenic 20%, mixed 39%, diabetes 24%, hypertension 24%, visual disturbance 4%,		Rx: sildenafil [25,100]T	
	Discontinued: /15/ Discont. AE: /1/ Discont. Insuff. resp.: /3/			

Grp: 1 sildenafil age: 58(28,85) duration: 3.7(0.5,25.6) Pts: 124
Pt. Desc: organic 41%, psychogenic 20%, mixed 39%, diabetes 24%, hypertension 24%, visual disturbance 4%, Rx: sildenafil [25,100]T
Discontinued: /15/ Discont. AE: /1/ Discont. Insuff. resp.: /3/

Grp: 90 placebo age: 55(27,84) duration: 3.4(0.5,21.7) Pts: 121
Pt. Desc: organic 41%, psychogenic 15%, mixed 44%, diabetes 18%, hypertension 24%, visual disturbance 580%, Rx: Placebo [25,100]T
Discontinued: /16/ Discont. AE: /0/ Discont. Insuff. resp.: /3/

Grp: 90 placebo age: 55(27,84) duration: 3.4(0.5,21.7) Pts: 121
Pt. Desc: organic 41%, psychogenic 15%, mixed 44%, diabetes 18%, hypertension 24%, visual disturbance 580%, Rx: Placebo [25,100]T
Discontinued: /16/ Discont. AE: /0/ Discont. Insuff. resp.: /3/

796190 Nurnberg, H. G., Hensley, P. L., Gelenberg, A. J., Fava, M., Lauriello, J., Paine, S.. Treatment of antidepressant-associated sexual dysfunction with sildenafil: a randomized controlled trial. 2003
Pts: 90 Controlled Trial USA Ext: PMF

Grp: 1 Patients treated with Sildenafil age: 44.9 duration: Pts: 45
Pt. Desc: Related to treatment with SRI for depression 100%, Depression in remission, HAM-D <=10 100%, Rx: sildenafil [50,100]
Discont. AE: /1/45 Discont. other: /2/45

Grp: 90 Patients treated with Placebo age: 44.8 duration: Pts: 45
Pt. Desc: Related to treatment with SRI for depression 100%, Depression in remission, HAM-D <=10 100%, Rx: sildenafil [50,100]
Discont. AE: /1/ Discont. Insuff. resp.: /5/

10027991 Hultling, C.. Partners' perceptions of the efficacy of sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction. 1999
Pts: 329 Controlled Trial Stockholm, Sweden ?? Ext: AJM

Grp: 0.1 All pts in the broad spectrum study age: 60(26,81) duration: 5(0.5,26) Pts: 329
Pt. Desc: organic 59%, psychogenic 15%, mixed 26%, Rx:

Grp: 1 Sildenafil treatment in broad spectrum study age: duration: Pts:
Pt. Desc: Rx: sildenafil [25,100]T

Grp: 90.1 Placebo for broad spectrum study age: duration: Pts:
Pt. Desc: Rx: Placebo [25,100]T

10027992 Hultling, C.. Partners' perceptions of the efficacy of sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction. 1999
Pts: 178 Controlled Trial Stockholm, Sweden?? Ext: AJM

Grp: 0.2 All patients in the spinal cord injury study age: 30(19,63) duration: 12(0.7,38) Pts: 178
Pt. Desc: spinal cord injury 100%, Rx:

Grp: 2 Sildenafil treatment for spinal cord injury study. age: duration: Pts: 178
Pt. Desc: spinal cord injury 100%, Rx: sildenafil [25,100]T

Grp: 90.2 Placebo for spinal cord injury study age: duration: Pts: 178
Pt. Desc: Rx: Placebo [25,100]T

10029991 Feldman, R., Meuleman, E. J., Steers, W.. Sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction: analysis of two flexible dose-escalation studies. Sildenafil Study Group. 1999
Pts: 329 Controlled Trial WV, CT, Netherlands Ext: AJM

Grp: 1 Sildenafil age: 60 duration: Pts: 163
Pt. Desc: Rx: sildenafil [25,100]T

Grp: 90 Placebo age: 59 duration: Pts: 166
Pt. Desc: Rx: Placebo [25,100]T

10029992 Feldman, R., Meuleman, E. J., Steers, W.. Sildenafil citrate (VIAGRA) in the treatment of erectile dysfunction: analysis of two flexible dose-escalation studies. Sildenafil Study Group. 1999
Pts: 315 Controlled Trial WV, CT, Netherlands Ext: AS

Grp: 1	Sildenafil	age: 55	duration:	Pts: 159
	Pt. Desc:		Rx: sildenafil [25,100]T	
Grp: 90	Placebo	age: 54	duration:	Pts: 156
	Pt. Desc:		Rx: Placebo [25,100]T	

10463991 Goldstein, I., Lue, T. F., Padma-Nathan, H., Rosen, R. C., Steers, W. D., Wicker, P. A.. Oral sildenafil in the treatment of erectile dysfunction. Sildenafil Study Group. 1998

Pts: 532 Controlled Trial: randomized dose response double-blind USA Ext: HSB

Grp: 1	All sildenafil patients	age: 58(24,87)	duration: 3.2	Pts: 316
	Pt. Desc: organic 78%, psychogenic 9%, mixed 13%, diabetes 13%, post-prostatectomy 12%, hypertension 30%, ishcemic heart disease 8%,		Rx: sildenafil [25,100]	
Grp: 1	All sildenafil patients	age: 58(24,87)	duration: 3.2	Pts: 316
	Pt. Desc: organic 78%, psychogenic 9%, mixed 13%, diabetes 13%, post-prostatectomy 12%, hypertension 30%, ishcemic heart disease 8%,		Rx: sildenafil [25,100]	
Grp: 1.1	25mg. sildenafil	age:	duration:	Pts: 102
	Pt. Desc:		Rx: sildenafil 25	
	Discontinued: /15/102 Discont. AE: /1/102 Discont. Insuff. resp.: /3/102 Discont. other: /11/102			
Grp: 1.2	50 mg. sildenafil	age:	duration:	Pts: 107
	Pt. Desc:		Rx: sildenafil 50	
	Discontinued: /8/107 Discont. AE: /1/107 Discont. Insuff. resp.: /2/107 Discont. other: /5/107			
Grp: 1.3	100 mg. sildenafil	age:	duration:	Pts: 107
	Pt. Desc:		Rx: sildenafil 100	
	Discontinued: /8/107 Discont. AE: /2/107 Discont. Insuff. resp.: /0/107 Discont. other: /6/107			
Grp: 90	Placebo	age: 57(20,79)	duration: 3.2	Pts: 216
	Pt. Desc: organic 77%, psychogenic 10%, mixed 13%, diabetes 15%, post-prostatectomy 10%, hypertension 26%, ischemic heart disease 8%,		Rx: Placebo 125	
	Discontinued: /36/216 Discont. AE: /1/216 Discont. Insuff. resp.: /11/216 Discont. other: /24/216			
Grp: 90	Placebo	age: 57(20,79)	duration: 3.2	Pts: 216
	Pt. Desc: organic 77%, psychogenic 10%, mixed 13%, diabetes 15%, post-prostatectomy 10%, hypertension 26%, ischemic heart disease 8%,		Rx: Placebo 125	
	Discontinued: /36/216 Discont. AE: /1/216 Discont. Insuff. resp.: /11/216 Discont. other: /24/216			

10463992 Goldstein, I., Lue, T. F., Padma-Nathan, H., Rosen, R. C., Steers, W. D., Wicker, P. A.. Oral sildenafil in the treatment of erectile dysfunction. Sildenafil Study Group. 1998

Pts: 329 Controlled Trial: randomized placebo controlled dose-escalation USA Ext: HSB

Grp: 1	Patients randomized to sildenafil	age: 60(26,79)	duration: 5	Pts: 163
	Pt. Desc: organic 55%, psychogenic 14%, mixed 31%, diabetes 8%, post-prostatectomy 9%, hypertension 24%, ischemic heart disease 15%,		Rx: sildenafil [25,100]T	
	Discontinued: /9/163 Discont. AE: /1/163 Discont. Insuff. resp.: /1/163 Discont. other: /7/163			
Grp: 1	Patients randomized to sildenafil	age: 60(26,79)	duration: 5	Pts: 163
	Pt. Desc: organic 55%, psychogenic 14%, mixed 31%, diabetes 8%, post-prostatectomy 9%, hypertension 24%, ischemic heart disease 15%,		Rx: sildenafil [25,100]T	
	Discontinued: /9/163 Discont. AE: /1/163 Discont. Insuff. resp.: /1/163 Discont. other: /7/163			
Grp: 1.1	Organic cause - sildenafil	age:	duration:	Pts: 90
	Pt. Desc: organic 100%,		Rx:	
Grp: 1.2	Psychogenic cause -sildenafil	age:	duration:	Pts: 23
	Pt. Desc: psychogenic 100%,		Rx:	
Grp: 1.3	Mixed cause - sildenafil	age:	duration:	Pts: 50
	Pt. Desc: mixed 100%,		Rx:	

Grp: 2	Patients continuing with sildenafil in open label extension	age:	duration:	Pts: 225
	Pt. Desc:		Rx:	
	Discontinued: /18/225 Discont. AE: /4/225 Discont. Insuff. resp.: /7/225 Discont. other: /7/225			
Grp: 90	Patients randomized to placebo	age: 59(31,81)	duration: 4.7	Pts: 166
	Pt. Desc: organic 63%, psychogenic 16%, mixed 22%, diabetes 11%, post-prostatectomy 11%, hypertension 28%, ischemic heart disease 8%,		Rx:	
	Discontinued: /13/166 Discont. AE: /1/166 Discont. Insuff. resp.: /3/166 Discont. other: /9/166			
Grp: 90	Patients randomized to placebo	age: 59(31,81)	duration: 4.7	Pts: 166
	Pt. Desc: organic 63%, psychogenic 16%, mixed 22%, diabetes 11%, post-prostatectomy 11%, hypertension 28%, ischemic heart disease 8%,		Rx:	
	Discontinued: /13/166 Discont. AE: /1/166 Discont. Insuff. resp.: /3/166 Discont. other: /9/166			
Grp: 90.1	Organic cause -placebo	age:	duration:	Pts: 104
	Pt. Desc: organic 100%,		Rx:	
Grp: 90.2	Psychogenic cause - placebo	age:	duration:	Pts: 26
	Pt. Desc: psychogenic 100%,		Rx:	
Grp: 90.3	Mixed cause - placebo	age:	duration:	Pts: 36
	Pt. Desc: mixed 100%,		Rx:	

796157991 Eardley, I., Ellis, P., Boolell, M., Wulff, M.. Onset and duration of action of sildenafil for the treatment of erectile dysfunction. 2002
Pts: 17 Controlled Trial England Ext: PMF

Grp: 1	Sildenafil results	age: 52(37,70)	duration: 3.1(0.5,19)	Pts: 17
	Pt. Desc:		Rx: sildenafil 50	
Grp: 90	Placebo results	age: 52(37,70)	duration: 3.1(0.5,19)	Pts: 17
	Pt. Desc:		Rx: Placebo 50	

796157992 Eardley, I., Ellis, P., Boolell, M., Wulff, M.. Onset and duration of action of sildenafil for the treatment of erectile dysfunction. 2002
Pts: 16 Controlled Trial England Ext: PMF

Grp: 1	Sildenafil results	age: 57(35,68)	duration: 1.9(0.3,8)	Pts: 16
	Pt. Desc:		Rx: sildenafil 100	
Grp: 90	Placebo results	age: 57(35,70)	duration: (0.5,)	Pts: 16
	Pt. Desc:		Rx: Placebo 100	

756003 Porst, H.. IC351 (tadalafil, Cialis): update on clinical experience. 2002

Pts: 294 Controlled Trial: randomized double blind Europe Ext: HSB

Grp: 1	Tadalafil 10mg	age:	duration:	Pts: 60
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, severe cardiac events in last 6 mo. 0%,		Rx: tadalafil 10	
Grp: 2	Tadalafil 25mg	age:	duration:	Pts: 58
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, severe cardiac event in last 6 mo. 0%,		Rx: tadalafil 25	
Grp: 3	Tadalafil 50mg	age:	duration:	Pts: 59
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, peyronies 0%, serious cardiac event in last 6 mo. 0%,		Rx: tadalafil 50	
Grp: 4	Tadalafil 100mg	age:	duration:	Pts: 59
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac event in last 6 mo. 0%,		Rx: tadalafil 100	
Grp: 90	Placebo	age:	duration:	Pts: 58
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, peyronies 0%, serious cardiac event in last 6 mo. 0%,		Rx: Placebo	

756005 Padma-Nathan, H., McMurray, J. G., Pullman, W. E., Whitaker, J. S., Saoud, J. B., Ferguson, K. M., Rosen, R. C.. On-demand IC351 (Cialis) enhances erectile function in patients with erectile dysfunction. 2001

Pts: 179 Controlled Trial: randomized double blind dose ranging US Ext: HSB

Grp: 1	All patients receiving tadalafil	age:	duration: (3,)	Pts: 143
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%,		Rx: tadalafil [2,25]	
Grp: 1.1	2 mg tadalafil	age: 58	duration: (3,)	Pts: 35
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.11	2 mg tadalafil - mild ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.12	2 mg tadalafil - mild-moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.13	2 mg tadalafil - moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.14	2 mg tadalafil - severe ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.2	5 mg tadalafil	age: 54	duration: (3,)	Pts: 37
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.21	5 mg tadalafil - mild ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.22	5 mg tadalafil - mild-moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.23	5 mg tadalafil - moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.24	5 mg tadalafil - severe ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.3	10 mg tadalfil	age: 55	duration: (3,)	Pts: 36
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.31	10 mg tadalafil - mild ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.32	10 mg tadalafil - mild-moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.33	10 mg tadalafil - moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.34	10 mg tadalafil - severe ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.4	25 mg tadalafil	age: 55	duration: (3,)	Pts: 36
	Pt. Desc:		Rx: tadalafil 25	

Grp: 1.41	25 mg tadalafil - mild ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 25	
Grp: 1.42	25 mg tadalafil - mild-moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 25	
Grp: 1.43	25 mg tadalafil - moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 25	
Grp: 1.44	25 mg tadalafil - severe ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: tadalafil 25	
Grp: 90	Placebo	age: 57	duration: (3,)	Pts: 35
	Pt. Desc: diabetes 0%, hypogonadism 0%, neurogenic 0%,		Rx: Placebo	
Grp: 90.1	placebo - mild ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	placebo - mild-moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	placebo - moderate ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	placebo - severe ef initially	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo	

796036 Brock, G. B., McMahon, C. G., Chen, K. K., Costigan, T., Shen, W., Watkins, V., Anglin, G., Whitaker, S.. Efficacy and safety of tadalafil for the treatment of erectile dysfunction: results of integrated analyses. 2002

Pts: 1112 Controlled Trial: combination of 5 multicenter double blind rcts Canada Ext: HSB

Grp: 1	2.5 mg Tadalafil	age: 60(36,79)	duration:	Pts: 74
	Pt. Desc: organic 68%, psychogenic 8%, mixed 24%, diabetes 24%, CAD 14%, hypertension 31%,		Rx: tadalafil 2.5	
	Discont. AE: /3/			
Grp: 1	2.5 mg Tadalafil	age: 60(36,79)	duration:	Pts: 74
	Pt. Desc: organic 68%, psychogenic 8%, mixed 24%, diabetes 24%, CAD 14%, hypertension 31%,		Rx: tadalafil 2.5	
	Discont. AE: /3/			
Grp: 1.1	mild symptoms	age:	duration:	Pts: 27
	Pt. Desc:		Rx: tadalafil 2.5	
Grp: 1.2	moderate symptoms	age:	duration:	Pts: 16
	Pt. Desc:		Rx: tadalafil 2.5	
Grp: 1.3	severe symptoms	age:	duration:	Pts: 31
	Pt. Desc:		Rx: tadalafil 2.5	
Grp: 2	5mg Tadalafil	age: 59(26,82)	duration:	Pts: 151
	Pt. Desc: organic 58%, psychogenic 10%, mixed 32%, diabetes 21%, CAD 7%, hypertension 34%,		Rx: tadalafil 5	
	Discont. AE: /1/			
Grp: 2	5mg Tadalafil	age: 59(26,82)	duration:	Pts: 151
	Pt. Desc: organic 58%, psychogenic 10%, mixed 32%, diabetes 21%, CAD 7%, hypertension 34%,		Rx: tadalafil 5	
	Discont. AE: /1/			
Grp: 2.1	mild symptoms	age:	duration:	Pts: 47
	Pt. Desc:		Rx: tadalafil 5	
Grp: 2.2	moderate symptoms	age:	duration:	Pts: 33
	Pt. Desc:		Rx: tadalafil 5	
Grp: 2.3	severe symptoms	age:	duration:	Pts: 71
	Pt. Desc:		Rx: tadalafil 5	
Grp: 3	10mg Tadalafil	age: 58(26,81)	duration:	Pts: 321
	Pt. Desc: diabetes 21%, CAD 6%, hypertension 28%,		Rx: tadalafil 10	
	Discont. AE: /5/			
Grp: 3	10mg Tadalafil	age: 58(26,81)	duration:	Pts: 321
	Pt. Desc: diabetes 21%, CAD 6%, hypertension 28%,		Rx: tadalafil 10	
	Discont. AE: /5/			

Grp: 3.1	mild symptoms	age:	duration:	Pts: 129
	Pt. Desc:		Rx: tadalafil 10	
Grp: 3.2	moderate symptoms	age:	duration:	Pts: 84
	Pt. Desc:		Rx: tadalafil 10	
Grp: 3.3	severe symptoms	age:	duration:	Pts: 107
	Pt. Desc:		Rx: tadalafil 10	
Grp: 4	20mg Tadalafil	age: 59(31,80)	duration:	Pts: 258
	Pt. Desc: organic 53%, psychogenic 10%, mixed 37%, diabetes 18%, CAD 9%, hypertension 28%,		Rx: tadalafil 20	
	Discont. AE: /8/			
Grp: 4	20mg Tadalafil	age: 59(31,80)	duration:	Pts: 258
	Pt. Desc: organic 53%, psychogenic 10%, mixed 37%, diabetes 18%, CAD 9%, hypertension 28%,		Rx: tadalafil 20	
	Discont. AE: /8/			
Grp: 4.1	mild symptoms	age:	duration:	Pts: 135
	Pt. Desc:		Rx: tadalafil 20	
Grp: 4.2	moderate symptoms	age:	duration:	Pts: 51
	Pt. Desc:		Rx: tadalafil 20	
Grp: 4.3	severe symptoms	age:	duration:	Pts: 72
	Pt. Desc:		Rx: tadalafil 20	
Grp: 90	Placebo	age: 59(22,81)	duration:	Pts: 308
	Pt. Desc: diabetes 23%, CAD 8%, hypertension 30%,		Rx: Placebo	
	Discont. AE: /4/			
Grp: 90	Placebo	age: 59(22,81)	duration:	Pts: 308
	Pt. Desc: diabetes 23%, CAD 8%, hypertension 30%,		Rx: Placebo	
	Discont. AE: /4/			
Grp: 90.1	mild symptoms	age:	duration:	Pts: 118
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	moderate symptoms	age:	duration:	Pts: 74
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	severe symptoms	age:	duration:	Pts: 114
	Pt. Desc:		Rx: Placebo	

756003991 Porst, H.. IC351 (tadalafil, Cialis): update on clinical experience. 2002

Pts: 212 Controlled Trial: randomized double blind phase 2B — Canada — Ext: HSB

Grp: 1	All patients receiving Tadalafil	age:	duration:	Pts: 171
	Pt. Desc:		Rx: tadalafil [2,25]	
Grp: 1.1	2 mg Tadalafil	age:	duration:	Pts: 42
	Pt. Desc:		Rx: tadalafil 2	
Grp: 1.2	5 mg Tadalafil	age:	duration:	Pts: 44
	Pt. Desc:		Rx: tadalafil 5	
Grp: 1.3	10mg Tadalafil	age:	duration:	Pts: 42
	Pt. Desc:		Rx: tadalafil 10	
Grp: 1.4	25 mg Tadalafil	age:	duration:	Pts: 43
	Pt. Desc:		Rx: tadalafil 25	
Grp: 90	Placebo	age:	duration:	Pts: 41
	Pt. Desc:		Rx: Placebo	

756003992 Porst, H.. IC351 (tadalafil, Cialis): update on clinical experience. 2002

Pts: 216 Controlled Trial: randomized double blind — Spain — Ext: HSB

Grp: 0	All patients	age:	duration:	Pts: 216
	Pt. Desc: diabetes 100%,		Rx:	
Grp: 1	Tadalafil 10 mg	age:	duration:	Pts: 73
	Pt. Desc:		Rx: tadalafil 10	

Grp: 2	Tadalafil 20 mg	age:	duration:	Pts: 72
	Pt. Desc:		Rx: tadalafil 20	
Grp: 90	Placebo	age:	duration:	Pts: 71
	Pt. Desc:		Rx: Placebo	

10237 Reiter, W. J., Pycha, A., Schatzl, G., Pokorny, A., Gruber, D. M., Huber, J. C., Marberger, M.. Dehydroepiandrosterone in the treatment of erectile dysfunction: a prospective, double-blind, randomized, placebo-controlled study. 1999

Pts: 40 Controlled Trial: Propsective, randomized, placebo-controlled Vienna, Austria Ext: AJM

Grp: 1	DHEA	age: 56.6(43,68)	duration: (0.5,)	Pts: 20
	Pt. Desc: diabetes 0%, neurogenic 0%, post-prostatectomy 0%, Discont. Insuff. resp.: /3/		Rx: DHEA 50	
Grp: 90	Placebo	age: 56.4(41,69)	duration: (0.5,)	Pts: 20
	Pt. Desc: diabetes 0%, neurogenic 0%, post-prostatectomy 0%, Discont. Insuff. resp.: /6/ Discont. other: /1/		Rx: Placebo 50	

10780 Aydin, S., Odabas, O., Ercan, M., Kara, H., Agargun, M. Y.. Efficacy of testosterone, trazodone and hypnotic suggestion in the treatment of non-organic male sexual dysfunction. 1996

Pts: 79 Controlled Trial: Randomized Turkey Ext: AJM

Grp: 1	testosterone	age: 38.7(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.1	testostersone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.2	testosterone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.3	testosterone age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.4	testosterone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Testosterone 120	
Grp: 2	trazodone	age: 39.5(21,)	duration:	Pts: 21
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.1	trazodone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.2	trazodone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.3	trazodone age 41-50	age: (41,50)	duration:	Pts: 7
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.4	trazodone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 3	hypnosis	age: 34.2(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: hypnosis	
Grp: 3.1	hypnosis age 21-30	age: (21,30)	duration:	Pts: 10
	Pt. Desc:		Rx: hypnosis	
Grp: 3.2	hypnosis age 31-40	age: (31,40)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.3	hypnosis age 41-50	age: (41,50)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.4	hypnosis age 51+	age: (51,)	duration:	Pts: 2
	Pt. Desc:		Rx: hypnosis	
Grp: 90	placebo	age: 39.1(21,)	duration:	Pts: 18
	Pt. Desc:		Rx: Placebo	
Grp: 90.1	placebo age 21-30	age: (21,30)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	placebo age 31-40	age: (31,40)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	placebo age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	placebo age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	

790779 Gomaa, A., Eissa, M., El-Gebaley, A.. The effect of topically applied vasoactive agents and testosterone versus testosterone in the treatment of erectile dysfunction in aged men with low sexual interest. 2001

Pts: 42 Controlled Trial: Randomized, double blind, crossover trial Assiut, Egypt Ext: AJM

Grp: 1	Testosterone cream	age: 54(41,67)	duration: (0.33,6)	Pts: 42
	Pt. Desc: organic 55%, psychogenic 45%, hypogonadism 100%, neurogenic 12%, post-prostatectomy 0%, vascular mixed or unspec. 43%,		Rx: 0.8% testosterone cream 2	
Grp: 1.1	Psychogenic patients on testosterone cream	age:	duration:	Pts: 19
	Pt. Desc:		Rx: 0.8% testosterone cream 2	
Grp: 1.2	Vasculogenic patients on testosterone cream	age:	duration:	Pts: 18
	Pt. Desc:		Rx: 0.8% testosterone cream 2	
Grp: 1.3	Neurogenic patients on testosterone cream	age:	duration:	Pts: 5
	Pt. Desc:		Rx: 0.8% testosterone cream 2	
Grp: 2	Polypharmacy cream	age: 54(41,67)	duration: (0.33,6)	Pts: 42
	Pt. Desc: organic 55%, psychogenic 45%, hypogonadism 100%, neurogenic 12%, post-prostatectomy 0%, vascular mixed or unspec. 43%,		Rx: Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	
Grp: 2.1	Psychogenic patients on polypharmacy cream	age:	duration:	Pts: 19
	Pt. Desc:		Rx: Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	
Grp: 2.2	Vasculogenic patients on polypharmacy cream	age:	duration:	Pts: 18
	Pt. Desc:		Rx: Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	
Grp: 2.3	Neurogenic patients on polypharmacy cream	age:	duration:	Pts: 5
	Pt. Desc:		Rx: Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	
Grp: 3	Testosterone cream then polypharmacy cream	age:	duration:	Pts: 21
	Pt. Desc:		Rx: testosterone followed by polypharmacy cream	
Grp: 4	Polypharmacy cream then testosterone cream	age:	duration:	Pts: 21
	Pt. Desc:		Rx: poplypharmacy cream followed by testosterone	

795502 Benkert, O., Witt, W., Adam, W., Leitz, A.. Effects of testosterone undecanoate on sexual potency and the hypothalamic-pituitary-gonadal axis of impotent males. 1979

Pts: 36 Controlled Trial: double blind/randomized controlled trial Germany Ext: AJM

Grp: 0	All patients	age: 56.5(45,75)	duration: (1,)	Pts: 36
	Pt. Desc:		Rx:	
Grp: 1	Experimental (testosterone)	age: (45,75)	duration: (1,)	Pts: 18
	Pt. Desc:		Rx: Testosterone 120	
	Discontinued: /5/ Discont. AE: /1/			
Grp: 90	Placebo	age: (45,75)	duration: (1,)	Pts: 18
	Pt. Desc:		Rx: Placebo 120	
	Discontinued: /2/ Discont. AE: /2/			

10558 Meinhardt, W., Schmitz, P. I., Kropman, R. F., de la Fuente, R. B., Lycklama, a. Nijeholt AA//Zwartendijk, J.. Trazodone, a double blind trial for treatment of erectile dysfunction. 1997

Pts: 69 Controlled Trial — Netherlands — Ext: MAA

Grp: 1	Trazodone treated	age: [54](26,80)	duration:	Pts: 32
	Pt. Desc: organic 38%, psychogenic 50%, mixed 12%, diabetes 16%, neurogenic 3%, peyronies 3%,		Rx: trazodone 150	
Grp: 1.1	Trazodone treated, with psychogenic impotence	age:	duration:	Pts: 16
	Pt. Desc: psychogenic 100%,		Rx: trazodone 150	
Grp: 90	Placebo treated	age: [55](39,81)	duration:	Pts: 37
	Pt. Desc: organic 35%, psychogenic 54%, mixed 11%, diabetes 19%, peyronies 3%, vascular mixed or unspec. 14%,		Rx: Placebo 150	
	Lost: /5/			
Grp: 90.1	Placebo treated, with psychogenic impotence	age:	duration:	Pts: 20
	Pt. Desc: psychogenic 100%,		Rx: Placebo 150	

10780 Aydin, S., Odabas, O., Ercan, M., Kara, H., Agargun, M. Y.. Efficacy of testosterone, trazodone and hypnotic suggestion in the treatment of non-organic male sexual dysfunction. 1996

Pts: 79 Controlled Trial: Randomized — Turkey — Ext: AJM

Grp: 1	testosterone	age: 38.7(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.1	testostersone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.2	testosterone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.3	testosterone age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Testosterone 120	
Grp: 1.4	testosterone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Testosterone 120	
Grp: 2	trazodone	age: 39.5(21,)	duration:	Pts: 21
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.1	trazodone age 21-30	age: (21,30)	duration:	Pts: 5
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.2	trazodone age 31-40	age: (31,40)	duration:	Pts: 6
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.3	trazodone age 41-50	age: (41,50)	duration:	Pts: 7
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 2.4	trazodone age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: trazodone [100,150]	
Grp: 3	hypnosis	age: 34.2(21,)	duration:	Pts: 20
	Pt. Desc:		Rx: hypnosis	
Grp: 3.1	hypnosis age 21-30	age: (21,30)	duration:	Pts: 10
	Pt. Desc:		Rx: hypnosis	
Grp: 3.2	hypnosis age 31-40	age: (31,40)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.3	hypnosis age 41-50	age: (41,50)	duration:	Pts: 4
	Pt. Desc:		Rx: hypnosis	
Grp: 3.4	hypnosis age 51+	age: (51,)	duration:	Pts: 2
	Pt. Desc:		Rx: hypnosis	
Grp: 90	placebo	age: 39.1(21,)	duration:	Pts: 18
	Pt. Desc:		Rx: Placebo	
Grp: 90.1	placebo age 21-30	age: (21,30)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	placebo age 31-40	age: (31,40)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	

Grp: 90.3	placebo age 41-50	age: (41,50)	duration:	Pts: 5
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	placebo age 51+	age: (51,)	duration:	Pts: 4
	Pt. Desc:		Rx: Placebo	

705000 Enzlin, P., Vanderschueren, D., Bonte, L., Vanderborght, W., Declercq, G., Demyttenaere, K.. Trazodone: a double-blind, placebo-controlled, randomized study of its effects in patients with erectile dysfunction without major organic findings. 2000

Pts: 34 Controlled Trial: Prospective, placebo controlled Belgium Ext: AJM

Grp: 1	Trazodone	age: 49	duration: (0.34,)	Pts: 16
	Pt. Desc:		Rx: trazodone 200	
Grp: 1	Trazodone	age: 49	duration: (0.34,)	Pts: 16
	Pt. Desc:		Rx: trazodone 200	
Grp: 90	Placebo	age: 46	duration: (0.34,)	Pts: 17
	Pt. Desc:		Rx: Placebo 200	
Grp: 90	Placebo	age: 46	duration: (0.34,)	Pts: 17
	Pt. Desc:		Rx: Placebo 200	

705001 Costabile, R. A., Spevak, M.. Oral trazodone is not effective therapy for erectile dysfunction: a double-blind, placebo controlled trial. 1999

Pts: 51 Controlled Trial: Placebo controlled, crossover Washington, DC Ext: AJM

Grp: 0	All patients	age:	duration:	Pts: 51
	Pt. Desc:		Rx:	
Grp: 1	Trazadone	age:	duration:	Pts: 48
	Pt. Desc:		Rx: trazodone 50	
Grp: 90	Placebo	age:	duration:	Pts: 48
	Pt. Desc:		Rx: Placebo 50	

705006 Kurt, U., Ozkardes, H., Altug, U., Germiyanoglu, C., Gurdal, M., Erol, D.. The efficacy of anti-serotoninergic agents in the treatment of erectile dysfunction. 1994

Pts: 100 Controlled Trial: placebo controlled, randomized trial Ankara, Turkey Ext: AJM

Grp: 0	All patients	age: 47(23,68)	duration: (0.5,)	Pts: 100
	Pt. Desc: psychogenic 100%,		Rx:	
	Lost: /5/ Discont. AE: /4/ Discont. other: /6/			
Grp: 1	Trazodone	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: trazodone 50	
	Discont. AE: /2/			
Grp: 2	Ketanserin	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Ketanserin 20	
	Discont. AE: /0/			
Grp: 3	Mianserin	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Mianserin 10	
	Discont. AE: /2/			
Grp: 90	Placebo	age:	duration:	Pts: 25
	Pt. Desc: psychogenic 100%,		Rx: Placebo T	

758007 Stark, S., Sachse, R., Liedl, T., Hensen, J., Rohde, G., Wensing, G., Horstmann, R., Schrott, K. M.. Vardenafil increases penile rigidity and tumescence in men with erectile dysfunction after a single oral dose. 2001

Pts: 24 Controlled Trial: Randomized, placebo-controlled, 3 way crossover Erlangen, Germany Ext: AJM

Grp: 1	20 mg vardenafil	age: 44.5(25,59)	duration: (0.5,)	Pts: 24
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: vardenafil 20	
Grp: 2	40 mg vardenafil	age: 44.5(25,59)	duration: (0.5,)	Pts: 24
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: vardenafil 40	
Grp: 90	Placebo	age: 44.5(25,59)	duration: (0.5,)	Pts: 24
	Pt. Desc: diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: Placebo 20	

758008 Porst, H., Rosen, R., Padma-Nathan, H., Goldstein, I., Giuliano, F., Ulbrich, E., Bandel, T.. The efficacy and tolerability of vardenafil, a new, oral, selective phosphodiesterase type 5 inhibitor, in patients with erectile dysfunction: the first at-home clinical trial. 2001

Pts: 601 Controlled Trial: randomized double blind dose ranging Europe and US Ext: HSB

Grp: 1	Vardenafil 5 mg	age: 53.3	duration: 2.8(0.5,)	Pts: 146
	Pt. Desc: organic 32%, psychogenic 28%, mixed 40%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis or low TSH 0%,		Rx: vardenafil 5	
	Lost: /1/ Discontinued: /18/			
Grp: 1	Vardenafil 5 mg	age: 53.3	duration: 2.8(0.5,)	Pts: 146
	Pt. Desc: organic 32%, psychogenic 28%, mixed 40%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis or low TSH 0%,		Rx: vardenafil 5	
	Lost: /1/ Discontinued: /18/			
Grp: 2	Vardenafil 10 mg	age: 52.2	duration: 3(0.5,)	Pts: 140
	Pt. Desc: organic 30%, psychogenic 25%, mixed 45%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis, or low TSH 0%,		Rx: vardenafil 10	
	Lost: /1/ Discontinued: /17/			
Grp: 2	Vardenafil 10 mg	age: 52.2	duration: 3(0.5,)	Pts: 140
	Pt. Desc: organic 30%, psychogenic 25%, mixed 45%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis, or low TSH 0%,		Rx: vardenafil 10	
	Lost: /1/ Discontinued: /17/			
Grp: 3	Vardenafil 20 mg	age: 51.6	duration: 2.9(0.5,)	Pts: 147
	Pt. Desc: organic 26%, psychogenic 25%, mixed 48%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis, or low TSH 0%,		Rx: vardenafil 20	
	Lost: /3/ Discontinued: /16/			
Grp: 3	Vardenafil 20 mg	age: 51.6	duration: 2.9(0.5,)	Pts: 147
	Pt. Desc: organic 26%, psychogenic 25%, mixed 48%, diabetes 0%, hypogonadism 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis, or low TSH 0%,		Rx: vardenafil 20	
	Lost: /3/ Discontinued: /16/			
Grp: 90	Placebo	age: 51.9	duration: 2.6(0.5,)	Pts: 147
	Pt. Desc: organic 34%, psychogenic 30%, mixed 36%, diabetes 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis or low TSH 0%,		Rx: Placebo	
	Lost: /5/ Discontinued: /22/			
Grp: 90	Placebo	age: 51.9	duration: 2.6(0.5,)	Pts: 147
	Pt. Desc: organic 34%, psychogenic 30%, mixed 36%, diabetes 0%, post-prostatectomy 0%, spinal cord injury 0%, serious cardiac disease, hepatitis or low TSH 0%,		Rx: Placebo	
	Lost: /5/ Discontinued: /22/			

758010 Klotz, T., Sachse, R., Heidrich, A., Jockenhovel, F., Rohde, G., Wensing, G., Horstmann, R., Engelmann, R.. Vardenafil increases penile rigidity and tumescence in erectile dysfunction patients: a RigiScan and pharmacokinetic study. 2001

Pts: 22 Controlled Trial: Randomized, placebo controlled, 3 way crossover Ext: AJM

Grp: 1	10 mg Vardenafil	age: 34.2(22,52)	duration: (0.5,)	Pts: 22
	Pt. Desc: diabetes 0%, hypogonadism 0%, neurogenic 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: vardenafil 10	
Grp: 2	20 mg Vardenafil	age: 34.2(22,52)	duration: (0.5,)	Pts: 22
	Pt. Desc: diabetes 0%, hypogonadism 0%, neurogenic 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: vardenafil 20	
Grp: 90	Placebo	age: 34.2(22,52)	duration: (0.5,)	Pts: 22
	Pt. Desc: diabetes 0%, hypogonadism 0%, neurogenic 0%, post-prostatectomy 0%, spinal cord injury 0%,		Rx: Placebo 10	

796006 Thadani, U., Smith, W., Nash, S., Bittar, N., Glasser, S., Narayan, P., Stein, R. A., Larkin, S., Mazzu, A., Tota, R., Pomerantz, K., Sundaresan, P.. The effect of vardenafil, a potent and highly selective phosphodiesterase-5 inhibitor for the treatment of erectile dysfunction, on the cardiovascular response to exercise in patients with coronary artery disease. 2002

Pts: 41 Controlled Trial: randomized double-blind crossover single dose USA Ext: HSB

Grp: 0	all patients--all with coronary artery disease	age: 61.9	duration:	Pts: 41
	Pt. Desc: diabetes 15%, CAD 100%,		Rx:	
Grp: 1	vardenafil	age:	duration:	Pts: 41
	Pt. Desc:		Rx: vardenafil	
Grp: 90	placebo	age:	duration:	Pts: 41
	Pt. Desc:		Rx: Placebo	

901052 Hellstrom, W. J., Gittelman, M., Karlin, G., Segerson, T., Thibonnier, M., Taylor, T., Padma-Nathan, H.. Vardenafil for treatment of men with erectile dysfunction: efficacy and safety in a randomized, double-blind, placebo-controlled trial. 2002

Pts: 805 Controlled Trial: phase 3 RCT double blind US and Canada Ext: AJM

Grp: 1	Vardenafil 5 mg	age: 57(18,)	duration: 3.6(0.5,)	Pts: 205
	Pt. Desc: organic 61%, psychogenic 7%, mixed 33%, diabetes 16%,		Rx: vardenafil 5	
Grp: 1	Vardenafil 5 mg	age: 57(18,)	duration: 3.6(0.5,)	Pts: 205
	Pt. Desc: organic 61%, psychogenic 7%, mixed 33%, diabetes 16%,		Rx: vardenafil 5	
	Lost: /22/ Discontinued: /77/ Discont. AE: /8/ Discont. Insuff. resp.: /26/ Discont. other: /21/			
Grp: 1.1	Vardenafil 5mg - mild ED	age:	duration:	Pts: 11
	Pt. Desc:		Rx: vardenafil 5	
Grp: 1.2	Vardenafil 5 mg - mild-moderate ED	age:	duration:	Pts: 50
	Pt. Desc:		Rx: vardenafil 5	
Grp: 1.3	Vardenafil 5 mg - moderate ED	age:	duration:	Pts: 41
	Pt. Desc:		Rx: vardenafil 5	
Grp: 1.4	Vardenafil 5 mg - severe ED	age:	duration:	Pts: 86
	Pt. Desc:		Rx: vardenafil 5	
Grp: 2	Vardenafil 10 mg	age: 57(18,)	duration: 3.6(0.5,)	Pts: 206
	Pt. Desc: organic 59%, psychogenic 7%, mixed 34%, diabetes 18%,		Rx: vardenafil 10	
	Lost: /20/ Discontinued: /55/ Discont. AE: /7/ Discont. Insuff. resp.: /10/ Discont. other: /18/			
Grp: 2	Vardenafil 10 mg	age: 57(18,)	duration: 3.6(0.5,)	Pts: 206
	Pt. Desc: organic 59%, psychogenic 7%, mixed 34%, diabetes 18%,		Rx: vardenafil 10	
Grp: 2.1	Vardenafil 10 mg - mild ED	age:	duration:	Pts: 9
	Pt. Desc:		Rx: vardenafil 10	
Grp: 2.2	Vardenafil 10 mg - mild-moderate ED	age:	duration:	Pts: 51
	Pt. Desc:		Rx: vardenafil 10	
Grp: 2.3	Vardenafil 10 mg - moderate ED	age:	duration:	Pts: 61
	Pt. Desc:		Rx: vardenafil 10	
Grp: 2.4	Vardenafil 10 mg - severe ED	age:	duration:	Pts: 71
	Pt. Desc:		Rx: vardenafil 10	

Grp: 3	Vardenafil 20 mg	age: 58(18,)	duration: 4.2(0.5,)	Pts: 197
	Pt. Desc: organic 60%, psychogenic 7%, mixed 33%, diabetes 20%,		Rx: vardenafil 20	
Grp: 3	Vardenafil 20 mg	age: 58(18,)	duration: 4.2(0.5,)	Pts: 197
	Pt. Desc: organic 60%, psychogenic 7%, mixed 33%, diabetes 20%,		Rx: vardenafil 20	
	Lost: /14/ Discontinued: /59/ Discont. AE: /15/ Discont. Insuff. resp.: /9/ Discont. other: /21/			
Grp: 3.1	Vardenafil 20 mg - mild ED	age:	duration:	Pts: 14
	Pt. Desc:		Rx: vardenafil 20	
Grp: 3.2	Vardenafil 20 mg - mild-moderate ED	age:	duration:	Pts: 39
	Pt. Desc:		Rx: vardenafil 20	
Grp: 3.3	Vardenafil 20 mg - moderate ED	age:	duration:	Pts: 52
	Pt. Desc:		Rx: vardenafil 20	
Grp: 3.4	Vardenafil 20 mg - severe ED	age:	duration:	Pts: 78
	Pt. Desc:		Rx: vardenafil 20	
Grp: 90	Placebo	age: 57(18,)	duration: 2.9(0.5,)	Pts: 197
	Pt. Desc: organic 54%, psychogenic 9%, mixed 37%, diabetes 19%,		Rx: Placebo	
	Lost: /28/ Discontinued: /106/ Discont. AE: /4/ Discont. Insuff. resp.: /39/ Discont. other: /35/			
Grp: 90	Placebo	age: 57(18,)	duration: 2.9(0.5,)	Pts: 197
	Pt. Desc: organic 54%, psychogenic 9%, mixed 37%, diabetes 19%,		Rx: Placebo	
Grp: 90.1	Placebo - mild ED	age:	duration:	Pts: 15
	Pt. Desc:		Rx: Placebo	
Grp: 90.2	Placebo - mild-moderate ED	age:	duration:	Pts: 44
	Pt. Desc:		Rx: Placebo	
Grp: 90.3	Placebo - moderate ED	age:	duration:	Pts: 65
	Pt. Desc:		Rx: Placebo	
Grp: 90.4	Placebo - severe ED	age:	duration:	Pts: 53
	Pt. Desc:		Rx: Placebo	

10400 Ernst, E., Pittler, M. H.. Yohimbine for erectile dysfunction: a systematic review and meta- analysis of randomized clinical trials. 1998

Pts: 419 Meta-analysis — Exeter, UK — Ext: AJM

Grp: 1	Yohimbine	age:	duration:	Pts:
	Pt. Desc:		Rx: yohimbine [5,5.4]	
Grp: 90	Control	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo [5,5.4]	

10532 Teloken, C., Rhoden, E. L., Sogari, P., Dambros, M., Souto, C. A.. Therapeutic effects of high dose yohimbine hydrochloride on organic erectile dysfunction. 1998

Pts: 22 Controlled Trial: single blind - one way crossover — Porto Alegre, Brazil — Ext: Meet

Grp: 1	Yohimbine	age: 58(28,69)	duration:	Pts: 22
	Pt. Desc: organic 100%,		Rx: yohimbine 100T	
Grp: 90	Placebo	age: 58(28,69)	duration:	Pts: 22
	Pt. Desc: organic 100%,		Rx: Placebo 100	

10559 Vogt, H. J., Brandl, P., Kockott, G., Schmitz, J. R., Wiegand, M. H., Schadrack, J., Gierend, M.. Double-blind, placebo-controlled safety and efficacy trial with yohimbine hydrochloride in the treatment of nonorganic erectile dysfunction. 1997

Pts: 86 Controlled Trial: placebo, double blind — Munich, Germany — Ext: DSS

Grp: 0	All patients	age: (28,71)	duration:	Pts: 86
	Pt. Desc:		Rx:	
Grp: 1	Yohimbine	age: 53.9	duration:	Pts: 43
	Pt. Desc:		Rx: yohimbine 30	
	Discontinued: /2/ Discont. AE: /2/			
Grp: 90	Placebo	age: 51.3	duration:	Pts: 43
	Pt. Desc:		Rx: Placebo 30	
	Discontinued: /3/ Discont. AE: /1/			

10631 Kunelius, P., Hakkinen, J., Lukkarinen, O.. Is high-dose yohimbine hydrochloride effective in the treatment of mixed-type impotence? A prospective, randomized, controlled double- blind crossover study. 1997

Pts: 29 Controlled Trial: Placebo, double blind, crossover, randomized — Oulu, Finland — Ext: MAA

Grp: 1	Yohimbine	age: 51(25,69)	duration:	Pts: 29
	Pt. Desc: mixed 100%,		Rx: yohimbine 36	
	Discontinued: /2/ Discont. AE: /2/			
Grp: 90	Placebo	age: 51(25,69)	duration:	Pts: 29
	Pt. Desc: mixed 100%,		Rx: yohimbine 36	

703069 Reid, K., Surridge, D. H., Morales, A., Condra, M., Harris, C., Owen, J., Fenemore, J.. Double-blind trial of yohimbine in treatment of psychogenic impotence. 1987

Pts: 48 Controlled Trial: double blind trial — Ontario, Canada — Ext: AJM

Grp: 1	Yohimbine	age: (18,70)	duration:	Pts: 29
	Pt. Desc: psychogenic 100%,		Rx: yohimbine 18	
Grp: 2	Placebo patients who got yohimbine in Phase II	age: (18,70)	duration:	Pts: 19
	Pt. Desc: psychogenic 100%,		Rx: yohimbine 18	
Grp: 90	Placebo	age: (18,70)	duration:	Pts: 19
	Pt. Desc: psychogenic 100%,		Rx: Placebo 18	

703070 Morales, A., Condra, M., Owen, J. A., Surridge, D. H., Fenemore, J., Harris, C.. Is yohimbine effective in the treatment of organic impotence? Results of a controlled trial. 1987

Pts: 100 Controlled Trial: Controlled with partial crossover — Ontario, Carnada — Ext: AJM

Grp: 1	Yohimbine	age: 56(18,70)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: yohimbine 18	
Grp: 2	Placebo pts who subsequently got yohimbine	age: (18,70)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: yohimbine 18	

Grp: 3	Pts who had a partial response or complete response	age: 54.9(18,70)	duration:	Pts:
	Pt. Desc: organic 100%, diabetes 38%,		Rx: yohimbine	
Grp: 4	Pts who had no response	age: 54.9(18,70)	duration:	Pts:
	Pt. Desc: organic 100%, diabetes 32%,		Rx: yohimbine	
Grp: 90	Placebo	age: 55(18,70)	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: yohimbine 18	

704037 Rowland, D. L., Kallan, K., Slob, A. K.. Yohimbine, erectile capacity, and sexual response in men. 1997

Pts: 26 Controlled Trial: Prospective, placebo-controlled, crossover Netherlands and Indiana, USA Ext: AJM

Grp: 1	Allpatients with ED	age: 48.6(18,)	duration: [3.8](0.5,)	Pts: 11
	Pt. Desc: psychogenic 100%, diabetes 9%,		Rx: yohimbine [5,10]	
Grp: 2	"Normal controls" (No ED)	age: 39.9(18,)	duration:	Pts: 15
	Pt. Desc:		Rx: yohimbine [5,10]	
Grp: 91	ED patients on placebo	age: 48.6(18,)	duration: 3.8(0.5,)	Pts: 11
	Pt. Desc: psychogenic 100%, diabetes 9%,		Rx: Placebo [5,10]	
Grp: 92	"Normal controls" on placebo	age: 39.9(18,)	duration:	Pts: 15
	Pt. Desc:		Rx: Placebo 10[,5]	

704108 Susset, J. G., Tessier, C. D., Wincze, J., Bansal, S., Malhotra, C., Schwacha, M. G.. Effect of yohimbine hydrochloride on erectile impotence: a double-blind study. 1989

Pts: 82 Controlled Trial: Placebo controlled, partial crossover Providence, RI Ext: AJM

Grp: 0	All patients	age: 61.2(40,73)	duration:	Pts: 82
	Pt. Desc:		Rx:	
	Discont. AE: /8/			
Grp: 0.1	All patients completing the study	age:	duration:	Pts: 71
	Pt. Desc: organic 56%, psychogenic 44%,		Rx:	
Grp: 1	All patients on yohimbine	age:	duration:	Pts: 82
	Pt. Desc:		Rx: yohimbine [5.4,10.8]	
	Discont. other: /3/			
Grp: 1.1	Mild ED	age:	duration:	Pts: 9
	Pt. Desc:		Rx: yohimbine	
Grp: 1.11	Normal cavernosogram	age:	duration:	Pts: 15
	Pt. Desc:		Rx: yohimbine	
Grp: 1.12	Questionable cavernosogram	age:	duration:	Pts: 10
	Pt. Desc:		Rx: yohimbine	
Grp: 1.13	Abnormal cavernosogram	age:	duration:	Pts: 7
	Pt. Desc:		Rx: yohimbine	
Grp: 1.14	Testosterone > 400	age:	duration:	Pts: 32
	Pt. Desc:		Rx: yohimbine	
Grp: 1.15	Testosterone 300 - 400	age:	duration:	Pts: 23
	Pt. Desc:		Rx: yohimbine	
Grp: 1.16	Testosterone <300	age:	duration:	Pts: 14
	Pt. Desc:		Rx: yohimbine	
Grp: 1.17	Normal reflex arousal	age:	duration:	Pts: 39
	Pt. Desc:		Rx: yohimbine	
Grp: 1.18	Unilateral abnormal arc	age:	duration:	Pts: 11
	Pt. Desc:		Rx: yohimbine	
Grp: 1.19	Bilateral abnormal arc	age:	duration:	Pts: 6
	Pt. Desc:		Rx: yohimbine	
Grp: 1.2	Moderate ED	age:	duration:	Pts: 25
	Pt. Desc:		Rx: yohimbine	
Grp: 1.21	Full daytime arousal	age:	duration:	Pts: 3
	Pt. Desc:		Rx: yohimbine	

Grp: 1.22	Partial daytime arousal	age:	duration:	Pts: 18
	Pt. Desc:		Rx: yohimbine	
Grp: 1.23	Minimal daytime arousal	age:	duration:	Pts: 50
	Pt. Desc:		Rx: yohimbine	
Grp: 1.24	Psychogenic	age:	duration:	Pts: 32
	Pt. Desc:		Rx: yohimbine	
Grp: 1.25	Organic	age:	duration:	Pts: 40
	Pt. Desc:		Rx: yohimbine	
Grp: 1.3	Severed ED	age:	duration:	Pts: 37
	Pt. Desc:		Rx: yohimbine	
Grp: 1.4	Duration of ED <2 years	age:	duration:	Pts: 21
	Pt. Desc:		Rx: yohimbine	
Grp: 1.5	Duration of ED 2-5 years	age:	duration:	Pts: 39
	Pt. Desc:		Rx: yohimbine	
Grp: 1.6	Duration of ED >5 years	age:	duration:	Pts: 10
	Pt. Desc:		Rx: yohimbine	
Grp: 1.7	PRI < 0.6	age:	duration:	Pts: 4
	Pt. Desc:		Rx: yohimbine	
Grp: 1.8	PRI 0.6 - 0.8	age:	duration:	Pts: 23
	Pt. Desc:		Rx: yohimbine	
Grp: 1.9	PRI >0.8	age:	duration:	Pts: 43
	Pt. Desc:		Rx: yohimbine	
Grp: 90	All patients on placebo	age:	duration:	Pts:
	Pt. Desc:		Rx: Placebo	
	Discont. other: /3/			

704145 Sobotka, J. J.. An evaluation of Afrodex in the management of male impotency: a double- blind crossover study. 1969

Pts: 50 Controlled Trial: Placebo controlled, crossover Phoenix, Arizona Ext: AJM

Grp: 1	All patients on Afrodex	age: 51.82(22,73)	duration: 1.18(0.5,3)	Pts: 50
	Pt. Desc: psychogenic 22%, diabetes 4%,		Rx: Afrodex T	
Grp: 1.1	Afrodex 1st	age: 53.25(26,73)	duration: 1.16(0.5,3)	Pts: 28
	Pt. Desc: psychogenic 21%,		Rx: Afrodex T	
Grp: 1.2	Afrodex 2nd	age: 50(22,71)	duration: 1.2(0.5,3)	Pts: 22
	Pt. Desc: psychogenic 23%, diabetes 5%,		Rx: Afrodex T	
Grp: 90	All patients on placebo	age: 51.82(22,73)	duration: 1.18(0.5,3)	Pts: 50
	Pt. Desc: psychogenic 22%,		Rx: Placebo T	
Grp: 90.1	Placebo 1st	age: 50(22,71)	duration: 1.2(0.5,3)	Pts: 22
	Pt. Desc: psychogenic 23%, diabetes 5%,		Rx: Placebo T	
Grp: 90.2	Placebo 2nd	age: 53.25(26,73)	duration: 1.16(0.5,3)	Pts: 28
	Pt. Desc: psychogenic 21%, diabetes 4%,		Rx: Placebo	

759003 Sommer, F., Obenaus, K., Engelmann, U.. Creative-dynamic image synthesis: a useful addition to the treatment options for impotence. 2001

Pts: 69 Controlled Trial: randomized placebo controlled Ext: AJM

Grp: 0	All patients	age: 46(26,63)	duration: (3,)	Pts: 69
	Pt. Desc: psychogenic 100%, hypogonadism 0%,		Rx:	
Grp: 1	Yohimbine	age:	duration:	Pts:
	Pt. Desc: psychogenic 100%,		Rx: yohimbine 30	
Grp: 90	Placebo	age:	duration:	Pts:
	Pt. Desc: psychogenic 100%,		Rx: Placebo 30	

796089 Lebret, T., Herve, J. M., Gorny, P., Worcel, M., Botto, H.. Efficacy and safety of a novel combination of L-arginine glutamate and yohimbine hydrochloride: a new oral therapy for erectile dysfunction. 2002

Pts: 48 Controlled Trial France Ext: PMF

Grp: 1	Results for Yohimbine Hydrochloride alone (YP)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: yohimbine 6	
	Discont. AE: /0/48 Discont. other: /3/48			
Grp: 1.1	Results for Yohimbine Hydrochloride alone with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: yohimbine 6	
Grp: 1.2	Results for Yohimbine Hydrochloride alone with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: post-prostatectomy 0%, non nerve sparing 0%,		Rx: yohimbine 6	
Grp: 2	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride (AY)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
	Discont. AE: /0/48 Discont. other: /3/48			
Grp: 2.1	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: post-prostatectomy 0%, non nerve sparing 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
Grp: 2.2	Results for L-Arginine Glutamate plus Yohimbine Hydrochloride with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Yohimbine + L-Arginine glutamate 6 grams 6	
Grp: 90	Results for Placebo (PP)	age: 56.7(18,)	duration: (0.25,)	Pts: 45
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	
	Discont. AE: /0/48 Discont. other: /3/48			
Grp: 90.1	Results for Placebo with IIEF EF Domain baseline <14	age:	duration: (0.25,)	Pts: 23
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	
Grp: 90.2	Results for Placebo with IIEF EF Domain baseline =>14	age:	duration: (0.25,)	Pts: 22
	Pt. Desc: neurogenic 0%, post-prostatectomy 0%,		Rx: Placebo	

703057991 Sonda, L. P., Mazo, R., Chancellor, M. B.. The role of yohimbine for the treatment of erectile impotence. 1990

Pts: 40 Controlled Trial: Placebo controlled, crossover trial US Ext: AJM

Grp: 0	All patients through both treatments	age:	duration:	Pts: 40
	Pt. Desc:		Rx:	
	Discontinued: /7/40			
Grp: 1	Yohimbine	age:	duration: (3,)	Pts: 40
	Pt. Desc:		Rx: yohimbine 16.2	
Grp: 1.1	Organic patients on yohimbine	age:	duration:	Pts:
	Pt. Desc: organic 100%,		Rx: yohimbine	
Grp: 1.2	Psychogenic patients on yohimbine	age:	duration:	Pts:
	Pt. Desc: psychogenic 100%,		Rx: yohimbine	
Grp: 90	Placebo	age:	duration:	Pts: 40
	Pt. Desc:		Rx: Placebo 16.2	

703057992 Sonda, L. P., Mazo, R., Chancellor, M. B.. The role of yohimbine for the treatment of erectile impotence. 1990

Pts: Case Series: Retrospective, uncontrolled Ext: AJM

Grp: 0	All pts in initial 16.2 mg study	age: 56(26,78)	duration: 17(0.33,22)	Pts: 215
	Pt. Desc: organic 100%, diabetes 66%, Hypertension 33%, Alcoholism 25%,		Rx: yohimbine 16.2	
Grp: 0	All pts in initial 16.2 mg study	age: 56(26,78)	duration: 17(0.33,22)	Pts: 215
	Pt. Desc: organic 100%, diabetes 66%, Hypertension 33%, Alcoholism 25%,		Rx: yohimbine 16.2	
Grp: 1	No response, then 21.6 mg per day	age:	duration:	Pts: 25
	Pt. Desc: organic 100%,		Rx: yohimbine 21.6	

Grp: 2	Partial response, then 21.6 mg per day	age:	duration:	Pts: 21
	Pt. Desc: organic 100%,		Rx: yohimbine 21.6	

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
Able to have intercourse								
10527	0	0	Able to have intercourse	MUSE [125,1000]T	37%	37*	100	**
10527	1	0	Able to have intercourse	MUSE 125	0%	0*	100	**
10527	2	0	Able to have intercourse	MUSE 250	17.95%*	7	39	
10527	3	0	Able to have intercourse	MUSE 500	31.15%*	19	61	*
10527	4	0	Able to have intercourse	MUSE 1000	38.24%*	13	34	*
10672	1	0	Able to have intercourse	MUSE [125,1000]	63.6%	42	66	
10672	90	0	Able to have intercourse	Placebo	12.5%	8*	66	
10672	1.1	0	Able to have intercourse	MUSE 125	39.4%	26*	66	*
10672	1.2	0	Able to have intercourse	MUSE 250	33.3%	22*	66	
10672	1.3	0	Able to have intercourse	MUSE 500	40%	26*	66	
10672	1.4	0	Able to have intercourse	MUSE 1000	50%	33*	66	
10672	1.5	0	Able to have intercourse	MUSE [125,1000]	65%	43*	66	*
10672	1.6	0	Able to have intercourse	MUSE [125,1000]	47%	31*	66	*
10672	1.7	0	Able to have intercourse	MUSE [125,1000]	64%	42*	66	*
701004	2.2	8	Able to have intercourse	MUSE	75.64%*	118	156	
701004	2.21	8	Able to have intercourse	MUSE	73.33%*	22	30	
701004	2.22	8	Able to have intercourse	MUSE	71.43%*	25	35	
701004	2.22	8	Able to have intercourse	MUSE	71.43%*	25	35	
701004	2.22	8	Able to have intercourse	MUSE	71.43%*	25	35	
701004	2.22	8	Able to have intercourse	MUSE	71.43%*	25	35	
701004	2.23	8	Able to have intercourse	MUSE	76.47%*	13	17	
701004	2.24	8	Able to have intercourse	MUSE	78.79%*	130	165	
701004	2.3	8	Able to have intercourse	MUSE 250	67.44%*	58	86	
701004	2.4	8	Able to have intercourse	MUSE 500	78.12%*	50	64	
701004	2.5	8	Able to have intercourse	MUSE 1000	91.03%*	71	78	
701004	2	8	Able to have intercourse	MUSE [250,1000]T	78.07%*	178	228	
701004	2	8	Able to have intercourse	MUSE [250,1000]T	78.07%*	178	228	
701004	2	8	Able to have intercourse	MUSE [250,1000]T	78.07%*	178	228	
701004	2	8	Able to have intercourse	MUSE [250,1000]T	78.07%*	178	228	
701004	2.1	8	Able to have intercourse	MUSE	83.33%*	60	72	
10184	1	12	Able to have intercourse	intracavernous PGE1 20	86.67%*	26	30	*
10184	2	12	Able to have intercourse	MUSE 100	53.33%*	16	30	*
10644	21.11	12	Able to have intercourse	MUSE [125,1000]T	64%			

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
10644	21.2	12	Able to have intercourse	MUSE [125,1000]T	67%	94*	140
10644	29.1	12	Able to have intercourse	Placebo [125,1000]T	22%	32*	145
10644	21.3	12	Able to have intercourse	MUSE [125,1000]T	72%	66*	91
10644	29.2	12	Able to have intercourse	Placebo [125,1000]T	22%	22*	98
10644	21.4	12	Able to have intercourse	MUSE [125,1000]T	59%	91*	154
10644	29.3	12	Able to have intercourse	Placebo [125,1000]T	9%	14*	159
10644	21.5	12	Able to have intercourse	MUSE [125,1000]T	64%	64*	100
10644	21.5	12	Able to have intercourse	MUSE [125,1000]T	64%	64*	100
10644	21.5	12	Able to have intercourse	MUSE [125,1000]T	64%	64*	100
10644	21.5	12	Able to have intercourse	MUSE [125,1000]T	64%	64*	100
10644	29.4	12	Able to have intercourse	Placebo [125,1000]T	23%	25*	109
10644	21.6	12	Able to have intercourse	MUSE [125,1000]T	73%		
10644	29.5	12	Able to have intercourse	Placebo [125,1000]T	27%		
10644	21.7	12	Able to have intercourse	MUSE [125,1000]T	67%		
10644	29.6	12	Able to have intercourse	Placebo [125,1000]T	20%		
10644	21.8	12	Able to have intercourse	MUSE [125,1000]T	65%		
10644	29.7	12	Able to have intercourse	Placebo [125,1000]T	15%		
10644	21.9	12	Able to have intercourse	MUSE [125,1000]T	62%		
10644	29.8	12	Able to have intercourse	Placebo [125,1000]T	14%		
10644	29.9	12	Able to have intercourse	Placebo [125,1000]T	19%		
755000	1.1	12	Able to have intercourse	MUSE [500,1000]T	80.39%*	41	51 *
10396992	1	12	Able to have intercourse	MUSE [125,1000]	68.66%*	46	67
10396992	90	12	Able to have intercourse	Placebo [125,1000]	10.96%*	8	73
10396992	1.11	12	Able to have intercourse	MUSE [125,1000]	67%		
10396992	90.1	12	Able to have intercourse	Placebo [125,1000]	15%		
10396992	1.12	12	Able to have intercourse	MUSE [125,1000]	68%		
10396992	90.11	12	Able to have intercourse	Placebo [125,1000]	12%		
10396992	1.13	12	Able to have intercourse	MUSE [125,1000]	70%		
10396992	90.12	12	Able to have intercourse	Placebo [125,1000]	8%		
10396992	1.14	12	Able to have intercourse	MUSE [125,1000]	74%	27*	37 **
10396992	90.13	12	Able to have intercourse	Placebo [125,1000]	7%	3*	43 **
10396992	1.15	12	Able to have intercourse	MUSE [125,1000]	64%	26*	41 **
10396992	90.14	12	Able to have intercourse	Placebo [125,1000]	16%	6*	38 **
10396992	1.16	12	Able to have intercourse	MUSE [125,1000]	73%	29*	40 **
10396992	90.15	12	Able to have intercourse	Placebo [125,1000]	11%	5*	44 **
10396992	1.17	12	Able to have intercourse	MUSE [125,1000]	68%	26*	38 **

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
10396992	90.16	12	Able to have intercourse	Placebo [125,1000]	14%	5*	37 **	
10396992	1.2	12	Able to have intercourse	MUSE [125,1000]	74%	19*	26 **	
10396992	90.2	12	Able to have intercourse	Placebo [125,1000]	7%	2*	33 **	
10396992	1.3	12	Able to have intercourse	MUSE [125,1000]	46%	6*	14 **	
10396992	90.3	12	Able to have intercourse	Placebo [125,1000]	1%	0*	12 **	
10396992	1.4	12	Able to have intercourse	MUSE [125,1000]	72%	14*	19 **	
10396992	90.4	12	Able to have intercourse	Placebo [125,1000]	13%	2*	17 **	
10396992	1.5	12	Able to have intercourse	MUSE [125,1000]	77%	15*	19 **	
10396992	90.5	12	Able to have intercourse	Placebo [125,1000]	23%	4*	19 **	
10396992	1.6	12	Able to have intercourse	MUSE [125,1000]	67%			
10396992	90.6	12	Able to have intercourse	Placebo [125,1000]	13%			
10396992	1.7	12	Able to have intercourse	MUSE [125,1000]	54%			
10396992	90.7	12	Able to have intercourse	Placebo [125,1000]	11%			
10396992	1.8	12	Able to have intercourse	MUSE [125,1000]	69%			
10396992	90.8	12	Able to have intercourse	Placebo [125,1000]	9%			
10396992	1.9	12	Able to have intercourse	MUSE [125,1000]	79%			
10396992	90.9	12	Able to have intercourse	Placebo [125,1000]	10%			
10297992	1	999	Able to have intercourse	MUSE [125,1000]	68.66%*	46	67	
10297992	90	999	Able to have intercourse	Placebo	10.96%*	8	73	

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
chose to use drug							
796111	1	24	Continuing to use drug	MUSE [250,1000]	100%	15	15

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
10527	0	0	Grade 5 erection	MUSE [125,1000]T	7%	7*	100 **
10527	1	0	Grade 5 erection	MUSE 125	0%	0*	100 **
10527	2	0	Grade 5 erection	MUSE 250	2.56%*	1	39
10527	3	0	Grade 5 erection	MUSE 500	3.28%*	2	61 *
10527	4	0	Grade 5 erection	MUSE 1000	9%	3	34 *
10644	1.1	0	maximal response grade 4 or 5	MUSE 125	12.3%	183*	1490 *
10644	1.2	0	maximal response grade 4 or 5	MUSE 250	16.6%	248*	1492 *
10644	1.3	0	maximal response grade 4 or 5	MUSE 500	39.6%	442*	1117 *
10644	1.4	0	maximal response grade 4 or 5	MUSE 1000	48.8%	556*	1140 *
755000	1	0	Grade 4-5 erection	MUSE T	75.64%*	59	78
10396991	0	0.143	Erection sufficient for intercourse (grade 4-5 erection)	MUSE [125,1000]T	65.16%*	159	244
701003	0	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE [125,1000]T	55.9%*	128	229
701003	1	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	58.29%*	102	175
701003	2	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	51.28%*	20	39
701003	3	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	40%*	6	15
701003	4	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	77.78%*	7	9
701003	5	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	70.59%*	12	17
701003	6	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60.36%*	67	111
701003	6	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60.36%*	67	111
701003	7	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60%*	39	65
701003	8	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60%*	6	10
701003	9	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	57.14%*	4	7
701003	10	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	54.17%*	13	24

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
701003	11	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	47.22%*	34	72
701003	12	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	55.56%*	15	27
701003	13	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	55.32%*	26	47
701003	14	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	34.4%	11*	32
701003	15	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	58%	40*	69
701003	16	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60.5%	52*	86
701003	17	8	Successful intercourse on 2 or more occasions or 66% of attempts	MUSE	60%	24*	40
10519	1	999	+ response (Grade 4 or 5 erection)	MUSE [125,1000]T	42.72%*	44	103
10519	2	999	+ response (Grade 4 or 5 erection)	Alprostadil intracavernous [5,40]T	69.9%*	72	103
10519	1	999	Grade 5 erection (full tumescence and rigidity)	MUSE [125,1000]T	9.71%*	10	103
10519	2	999	Grade 5 erection (full tumescence and rigidity)	Alprostadil intracavernous [5,40]T	48%	49	103
10297991	0	999	Erection sufficient for intercourse or full erection	MUSE [125,1000]T	63.86%*	159	249 **

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response?							
10644	21	12	Attempts resulting in intercourse	MUSE [125,1000]T	50.4%	2485	4933
10644	29	12	Attempts resulting in intercourse	Placebo [125,1000]T	10.4%	454	4346
10644	29	12	Attempts resulting in intercourse	Placebo [125,1000]T	10.4%	454	4346
10644	21.1	12	Attempts resulting in intercourse	MUSE [125,1000]T	69.2%	2485	3593
10644	21	12	Attempts resulting in intercourse or orgasm	MUSE [125,1000]T	56.3%	2770	4921
10644	29	12	Attempts resulting in intercourse or orgasm	Placebo [125,1000]T	15.4%	668	4331
10644	29	12	Attempts resulting in intercourse or orgasm	Placebo [125,1000]T	15.4%	668	4331
10644	21.1	12	Attempts resulting in intercourse or orgasm	MUSE [125,1000]T	72.8%	2612	3586
10644	21	12	Attempts resulting in intercourse, orgasm or 10min sufficient erection	MUSE [125,1000]T	57%	2797	4906
10644	29	12	Attempts resulting in intercourse, orgasm or 10min sufficient erection	Placebo [125,1000]T	15.4%	669	4331
10644	29	12	Attempts resulting in intercourse, orgasm or 10min sufficient erection	Placebo [125,1000]T	15.4%	669	4331
10644	21.1	12	Attempts resulting in intercourse, orgasm or 10min sufficient erection	MUSE [125,1000]T	73.7%	2634	3572

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
796111	1	24	Only effective on every third occasion or worse	MUSE [250,1000]	33%	5	15

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
uncategorized							
10035	1	0	passed penile buckling test	ICI alprostadil [,40]T	61.1%	58	95
10035	2	0	passed penile buckling test	MUSE [,1000]T	21.1%	20	95
10035	1	0	patient assessed grade 3 erection	ICI alprostadil [,40]T	66.3%	63	95
10035	2	0	patient assessed grade 3 erection	MUSE [,1000]T	26.3%	25	95 *
10035	1	0	physian assessed grade 3 erection	ICI alprostadil [,40]T	62.1%	59	95
10035	2	0	physian assessed grade 3 erection	MUSE [,1000]T	20%	1995	95 *
10527	0	0	Grade 4 erection	MUSE [125,1000]T	30%	30*	100 **
10527	1	0	Grade 4 erection	MUSE 125	0%	0*	100 **
10527	2	0	Grade 4 erection	MUSE 250	156.41%*	61	39
10527	3	0	Grade 4 erection	MUSE 500	27.87%*	17	61 *
10527	4	0	Grade 4 erection	MUSE 1000	29%	10	34 *
10644	1.1	0	administration comfortable	MUSE 125	48.5%	723*	1490 *
10644	1.2	0	administration comfortable	MUSE 250	48.6%	725*	1492 *
10644	1.3	0	administration comfortable	MUSE 500	51.8%	579*	1117 *
10644	1.4	0	administration comfortable	MUSE 1000	50.1%	571*	1140 *
10644	1.1	0	administration neutral	MUSE 125	26.8%	399*	1490 *
10644	1.2	0	administration neutral	MUSE 250	26.8%	400*	1492 *
10644	1.3	0	administration neutral	MUSE 500	24.5%	274*	1117 *
10644	1.4	0	administration neutral	MUSE 1000	26.1%	298*	1140 *
10644	1.1	0	administration uncomfortable	MUSE 125	8.7%	130*	1490 *
10644	1.2	0	administration uncomfortable	MUSE 250	10.7%	160*	1492 *
10644	1.3	0	administration uncomfortable	MUSE 500	8.9%	99*	1117 *
10644	1.4	0	administration uncomfortable	MUSE 1000	9%	103*	1140 *
10644	1.1	0	administration very comfortable	MUSE 125	15.7%	234*	1490 *
10644	1.2	0	administration very comfortable	MUSE 250	13%	194*	1492 *
10644	1.3	0	administration very comfortable	MUSE 500	14.2%	159*	1117 *
10644	1.4	0	administration very comfortable	MUSE 1000	12.5%	142*	1140 *
10644	1.1	0	administration very uncomfortable	MUSE 125	0.4%	6*	1490 *
10644	1.2	0	administration very uncomfortable	MUSE 250	0.9%	13*	1492 *
10644	1.3	0	administration very uncomfortable	MUSE 500	0.7%	8*	1117 *
10644	1.4	0	administration very uncomfortable	MUSE 1000	2.4%	27*	1140 *
10644	1	0	grade 4 or 5 erection on any dose	MUSE [125,1000]T	65.9%	996	1511
10672	1	0	EAS >=3	MUSE [125,1000]	75.4%	49	65
10672	90	0	EAS >=3	Placebo	12.7%	8*	65

Appendix 3B - Binary Efficacy Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
10672	1.1	0	EAS >=3	MUSE 125	45.5%	30*	65
10672	1.2	0	EAS >=3	MUSE 250	51.5%	33*	65
10672	1.3	0	EAS >=3	MUSE 500	53.3%	35*	65
10672	1.4	0	EAS >=3	MUSE 1000	55%	36*	65
10672	1	0	EAS>=4	MUSE [125,1000]	49.2%	32	65
10672	90	0	EAS>=4	Placebo	4.8%	3*	65
10672	1.1	0	EAS>=4	MUSE 125	19.7%	13*	65
10672	1.2	0	EAS>=4	MUSE 250	30.3%	20*	65
10672	1.3	0	EAS>=4	MUSE 500	26.7%	17*	65
10672	1.4	0	EAS>=4	MUSE 1000	31.7%	21*	65
796111	1	0	Patients successfully treated in clinic	MUSE [250,1000]	35%	35	100
796111	1.1	0	Patients successfully treated in clinic	MUSE [250,1000]	30.8%	20	65
796111	1.11	0	Patients successfully treated in clinic	MUSE [250,1000]	36%	8	22
796111	1.12	0	Patients successfully treated in clinic	MUSE [250,1000]	30%	6	20
796111	1.13	0	Patients successfully treated in clinic	MUSE [250,1000]	25%	4	16
796111	1.14	0	Patients successfully treated in clinic	MUSE [250,1000]	33%	2	6
796111	1.2	0	Patients successfully treated in clinic	MUSE [250,1000]	42%	15	36
10035	1.1	3	>=75% successful	ICI alprostadil [,40]	75%	51	68
10035	2.1	3	>=75% successful	MUSE [,1000]	36.8%	25	68
10035	1.1	3	at least one erection sufficient for intercourse	ICI alprostadil [,40]	92.6%	63	68
10035	2.1	3	at least one erection sufficient for intercourse	MUSE [,1000]	61.8%	42	68
10519	1	999	Grade 4 erection (full tumescence and partial rigidty)	MUSE [125,1000]T	33.01%*	34	103
10519	2	999	Grade 4 erection (full tumescence and partial rigidty)	Alprostadil intracavernous [5,40]T	22.33%*	23	103
701004	1	999	Grade 4 or 5 erections in clinic	MUSE [250,1000]T	59.28%*	198	334
701004	1.1	999	Grade 4 or 5 erections in clinic	MUSE	64%*	64	100
701004	1.2	999	Grade 4 or 5 erections in clinic	MUSE	57.26%*	134	234
701004	1.21	999	Grade 4 or 5 erections in clinic	MUSE	66.67%*	36	54
701004	1.22	999	Grade 4 or 5 erections in clinic	MUSE	69.81%*	37	53
701004	1.22	999	Grade 4 or 5 erections in clinic	MUSE	69.81%*	37	53
701004	1.23	999	Grade 4 or 5 erections in clinic	MUSE	40.91%*	9	22
701004	1.24	999	Grade 4 or 5 erections in clinic	MUSE	58.87%*	136	231

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
Able to have intercourse								
10184	1	12	Able to have intercourse	intracavernous PGE1 20	86.67%*	26	30	*
10184	2	12	Able to have intercourse	MUSE 100	53.33%*	16	30	*

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
chose to use drug							
700015	90	4	GEQ#2-would take drug if available	Placebo [25,75]T	37%	13*	35
700015	1	4	GEQ2--would take drug if available	sildenafil [25,75]T	94%	33*	35

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
10780	1	4	Good result	Testosterone 120	40%*	8	20 *
10780	2	4	Good result	trazodone [100,150]	38.1%*	8	21 *
10780	3	4	Good result	hypnosis	60%*	12	20 *
10780	90	4	Good result	Placebo	33.33%*	6	18 *
10780	1.1	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.1	4	positive response	trazodone [100,150]	100%*	4	4 *
10780	3.1	4	positive response	hypnosis	80%*	8	10 *
10780	90.1	4	positive response	Placebo	50%*	2	4 *
10780	1.2	4	positive response	Testosterone 120	83.33%*	5	6 *
10780	2.2	4	positive response	trazodone [100,150]	66.67%*	4	6 *
10780	3.2	4	positive response	hypnosis	100%*	4	4 *
10780	90.2	4	positive response	Placebo	40%*	2	5 *
10780	1.3	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.3	4	positive response	trazodone [100,150]	57.14%*	4	7 *
10780	3.3	4	positive response	hypnosis	100%*	4	4 *
10780	90.3	4	positive response	Placebo	60%*	3	5 *
10780	1.4	4	positive response	Testosterone 120	25%*	1	4 *
10780	2.4	4	positive response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	positive response	hypnosis	0%*	0	2 *
10780	90.4	4	positive response	Placebo	0%*	0	4 *
705006	1	4	Positive response	trazodone 50	65.2%	15*	23 *
705006	2	4	Positive response	Ketanserin 20	19.1%	4*	21 *
705006	3	4	Positive response	Mianserin 10	31.6%	6*	19 *
705006	90	4	Positive response	Placebo T	13.6%	3*	22 *
790779	1.1	4	Full erections	0.8% testosterone cream 2	57.89%*	11	19 *
790779	2.1	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	84.21%*	16	19 *
790779	1.2	4	Full erections	0.8% testosterone cream 2	11.11%*	2	18 *
790779	2.2	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	55.56%*	10	18 *
790779	1.3	4	Full erections	0.8% testosterone cream 2	0%*	0	5 *

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
790779	2.3	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	40%*	2	5	*
790779	3	4	Full erections	testosterone followed by polypharmacy cream	14%	3*	21	**
790779	4	4	Full erections	poplypharmacy cream followed by testosterone	43%	9*	21	**
10519	1	999	+ response (Grade 4 or 5 erection)	MUSE [125,1000]T	42.72%*	44	103	
10519	2	999	+ response (Grade 4 or 5 erection)	Alprostadil intracavernous [5,40]T	69.9%*	72	103	
10519	1	999	Grade 5 erection (full tumescence and rigidity)	MUSE [125,1000]T	9.71%*	10	103	
10519	2	999	Grade 5 erection (full tumescence and rigidity)	Alprostadil intracavernous [5,40]T	48%	49	103	

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections							
700015	1	4	Improved quality of erections (GEQ1)	sildenafil [25,75]T	94%	32*	34
700015	90	4	Improved quality of erections (GEQ1)	Placebo [25,75]T	25%	8*	34

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
increased libido								
790779	1	4	Increased frequency of thoughts about sex & excitement about sex	0.8% testosterone cream 2	62%	26*	42 **	
790779	2	4	Increased frequency of thoughts about sex & excitement about sex	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	85%	36*	42 **	

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
10780	1.1	4	neative response	Testosterone 120	40%*	2	5 *
10780	2.1	4	negative response	trazodone [100,150]	0%*	0	4 *
10780	3.1	4	negative response	hypnosis	20%*	2	10 *
10780	90.1	4	negative response	Placebo	50%*	2	4 *
10780	1.2	4	negative response	Testosterone 120	16.67%*	1	6 *
10780	2.2	4	negative response	trazodone [100,150]	33.33%*	2	6 *
10780	3.2	4	negative response	hypnosis	0%*	0	4 *
10780	90.2	4	negative response	Placebo	60%*	3	5 *
10780	1.3	4	negative response	Testosterone 120	40%*	2	5 *
10780	2.3	4	negative response	trazodone [100,150]	42.86%*	3	7 *
10780	3.3	4	negative response	hypnosis	0%*	0	4 *
10780	90.3	4	negative response	Placebo	40%*	2	5 *
10780	1.4	4	negative response	Testosterone 120	75%*	3	4 *
10780	2.4	4	negative response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	negative response	hypnosis	100%*	2	2 *
10780	90.4	4	negative response	Placebo	100%*	4	4 *
10780	1	4	No response	Testosterone 120	40%*	8	20 *
10780	2	4	No response	trazodone [100,150]	33.33%*	7	21 *
10780	3	4	No response	hypnosis	20%*	4	20 *
10780	90	4	No response	Placebo	61.11%*	11	18 *
790779	1.1	4	No erections	0.8% testosterone cream 2	42.11%*	8	19 *
790779	2.1	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	15.79%*	3	19 *
790779	1.2	4	No erections	0.8% testosterone cream 2	83.33%*	15	18 *
790779	2.2	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	22.22%*	4	18 *
790779	1.3	4	No erections	0.8% testosterone cream 2	80%*	4	5 *
790779	2.3	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	40%*	2	5 *

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
partial response								
790779	1.1	4	Partial erections	0.8% testosterone cream 2	0%*	0	19	*
790779	2.1	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	19	*
790779	1.2	4	Partial erections	0.8% testosterone cream 2	5.56%*	1	18	*
790779	2.2	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	11.11%*	2	18	*
790779	1.3	4	Partial erections	0.8% testosterone cream 2	20%*	1	5	*
790779	2.3	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	5	*

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
uncategorized							
10035	1	0	passed penile buckling test	ICI alprostadil [,40]T	61.1%	58	95
10035	2	0	passed penile buckling test	MUSE [,1000]T	21.1%	20	95
10035	1	0	patient assessed grade 3 erection	ICI alprostadil [,40]T	66.3%	63	95
10035	2	0	patient assessed grade 3 erection	MUSE [,1000]T	26.3%	25	95 *
10035	1	0	physian assessed grade 3 erection	ICI alprostadil [,40]T	62.1%	59	95
10035	2	0	physian assessed grade 3 erection	MUSE [,1000]T	20%	1995	95 *
796089	1	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	26.7%	12*	45 *
796089	2	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	35.6%	16*	45 *
796089	90	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	13.3%	6*	45 *
796089	1.1	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	26.1%	6*	23 *
796089	2.1	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	17.4%	4*	23 *
796089	90.1	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	4.4%	1*	23 *
796089	1.2	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	27.3%	6*	22 *
796089	2.2	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	54.6%	12*	22 *
796089	90.2	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	22.7%	5*	22 *
796089	1	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	28.9%	13*	45 *
796089	2	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	40%	18*	45 *
796089	90	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	17.8%	8*	45 *
796089	1.1	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	30.4%	7*	23 *
796089	2.1	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	26.1%	6*	23 *
796089	90.1	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	13%	3*	23 *
796089	1.2	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	27.3%	6*	22 *

Appendix 3B - Binary Efficacy Data
Studies Including Other

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
796089	2.2	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	54.6%	12*	22 *
796089	90.2	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	22.7%	5*	22 *
10035	1.1	3	>=75% successful	ICI alprostadil [,40]	75%	51	68
10035	2.1	3	>=75% successful	MUSE [,1000]	36.8%	25	68
10035	1.1	3	at least one erection sufficient for intercourse	ICI alprostadil [,40]	92.6%	63	68
10035	2.1	3	at least one erection sufficient for intercourse	MUSE [,1000]	61.8%	42	68
10780	1	4	Moderate result	Testosterone 120	20%*	4	20 *
10780	2	4	Moderate result	trazodone [100,150]	28.57%*	6	21 *
10780	3	4	Moderate result	hypnosis	20%*	4	20 *
10780	90	4	Moderate result	Placebo	5.56%*	1	18 *
790779	1.1	4	Tumescence	0.8% testosterone cream 2	0%*	0	19 *
790779	2.1	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	19 *
790779	1.2	4	Tumescence	0.8% testosterone cream 2	0%*	0	18 *
790779	2.2	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	11.11%*	2	18 *
790779	1.3	4	Tumescence	0.8% testosterone cream 2	0%*	0	5 *
790779	2.3	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	20%*	1	5 *
10519	1	999	Grade 4 erection (full tumescence and partial rigidty)	MUSE [125,1000]T	33.01%*	34	103
10519	2	999	Grade 4 erection (full tumescence and partial rigidty)	Alprostadil intracavernous [5,40]T	22.33%*	23	103

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
Able to have intercourse								
10024	1	6	Able to have intercourse	sildenafil [25,100]T	80%	133*	166	
10024	90	6	Able to have intercourse	Placebo [25,100]T	10%	17*	166	
700002	1	6	Able to have intercourse	sildenafil [25,100]T	55%	33*	60	**
700002	90	6	Able to have intercourse	Placebo [25,100]T	18%	11*	60	**
796021	90	6	Able to have intercourse	Placebo [25,100]T	36.3%	41*	114	*
796021	1	6	Able to have intercourse	sildenafil [25,100]T	80.9%	95*	118	*
796021	1	6	Able to have intercourse	sildenafil [25,100]T	80.9%	95*	118	*
796021	90	6	Able to have intercourse	Placebo [25,100]T	36.3%	41*	114	*
796021	2	6	Able to have intercourse	sildenafil [25,100]T	80.2%	67*	83	*
796021	2	6	Able to have intercourse	sildenafil [25,100]T	80.2%	67*	83	*
796021	91	6	Able to have intercourse	Placebo [25,100]T	28.7%	25*	88	*
796021	91	6	Able to have intercourse	Placebo [25,100]T	28.7%	25*	88	*
10062	0	8	Able to have intercourse	sildenafil [50,100]T	73.2%	115*	157	*
105033	1	12	Able to have intercourse	sildenafil [25,100]T	68.61%*	94	137	
105033	1	12	Able to have intercourse	sildenafil [25,100]T	68.61%*	94	137	
105033	1	12	Able to have intercourse	sildenafil [25,100]T	68.61%*	94	137	
105033	1	12	Able to have intercourse	sildenafil [25,100]T	68.61%*	94	137	
105033	90	12	Able to have intercourse	Placebo [25,100]T	23.19%*	32	138	
105033	90	12	Able to have intercourse	Placebo [25,100]T	23.19%*	32	138	
105033	90	12	Able to have intercourse	Placebo [25,100]T	23.19%*	32	138	
105033	90	12	Able to have intercourse	Placebo [25,100]T	23.19%*	32	138	
200300	1	12	Able to have intercourse	sildenafil [25,100]T	70%	87*	124	*
200300	90	12	Able to have intercourse	Placebo [25,100]T	17%	21*	121	*
700006	1	12	Able to have intercourse	sildenafil [25,100]T	89.4%	59	66	
700006	90	12	Able to have intercourse	Placebo [25,100]T	12.9%	9	70	
10029991	1	12	Successful at intercourse	sildenafil [25,100]T	69%	112*	163	**
10029991	90	12	Successful attempts at intercourse	Placebo [25,100]T	22%	37*	166	**
10029992	1	12	Successful attempts at intercourse	sildenafil [25,100]T	60%	95*	159	**
10029992	90	12	Successful attempts at intercourse	Placebo [25,100]T	20%	31*	156	**
10027992	2	999	Able to have intercourse	sildenafil [25,100]T	80%	133*	166	
10027992	90.2	999	Able to have intercourse	Placebo [25,100]T	10%	17*	166	

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
chose not to use drug							
10169	90	6	Preferred placebo over sildeanfil	Placebo [25,100]T	4%	7	168
10169	90.3	6	Preferred placebo over sildeanfil	Placebo [25,100]T	4%	4	90
10169	90.4	6	Preferred placebo over sildeanfil	Placebo [25,100]T	4%	3	78
10169	90.5	6	Preferred placebo over sildeanfil	Placebo [25,100]T	5%	7	143

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
chose to use drug							
10252	1.2	4	want to continue treatment	sildenafil 50	67%	8	12
10252	90.2	4	want to continue treatment	Placebo 50	15.4%	2	13
700015	90	4	GEQ#2-would take drug if available	Placebo [25,75]T	37%	13*	35
700015	1	4	GEQ2--would take drug if available	sildenafil [25,75]T	94%	33*	35
10169	1	6	Preferred sildenafil over placebo	sildenafil [25,100]T	76%	127	168
10169	1.3	6	Preferred sildenafil over placebo	sildenafil [25,100]T	73%	66	90
10169	1.4	6	Preferred sildenafil over placebo	sildenafil [25,100]T	78%	61	78
10169	1.5	6	Preferred sildenafil over placebo	sildenafil [25,100]T	78%	111	143
10169	1.6	6	Preferred sildenafil over placebo	sildenafil [25,100]T	100%	25	25

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
10169	1	6	Successful intercourse for more than 60% of attempts	sildenafil [25,100]T	42%	73	175
10169	90	6	Successful intercouse for more than 60% of attempts	Placebo [25,100]T	3%	6	174
10062	12	8	Good result	sildenafil [50,100]T	0%	0	24 *
10062	0	8	Good results	sildenafil [50,100]T	31.84%	50	157 *
10062	1	8	Good results	sildenafil [50,100]T	25%	1*	4 **
10062	2	8	Good results	sildenafil [50,100]T	33%	1*	2 **
10062	3	8	Good results	sildenafil [50,100]T	100%	1*	1 **
10062	4	8	Good results	sildenafil [50,100]T	33%	1*	2 **
10062	5	8	Good results	sildenafil [50,100]T	17.3%	4*	24 **
10062	5	8	Good results	sildenafil [50,100]T	17.3%	4*	24 **
10062	6	8	Good results	sildenafil [50,100]T	26.7%	4*	15 **
10062	7	8	Good results	sildenafil [50,100]T	30%	5*	17 **
10062	8	8	Good results	sildenafil [50,100]T	0%	0*	8 **
10062	9	8	Good results	sildenafil [50,100]T	0%	0*	7 **
700008	1.3	10	"Good response"	sildenafil	90%*	9	10
105033	1	12	ahcieved and maintained on almost all occasions	sildenafil [25,100]T	59.12%*	81	137
105033	1	12	ahcieved and maintained on almost all occasions	sildenafil [25,100]T	59.12%*	81	137
105033	90	12	ahcieved and maintained on almost all occasions	Placebo [25,100]T	15.22%*	21	138
105033	90	12	ahcieved and maintained on almost all occasions	Placebo [25,100]T	15.22%*	21	138
10027991	1	12	81-100% attempts at intercourse successful	sildenafil [25,100]T		41	
10027991	90.1	12	81-100% attempts at intercourse successful	Placebo [25,100]T		8	
200110	1	999	satisfactory response as assessed by the patient, his partner, and by the IIEF	sildenafil [25,100]T	68.18%*	30	44 *
10027992	2	999	81-100% attempts at intercourse successful	sildenafil [25,100]T	24.16%*	43	178 **
10027992	90.2	999	81-100% attempts at intercourse successful	Placebo [25,100]T	1.69%*	3	178 **

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
improved duration								
10103	0	8	improved IIEF Q4	sildenafil [50,200]T	42%	34	84	**
10103	1	8	improved IIEF Q4	sildenafil	46%	23*	50	**
10103	2	8	improved IIEF Q4	sildenafil	39%	9*	23	**
10103	3	8	improved IIEF Q4	sildenafil	10%	1*	11	**

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
improved erections								
10338	1	1.5	improved	sildenafil	50%*	10	20	
10338	2	1.5	improved	sildenafil	52.38%*	11	21	*
10338	90	1.5	improved	Placebo	9.52%*	2	21	*
10252	1.2	4	improvement in erections	sildenafil 50	75%	9	12	
10252	90.2	4	improvement in erections	Placebo 50	7.1%	1	14	
10252	1.21	4	Improvement in erections	sildenafil 50	100%	5	5	
10252	1.22	4	Improvement in erections	sildenafil 50	57%	4	7	
700015	1	4	Improved quality of erections (GEQ1)	sildenafil [25,75]T	94%	32*	34	
700015	90	4	Improved quality of erections (GEQ1)	Placebo [25,75]T	25%	8*	34	
700016	1	4	Improved erections	sildenafil 10	64%	54*	84	*
700016	2	4	Improved erections	sildenafil 25	79%	65*	82	*
700016	3	4	Improved erections	sildenafil 50	88%	67*	76	*
700016	90	4	Improved erections	Placebo 999	38%	35*	91	*
700016	4	4	Improved erections	sildenafil 10	67%	36*	53	**
700016	6	4	Improved erections	sildenafil 25	82%	43*	52	**
700016	8	4	Improved erections	sildenafil 50	82%	39*	48	**
700016	91	4	Improved erections	Placebo	44%	22*	51	**
700016	5	4	Improved erections	sildenafil 10	60%	22*	36	**
700016	7	4	Improved erections	sildenafil 25	78%	25*	32	**
700016	9	4	Improved erections	sildenafil 50	97%	32*	33	**
700016	92	4	Improved erections	Placebo	33%	15*	44	**
750019	1	4	Improvement in erectile dysfunction (global efficacy question)	sildenafil [25,100]T	78.57%*	11	14	*
750019	90	4	Improvement in erectile dysfunction (global efficacy question)	Placebo [25,100]T	16.67%*	3	18	*
750019	90.1	4	Improvement in erectile dysfunction (global efficacy question)	Placebo	0%*	0	10	*
10024	1	6	Improved erections	sildenafil [25,100]T	83%	139*	168	
10024	90	6	Improved erections	Placebo [25,100]T	12%	20*	168	
10169	1.3	6	Improved ability to have intercourse	sildenafil [25,100]T	76%	68	89	
10169	1.4	6	Improved ability to have intercourse	sildenafil [25,100]T	84%	65	77	
10169	1.5	6	Improved ability to have intercourse	sildenafil [25,100]T	82%	116	141	
10169	1	6	Improved ability to have sexual intercourse	sildenafil [25,100]T	80%	132	166	

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
10169	90	6	Improved ability to have sexual intercourse	Placebo [25,100]T	10%	17	166	
10169	90.3	6	Improved ability to have sexual intercourse	Placebo [25,100]T	7%	6	89	
10169	90.4	6	Improved ability to have sexual intercourse	Placebo [25,100]T	14%	11	77	
10169	90.5	6	Improved ability to have sexual intercourse	Placebo [25,100]T	12%	17	141	
10169	90	6	Improved erections per atient	Placebo [25,100]T	4%	7	168	
10169	90.3	6	Improved erections per atient	Placebo [25,100]T	4%	4	90	
10169	90.4	6	Improved erections per atient	Placebo [25,100]T	4%	3	78	
10169	90.5	6	Improved erections per atient	Placebo [25,100]T	5%	7	143	
10169	1	6	Improved erections per patient	sildenafil [25,100]T	76%	127	168	
10169	1.3	6	Improved erections per patient	sildenafil [25,100]T	73%	66	90	
10169	1.4	6	Improved erections per patient	sildenafil [25,100]T	78%	61	78	
10169	1.5	6	Improved erections per patient	sildenafil [25,100]T	78%	111	143	
10169	1.6	6	Improved erections per patient	sildenafil [25,100]T	64%	16	25	
700002	1	6	Improved erections	sildenafil [25,100]T	45%	27*	60	**
700002	90	6	Improved erections	Placebo [25,100]T	8%	5*	60	**
796021	3	6	GEQ- improved erections	sildenafil [25,100]T	88.2%	129*	146	**
796021	92	6	GEQ- improved erections	Placebo [25,100]T	36.2%	48*	133	**
796021	4	6	GEQ- improved erections	sildenafil [25,100]T	70.9%	54*	76	**
796021	4	6	GEQ- improved erections	sildenafil [25,100]T	70.9%	54*	76	**
796021	93	6	GEQ- improved erections	Placebo [25,100]T	29.1%	18*	61	**
796021	93	6	GEQ- improved erections	Placebo [25,100]T	29.1%	18*	61	**
796021	5	6	GEQ- improved erections	sildenafil [25,100]T	92.1%			
796021	94	6	GEQ- improved erections	Placebo [25,100]T	66%			
796021	6	6	GEQ- improved erections	sildenafil [25,100]T	81.1%			
796021	95	6	GEQ- improved erections	Placebo [25,100]T	32.3%			
796021	7	6	GEQ- improved erections	sildenafil [25,100]T	66.1%			
796021	96	6	GEQ- improved erections	Placebo [25,100]T	26.3%			
796021	1	6	GEQ-improved erection	sildenafil [25,100]T	78.8%	93*	118	*
796021	1	6	GEQ-improved erection	sildenafil [25,100]T	78.8%	93*	118	*
796021	90	6	GEQ-improved erection	Placebo [25,100]T	37.7%	43*	114	*
796021	90	6	GEQ-improved erection	Placebo [25,100]T	37.7%	43*	114	*
796021	2	6	GEQ-improved erection	sildenafil [25,100]T	81.8%	68*	83	*
796021	2	6	GEQ-improved erection	sildenafil [25,100]T	81.8%	68*	83	*
796021	91	6	GEQ-improved erection	Placebo [25,100]T	29.2%	26*	88	*
796021	91	6	GEQ-improved erection	Placebo [25,100]T	29.2%	26*	88	*

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
10103	0	8	improved IIEF Q3	sildenafil [50,200]T	53%	45	84 **
10103	1	8	improved IIEF Q3	sildenafil	58%*	29	50
10103	2	8	improved IIEF Q3	sildenafil	56.52%*	13	23
10103	3	8	improved IIEF Q3	sildenafil	20%	2*	11 **
10031	1	12	Improved erections	sildenafil [25,100]T	74%	121*	163 **
10031	90	12	Improved erections	Placebo [25,100]T	16%	27*	166 **
10223	1	12	Improved erections (global efficacy question)	sildenafil [25,100]T	81%	46*	57 **
10223	90	12	Improved erections (global efficacy question)	Placebo [25,100]T	18%	10*	54 **
10263	1	12	Improved erections	sildenafil [25,100]T	56.49%*	74	131
10263	90	12	Improved erections	Placebo [25,100]T	10.24%*	13	127
10263	1.1	12	Improved erections	sildenafil [25,100]T	72%	21*	29 *
10263	90.1	12	Improved erections	Placebo [25,100]T	7%	2*	27 *
10263	1.11	12	Improved erections	sildenafil [25,100]T	55%	11*	20 *
10263	90.11	12	Improved erections	Placebo [25,100]T	19%	5*	26 *
10263	1.12	12	Improved erections	sildenafil [25,100]T	57%	63*	111 *
10263	90.12	12	Improved erections	Placebo [25,100]T	8%	8*	100 *
10263	1.2	12	Improved erections	sildenafil [25,100]T	53%	33*	62 *
10263	90.2	12	Improved erections	Placebo [25,100]T	11%	8*	70 *
10263	1.3	12	Improved erections	sildenafil [25,100]T	50%	20*	40 *
10263	90.3	12	Improved erections	Placebo [25,100]T	10%	3*	29 *
10263	1.4	12	Improved erections	sildenafil [25,100]T	59%	30*	51 *
10263	90.4	12	Improved erections	Placebo [25,100]T	11%	4*	36 *
10263	1.5	12	Improved erections	sildenafil [25,100]T	65%	22*	34 *
10263	90.5	12	Improved erections	Placebo [25,100]T	8%	4*	49 *
10263	1.6	12	Improved erections	sildenafil [25,100]T	48%	22*	46 *
10263	90.6	12	Improved erections	Placebo [25,100]T	12%	5*	41 *
10263	1.7	12	Improved erections	sildenafil [25,100]T	69%	27*	39 *
10263	90.7	12	Improved erections	Placebo [25,100]T	7%	3*	41 *
10263	1.8	12	Improved erections	sildenafil [25,100]T	51%	20*	39 *
10263	90.8	12	Improved erections	Placebo [25,100]T	13%	5*	40 *
10263	1.9	12	Improved erections	sildenafil [25,100]T	51%	27*	53 *
10263	90.9	12	Improved erections	Placebo [25,100]T	11%	5*	45 *
105033	90	12	GEQ improved	Placebo [25,100]T	19.49%*	23	118

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
105033	90	12	GEQ improved	Placebo [25,100]T	19.49%*	23	118	
105033	1	12	improved GEQ	sildenafil [25,100]T	74.26%*	101	136	
105033	1	12	improved GEQ	sildenafil [25,100]T	74.26%*	101	136	
105100	1	12	GEQ - Improved erections	sildenafil 25	67%	80*	119	
105100	2	12	GEQ - Improved erections	sildenafil 50	78%	95*	122	
105100	3	12	GEQ - Improved erections	sildenafil 100	86%	101*	118	
105100	90	12	GEQ - Improved erections	Placebo	24%	27*	114	
200300	1	12	Improved erections	sildenafil [25,100]T	70%	87*	124	*
200300	90	12	Improved erections	Placebo [25,100]T	17%	21*	121	*
700003	1	12	Improved erections (GEQ)	sildenafil [25,100]T	65%	66*	102	*
700003	90	12	Improved erections (GEQ)	Placebo [25,100]T	11%	11*	103	*
700003	1.1	12	Improved erections (GEQ)	sildenafil	60%	28*	47	*
700003	90.1	12	Improved erections (GEQ)	Placebo	12%	6*	48	*
700003	1.2	12	Improved erections (GEQ)	sildenafil	62%	30*	48	*
700003	90.2	12	Improved erections (GEQ)	Placebo	12%	6*	48	*
700003	1.3	12	Improved erections (GEQ)	sildenafil	67%	30*	45	*
700003	90.3	12	Improved erections (GEQ)	Placebo	6%	2*	32	*
700003	1.4	12	Improved erections (GEQ)	sildenafil	62%	36*	58	*
700003	90.4	12	Improved erections (GEQ)	Placebo	16%	11*	70	*
700006	1	12	Improved erections	sildenafil [25,100]T	90.9%	60	66	
700006	90	12	Improved erections	Placebo [25,100]T	11.4%	8	70	
700006	1	12	Treatment response	sildenafil [25,100]T	72.7%	48	66	
700006	90	12	Treatment response	Placebo [25,100]T	14.3%	10	70	
700009	1	12	Improved erections	sildenafil [25,100]T	88.2%	105*	119	**
700009	90	12	Improved erections	Placebo [25,100]T	38.4%	45*	117	**
700018	1	12	improved over last 4 weeks	sildenafil [25,100]T	82%	130*	159	**
700018	1	12	improved over last 4 weeks	sildenafil [25,100]T	82%	130*	159	**
700018	90	12	improved over last 4 weeks	Placebo [25,100]T	24%	37*	156	**
700018	90	12	improved over last 4 weeks	Placebo [25,100]T	24%	37*	156	**
700020	1	12	improved quality of erections	sildenafil [25,100]T	87%	109*	125	*
700020	1	12	improved quality of erections	sildenafil [25,100]T	87%	109*	125	*
700020	90	12	improved quality of erections	Placebo [25,100]T	32.7%	40*	121	*
700020	90	12	improved quality of erections	Placebo [25,100]T	32.7%	40*	121	*
750205	1	12	Improved erections	sildenafil [25,100]	69%	158*	229	*

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
750205	91	12	Improved erections	Placebo [25,100]T	10%	3*	30 *
750205	2	12	Improved erections	sildenafil [25,100]T	50%	20*	40 *
750205	90	12	Improved erections	Placebo [25,100]	18%	25*	141 *
796061	1	12	GEQ - improved erection	sildenafil [50,100]T	77%	49*	64 *
796061	1	12	GEQ - improved erection	sildenafil [50,100]T	77%	49*	64 *
796061	90	12	GEQ - improved erections	Placebo [50,100]T	46%	33*	72 *
796061	90	12	GEQ - improved erections	Placebo [50,100]T	46%	33*	72 *
796062	1	12	GEQ improved erections	sildenafil [25,100]T	77.27%	51*	66 *
796062	90	12	GEQ improved erections	Placebo [25,100]T	33.8%	22*	65 *
10027991	1	12	Improvement	sildenafil [25,100]T	74%	101*	136
10027991	90.1	12	Improvement	Placebo [25,100]T	16%	23*	141
10029991	1	12	Improved erections	sildenafil [25,100]T	74%	121*	163 **
10029991	90	12	Improved erections	Placebo [25,100]T	16%	27*	166 **
10029992	1	12	Improved erections	sildenafil [25,100]T	82%	130*	159 **
10029992	90	12	Improved erections	Placebo [25,100]T	24%	37*	156 **
10463992	1	12	GEQ-improved erections	sildenafil [25,100]T	74%	101	163
10463992	1	12	GEQ-improved erections	sildenafil [25,100]T	74%	101	163
10463992	90	12	GEQ-improved erections		19%	23	166
10463992	90	12	GEQ-improved erections		19%	23	166
10463991	90	24	GEQ-improved erections	Placebo 125	25%	54*	216 **
10463991	90	24	GEQ-improved erections	Placebo 125	25%	54*	216 **
10463991	1.1	24	GEQ-improved erections	sildenafil 25	56%	57*	102 **
10463991	1.2	24	GEQ-improved erections	sildenafil 50	77%	82*	107 **
10463991	1.3	24	GEQ-improved erections	sildenafil 100	84%	90*	107 **
10023	1	26	improved GEQ	sildenafil [25,100]T	79%	126*	159 **
10023	90	26	improved GEQ	Placebo [25,100]T	23%	36*	156 **
700018	1	26	improved over last 4 weeks	sildenafil [25,100]T	79%	126*	159 **
700018	1	26	improved over last 4 weeks	sildenafil [25,100]T	79%	126*	159 **
700018	90	26	improved over last 4 weeks	Placebo [25,100]T	23%	36*	156 **
700018	90	26	improved over last 4 weeks	Placebo [25,100]T	23%	36*	156 **
10161	0	999	Improved erectile function (rating, duration, frequency, and confidence)	Placebo [25,50]sildenafil [25,50]	62.5%*	5	8

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
104993	1	999	Improved erections	sildenafil [5,100]	70%			
104993	90	999	Improved erections	Placebo [5,100]	21%			
104993	2	999	Improved erections	sildenafil [5,100]	72%			
104993	91	999	Improved erections	Placebo [5,100]	27%			
700023	3	999	Improved erectile function	sildenafil	80%*	12	15	
700023	92	999	Improved erectile function	Placebo	13.33%*	2	15	
750019	2	999	Improvement in erectile dysfunction (global efficacy question)	sildenafil T	100%*	10	10	*
750019	3	999	Improvement in erectile dysfunction (global efficacy question)	sildenafil	77.78%*	7	9	*
750019	4	999	Improvement in erectile dysfunction (global efficacy question)	sildenafil	93.33%*	14	15	*
750019	5	999	Improvement in erectile dysfunction (global efficacy question)	sildenafil	90.91%*	10	11	*
750019	6	999	Improvement in erectile dysfunction (global efficacy question)	sildenafil	84.62%*	11	13	*
10027992	2	999	Improvement	sildenafil [25,100]T	83%	139*	168	
10027992	90.2	999	Improvement	Placebo [25,100]T	20%	34*	168	

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections - part							
700016	1	4	Improved quality of erection assessed by partner	sildenafil 10	64%	54*	84 *
700016	2	4	Improved quality of erection assessed by partner	sildenafil 25	78%	64*	82 *
700016	3	4	Improved quality of erection assessed by partner	sildenafil 50	83%	63*	76 *
700016	90	4	Improved quality of erection assessed by partner	Placebo 999	39%	35*	91 *

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
10169	1	6	No successful attempt at intercourse	sildenafil [25,100]T	24%	43	175
10169	90	6	No successful attempts at intercouse	Placebo [25,100]T	76%	129	174
10062	12	8	Bad result	sildenafil [50,100]T	83%	20*	24 *
10062	0	8	bad results	sildenafil [50,100]T	37.85%	61	157 *
10062	10	8	Bad results	sildenafil [50,100]T	33.64%		
10062	11	8	Bad results	sildenafil [50,100]T	77%		
10027991	1	12	0% attempts at intercourse successful	sildenafil [25,100]T		31	
10027991	90.1	12	0% attempts at intercourse successful	Placebo [25,100]T		97	
10027992	2	999	0% attempts at intercourse successful	sildenafil [25,100]T	24.16%*	43	178 **
10027992	90.2	999	0% attempts at intercourse successful	Placebo [25,100]T	72.47%*	129	178 **

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
partial response							
10062	12	8	Fair result	sildenafil [50,100]T	17%	4*	24 *
10062	0	8	fair results	sildenafil [50,100]T	29.29%	46	157 *

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
Patient Satisfied							
200300	1	12	Patient satisfied	sildenafil [25,100]T	75%	93	124
200300	90	12	Patient satisfied	Placebo [25,100]T	30%	36	121

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
uncategorized							
10252	1.1	0	>60% erection at base	sildenafil 50	65.38%*	17	26
10252	90.1	0	>60% erection at base	Placebo 50	7.69%*	2	26
10252	1.1	0	>60% erection at tip	sildenafil 50	46.15%*	12	26
10252	90.1	0	>60% erection at tip	Placebo 50	3.85%*	1	26
10252	1.1	0	>80% erection at base	sildenafil 50	34.62%*	9	26
10252	90.1	0	>80% erection at base	Placebo 50	3.85%*	1	26
10252	1.1	0	>80% erection at tip	sildenafil 50	23.08%*	6	26
10252	90.1	0	>80% erection at tip	Placebo 50	0%*	0	26
10252	1.1	0	subject assessment of best erection = 4	sildenafil 50	34.62%*	9	26
10252	90.1	0	subject assessment of best erection = 4	Placebo 50	7.69%*	2	26
10252	1.1	0	suject assessment of best erection =3	sildenafil 50	46.15%*	12	26
10252	90.1	0	suject assessment of best erection =3	Placebo 50	11.54%*	3	26
796157991	1	0	Responders - 60% rigidity	sildenafil 50	82%	14	17
796157991	90	0	Responders - 60% rigidity	Placebo 50	53%	9	17
796157991	1	0	Responders - Grade 3 or 4 Erection	sildenafil 50	71%	12	17
796157991	90	0	Responders - Grade 3 or 4 Erection	Placebo 50	35%	6	17
796157992	1	0	Responders - 60% rigidity/Grade 3-4	sildenafil 100	75%	12	16
796157992	90	0	Responders - 60% rigidity/Grade 3-4	Placebo 100	31%	5	16
10062	0	8	patient chose to alternate treatments	sildenafil [50,100]T	25%	39*	157 *
10062	0	8	patient chose to continue sildenafil exclusively	sildenafil [50,100]T	32%	50*	157 *
10062	0	8	patient chose to use ICI exclusively	sildenafil [50,100]T	34%	53*	157 *
10263	1	12	At least one successful intercourse attempt	sildenafil [25,100]T	60.68%*	71	117
10263	90	12	At least one successful intercourse attempt	Placebo [25,100]T	21.93%*	25	114
10263	1	12	Improved proportion of successful intercourse attempts	sildenafil [25,100]T	47.86%*	56	117
10263	90	12	Improved proportion of successful intercourse attempts	Placebo [25,100]T	12.28%*	14	114
105033	1	12	maintained after penetration	sildenafil [25,100]T	62.04%*	85	137
105033	1	12	maintained after penetration	sildenafil [25,100]T	62.04%*	85	137
105033	90	12	maintained after penetration	Placebo [25,100]T	15.94%*	22	138
105033	90	12	maintained after penetration	Placebo [25,100]T	15.94%*	22	138

Appendix 3B - Binary Efficacy Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
10027991	1	12	1-20% attempts at intercourse successful	sildenafil [25,100]T		10		
10027991	90.1	12	1-20% attempts at intercourse successful	Placebo [25,100]T		12		
10027991	1	12	21-40% attempts at intercourse successful	sildenafil [25,100]T		17		
10027991	90.1	12	21-40% attempts at intercourse successful	Placebo [25,100]T		19		
10027991	1	12	41-60% attempts at intercourse successful	sildenafil [25,100]T		29		
10027991	90.1	12	41-60% attempts at intercourse successful	Placebo [25,100]T		13		
10027991	1	12	61-80% attempts at intercourse successful	sildenafil [25,100]T		29		
10027991	90.1	12	61-80% attempts at intercourse successful	Placebo [25,100]T		5		
10028	1	26	Grade 3-4 erections (hard enough for intercourse) over past 4 weeks	sildenafil 25	72%	68*	95	
10028	2	26	Grade 3-4 erections (hard enough for intercourse) over past 4 weeks	sildenafil 50	80%	81*	101	
10028	3	26	Grade 3-4 erections (hard enough for intercourse) over past 4 weeks	sildenafil 100	85%	82*	97	
10028	90	26	Grade 3-4 erections (hard enough for intercourse) over past 4 weeks	Placebo 25	50%	97*	194	
10161	0	999	Improved on placebo	Placebo [25,50]sildenafil [25,50]	25%*	2	8	
10622	1	999	Base rigidity >80% for >20 minutes	sildenafil 50	50%*	6	12	
10622	90	999	Base rigidity >80% for >20 minutes	Placebo	0%*	0	12	
10027992	2	999	1-20% attempts at intercourse successful	sildenafil [25,100]T	10.11%*	18	178	**
10027992	90.2	999	1-20% attempts at intercourse successful	Placebo [25,100]T	11.8%*	21	178	**
10027992	2	999	21-40% attempts at intercourse successful	sildenafil [25,100]T	7.3%*	13	178	**
10027992	90.2	999	21-40% attempts at intercourse successful	Placebo [25,100]T	6.74%*	12	178	**
10027992	2	999	41-60% attempts at intercourse successful	sildenafil [25,100]T	15.73%*	28	178	**
10027992	90.2	999	41-60% attempts at intercourse successful	Placebo [25,100]T	3.37%*	6	178	**
10027992	2	999	61-80% attempts at intercourse successful	sildenafil [25,100]T	16.85%*	30	178	**
10027992	90.2	999	61-80% attempts at intercourse successful	Placebo [25,100]T	1.69%*	3	178	**

Appendix 3B - Binary Efficacy Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
Able to have intercourse							
756003	1	3	Able to have intercourse	tadalafil 10	82%	49*	60 *
756003	2	3	Able to have intercourse	tadalafil 25	80%	46*	58 *
756003	3	3	Able to have intercourse	tadalafil 50	93%	55*	59 *
756003	4	3	Able to have intercourse	tadalafil 100	86%	51*	59 *
756003	90	3	Able to have intercourse	Placebo	40%	23*	58 *
756003991	90	8	Able to have intercourse	Placebo	33%	14*	41 *
756003991	1.1	8	Able to have intercourse	tadalafil 2	46%	19*	42 *
756003991	1.2	8	Able to have intercourse	tadalafil 5	50%	22*	44 *
756003991	1.3	8	Able to have intercourse	tadalafil 10	60%	25*	42 *
756003991	1.4	8	Able to have intercourse	tadalafil 25	73%	31*	43 *
756003992	1	12	Able to have intercourse	tadalafil 10	44%	32*	73 *
756003992	2	12	Able to have intercourse	tadalafil 20	51%	37*	72 *
756003992	90	12	Able to have intercourse	Placebo	16%	11*	71 *

Appendix 3B - Binary Efficacy Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
796036	1	12	IIEF >= 26 at endpoint	tadalafil 2.5	21%	16*	74 **
796036	1	12	IIEF >= 26 at endpoint	tadalafil 2.5	21%	16*	74 **
796036	2	12	IIEF >= 26 at endpoint	tadalafil 5	23%	35*	151 **
796036	2	12	IIEF >= 26 at endpoint	tadalafil 5	23%	35*	151 **
796036	3	12	IIEF >= 26 at endpoint	tadalafil 10	40%	128*	321 **
796036	3	12	IIEF >= 26 at endpoint	tadalafil 10	40%	128*	321 **
796036	4	12	IIEF >= 26 at endpoint	tadalafil 20	59%	152*	258 **
796036	4	12	IIEF >= 26 at endpoint	tadalafil 20	59%	152*	258 **
796036	90	12	IIEF >= 26 at endpoint	Placebo	11%	34*	308 **
796036	90	12	IIEF >= 26 at endpoint	Placebo	11%	34*	308 **

Appendix 3B - Binary Efficacy Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections							
756003	1	3	GAQ improved erection	tadalafil 10	90%	54*	60 *
756003	2	3	GAQ improved erections	tadalafil 25	85%	49*	58 *
756003	3	3	GAQ improved erections	tadalafil 50	86%	51*	59 *
756003	4	3	GAQ improved erections	tadalafil 100	81%	48*	59 *
756003	90	3	GAQ improved erections	Placebo	38%	22*	58 *
756005	1.1	3	GAQ	tadalafil 2	51.4%	18*	35 **
756005	1.2	3	GAQ	tadalafil 5	59.5%	22*	37 **
756005	1.3	3	GAQ	tadalafil 10	80.6%	29*	36 **
756005	1.4	3	GAQ	tadalafil 25	80.6%	29*	36 **
756005	90	3	GAQ	Placebo	17.1%	6*	35 **
756005	1.11	3	GAQ	tadalafil 2	100%		
756005	1.21	3	GAQ	tadalafil 5	50%		
756005	1.31	3	GAQ	tadalafil 10	100%		
756005	1.41	3	GAQ	tadalafil 25	83.3%		
756005	90.1	3	GAQ	Placebo	50%		
756005	1.12	3	GAQ	tadalafil 2	76.9%		
756005	1.22	3	GAQ	tadalafil 5	61.5%		
756005	1.32	3	GAQ	tadalafil 10	71.4%		
756005	1.42	3	GAQ	tadalafil 25	100%		
756005	90.2	3	GAQ	Placebo	16.7%		
756005	1.13	3	GAQ	tadalafil 2	50%		
756005	1.23	3	GAQ	tadalafil 5	60%		
756005	1.33	3	GAQ	tadalafil 10	90%		
756005	1.43	3	GAQ	tadalafil 25	75%		
756005	90.3	3	GAQ	Placebo	20%		
756005	1.14	3	GAQ	tadalafil 2	14.3%		
756005	1.24	3	GAQ	tadalafil 5	50%		
756005	1.34	3	GAQ	tadalafil 10	80%		
756005	1.44	3	GAQ	tadalafil 25	80%		
756005	90.4	3	GAQ	Placebo	16.7%		
756003991	90	8	GAQ improved erections	Placebo	28%	11*	41 *
756003991	1.1	8	GAQ improved erections	tadalafil 2	62%	26*	42 *
756003991	1.2	8	GAQ improved erections	tadalafil 5	57%	25*	44 *
756003991	1.3	8	GAQ improved erections	tadalafil 10	68%	29*	42 *

Appendix 3B - Binary Efficacy Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
756003991	1.4	8	GAQ improved erections	tadalafil 25	88%	38*	43 *
796036	1	12	GAQ improved erection	tadalafil 2.5	42%	31*	74
796036	1	12	GAQ improved erection	tadalafil 2.5	42%	31*	74
796036	2	12	GAQ improved erection	tadalafil 5	50%	76*	151
796036	2	12	GAQ improved erection	tadalafil 5	50%	76*	151
796036	3	12	GAQ improved erection	tadalafil 10	67%	215*	321
796036	3	12	GAQ improved erection	tadalafil 10	67%	215*	321
796036	4	12	GAQ improved erection	tadalafil 20	81%	134*	165
796036	4	12	GAQ improved erection	tadalafil 20	81%	134*	165
796036	90	12	GAQ improved erection	Placebo	35%	91*	261
796036	90	12	GAQ improved erection	Placebo	35%	91*	261
756003992	2	12	GAQ improved erection	tadalafil 20	64%	46*	72 *
756003992	1	12	GAQ improved erections	tadalafil 10	56%	41*	73 *
756003992	90	12	GAQ improved erections	Placebo	25%	18*	71 *

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
10780	1	4	Good result	Testosterone 120	40%*	8	20 *
10780	2	4	Good result	trazodone [100,150]	38.1%*	8	21 *
10780	3	4	Good result	hypnosis	60%*	12	20 *
10780	90	4	Good result	Placebo	33.33%*	6	18 *
10780	1.1	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.1	4	positive response	trazodone [100,150]	100%*	4	4 *
10780	3.1	4	positive response	hypnosis	80%*	8	10 *
10780	90.1	4	positive response	Placebo	50%*	2	4 *
10780	1.2	4	positive response	Testosterone 120	83.33%*	5	6 *
10780	2.2	4	positive response	trazodone [100,150]	66.67%*	4	6 *
10780	3.2	4	positive response	hypnosis	100%*	4	4 *
10780	90.2	4	positive response	Placebo	40%*	2	5 *
10780	1.3	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.3	4	positive response	trazodone [100,150]	57.14%*	4	7 *
10780	3.3	4	positive response	hypnosis	100%*	4	4 *
10780	90.3	4	positive response	Placebo	60%*	3	5 *
10780	1.4	4	positive response	Testosterone 120	25%*	1	4 *
10780	2.4	4	positive response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	positive response	hypnosis	0%*	0	2 *
10780	90.4	4	positive response	Placebo	0%*	0	4 *
790779	1.1	4	Full erections	0.8% testosterone cream 2	57.89%*	11	19 *
790779	2.1	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	84.21%*	16	19 *
790779	1.2	4	Full erections	0.8% testosterone cream 2	11.11%*	2	18 *
790779	2.2	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	55.56%*	10	18 *
790779	1.3	4	Full erections	0.8% testosterone cream 2	0%*	0	5 *
790779	2.3	4	Full erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	40%*	2	5 *
790779	3	4	Full erections	testosterone followed by polypharmacy cream	14%	3*	21 **

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
790779	4	4	Full erections	poplypharmacy cream followed by testosterone	43%	9*	21 **	

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections							
795502	90	12	Therapeutic effect	Placebo 120	56.25%*	9	16
795502	1	12	Therapeutic effect	Testosterone 120	61.54%*	8	13

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
increased libido								
790779	1	4	Increased frequency of thoughts about sex & excitement about sex	0.8% testosterone cream 2	62%	26*	42 **	
790779	2	4	Increased frequency of thoughts about sex & excitement about sex	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	85%	36*	42 **	

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
10780	1.1	4	neative response	Testosterone 120	40%*	2	5 *
10780	2.1	4	negative response	trazodone [100,150]	0%*	0	4 *
10780	3.1	4	negative response	hypnosis	20%*	2	10 *
10780	90.1	4	negative response	Placebo	50%*	2	4 *
10780	1.2	4	negative response	Testosterone 120	16.67%*	1	6 *
10780	2.2	4	negative response	trazodone [100,150]	33.33%*	2	6 *
10780	3.2	4	negative response	hypnosis	0%*	0	4 *
10780	90.2	4	negative response	Placebo	60%*	3	5 *
10780	1.3	4	negative response	Testosterone 120	40%*	2	5 *
10780	2.3	4	negative response	trazodone [100,150]	42.86%*	3	7 *
10780	3.3	4	negative response	hypnosis	0%*	0	4 *
10780	90.3	4	negative response	Placebo	40%*	2	5 *
10780	1.4	4	negative response	Testosterone 120	75%*	3	4 *
10780	2.4	4	negative response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	negative response	hypnosis	100%*	2	2 *
10780	90.4	4	negative response	Placebo	100%*	4	4 *
10780	1	4	No response	Testosterone 120	40%*	8	20 *
10780	2	4	No response	trazodone [100,150]	33.33%*	7	21 *
10780	3	4	No response	hypnosis	20%*	4	20 *
10780	90	4	No response	Placebo	61.11%*	11	18 *
790779	1.1	4	No erections	0.8% testosterone cream 2	42.11%*	8	19 *
790779	2.1	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	15.79%*	3	19 *
790779	1.2	4	No erections	0.8% testosterone cream 2	83.33%*	15	18 *
790779	2.2	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	22.22%*	4	18 *
790779	1.3	4	No erections	0.8% testosterone cream 2	80%*	4	5 *
790779	2.3	4	No erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	40%*	2	5 *

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
partial response								
790779	1.1	4	Partial erections	0.8% testosterone cream 2	0%*	0	19	*
790779	2.1	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	19	*
790779	1.2	4	Partial erections	0.8% testosterone cream 2	5.56%*	1	18	*
790779	2.2	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	11.11%*	2	18	*
790779	1.3	4	Partial erections	0.8% testosterone cream 2	20%*	1	5	*
790779	2.3	4	Partial erections	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	5	*

Appendix 3B - Binary Efficacy Data
Studies Including Testosterone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
uncategorized							
10780	1	4	Moderate result	Testosterone 120	20%*	4	20 *
10780	2	4	Moderate result	trazodone [100,150]	28.57%*	6	21 *
10780	3	4	Moderate result	hypnosis	20%*	4	20 *
10780	90	4	Moderate result	Placebo	5.56%*	1	18 *
790779	1.1	4	Tumescence	0.8% testosterone cream 2	0%*	0	19 *
790779	2.1	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	0%*	0	19 *
790779	1.2	4	Tumescence	0.8% testosterone cream 2	0%*	0	18 *
790779	2.2	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	11.11%*	2	18 *
790779	1.3	4	Tumescence	0.8% testosterone cream 2	0%*	0	5 *
790779	2.3	4	Tumescence	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	20%*	1	5 *

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
chose not to use drug								
10558	90	4	"Medication works, but too many side effects"	Placebo 150	3.12%*	1	32	*
10558	1	4	"Works well, but too many side effects"	trazodone 150	3.85%*	1	26	*
10558	1.1	4	"Works well, or works well but too many side effects"	trazodone 150	143.75%*	23	16	**
10558	90.1	4	"Works well, or works well but too many side effects"	Placebo 150	15%	3*	20	**

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
10558	90	4	"Medication works well"	Placebo 150	15.62%*	5	32 *
10558	1	4	"Works well"	trazodone 150	15.38%*	4	26 *
10780	1	4	Good result	Testosterone 120	40%*	8	20 *
10780	2	4	Good result	trazodone [100,150]	38.1%*	8	21 *
10780	3	4	Good result	hypnosis	60%*	12	20 *
10780	90	4	Good result	Placebo	33.33%*	6	18 *
10780	1.1	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.1	4	positive response	trazodone [100,150]	100%*	4	4 *
10780	3.1	4	positive response	hypnosis	80%*	8	10 *
10780	90.1	4	positive response	Placebo	50%*	2	4 *
10780	1.2	4	positive response	Testosterone 120	83.33%*	5	6 *
10780	2.2	4	positive response	trazodone [100,150]	66.67%*	4	6 *
10780	3.2	4	positive response	hypnosis	100%*	4	4 *
10780	90.2	4	positive response	Placebo	40%*	2	5 *
10780	1.3	4	positive response	Testosterone 120	60%*	3	5 *
10780	2.3	4	positive response	trazodone [100,150]	57.14%*	4	7 *
10780	3.3	4	positive response	hypnosis	100%*	4	4 *
10780	90.3	4	positive response	Placebo	60%*	3	5 *
10780	1.4	4	positive response	Testosterone 120	25%*	1	4 *
10780	2.4	4	positive response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	positive response	hypnosis	0%*	0	2 *
10780	90.4	4	positive response	Placebo	0%*	0	4 *
705006	1	4	Positive response	trazodone 50	65.2%	15*	23 *
705006	2	4	Positive response	Ketanserin 20	19.1%	4*	21 *
705006	3	4	Positive response	Mianserin 10	31.6%	6*	19 *
705006	90	4	Positive response	Placebo T	13.6%	3*	22 *

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
improved erections								
705001	1	999	Improved erections	trazodone 50	19%	9*	48 **	
705001	90	999	Improved erections	Placebo 50	24%	12*	48 **	

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
increased libido							
705001	1	999	Improved sex drive	trazodone 50	35%	17*	48 **
705001	90	999	Improved sex drive	Placebo 50	40%	19*	48 **

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
10558	1	4	"Does not work"	trazodone 150	57.69%*	15	26 *
10558	90	4	"Does not work"	Placebo 150	62.5%*	20	32 *
10558	90	4	"Work,s but insufficiently"	Placebo 150	18.75%*	6	32 *
10558	1	4	"Works, but insufficiently"	trazodone 150	23.08%*	6	26 *
10780	1.1	4	neative response	Testosterone 120	40%*	2	5 *
10780	2.1	4	negative response	trazodone [100,150]	0%*	0	4 *
10780	3.1	4	negative response	hypnosis	20%*	2	10 *
10780	90.1	4	negative response	Placebo	50%*	2	4 *
10780	1.2	4	negative response	Testosterone 120	16.67%*	1	6 *
10780	2.2	4	negative response	trazodone [100,150]	33.33%*	2	6 *
10780	3.2	4	negative response	hypnosis	0%*	0	4 *
10780	90.2	4	negative response	Placebo	60%*	3	5 *
10780	1.3	4	negative response	Testosterone 120	40%*	2	5 *
10780	2.3	4	negative response	trazodone [100,150]	42.86%*	3	7 *
10780	3.3	4	negative response	hypnosis	0%*	0	4 *
10780	90.3	4	negative response	Placebo	40%*	2	5 *
10780	1.4	4	negative response	Testosterone 120	75%*	3	4 *
10780	2.4	4	negative response	trazodone [100,150]	50%*	2	4 *
10780	3.4	4	negative response	hypnosis	100%*	2	2 *
10780	90.4	4	negative response	Placebo	100%*	4	4 *
10780	1	4	No response	Testosterone 120	40%*	8	20 *
10780	2	4	No response	trazodone [100,150]	33.33%*	7	21 *
10780	3	4	No response	hypnosis	20%*	4	20 *
10780	90	4	No response	Placebo	61.11%*	11	18 *

Appendix 3B - Binary Efficacy Data
Studies Including Trazodone

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
uncategorized							
705000	1	-1	Presence of morning erections	trazodone 200	45%	7*	16 **
705000	90	-1	Presence of morning erections	Placebo 200	27%	5*	17 **
10780	1	4	Moderate result	Testosterone 120	20%*	4	20 *
10780	2	4	Moderate result	trazodone [100,150]	28.57%*	6	21 *
10780	3	4	Moderate result	hypnosis	20%*	4	20 *
10780	90	4	Moderate result	Placebo	5.56%*	1	18 *
705000	1	4	Presence of morning erections	trazodone 200	47%	8*	16 **
705000	90	4	Presence of morning erections	Placebo 200	46%	8*	17 **

Appendix 3B - Binary Efficacy Data
Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
Able to have intercourse							
758008	1	0	Able to have intercourse	vardenafil 5	13.9%	18*	128 *
758008	2	0	Able to have intercourse	vardenafil 10	12.3%	15*	123 *
758008	3	0	Able to have intercourse	vardenafil 20	14.1%	18*	131 *
758008	90	0	Able to have intercourse	Placebo	12.6%	16*	124 *
758008	1	12	Able to have intercourse	vardenafil 5	61.9%	79*	128 *
758008	2	12	Able to have intercourse	vardenafil 10	57.4%	71*	123 *
758008	3	12	Able to have intercourse	vardenafil 20	65.3%	86*	131 *
758008	90	12	Able to have intercourse	Placebo	27%	33*	124 *

Appendix 3B - Binary Efficacy Data
Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
good response							
901052	1.1	26	"return to normal" (IIEF EF>=26)	vardenafil 5	63.6%	7*	11 *
901052	2.1	26	"return to normal" (IIEF EF>=26)	vardenafil 10	88.9%	8*	9 *
901052	3.1	26	"return to normal" (IIEF EF>=26)	vardenafil 20	78.6%	11*	14 *
901052	90.1	26	"return to normal" (IIEF EF>=26)	Placebo	21.4%	3*	14 *
901052	1.2	26	"return to normal" (IIEF EF>=26)	vardenafil 5	44%	22*	50 *
901052	2.2	26	"return to normal" (IIEF EF>=26)	vardenafil 10	54.9%	28*	51 *
901052	3.2	26	"return to normal" (IIEF EF>=26)	vardenafil 20	47.4%	18*	38 *
901052	90.2	26	"return to normal" (IIEF EF>=26)	Placebo	16.7%	7*	42 *
901052	1.3	26	"return to normal" (IIEF EF>=26)	vardenafil 5	36.6%	15*	41 *
901052	2.3	26	"return to normal" (IIEF EF>=26)	vardenafil 10	50.8%	31*	61 *
901052	3.3	26	"return to normal" (IIEF EF>=26)	vardenafil 20	50%	26*	52 *
901052	90.3	26	"return to normal" (IIEF EF>=26)	Placebo	17.2%	11*	64 *
901052	1.4	26	"return to normal" (IIEF EF>=26)	vardenafil 5	14.2%	12*	84 *
901052	2.4	26	"return to normal" (IIEF EF>=26)	vardenafil 10	25.7%	18*	70 *
901052	3.4	26	"return to normal" (IIEF EF>=26)	vardenafil 20	39.5%	30*	76 *
901052	90.4	26	"return to normal" (IIEF EF>=26)	Placebo	4%	2*	50 *

Appendix 3B - Binary Efficacy Data
Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections							
758008	1	12	GAQ	vardenafil 5	66%	84*	128 *
758008	2	12	GAQ	vardenafil 10	76%	93*	123 *
758008	3	12	GAQ	vardenafil 20	80%	105*	131 *
758008	90	12	GAQ	Placebo	30%	37*	124 *
901052	1	12	GAQ -rx of last 4 weeks improved erection	vardenafil 5	64.5%	100*	155 *
901052	2	12	GAQ -rx of last 4 weeks improved erection	vardenafil 10	72.9%	123*	169 *
901052	3	12	GAQ -rx of last 4 weeks improved erection	vardenafil 20	80.9%	124*	153 *
901052	90	12	GAQ -rx of last 4 weeks improved erection	Placebo	38.6%	43*	111 *
901052	1	26	GAQ -last observation carryforward	vardenafil 5	55.9%	98*	176
901052	2	26	GAQ -last observation carryforward	vardenafil 10	76.5%	139*	182
901052	3	26	GAQ -last observation carryforward	vardenafil 20	80.7%	136*	169
901052	90	26	GAQ -last observation carryforward	Placebo	22.9%	34*	150
901052	1	26	GAQ -rx of last 4 weeks improved erection	vardenafil 5	64.9%	83*	128
901052	2	26	GAQ -rx of last 4 weeks improved erection	vardenafil 10	79.8%	118*	148
901052	3	26	GAQ -rx of last 4 weeks improved erection	vardenafil 20	85.2%	119*	140
901052	90	26	GAQ -rx of last 4 weeks improved erection	Placebo	27.6%	25*	91

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
good response								
10532	1	4	complete response	yohimbine 100T	13.64%*	3	22	
10532	90	4	complete response	Placebo 100	4.55%*	1	22	
704037	1	4	"Strong effect"	yohimbine [5,10]	27.27%*	3	11	*
704037	91	4	"Strong effect"	Placebo [5,10]	0%*	0	11	**
703057992	0	6	Complete improvement in erections	yohimbine 16.2	4.65%*	10	215	
703057992	0	6	Complete improvement in erections	yohimbine 16.2	4.65%*	10	215	
10559	1	8	+ objective response (see pg. 1)	yohimbine 30	31.71%*	13	41	
10559	90	8	+ objective response (see pg. 1)	Placebo 30	14.29%*	6	42	
10559	1	8	+ overall response	yohimbine 30	70.73%*	29	41	
10559	90	8	+ overall response	Placebo 30	45.24%*	19	42	
10559	1	8	+ subjective response (see pg. 1)	yohimbine 30	58.54%*	24	41	
10559	90	8	+ subjective response (see pg. 1)	Placebo 30	39.02%*	16	41	
703069	1	10	Complete response	yohimbine 18	31.03%*	9	29	
703069	90	10	Complete response	Placebo 18	5.26%*	1	19	
703069	2	10	Complete response	yohimbine 18	15.79%*	3	19	
703070	1	10	Complete response	yohimbine 18	21.3%			
703070	2	10	Complete response	yohimbine 18	18.2%			
703070	90	10	Complete response	yohimbine 18	13.8%			
704108	1	999	Full improvement in erections	yohimbine [5.4,10.8]	14.08%*	10	71	
703057992	1	999	Complete improvement in erections	yohimbine 21.6	8%*	2	25	
703057992	2	999	Complete improvement in erections	yohimbine 21.6	19.05%*	4	21	

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
improved erections							
10631	1	3.6	"Adequate help" with erections	yohimbine 36	11.11%*	3	27
10631	90	3.6	"Adequate help" with erections	yohimbine 36	7.41%*	2	27
10631	1	3.6	"Some help" with erections	yohimbine 36	33.33%*	9	27
10631	90	3.6	"Some help" with erections	yohimbine 36	40.74%*	11	27
704108	1.1	4	Improvement	yohimbine	66.67%*	6	9
704108	1.2	4	Improvement	yohimbine	44%*	11	25
704108	1.11	4	Improvement	yohimbine	46.67%*	7	15
704108	1.12	4	Improvement	yohimbine	20%*	2	10
704108	1.13	4	Improvement	yohimbine	28.57%*	2	7
704108	1.14	4	Improvement	yohimbine	46.88%*	15	32
704108	1.15	4	Improvement	yohimbine	39.13%*	9	23
704108	1.16	4	Improvement	yohimbine	7.14%*	1	14
704108	1.17	4	Improvement	yohimbine	43.59%*	17	39
704108	1.18	4	Improvement	yohimbine	45.45%*	5	11
704108	1.19	4	Improvement	yohimbine	0%*	0	6
704108	1.21	4	Improvement	yohimbine	33.33%*	1	3
704108	1.22	4	Improvement	yohimbine	55.56%*	10	18
704108	1.23	4	Improvement	yohimbine	28%*	14	50
704108	1.24	4	Improvement	yohimbine	37.5%	12*	32 *
704108	1.25	4	Improvement	yohimbine	32.5%	13*	40 *
704108	1.4	4	Improvement	yohimbine	80.95%*	17	21
704108	1.5	4	Improvement	yohimbine	15.38%*	6	39
704108	1.6	4	Improvement	yohimbine	20%*	2	10
704108	1.7	4	Improvement	yohimbine	0%*	0	4
704108	1.8	4	Improvement	yohimbine	21.74%*	5	23
704108	1.9	4	Improvement	yohimbine	46.51%*	20	43
703057991	1	4	Improved erections	yohimbine 16.2	48.48%*	16	33
703057991	90	4	Improved erections	Placebo 16.2	30.3%*	10	33
703057991	1.1	4	Improved erections	yohimbine	45%*	9	20
703057991	1.2	4	Improved erections	yohimbine	15.38%*	2	13
704108	1.3	999	Improvement	yohimbine	21.62%*	8	37
759003	90	999	Significant improvement	Placebo 30	15%*	3	20 *
759003	1	999	Significant improvement	yohimbine 30	20%*	4	20 *

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
negative response							
10631	1	3.6	No effect	yohimbine 36	55.56%*	15	27
10631	90	3.6	No effect	yohimbine 36	51.85%*	14	27
10532	1	4	no response	yohimbine 100T	18.18%*	4	22
10532	90	4	no response	Placebo 100	50%*	11	22
10532	1	4	partial response - no intercourse	yohimbine 100T	54.55%*	12	22
10532	90	4	partial response - no intercourse	Placebo 100	40.91%*	9	22
10532	1	4	worse	yohimbine 100T	13.64%*	3	22
10532	90	4	worse	Placebo 100	0%*	0	22
704037	1	4	"No effect"	yohimbine [5,10]	27.27%*	3	11 *
704037	91	4	"No effect"	Placebo [5,10]	90.91%*	10	11 **
703057992	0	6	No improvement in erections	yohimbine 16.2	61.86%*	133	215
703057992	0	6	No improvement in erections	yohimbine 16.2	61.86%*	133	215
703069	1	10	No response	yohimbine 18	37.93%*	11	29
703069	90	10	No response	Placebo 18	84.21%*	16	19
703069	2	10	No response	yohimbine 18	78.95%*	15	19
703070	2	10	No response	yohimbine 18	54.5%		
703070	1	10	No response	yohimbine 18	57.4%		
703070	90	10	No response	yohimbine 18	72.4%		
704108	1	999	No improvement in erections	yohimbine [5.4,10.8]	64.79%*	46	71
759003	90	999	No improvement or worse	Placebo 30	55%*	11	20 *
759003	1	999	No improvement or worse	yohimbine 30	35%*	7	20 *
703057992	1	999	No improvement in erections	yohimbine 21.6	56%*	14	25
703057992	2	999	No improvement in erections	yohimbine 21.6	38.1%*	8	21

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y	
partial response								
704037	1	4	"Partial effect"	yohimbine [5,10]	45.45%*	5	11	*
704037	91	4	"Partial effect"	Placebo [5,10]	9.09%*	1	11	**
703057992	0	6	Partial improvement in erections	yohimbine 16.2	33.49%*	72	215	
703057992	0	6	Partial improvement in erections	yohimbine 16.2	33.49%*	72	215	
703069	1	10	Partial response	yohimbine 18	31.03%*	9	29	
703069	90	10	Partial response	Placebo 18	10.53%*	2	19	
703069	2	10	Partial response	yohimbine 18	5.26%*	1	19	
703070	1	10	Partial response	yohimbine 18	21.3%			
703070	2	10	Partial response	yohimbine 18	27.3%			
703070	90	10	Partial response	yohimbine 18	13.8%			
704108	1	999	Partial improvement in erections	yohimbine [5.4,10.8]	21.13%*	15	71	
759003	90	999	Slight improvement	Placebo 30	30%*	6	20	*
759003	1	999	Slight improvement	yohimbine 30	45%*	9	20	*
703057992	1	999	Partial improvement in erections	yohimbine 21.6	36%*	9	25	
703057992	2	999	Partial improvement in erections	yohimbine 21.6	42.86%*	9	21	

Appendix 3B - Binary Efficacy Data
Studies Including Yohimbine

uncategorized

Ref#	Grp #	Wks	Outcome	Treatment	%	X	Y
796089	1	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	26.7%	12*	45 *
796089	2	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	35.6%	16*	45 *
796089	90	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	13.3%	6*	45 *
796089	1.1	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	26.1%	6*	23 *
796089	2.1	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	17.4%	4*	23 *
796089	90.1	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	4.4%	1*	23 *
796089	1.2	2	Investigator evaluated % administrations resulting in successful intercourse	yohimbine 6	27.3%	6*	22 *
796089	2.2	2	Investigator evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	54.6%	12*	22 *
796089	90.2	2	Investigator evaluated % administrations resulting in successful intercourse	Placebo	22.7%	5*	22 *
796089	1	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	28.9%	13*	45 *
796089	2	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	40%	18*	45 *
796089	90	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	17.8%	8*	45 *
796089	1.1	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	30.4%	7*	23 *
796089	2.1	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	26.1%	6*	23 *
796089	90.1	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	13%	3*	23 *
796089	1.2	2	Patient evaluated % administrations resulting in successful intercourse	yohimbine 6	27.3%	6*	22 *
796089	2.2	2	Patient evaluated % administrations resulting in successful intercourse	Yohimbine + L-Arginine glutamate 6 grams 6	54.6%	12*	22 *
796089	90.2	2	Patient evaluated % administrations resulting in successful intercourse	Placebo	22.7%	5*	22 *

Appendix 3C - IIEF Scaled Data
Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
10035	1.1	3	Erectile Function	ICI alprostadil [,40]	68	9.2[5.6]	25.3[6.9]		
10035	2.1	3	Erectile Function	MUSE [,1000]	68	9.2[5.6]	17.3[9.3]		
Interc. Satisfaction									
10035	1.1	3	Interc. Satisfaction	ICI alprostadil [,40]	68	4.9[3.8]	10.7[2.9]		
10035	2.1	3	Interc. Satisfaction	MUSE [,1000]	68	4.9[3.8]	7.9[4]		
Quest. 3									
10035	1.1	3	Quest. 3	ICI alprostadil [,40]	68	1.7	4.4		
10035	2.1	3	Quest. 3	MUSE [,1000]	68	1.7	3		
Quest. 4									
10035	1.1	3	Quest. 4	ICI alprostadil [,40]	68	1.3	4.2		
10035	2.1	3	Quest. 4	MUSE [,1000]	68	1.3	2.8		

Appendix 3C - IIEF Scaled Data
Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
796089	1	2	Erectile Function	yohimbine 6	45	14.3[5.64]	15.4[6.49]		
796089	1.2	2	Erectile Function	yohimbine 6	22		18.2[5.59]		
796089	2	2	Erectile Function	Yohimbine + L-Arginine glutamate 6 grams 6	45	14.3[5.64]	17.2[7.17]		
796089	2.2	2	Erectile Function	Yohimbine + L-Arginine glutamate 6 grams 6	22		22.2[4.99]		
796089	90	2	Erectile Function	Placebo	45	14.3[5.64]	14.1[6.56]		
796089	90.2	2	Erectile Function	Placebo	22		16.9[6.91]		
10035	1.1	3	Erectile Function	ICI alprostadil [,40]	68	9.2[5.6]	25.3[6.9]		
10035	2.1	3	Erectile Function	MUSE [,1000]	68	9.2[5.6]	17.3[9.3]		
Interc. Satisfaction									
796089	1	2	Interc. Satisfaction	yohimbine 6	45	7[2.05]	7.4[2.24]		
796089	1.2	2	Interc. Satisfaction	yohimbine 6	22		7.8[2.28]		
796089	2	2	Interc. Satisfaction	Yohimbine + L-Arginine glutamate 6 grams 6	45	7[2.05]	7.7[2.97]		
796089	2.2	2	Interc. Satisfaction	Yohimbine + L-Arginine glutamate 6 grams 6	22		9.1[2.73]		
796089	90	2	Interc. Satisfaction	Placebo	45	7[2.05]	6.9[2.43]		
796089	90.2	2	Interc. Satisfaction	Placebo	22		7.1[2.65]		
10035	1.1	3	Interc. Satisfaction	ICI alprostadil [,40]	68	4.9[3.8]	10.7[2.9]		
10035	2.1	3	Interc. Satisfaction	MUSE [,1000]	68	4.9[3.8]	7.9[4]		

Appendix 3C - IIEF Scaled Data
Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quest. 3									
796089	1	2	Quest. 3	yohimbine 6	45	2.7[2.69]	2.7[1.47]		
796089	1.2	2	Quest. 3	yohimbine 6	22		3.3[1.49]		
796089	2	2	Quest. 3	Yohimbine + L-Arginine glutamate 6 grams 6	45	2.7[2.69]	3[1.49]		
796089	2.2	2	Quest. 3	Yohimbine + L-Arginine glutamate 6 grams 6	22		3.9[1.17]		
796089	90	2	Quest. 3	Placebo	45	2.7[2.69]	2.5[1.49]		
796089	90.2	2	Quest. 3	Placebo	22		3.1[1.63]		
10035	1.1	3	Quest. 3	ICI alprostadil [,40]	68	1.7	4.4		
10035	2.1	3	Quest. 3	MUSE [,1000]	68	1.7	3		
Quest. 4									
796089	1	2	Quest. 4	yohimbine 6	45	2.2[1.34]	2.4[1.34]		
796089	1.2	2	Quest. 4	yohimbine 6	22		2.8[1.33]		
796089	2	2	Quest. 4	Yohimbine + L-Arginine glutamate 6 grams 6	45	2.2[1.34]	2.8[1.53]		
796089	2.2	2	Quest. 4	Yohimbine + L-Arginine glutamate 6 grams 6	22		3.9[1.23]		
796089	90	2	Quest. 4	Placebo	45	2.2[1.34]	2.2[1.42]		
796089	90.2	2	Quest. 4	Placebo	22		2.7[1.58]		
10035	1.1	3	Quest. 4	ICI alprostadil [,40]	68	1.3	4.2		
10035	2.1	3	Quest. 4	MUSE [,1000]	68	1.3	2.8		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
750019	1	4	Erectile Function	sildenafil [25,100]T	14	10.5	23.6		
750019	90	4	Erectile Function	Placebo [25,100]T	18	7.3	10.6		
750019	90.1	4	Erectile Function	Placebo	10	11.2	11.8		
796021	1	6	Erectile Function	sildenafil [25,100]T	118 *	14.1	23.3		
796021	1	6	Erectile Function	sildenafil [25,100]T	118 *	14.1	23.3		
796021	2	6	Erectile Function	sildenafil [25,100]T	83 *	13.5	23.2		
796021	2	6	Erectile Function	sildenafil [25,100]T	83 *	13.5	23.2		
796021	3	6	Erectile Function	sildenafil [25,100]T	146 **	17.34	24.38		
796021	4	6	Erectile Function	sildenafil [25,100]T	76 **	5.16	18.75		
796021	4	6	Erectile Function	sildenafil [25,100]T	76 **	5.16	18.75		
796021	5	6	Erectile Function	sildenafil [25,100]T		14.77	24.84		
796021	6	6	Erectile Function	sildenafil [25,100]T		12.89	22.97		
796021	7	6	Erectile Function	sildenafil [25,100]T		11.95	19.22		
796021	90	6	Erectile Function	Placebo [25,100]T	114 *	14.1	17.6		
796021	90	6	Erectile Function	Placebo [25,100]T	114 *	14.1	17.6		
796021	91	6	Erectile Function	Placebo [25,100]T	88 *	13.5	16.4		
796021	91	6	Erectile Function	Placebo [25,100]T	88 *	13.5	16.4		
796021	92	6	Erectile Function	Placebo [25,100]T	133 **	17.34	19.45		
796021	93	6	Erectile Function	Placebo [25,100]T	61 **	5.16	11.95		
796021	93	6	Erectile Function	Placebo [25,100]T	61 **	5.16	11.95		
796021	94	6	Erectile Function	Placebo [25,100]T		14.77	18.52		
796021	95	6	Erectile Function	Placebo [25,100]T		12.89	17.11		
796021	96	6	Erectile Function	Placebo [25,100]T		11.95	14.53		
796190	1	6	Erectile Function	sildenafil [50,100]	44	17.8[7.3]	27.1[3.7]	8.4(2.9,14)	
796190	90	6	Erectile Function	sildenafil [50,100]	45	16.3[7.4]	17.1[8.1]		
10103	0	8	Erectile Function	sildenafil [50,200]T	66	9[8]	14[10]	5[9]	
10103	1	8	Erectile Function	sildenafil	37	8[7]	16[10]	8[7]	
10103	2	8	Erectile Function	sildenafil	19	11[8]	15[10]	3[9]	
10103	3	8	Erectile Function	sildenafil	10	8[9]	8[6]	0[10]	
105100	1	12	Erectile Function	sildenafil 25	128 **	12.82	18.83[0.73e]		
105100	2	12	Erectile Function	sildenafil 50	132 **	12.82	20.91[0.73e]		
105100	3	12	Erectile Function	sildenafil 100	127 **	12.82	22.45[0.64e]		

Appendix 3C - IIEF Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
105100	90	12	Erectile Function	Placebo	127 **	12.82	12.82[0.36e]		
700003	1	12	Erectile Function	sildenafil [25,100]T	45	10.4	20.4[1.24e]		
700003	1.1	12	Erectile Function	sildenafil	44	10.2	19.1[2.03]		
700003	1.2	12	Erectile Function	sildenafil	67	10	18.2[1.95e]		
700003	1.3	12	Erectile Function	sildenafil	45 *	10.9	19.7[2.33e]		
700003	1.4	12	Erectile Function	sildenafil	58 *	10.2	21[1.72e]		
700003	90	12	Erectile Function	Placebo [25,100]T	98	10.4	11.5[1.17e]		
700003	90.1	12	Erectile Function	Placebo	46	10.2	10.8[1.78e]		
700003	90.2	12	Erectile Function	Placebo	43	10	9.5[1.95e]		
700003	90.3	12	Erectile Function	Placebo	32 *	10.9	10.3[2.21e]		
700003	90.4	12	Erectile Function	Placebo	70 *	10.2	12.7[1.61e]		
700006	1	12	Erectile Function	sildenafil [25,100]T	66	9.3[5.9]	23.4[1.5e]		
700006	90	12	Erectile Function	Placebo [25,100]T	70	9.3[5.9]	12.4[1.2e]		
700009	1	12	Erectile Function	sildenafil [25,100]T	110	13.54	24.25		
700009	90	12	Erectile Function	Placebo [25,100]T	110	13.54	18.07		
700018	1	12	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.44[0.69e]		
700018	1	12	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.44[0.69e]		
700018	1	12	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.44[0.69e]		
700018	1	12	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.44[0.69e]		
700018	90	12	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.23[0.73e]		
700018	90	12	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.23[0.73e]		
700018	90	12	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.23[0.73e]		
700018	90	12	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.23[0.73e]		
700020	1	12	Erectile Function	sildenafil [25,100]T	125	13.34	25.09		
700020	1	12	Erectile Function	sildenafil [25,100]T	125	13.34	25.09		
700020	1	12	Erectile Function	sildenafil [25,100]T	125	13.34	25.09		
700020	1	12	Erectile Function	sildenafil [25,100]T	125	13.34	25.09		
700020	90	12	Erectile Function	Placebo [25,100]T	121	13.34	15.51		
700020	90	12	Erectile Function	Placebo [25,100]T	121	13.34	15.51		
700020	90	12	Erectile Function	Placebo [25,100]T	121	13.34	15.51		
700020	90	12	Erectile Function	Placebo [25,100]T	121	13.34	15.51		
796061	1	12	Erectile Function	sildenafil [50,100]T	64 *	13.6[2.47]	22.1[0.87e]		
796061	1	12	Erectile Function	sildenafil [50,100]T	64 *	13.6[2.47]	22.1[0.87e]		
796061	1	12	Erectile Function	sildenafil [50,100]T	64 *	13.6[2.47]	22.1[0.87e]		
796061	1	12	Erectile Function	sildenafil [50,100]T	64 *	13.6[2.47]	22.1[0.87e]		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
796061	90	12	Erectile Function	Placebo [50,100]T	72 *	13.6[2.47]	18.4[1.02e]		
796061	90	12	Erectile Function	Placebo [50,100]T	72 *	13.6[2.47]	18.4[1.02e]		
796061	90	12	Erectile Function	Placebo [50,100]T	72 *	13.6[2.47]	18.4[1.02e]		
796061	90	12	Erectile Function	Placebo [50,100]T	72 *	13.6[2.47]	18.4[1.02e]		
796062	1	12	Erectile Function	sildenafil [25,100]T	66	14.52	20.19[0.63e]		
796062	90	12	Erectile Function	Placebo [25,100]T	65	14.52	15.86[0.65e]		
796063	1	12	Erectile Function	sildenafil [25,100]T	109	11.7	22.4		
796063	1	12	Erectile Function	sildenafil [25,100]T	109	11.7	22.4		
796063	1	12	Erectile Function	sildenafil [25,100]T	109	11.7	22.4		
796063	1	12	Erectile Function	sildenafil [25,100]T	109	11.7	22.4		
796063	90	12	Erectile Function	Placebo [25,100]T	105	11.7	14.6		
796063	90	12	Erectile Function	Placebo [25,100]T	105	11.7	14.6		
796063	90	12	Erectile Function	Placebo [25,100]T	105	11.7	14.6		
796063	90	12	Erectile Function	Placebo [25,100]T	105	11.7	14.6		
10463992	1	12	Erectile Function	sildenafil [25,100]T	136	11[0.47e]	21.54[0.94e]		
10463992	1	12	Erectile Function	sildenafil [25,100]T	136	11[0.47e]	21.54[0.94e]		
10463992	1	12	Erectile Function	sildenafil [25,100]T	136	11[0.47e]	21.54[0.94e]		
10463992	1	12	Erectile Function	sildenafil [25,100]T	136	11[0.47e]	21.54[0.94e]		
700018	1	26	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.91[0.68e]		
700018	1	26	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.91[0.68e]		
700018	1	26	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.91[0.68e]		
700018	1	26	Erectile Function	sildenafil [25,100]T	159 **	11.05[0.55e]	21.91[0.68e]		
700018	90	26	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.26[0.68e]		
700018	90	26	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.26[0.68e]		
700018	90	26	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.26[0.68e]		
700018	90	26	Erectile Function	Placebo [25,100]T	156 **	11.77[0.68e]	13.26[0.68e]		
750019	2	999	Erectile Function	sildenafil T	10	11.7	28.5		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Interc. Satisfaction

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
796021	1	6	Interc. Satisfaction	sildenafil [25,100]T	118 *	6.4	11.4		
796021	1	6	Interc. Satisfaction	sildenafil [25,100]T	118 *	6.4	11.4		
796021	2	6	Interc. Satisfaction	sildenafil [25,100]T	83 *	6.69	10.6		
796021	2	6	Interc. Satisfaction	sildenafil [25,100]T	83 *	6.69	10.6		
796021	90	6	Interc. Satisfaction	Placebo [25,100]T	114 *	6.4	9.27		
796021	90	6	Interc. Satisfaction	Placebo [25,100]T	114 *	6.4	9.27		
796021	91	6	Interc. Satisfaction	Placebo [25,100]T	88 *	6.69	7.94		
796021	91	6	Interc. Satisfaction	Placebo [25,100]T	88 *	6.69	7.94		
796190	1	6	Interc. Satisfaction	sildenafil [50,100]	44	6.4[2.4]	10.7[2.6]	4.1(1.9,6.2)	
796190	90	6	Interc. Satisfaction	sildenafil [50,100]	45	7[2.1]	7.2[2.3]		
10103	0	8	Interc. Satisfaction	sildenafil [50,200]T	66	5[5]	7[4]	2[4]	
105100	1	12	Interc. Satisfaction	sildenafil 25	128 **	6	8.91[0.36e]		
105100	2	12	Interc. Satisfaction	sildenafil 50	132 **	6	10[0.36e]		
105100	3	12	Interc. Satisfaction	sildenafil 100	127 **	6	10.36[0.27e]		
105100	90	12	Interc. Satisfaction	Placebo	127 **	6	6.55[0.36e]		
700006	1	12	Interc. Satisfaction	sildenafil [25,100]T	66	4.9[3.5]	10.9[0.7e]		
700006	90	12	Interc. Satisfaction	Placebo [25,100]T	70	4.9[3.5]	6.9[0.6e]		
700009	1	12	Interc. Satisfaction	sildenafil [25,100]T	110	5.31	9.58		
700009	90	12	Interc. Satisfaction	Placebo [25,100]T	111	5.31	8.1		
700018	1	12	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.53[0.35e]		
700018	1	12	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.53[0.35e]		
700018	1	12	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.53[0.35e]		
700018	1	12	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.53[0.35e]		
700018	90	12	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.82[0.35e]		
700018	90	12	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.82[0.35e]		
700018	90	12	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.82[0.35e]		
700018	90	12	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.82[0.35e]		
700020	1	12	Interc. Satisfaction	sildenafil [25,100]T	125	6.71	10.75		
700020	1	12	Interc. Satisfaction	sildenafil [25,100]T	125	6.71	10.75		
700020	1	12	Interc. Satisfaction	sildenafil [25,100]T	125	6.71	10.75		
700020	1	12	Interc. Satisfaction	sildenafil [25,100]T	125	6.71	10.75		
700020	90	12	Interc. Satisfaction	Placebo [25,100]T	121	6.71	8.4		

Appendix 3C - IIEF Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700020	90	12	Interc. Satisfaction	Placebo [25,100]T	121	6.71	8.4		
700020	90	12	Interc. Satisfaction	Placebo [25,100]T	121	6.71	8.4		
700020	90	12	Interc. Satisfaction	Placebo [25,100]T	121	6.71	8.4		
796061	1	12	Interc. Satisfaction	sildenafil [50,100]T	64 *	7.4[1.6]	10.8[0.29e]		
796061	1	12	Interc. Satisfaction	sildenafil [50,100]T	64 *	7.4[1.6]	10.8[0.29e]		
796061	1	12	Interc. Satisfaction	sildenafil [50,100]T	64 *	7.4[1.6]	10.8[0.29e]		
796061	1	12	Interc. Satisfaction	sildenafil [50,100]T	64 *	7.4[1.6]	10.8[0.29e]		
796061	90	12	Interc. Satisfaction	Placebo [50,100]T	72 *	7.4[1.6]	9.4[0.15e]		
796061	90	12	Interc. Satisfaction	Placebo [50,100]T	72 *	7.4[1.6]	9.4[0.15e]		
796061	90	12	Interc. Satisfaction	Placebo [50,100]T	72 *	7.4[1.6]	9.4[0.15e]		
796061	90	12	Interc. Satisfaction	Placebo [50,100]T	72 *	7.4[1.6]	9.4[0.15e]		
796062	1	12	Interc. Satisfaction	sildenafil [25,100]T	66	7.31	11.04[0.35e]		
796062	90	12	Interc. Satisfaction	Placebo [25,100]T	65	7.31	8.4[0.36e]		
796063	1	12	Interc. Satisfaction	sildenafil [25,100]T	109	6.5	10		
796063	1	12	Interc. Satisfaction	sildenafil [25,100]T	109	6.5	10		
796063	1	12	Interc. Satisfaction	sildenafil [25,100]T	109	6.5	10		
796063	1	12	Interc. Satisfaction	sildenafil [25,100]T	109	6.5	10		
796063	90	12	Interc. Satisfaction	Placebo [25,100]T	105	6.5	8.1		
796063	90	12	Interc. Satisfaction	Placebo [25,100]T	105	6.5	8.1		
796063	90	12	Interc. Satisfaction	Placebo [25,100]T	105	6.5	8.1		
796063	90	12	Interc. Satisfaction	Placebo [25,100]T	105	6.5	8.1		
10463992	1	12	Interc. Satisfaction	sildenafil [25,100]T	138	5.67[0.33e]	10.67[0.42e]		
10463992	1	12	Interc. Satisfaction	sildenafil [25,100]T	138	5.67[0.33e]	10.67[0.42e]		
10463992	1	12	Interc. Satisfaction	sildenafil [25,100]T	138	5.67[0.33e]	10.67[0.42e]		
10463992	1	12	Interc. Satisfaction	sildenafil [25,100]T	138	5.67[0.33e]	10.67[0.42e]		
700018	1	26	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.52[0.33e]		
700018	1	26	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.52[0.33e]		
700018	1	26	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.52[0.33e]		
700018	1	26	Interc. Satisfaction	sildenafil [25,100]T	159 **	6.64[0.33e]	10.52[0.33e]		
700018	90	26	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.74[0.35e]		
700018	90	26	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.74[0.35e]		
700018	90	26	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.74[0.35e]		
700018	90	26	Interc. Satisfaction	Placebo [25,100]T	156 **	6.71[0.36e]	7.74[0.35e]		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quest. 3									
10024	1	6	Quest. 3	sildenafil [25,100]T	175 *	1.96	3.83		
10024	90	6	Quest. 3	Placebo [25,100]T	174 *	1.96	2.16		
10169	1	6	Quest. 3	sildenafil [25,100]T	155	1.96	3.83		
10169	1.3	6	Quest. 3	sildenafil [25,100]T	90 *		3.63		
10169	1.4	6	Quest. 3	sildenafil [25,100]T	78 *		4.13		
10169	90	6	Quest. 3	Placebo [25,100]T	158	1.96	2.16		
700002	1	6	Quest. 3	sildenafil [25,100]T	60 **	1.5[1.4]	2.8[1.7]		
700002	90	6	Quest. 3	Placebo [25,100]T	60 **	1.5[1.4]	1.6[1.1]		
796021	1	6	Quest. 3	sildenafil [25,100]T	118 *	2.55	4.06		
796021	1	6	Quest. 3	sildenafil [25,100]T	118 *	2.55	4.06		
796021	2	6	Quest. 3	sildenafil [25,100]T	83 *	2.39	3.97		
796021	2	6	Quest. 3	sildenafil [25,100]T	83 *	2.39	3.97		
796021	3	6	Quest. 3	sildenafil [25,100]T	146 **	3.16	4.2		
796021	4	6	Quest. 3	sildenafil [25,100]T	76 **	0.73	3.23		
796021	4	6	Quest. 3	sildenafil [25,100]T	76 **	0.73	3.23		
796021	5	6	Quest. 3	sildenafil [25,100]T		2.67	4.31		
796021	6	6	Quest. 3	sildenafil [25,100]T		2.26	3.96		
796021	7	6	Quest. 3	sildenafil [25,100]T		2.05	3.3		
796021	90	6	Quest. 3	Placebo [25,100]T	114 *	2.55	3.05		
796021	90	6	Quest. 3	Placebo [25,100]T	114 *	2.55	3.05		
796021	91	6	Quest. 3	Placebo [25,100]T	88 *	2.39	2.95		
796021	91	6	Quest. 3	Placebo [25,100]T	88 *	2.39	2.95		
796021	92	6	Quest. 3	Placebo [25,100]T	133 **	3.16	3.37		
796021	93	6	Quest. 3	Placebo [25,100]T	61 **	0.73	2.08		
796021	93	6	Quest. 3	Placebo [25,100]T	61 **	0.73	2.08		
796021	94	6	Quest. 3	Placebo [25,100]T		2.67	3.3		
796021	95	6	Quest. 3	Placebo [25,100]T		2.26	2.92		
796021	96	6	Quest. 3	Placebo [25,100]T		2.05	2.53		
796190	1	6	Quest. 3	sildenafil [50,100]	44	3.2[1.4]	4.4[1.1]	1.2(0.2,2.3)	
796190	90	6	Quest. 3	sildenafil [50,100]	45	3.1[1.6]	3.1[1.6]		
10103	0	8	Quest. 3	sildenafil [50,200]T	66	1.3[1.4]	2.4[1.8]		
10026	1	12	Quest. 3	sildenafil [25,100]T	163		3.9		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
10026	90	12	Quest. 3	Placebo [25,100]T	166		2.3		
10031	1	12	Quest. 3	sildenafil [25,100]T	138		3.9[0.05]		
10031	90	12	Quest. 3	Placebo [25,100]T	138		2.3[0.1]		
10223	1	12	Quest. 3	sildenafil [25,100]T	56	1.72	3.58		
10223	90	12	Quest. 3	Placebo [25,100]T	53	1.72	1.69		
10263	1	12	Quest. 3	sildenafil [25,100]T	131	1.8	3.2		
10263	1.1	12	Quest. 3	sildenafil [25,100]T	29		3.9[0.6e]		
10263	1.11	12	Quest. 3	sildenafil [25,100]T	20	2	2.9[0.7e]		
10263	1.12	12	Quest. 3	sildenafil [25,100]T	111	1.8	3.3[0.3e]		
10263	1.2	12	Quest. 3	sildenafil [25,100]T	62		3.3[0.4e]		
10263	1.3	12	Quest. 3	sildenafil [25,100]T	40		2.9[0.6e]		
10263	1.4	12	Quest. 3	sildenafil [25,100]T	51		4.3[0.5e]		
10263	1.5	12	Quest. 3	sildenafil [25,100]T	34		3.4[0.5e]		
10263	1.6	12	Quest. 3	sildenafil [25,100]T	46		2.5[0.4e]		
10263	1.7	12	Quest. 3	sildenafil [25,100]T	39		3.9[0.5e]		
10263	1.8	12	Quest. 3	sildenafil [25,100]T	39		2.4[0.8e]		
10263	1.9	12	Quest. 3	sildenafil [25,100]T	53		2.9[0.4e]		
10263	90	12	Quest. 3	Placebo [25,100]T	126	1.6	2		
10263	90.1	12	Quest. 3	Placebo [25,100]T	27		2.4[0.6e]		
10263	90.11	12	Quest. 3	Placebo [25,100]T	26	1.8	2.1[0.6e]		
10263	90.12	12	Quest. 3	Placebo [25,100]T	100	1.5	2.1[0.3e]		
10263	90.2	12	Quest. 3	Placebo [25,100]T	70		2.5[0.4e]		
10263	90.3	12	Quest. 3	Placebo [25,100]T	29		1.4[0.6e]		
10263	90.4	12	Quest. 3	Placebo [25,100]T	36		3[0.6e]		
10263	90.5	12	Quest. 3	Placebo [25,100]T	49		2.2[0.4e]		
10263	90.6	12	Quest. 3	Placebo [25,100]T	41		1.3[0.4e]		
10263	90.8	12	Quest. 3	Placebo [25,100]T	40		1.6[0.8e]		
10263	90.9	12	Quest. 3	Placebo [25,100]T	45		1.8[0.4e]		
105100	1	12	Quest. 3	sildenafil 25	121	2.2	3.18[0.12e]		
105100	2	12	Quest. 3	sildenafil 50	123	2.2	3.65[0.12e]		
105100	3	12	Quest. 3	sildenafil 100	120	2.2	3.79[0.12e]		
105100	90	12	Quest. 3	Placebo	117	2.2	2.17[0.15e]		
200300	1	12	Quest. 3	sildenafil [25,100]T	121	1.8	3.7[0.2e]		
200300	90	12	Quest. 3	Placebo [25,100]T	119	1.8	2.3[0.2e]		
700003	1	12	Quest. 3	sildenafil [25,100]T	101	1.77	3.42[0.23e]		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700003	1.1	12	Quest. 3	sildenafil	47	1.69	3.06[0.4]		
700003	1.2	12	Quest. 3	sildenafil	47	1.69	3.04[0.36e]		
700003	1.3	12	Quest. 3	sildenafil	43	1.84	3.51[0.43e]		
700003	1.4	12	Quest. 3	sildenafil	58	1.73	3.41[0.32e]		
700003	90	12	Quest. 3	Placebo [25,100]T	101	1.77	1.86[0.22e]		
700003	90.1	12	Quest. 3	Placebo	47	1.69	1.59[0.34e]		
700003	90.3	12	Quest. 3	Placebo	32	1.84	1.74[0.41e]		
700003	90.4	12	Quest. 3	Placebo	69	1.73	2[0.3e]		
700006	1	12	Quest. 3	sildenafil [25,100]T	66	1.6[1.3]	3.7[0.3e]		
700006	90	12	Quest. 3	Placebo [25,100]T	70	1.6[1.3]	2.2[0.2e]		
700009	1	12	Quest. 3	sildenafil [25,100]T	110	2.3	4.17		
700009	90	12	Quest. 3	Placebo [25,100]T	111	2.3	2.98		
700018	1	12	Quest. 3	sildenafil [25,100]T	159 **	1.85	3.54[0.15e]		
700018	1	12	Quest. 3	sildenafil [25,100]T	159 **	1.85	3.54[0.15e]		
700018	1	12	Quest. 3	sildenafil [25,100]T	159 **	1.85	3.54[0.15e]		
700018	1	12	Quest. 3	sildenafil [25,100]T	159 **	1.85	3.54[0.15e]		
700018	90	12	Quest. 3	Placebo [25,100]T	156 **	1.94	2.16[0.16e]		
700018	90	12	Quest. 3	Placebo [25,100]T	156 **	1.94	2.16[0.16e]		
700018	90	12	Quest. 3	Placebo [25,100]T	156 **	1.94	2.16[0.16e]		
700018	90	12	Quest. 3	Placebo [25,100]T	156 **	1.94	2.16[0.16e]		
700020	1	12	Quest. 3	sildenafil [25,100]T	125	2.26	4.22		
700020	1	12	Quest. 3	sildenafil [25,100]T	125	2.26	4.22		
700020	1	12	Quest. 3	sildenafil [25,100]T	125	2.26	4.22		
700020	1	12	Quest. 3	sildenafil [25,100]T	125	2.26	4.22		
700020	90	12	Quest. 3	Placebo [25,100]T	121	2.26	2.59		
700020	90	12	Quest. 3	Placebo [25,100]T	121	2.26	2.59		
700020	90	12	Quest. 3	Placebo [25,100]T	121	2.26	2.59		
700020	90	12	Quest. 3	Placebo [25,100]T	121	2.26	2.59		
750205	1	12	Quest. 3	sildenafil [25,100]	226	1.7	3.1(2.85,3.35)		
750205	2	12	Quest. 3	sildenafil [25,100]T	40	1.6	3(2.38,3.5)		
750205	90	12	Quest. 3	Placebo [25,100]	139	1.7	1.9(1.59,2.07)		
750205	91	12	Quest. 3	Placebo [25,100]T	29	1.6	1.4(0.99,1.9)		
796061	1	12	Quest. 3	sildenafil [50,100]T	64 *	2.35[1.22]	4.01[0.2e]		
796061	1	12	Quest. 3	sildenafil [50,100]T	64 *	2.35[1.22]	4.01[0.2e]		
796061	1	12	Quest. 3	sildenafil [50,100]T	64 *	2.35[1.22]	4.01[0.2e]		

Appendix 3C - IIEF Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
796061	1	12	Quest. 3	sildenafil [50,100]T	64 *	2.35[1.22]	4.01[0.2e]		
796061	90	12	Quest. 3	Placebo [50,100]T	72 *	2.35[1.22]	3.21[0.15e]		
796061	90	12	Quest. 3	Placebo [50,100]T	72 *	2.35[1.22]	3.21[0.15e]		
796061	90	12	Quest. 3	Placebo [50,100]T	72 *	2.35[1.22]	3.21[0.15e]		
796061	90	12	Quest. 3	Placebo [50,100]T	72 *	2.35[1.22]	3.21[0.15e]		
796062	1	12	Quest. 3	sildenafil [25,100]T	66	2.31[1.36]	3.84[0.17e]		0.66
796062	90	12	Quest. 3	Placebo [25,100]T	65	2.31[1.36]	2.66[0.18e]		0.15
796063	1	12	Quest. 3	sildenafil [25,100]T	109	2.07[0.09e]	3.93[0.15e]		
796063	1	12	Quest. 3	sildenafil [25,100]T	109	2.07[0.09e]	3.93[0.15e]		
796063	1	12	Quest. 3	sildenafil [25,100]T	109	2.07[0.09e]	3.93[0.15e]		
796063	1	12	Quest. 3	sildenafil [25,100]T	109	2.07[0.09e]	3.93[0.15e]		
796063	90	12	Quest. 3	Placebo [25,100]T	105	2.07[0.09e]	2.56[0.15e]		
796063	90	12	Quest. 3	Placebo [25,100]T	105	2.07[0.09e]	2.56[0.15e]		
796063	90	12	Quest. 3	Placebo [25,100]T	105	2.07[0.09e]	2.56[0.15e]		
796063	90	12	Quest. 3	Placebo [25,100]T	105	2.07[0.09e]	2.56[0.15e]		
10029991	1	12	Quest. 3	sildenafil [25,100]T	138	2.03	3.87[0.11e]		
10029991	90	12	Quest. 3	Placebo [25,100]T	138	2.03	2.28[0.14e]		
10029992	1	12	Quest. 3	sildenafil [25,100]T	136	1.89	3.64[0.13e]		
10029992	90	12	Quest. 3	Placebo [25,100]T	118	1.89	2.16[0.16e]		
10463992	1	12	Quest. 3	sildenafil [25,100]T	138	2[0.1e]	3.9[0.1e]		0.95
10463992	1	12	Quest. 3	sildenafil [25,100]T	138	2[0.1e]	3.9[0.1e]		0.95
10463992	1	12	Quest. 3	sildenafil [25,100]T	138	2[0.1e]	3.9[0.1e]		0.95
10463992	1	12	Quest. 3	sildenafil [25,100]T	138	2[0.1e]	3.9[0.1e]		0.95
10463991	1.1	24	Quest. 3	sildenafil 25	96	2[0.2e]	3.2[0.2e]		0.6
10463991	1.2	24	Quest. 3	sildenafil 50	105	1.9[0.2e]	3.5[0.2e]		0.84
10463991	1.3	24	Quest. 3	sildenafil 100	101	2[0.2e]	4[0.2e]		1
10463991	90	24	Quest. 3	Placebo 125	199	2.1[0.1e]	2.2[0.2e]		0.05
10463991	90	24	Quest. 3	Placebo 125	199	2.1[0.1e]	2.2[0.2e]		0.05
10463991	90	24	Quest. 3	Placebo 125	199	2.1[0.1e]	2.2[0.2e]		0.05
10463991	90	24	Quest. 3	Placebo 125	199	2.1[0.1e]	2.2[0.2e]		0.05
10023	1	26	Quest. 3	sildenafil [25,100]T	144		3.6		
10023	90	26	Quest. 3	Placebo [25,100]T	130		2.2		
700018	1	26	Quest. 3	sildenafil [25,100]T	159 **	1.91	3.65[0.14e]		
700018	1	26	Quest. 3	sildenafil [25,100]T	159 **	1.91	3.65[0.14e]		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700018	1	26	Quest. 3	sildenafil [25,100]T	159 **	1.91	3.65[0.14e]		
700018	1	26	Quest. 3	sildenafil [25,100]T	159 **	1.91	3.65[0.14e]		
700018	90	26	Quest. 3	Placebo [25,100]T	156 **	1.65	2.22[0.15e]		
700018	90	26	Quest. 3	Placebo [25,100]T	156 **	1.65	2.22[0.15e]		
700018	90	26	Quest. 3	Placebo [25,100]T	156 **	1.65	2.22[0.15e]		
700018	90	26	Quest. 3	Placebo [25,100]T	156 **	1.65	2.22[0.15e]		
104993	1	999	Quest. 3	sildenafil [5,100]			3.41		
104993	2	999	Quest. 3	sildenafil [5,100]			3.43		
104993	90	999	Quest. 3	Placebo [5,100]			2.08		
104993	91	999	Quest. 3	Placebo [5,100]			2.02		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quest. 4									
10024	1	6	Quest. 4	sildenafil [25,100]T	175 *	1.54	3.61[0.15]		
10024	90	6	Quest. 4	Placebo [25,100]T	174 *	1.54	1.68[0.2]		
10169	1	6	Quest. 4	sildenafil [25,100]T	155	1.54	3.61		
10169	1.3	6	Quest. 4	sildenafil [25,100]T	90 *		3.36		
10169	1.4	6	Quest. 4	sildenafil [25,100]T	78 *		3.94		
10169	90	6	Quest. 4	Placebo [25,100]T	158	1.54	1.68		
700002	1	6	Quest. 4	sildenafil [25,100]T	60 **	1.3[1.4]	2.6[1.7]		
700002	90	6	Quest. 4	Placebo [25,100]T	60 **	1.3[1.4]	1.5[1]		
796021	1	6	Quest. 4	sildenafil [25,100]T	118 *	2.24	3.93		
796021	1	6	Quest. 4	sildenafil [25,100]T	118 *	2.24	3.93		
796021	2	6	Quest. 4	sildenafil [25,100]T	83 *	2.11	3.82		
796021	2	6	Quest. 4	sildenafil [25,100]T	83 *	2.11	3.82		
796021	3	6	Quest. 4	sildenafil [25,100]T	146 **	2.81	4.04		
796021	4	6	Quest. 4	sildenafil [25,100]T	76 **	0.62	3.12		
796021	4	6	Quest. 4	sildenafil [25,100]T	76 **	0.62	3.12		
796021	5	6	Quest. 4	sildenafil [25,100]T		2.26	4.18		
796021	6	6	Quest. 4	sildenafil [25,100]T		1.99	3.8		
796021	7	6	Quest. 4	sildenafil [25,100]T		1.82	3.01		
796021	90	6	Quest. 4	Placebo [25,100]T	114 *	2.24	2.88		
796021	90	6	Quest. 4	Placebo [25,100]T	114 *	2.24	2.88		
796021	91	6	Quest. 4	Placebo [25,100]T	88 *	2.11	2.62		
796021	91	6	Quest. 4	Placebo [25,100]T	88 *	2.11	2.62		
796021	92	6	Quest. 4	Placebo [25,100]T	133 **	2.81	3.12		
796021	93	6	Quest. 4	Placebo [25,100]T	61 **	0.62	1.87		
796021	93	6	Quest. 4	Placebo [25,100]T	61 **	0.62	1.87		
796021	94	6	Quest. 4	Placebo [25,100]T		2.26	2.26		
796021	95	6	Quest. 4	Placebo [25,100]T		1.99	2.81		
796021	96	6	Quest. 4	Placebo [25,100]T		1.82	2.29		
796190	1	6	Quest. 4	sildenafil [50,100]	44	2.9[1.6]	4.2[1.2]	1.2(0.07,2.3)	
796190	90	6	Quest. 4	sildenafil [50,100]	45	2.6[1.6]	2.7[1.6]		
10103	0	8	Quest. 4	sildenafil [50,200]T	66	1.4[1.6]	2.4[1.8]		
10026	1	12	Quest. 4	sildenafil [25,100]T	163		3.6		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
10026	90	12	Quest. 4	Placebo [25,100]T	166		1.8		
10031	1	12	Quest. 4	sildenafil [25,100]T	137		3.6[0.1]		
10031	90	12	Quest. 4	Placebo [25,100]T	138		1.8[0.1]		
10223	1	12	Quest. 4	sildenafil [25,100]T	55	1.56	3.68		
10223	90	12	Quest. 4	Placebo [25,100]T	53	1.56	1.64		
10263	1	12	Quest. 4	sildenafil [25,100]T	131	1.5	2.9		
10263	1.1	12	Quest. 4	sildenafil [25,100]T	29		3.7[0.6e]		
10263	1.11	12	Quest. 4	sildenafil [25,100]T	20	1.7	2.8[0.6e]		
10263	1.12	12	Quest. 4	sildenafil [25,100]T	111	1.5	3[0.3e]		
10263	1.2	12	Quest. 4	sildenafil [25,100]T	62		2.8[0.4e]		
10263	1.3	12	Quest. 4	sildenafil [25,100]T	40		2.8[0.6e]		
10263	1.4	12	Quest. 4	sildenafil [25,100]T	51		2.9[0.6e]		
10263	1.5	12	Quest. 4	sildenafil [25,100]T	34		3.3[0.4e]		
10263	1.6	12	Quest. 4	sildenafil [25,100]T	46		2.7[0.5e]		
10263	1.7	12	Quest. 4	sildenafil [25,100]T	39		2.9[0.5e]		
10263	1.8	12	Quest. 4	sildenafil [25,100]T	39		2.3[0.8e]		
10263	1.9	12	Quest. 4	sildenafil [25,100]T	53		3.1[0.4e]		
10263	90	12	Quest. 4	Placebo [25,100]T	125	1.4	1.6		
10263	90.1	12	Quest. 4	Placebo [25,100]T	27		2.1[0.6e]		
10263	90.11	12	Quest. 4	Placebo [25,100]T	26	1.2	1.8[0.6e]		
10263	90.12	12	Quest. 4	Placebo [25,100]T	100	1.3	1.7[0.3e]		
10263	90.2	12	Quest. 4	Placebo [25,100]T	70		1.7[0.4e]		
10263	90.3	12	Quest. 4	Placebo [25,100]T	29		1.4[0.7e]		
10263	90.4	12	Quest. 4	Placebo [25,100]T	36		1.6[0.6e]		
10263	90.5	12	Quest. 4	Placebo [25,100]T	49		1.7[0.4e]		
10263	90.6	12	Quest. 4	Placebo [25,100]T	41		1.6[0.5e]		
10263	90.8	12	Quest. 4	Placebo [25,100]T	40		1.5[0.9e]		
10263	90.9	12	Quest. 4	Placebo [25,100]T	45		2[0.4e]		
105100	1	12	Quest. 4	sildenafil 25	119	1.83	2.99[0.12e]		
105100	2	12	Quest. 4	sildenafil 50	122	1.83	3.4[0.12e]		
105100	3	12	Quest. 4	sildenafil 100	118	1.83	3.63[0.12e]		
105100	90	12	Quest. 4	Placebo	115	1.83	1.96[0.15e]		
200300	1	12	Quest. 4	sildenafil [25,100]T	121	1.5	3.5[0.2e]		
200300	90	12	Quest. 4	Placebo [25,100]T	119	1.5	1.9[0.2e]		
700003	1	12	Quest. 4	sildenafil [25,100]T	47	1.49	3.35[0.24e]		

Appendix 3C - IIEF Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700003	1.1	12	Quest. 4	sildenafil	47	1.45	2.84[0.41e]		
700003	1.2	12	Quest. 4	sildenafil	69	1.45	3.04[0.37e]		
700003	1.3	12	Quest. 4	sildenafil	45 *	1.65	3.46[0.44e]		
700003	1.4	12	Quest. 4	sildenafil	58 *	1.42	3.21[0.34e]		
700003	90	12	Quest. 4	Placebo [25,100]T	101	1.49	1.84[0.23e]		
700003	90.1	12	Quest. 4	Placebo	46	1.45	1.6[0.36e]		
700003	90.3	12	Quest. 4	Placebo	32 *	1.65	1.75[0.43e]		
700003	90.4	12	Quest. 4	Placebo	70 *	1.42	1.95[0.31e]		
700006	1	12	Quest. 4	sildenafil [25,100]T	66	1.4[1.1]	3.9[0.3e]		
700006	90	12	Quest. 4	Placebo [25,100]T	70	1.4[1.1]	2[0.2e]		
700009	1	12	Quest. 4	sildenafil [25,100]T	110	2.02	4.14		
700009	90	12	Quest. 4	Placebo [25,100]T	111	2.02	2.88		
700018	1	12	Quest. 4	sildenafil [25,100]T	159 **	1.63	3.53[0.15e]		
700018	1	12	Quest. 4	sildenafil [25,100]T	159 **	1.63	3.53[0.15e]		
700018	1	12	Quest. 4	sildenafil [25,100]T	159 **	1.63	3.53[0.15e]		
700018	1	12	Quest. 4	sildenafil [25,100]T	159 **	1.63	3.53[0.15e]		
700018	90	12	Quest. 4	Placebo [25,100]T	156 **	1.64	2.01[0.16e]		
700018	90	12	Quest. 4	Placebo [25,100]T	156 **	1.64	2.01[0.16e]		
700018	90	12	Quest. 4	Placebo [25,100]T	156 **	1.64	2.01[0.16e]		
700018	90	12	Quest. 4	Placebo [25,100]T	156 **	1.64	2.01[0.16e]		
700020	1	12	Quest. 4	sildenafil [25,100]T	125	1.93	4.15		
700020	1	12	Quest. 4	sildenafil [25,100]T	125	1.93	4.15		
700020	1	12	Quest. 4	sildenafil [25,100]T	125	1.93	4.15		
700020	1	12	Quest. 4	sildenafil [25,100]T	125	1.93	4.15		
700020	90	12	Quest. 4	Placebo [25,100]T	121	1.93	2.41		
700020	90	12	Quest. 4	Placebo [25,100]T	121	1.93	2.41		
700020	90	12	Quest. 4	Placebo [25,100]T	121	1.93	2.41		
700020	90	12	Quest. 4	Placebo [25,100]T	121	1.93	2.41		
750205	1	12	Quest. 4	sildenafil [25,100]	220	1.4	3(2.79,3.25)		
750205	2	12	Quest. 4	sildenafil [25,100]T	40	1.5	2.8(2.1,3.34)		
750205	90	12	Quest. 4	Placebo [25,100]	139	1.4	1.6(1.39,1.8)		
750205	91	12	Quest. 4	Placebo [25,100]T	29	1.5	1.2(0.79,1.57)		
796061	1	12	Quest. 4	sildenafil [50,100]T	64 *	2.04[1.15]	3.85[0.18e]		
796061	1	12	Quest. 4	sildenafil [50,100]T	64 *	2.04[1.15]	3.85[0.18e]		
796061	1	12	Quest. 4	sildenafil [50,100]T	64 *	2.04[1.15]	3.85[0.18e]		

Appendix 3C - IIEF Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
796061	1	12	Quest. 4	sildenafil [50,100]T	64 *	2.04[1.15]	3.85[0.18e]		
796061	90	12	Quest. 4	Placebo [50,100]T	72 *	2.04[1.15]	2.88[0.15e]		
796061	90	12	Quest. 4	Placebo [50,100]T	72 *	2.04[1.15]	2.88[0.15e]		
796061	90	12	Quest. 4	Placebo [50,100]T	72 *	2.04[1.15]	2.88[0.15e]		
796061	90	12	Quest. 4	Placebo [50,100]T	72 *	2.04[1.15]	2.88[0.15e]		
796062	1	12	Quest. 4	sildenafil [25,100]T	66	2.03[1.23]	3.61[0.18e]		0.78
796062	90	12	Quest. 4	Placebo [25,100]T	65	2.03[1.23]	2.46[0.18e]		0.21
796063	1	12	Quest. 4	sildenafil [25,100]T	109	1.75[0.08e]	3.83[0.15e]		
796063	1	12	Quest. 4	sildenafil [25,100]T	109	1.75[0.08e]	3.83[0.15e]		
796063	1	12	Quest. 4	sildenafil [25,100]T	109	1.75[0.08e]	3.83[0.15e]		
796063	1	12	Quest. 4	sildenafil [25,100]T	109	1.75[0.08e]	3.83[0.15e]		
796063	90	12	Quest. 4	Placebo [25,100]T	105	1.75[0.08e]	2.33[0.15e]		
796063	90	12	Quest. 4	Placebo [25,100]T	105	1.75[0.08e]	2.33[0.15e]		
796063	90	12	Quest. 4	Placebo [25,100]T	105	1.75[0.08e]	2.33[0.15e]		
796063	90	12	Quest. 4	Placebo [25,100]T	105	1.75[0.08e]	2.33[0.15e]		
10029991	1	12	Quest. 4	sildenafil [25,100]T	137	1.52	3.63[0.1]		
10029991	90	12	Quest. 4	Placebo [25,100]T	138	1.52	1.79[0.1]		
10029992	1	12	Quest. 4	sildenafil [25,100]T	136	1.63	3.53[0.15]		
10029992	90	12	Quest. 4	Placebo [25,100]T	116	1.63	2.07[0.15]		
10463992	1	12	Quest. 4	sildenafil [25,100]T	137	1.5[0.1e]	3.6[0.1e]		1.4
10463992	1	12	Quest. 4	sildenafil [25,100]T	137	1.5[0.1e]	3.6[0.1e]		1.4
10463992	1	12	Quest. 4	sildenafil [25,100]T	137	1.5[0.1e]	3.6[0.1e]		1.4
10463992	1	12	Quest. 4	sildenafil [25,100]T	137	1.5[0.1e]	3.6[0.1e]		1.4
10463991	1.1	24	Quest. 4	sildenafil 25	96	1.4[0.1e]	3.1[0.2e]		1.21
10463991	1.2	24	Quest. 4	sildenafil 50	105	0.5[0.1e]	3.5[0.2e]		1.33
10463991	1.3	24	Quest. 4	sildenafil 100	101	1.7[0.1e]	3.9[0.2e]		1.3
10463991	90	24	Quest. 4	Placebo 125	199	1.7[0.1e]	2.1[0.2e]		0.24
10463991	90	24	Quest. 4	Placebo 125	199	1.7[0.1e]	2.1[0.2e]		0.24
10463991	90	24	Quest. 4	Placebo 125	199	1.7[0.1e]	2.1[0.2e]		0.24
10463991	90	24	Quest. 4	Placebo 125	199	1.7[0.1e]	2.1[0.2e]		0.24
10023	1	26	Quest. 4	sildenafil [25,100]T	144		3.6		
10023	90	26	Quest. 4	Placebo [25,100]T	128		2.1		
700018	1	26	Quest. 4	sildenafil [25,100]T	159 **	1.91	3.58[0.15e]		
700018	1	26	Quest. 4	sildenafil [25,100]T	159 **	1.91	3.58[0.15e]		

Appendix 3C - IIEF Scaled Data
Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700018	1	26	Quest. 4	sildenafil [25,100]T	159 **	1.91	3.58[0.15e]		
700018	1	26	Quest. 4	sildenafil [25,100]T	159 **	1.91	3.58[0.15e]		
700018	90	26	Quest. 4	Placebo [25,100]T	156 **	1.65	2.1[0.16e]		
700018	90	26	Quest. 4	Placebo [25,100]T	156 **	1.65	2.1[0.16e]		
700018	90	26	Quest. 4	Placebo [25,100]T	156 **	1.65	2.1[0.16e]		
700018	90	26	Quest. 4	Placebo [25,100]T	156 **	1.65	2.1[0.16e]		
104993	1	999	Quest. 4	sildenafil [5,100]			3.28		
104993	2	999	Quest. 4	sildenafil [5,100]			3.36		
104993	90	999	Quest. 4	Placebo [5,100]			1.9		
104993	91	999	Quest. 4	Placebo [5,100]			1.81		

Appendix 3C - IIEF Scaled Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
756003	1	3	Erectile Function	tadalafil 10	60		26		
756003	2	3	Erectile Function	tadalafil 25	58		25		
756003	3	3	Erectile Function	tadalafil 50	59		27		
756003	4	3	Erectile Function	tadalafil 100	59		26		
756003	90	3	Erectile Function	Placebo	58		19		
756005	1.1	3	Erectile Function	tadalafil 2	35 **	15.3[6.9e]	19.3[1.5e]	4.1[1.1e]	
756005	1.2	3	Erectile Function	tadalafil 5	37 **	15.5[4.9e]	22.9[1e]	7.3[1e]	
756005	1.3	3	Erectile Function	tadalafil 10	36 **	15.8[6.6e]	23.6[1.1e]	7.8[1.2e]	
756005	1.4	3	Erectile Function	tadalafil 25	36 **	14.9[6.8e]	24.2[1.2e]	9.4[1.2e]	
756005	90	3	Erectile Function	Placebo	35	13.7[6.6e]	14.7[1.2e]	1[0.9e]	
796036	1	12	Erectile Function	tadalafil 2.5	74 **		16.6	3.2	
796036	1	12	Erectile Function	tadalafil 2.5	74 **		16.6	3.2	
796036	1	12	Erectile Function	tadalafil 2.5	74 **		16.6	3.2	
796036	1	12	Erectile Function	tadalafil 2.5	74 **		16.6	3.2	
796036	2	12	Erectile Function	tadalafil 5	151 **		17.7	4.6	
796036	2	12	Erectile Function	tadalafil 5	151 **		17.7	4.6	
796036	2	12	Erectile Function	tadalafil 5	151 **		17.7	4.6	
796036	2	12	Erectile Function	tadalafil 5	151 **		17.7	4.6	
796036	3	12	Erectile Function	tadalafil 10	321 **		21.1	6.5	
796036	3	12	Erectile Function	tadalafil 10	321 **		21.1	6.5	
796036	3	12	Erectile Function	tadalafil 10	321 **		21.1	6.5	
796036	3	12	Erectile Function	tadalafil 10	321 **		21.1	6.5	
796036	4	12	Erectile Function	tadalafil 20	258 **		23.9	7.9	
796036	4	12	Erectile Function	tadalafil 20	258 **		23.9	7.9	
796036	4	12	Erectile Function	tadalafil 20	258 **		23.9	7.9	
796036	4	12	Erectile Function	tadalafil 20	258 **		23.9	7.9	
756003992	1	12	Erectile Function	tadalafil 10	73 *	12.1		0.1	
756003992	2	12	Erectile Function	tadalafil 20	72 *	12.1		6.4	
756003992	90	12	Erectile Function	Placebo	71 *	12.1		7.3	

Appendix 3C - IIEF Scaled Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Interc. Satisfaction									
756005	1.1	3	Interc. Satisfaction	tadalafil 2	35 **		8.7[0.6e]	2.5[0.5e]	
756005	1.2	3	Interc. Satisfaction	tadalafil 5	37 **		9.9[0.4e]	3.4[0.4e]	
756005	1.3	3	Interc. Satisfaction	tadalafil 10	36 **		10.4[0.5e]	3.2[0.6e]	
756005	1.4	3	Interc. Satisfaction	tadalafil 25	36 **		10.8[0.6e]	4.2[0.6e]	
756005	90	3	Interc. Satisfaction	Placebo	35		7.4[0.4e]	1.3[0.4e]	
796036	1	12	Interc. Satisfaction	tadalafil 2.5	74 **		7.8	1.6	
796036	1	12	Interc. Satisfaction	tadalafil 2.5	74 **		7.8	1.6	
796036	1	12	Interc. Satisfaction	tadalafil 2.5	74 **		7.8	1.6	
796036	1	12	Interc. Satisfaction	tadalafil 2.5	74 **		7.8	1.6	
796036	2	12	Interc. Satisfaction	tadalafil 5	151 **		8.5	1.6	
796036	2	12	Interc. Satisfaction	tadalafil 5	151 **		8.5	1.6	
796036	2	12	Interc. Satisfaction	tadalafil 5	151 **		8.5	1.6	
796036	2	12	Interc. Satisfaction	tadalafil 5	151 **		8.5	1.6	
796036	3	12	Interc. Satisfaction	tadalafil 10	321 **		9.3	2.6	
796036	3	12	Interc. Satisfaction	tadalafil 10	321 **		9.3	2.6	
796036	3	12	Interc. Satisfaction	tadalafil 10	321 **		9.3	2.6	
796036	3	12	Interc. Satisfaction	tadalafil 10	321 **		9.3	2.6	
796036	4	12	Interc. Satisfaction	tadalafil 20	258 **		10.5	3.4	
796036	4	12	Interc. Satisfaction	tadalafil 20	258 **		10.5	3.4	
796036	4	12	Interc. Satisfaction	tadalafil 20	258 **		10.5	3.4	
796036	4	12	Interc. Satisfaction	tadalafil 20	258 **		10.5	3.4	
Quest. 3									
756003	1	3	Quest. 3	tadalafil 10	60		4.4		
756003	2	3	Quest. 3	tadalafil 25	58		4.3		
756003	3	3	Quest. 3	tadalafil 50	59		4.7		
756003	90	3	Quest. 3	Placebo	58		3.3	0.25	
756005	1.1	3	Quest. 3	tadalafil 2	35 **	3[0.3e]	3.5[0.3e]	0.6[0.2e]	
756005	1.2	3	Quest. 3	tadalafil 5	37 **	3.1[0.2e]	4.2[0.2e]	1.2[0.2e]	
756005	1.3	3	Quest. 3	tadalafil 10	36 **	3.1[0.3e]	4.1[0.2e]	1[0.2e]	
756005	1.4	3	Quest. 3	tadalafil 25	36 **	2.8[0.3e]	4.2[0.2e]	1.3[0.2e]	
756005	90	3	Quest. 3	Placebo	35	2.6[0.3e]	2.5[0.3e]	-0.3[0.2e]	

Appendix 3C - IIEF Scaled Data
Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quest. 4									
756003	1	3	Quest. 4	tadalafil 10	60		4.2		
756003	2	3	Quest. 4	tadalafil 25	58		4.2		
756003	3	3	Quest. 4	tadalafil 50	59		4.5		
756003	4	3	Quest. 4	tadalafil 100	59		4.4		
756003	90	3	Quest. 4	Placebo	58		2.9	0.51	
756005	1.1	3	Quest. 4	tadalafil 2	35 **	2.5[0.2e]	3.1[0.3e]	0.8[0.2e]	
756005	1.2	3	Quest. 4	tadalafil 5	37 **	2.3[0.2e]	3.7[0.2e]	1.4[0.2e]	
756005	1.3	3	Quest. 4	tadalafil 10	36 **	2.4[0.2e]	4[0.2e]	1.7[0.2e]	
756005	90	3	Quest. 4	Placebo	35	1.9[0.2e]	2.4[0.3e]	0.2[0.2e]	

Appendix 3C - IIEF Scaled Data
Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
758008	1	12	Erectile Function	vardenafil 5	146	14.2[5.8]	20.9[7.3]	5.7	
758008	2	12	Erectile Function	vardenafil 10	140	14.1[6.1]	22.1[7.5]	8	
758008	3	12	Erectile Function	vardenafil 20	147	13.8[5.7]	22.8[7.5]	9	
758008	90	12	Erectile Function	Placebo	147	14[5.7]	15.6[7.3]	1.6	
901052	1	12	Erectile Function	vardenafil 5	190	12.5	18.4		
901052	2	12	Erectile Function	vardenafil 10	196	13.4	20.6		
901052	3	12	Erectile Function	vardenafil 20	186	12.8	21.4		
901052	90	12	Erectile Function	Placebo	177	13.6	15		
901052	1	26	Erectile Function	vardenafil 5	190	12.5	17.8		
901052	2	26	Erectile Function	vardenafil 10	196	13.4	21.2		
901052	3	26	Erectile Function	vardenafil 20	186	12.8	21.8		
901052	90	26	Erectile Function	Placebo	177	13.6	14.8		
Interc. Satisfaction									
758008	1	12	Interc. Satisfaction	vardenafil 5	146	7.1[2.3]	10[3.3]	2.9	
758008	2	12	Interc. Satisfaction	vardenafil 10	140	7.1[2.4]	10.6[3.1]	3.5	
758008	3	12	Interc. Satisfaction	vardenafil 20	147	7.1[2.5]	10.7[3.2]	3.6	
758008	90	12	Interc. Satisfaction	Placebo	147	7.3[2.3]	8.3[2.9]	1	
Quest. 3									
758008	1	12	Quest. 3	vardenafil 5	146	2.5[1.4]	3.7[1.5]	1.2[1.7]	
758008	2	12	Quest. 3	vardenafil 10	140	2.6[1.4]	3.9[1.5]	1.3[1.5]	
758008	3	12	Quest. 3	vardenafil 20	147	2.5[1.4]	4[1.4]	1.5[1.7]	
758008	90	12	Quest. 3	Placebo	147	2.5[1.4]	2.7[1.5]	0.2[1.5]	
Quest. 4									
758008	1	12	Quest. 4	vardenafil 5	146	2.1[1.2]	3.5[1.5]	1.4[1.7]	
758008	2	12	Quest. 4	vardenafil 10	140	2.1[1.3]	3.6[1.5]	1.5[1.6]	
758008	3	12	Quest. 4	vardenafil 20	147	2.1[1.2]	3.8[1.4]	1.7[1.6]	
758008	90	12	Quest. 4	Placebo	147	2[1.2]	2.5[1.5]	0.5[1.7]	

Appendix 3C - IIEF Scaled Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Erectile Function									
796089	1	2	Erectile Function	yohimbine 6	45	14.3[5.64]	15.4[6.49]		
796089	1.2	2	Erectile Function	yohimbine 6	22		18.2[5.59]		
796089	2	2	Erectile Function	Yohimbine + L-Arginine glutamate 6 grams 6	45	14.3[5.64]	17.2[7.17]		
796089	2.2	2	Erectile Function	Yohimbine + L-Arginine glutamate 6 grams 6	22		22.2[4.99]		
796089	90	2	Erectile Function	Placebo	45	14.3[5.64]	14.1[6.56]		
796089	90.2	2	Erectile Function	Placebo	22		16.9[6.91]		
Interc. Satisfaction									
796089	1	2	Interc. Satisfaction	yohimbine 6	45	7[2.05]	7.4[2.24]		
796089	1.2	2	Interc. Satisfaction	yohimbine 6	22		7.8[2.28]		
796089	2	2	Interc. Satisfaction	Yohimbine + L-Arginine glutamate 6 grams 6	45	7[2.05]	7.7[2.97]		
796089	2.2	2	Interc. Satisfaction	Yohimbine + L-Arginine glutamate 6 grams 6	22		9.1[2.73]		
796089	90	2	Interc. Satisfaction	Placebo	45	7[2.05]	6.9[2.43]		
796089	90.2	2	Interc. Satisfaction	Placebo	22		7.1[2.65]		
Quest. 3									
796089	1	2	Quest. 3	yohimbine 6	45	2.7[2.69]	2.7[1.47]		
796089	1.2	2	Quest. 3	yohimbine 6	22		3.3[1.49]		
796089	2	2	Quest. 3	Yohimbine + L-Arginine glutamate 6 grams 6	45	2.7[2.69]	3[1.49]		
796089	2.2	2	Quest. 3	Yohimbine + L-Arginine glutamate 6 grams 6	22		3.9[1.17]		
796089	90	2	Quest. 3	Placebo	45	2.7[2.69]	2.5[1.49]		
796089	90.2	2	Quest. 3	Placebo	22		3.1[1.63]		

Appendix 3C - IIEF Scaled Data
Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quest. 4									
796089	1	2	Quest. 4	yohimbine 6	45	2.2[1.34]	2.4[1.34]		
796089	1.2	2	Quest. 4	yohimbine 6	22		2.8[1.33]		
796089	2	2	Quest. 4	Yohimbine + L-Arginine glutamate 6 grams 6	45	2.2[1.34]	2.8[1.53]		
796089	2.2	2	Quest. 4	Yohimbine + L-Arginine glutamate 6 grams 6	22		3.9[1.23]		
796089	90	2	Quest. 4	Placebo	45	2.2[1.34]	2.2[1.42]		
796089	90.2	2	Quest. 4	Placebo	22		2.7[1.58]		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
% of attempts resulting in intercourse (part surv)									
795500991	1	4	% of attempts resulting in intercourse (part surv)[0,100]	Apomorphine 3	194 **	24.2	49.3		
795500991	1	4	% of erections firm for intercourse-partner survey[0,100]	Apomorphine 3	194 **	24.3	48.3		
795500991	90	4	% of erections firm for intercourse-partner survey[0,100]	Placebo 3	194 **	24.3	34		
795500992	1	4	% of attempts resulting in intercourse (part surv)[0,100]	Apomorphine 3	102 **	24	50.9		
795500992	2	4	% of attempts resulting in intercourse (part surv)[0,100]	Apomorphine 4	102 **	24	52.3		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Sexual encounter profile									
750054	1	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	36	1.63	3.43		
750054	2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	36	1.63	3.23		
750054	3	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	1.63	3.37		
750054	4	999	Sexual encounter profile[0,6]	sildenafil 100	36	1.63	3.5		
750054	1.1	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	7	1.45	3.2		
750054	2.1	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	7	1.45	2.41		
750054	3.1	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	7	1.45	2.86		
750054	4.1	999	Sexual encounter profile[0,6]	sildenafil 100	7	1.45	2.53		
750054	1.2	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	29	1.67	3.6		
750054	2.2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	29	1.67	3.45		
750054	3.2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	29	1.67	3.42		
750054	4.2	999	Sexual encounter profile[0,6]	sildenafil 100	29	1.67	3.69		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Successful intercourse rate									
795501	1.2	4	Successful intercourse rate[0,100]	Apomorphine [2,3]	234	21	35		
795501	90.2	4	Successful intercourse rate[0,100]	Placebo [2,3]		23	26		
795500991	1	4	% of attempts resulting in intercourse[0,100]	Apomorphine 3	163	22.9	48		
795500991	90	4	% of attempts resulting in intercourse[0,100]	Placebo 3	194 **	24.2	34.6		
795500991	90	4	% of attempts resulting in intercourse[0,100]	Placebo 3	163	22.9	34		
795500992	1	4	% of attempts resulting in intercourse[0,100]	Apomorphine 3	80	23.5	48.4		
795500992	2	4	% of attempts resulting in intercourse[0,100]	Apomorphine 4	80	23.5	49.6		
795501	1	8	Successful intercourse rate[0,100]	Apomorphine [2,4]	254 **	21	38		
795501	90	8	Successful intercourse rate[0,100]	Placebo [2,4]	253 **	23	28		
750054	1	999	Proportion of successful vaginal penetration[0,1]	40mg phentolamine + 6 mg apomorphine 40	36	0.13	0.58		
750054	2	999	Proportion of successful vaginal penetration[0,1]	40 mg phentolamine + 150mg papaverine 40	36	0.13	0.55		
750054	3	999	Proportion of successful vaginal penetration[0,1]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	0.13	0.59		
750054	4	999	Proportion of successful vaginal penetration[0,1]	sildenafil 100	36	0.13	0.58		
750054	1	999	Proportion of vaginal intercourse and orgasm[0,1]	40mg phentolamine + 6 mg apomorphine 40	36	0.06	0.46		
750054	2	999	Proportion of vaginal intercourse and orgasm[0,1]	40 mg phentolamine + 150mg papaverine 40	36	0.06	0.42		
750054	3	999	Proportion of vaginal intercourse and orgasm[0,1]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	0.06	0.45		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
750054	4	999	Proportion of vaginal intercourse and orgasm[0,1]	sildenafil 100	36	0.06	0.44		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
% of erections firm enough for intercourse									
795500991	1.1	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	45	38	66		
795500991	1	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	163	21.9	46.9		
795500991	90	4	% of erections firm enough for intercourse[,]	Placebo 3	163	21.9	32.3		
795500991	90.1	4	% of erections firm enough for intercourse[0,100]	Placebo 3	45	38	51		
795500991	1.2	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	46	23	55		
795500991	90.2	4	% of erections firm enough for intercourse[0,100]	Placebo 3	46	23	35		
795500991	1.3	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	49	11	33		
795500991	90.3	4	% of erections firm enough for intercourse[0,100]	Placebo 3	49	11	25		
795500991	1.4	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	14	13	42		
795500991	90.4	4	% of erections firm enough for intercourse[0,100]	Placebo 3	14	13	28		
795500991	1.5	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	44	18	50		
795500991	1.6	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	74	22	44		
795500991	90.6	4	% of erections firm enough for intercourse[0,100]	Placebo 3	74	22	32		
795500991	1.7	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	27	21	39		
795500991	90.7	4	% of erections firm enough for intercourse[0,100]	Placebo 3	27	21	29		
795500992	1	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	80	24.3	49.4		
795500992	2	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	80	24.3	50.2		
795500992	1.2	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	28	33	64		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
795500992	1.1	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	16	46	75		
795500992	2.1	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	16	46	74		
795500992	2.2	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	28	33	60		
795500992	1.3	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	25	9	29		
795500992	2.3	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	25	9	37		
795500992	1.4	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	10	17	49		
795500992	2.4	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	10	17	40		
795500992	1.5	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	16	18	44		
795500992	2.5	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	16	18	40		
795500992	1.6	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	24	18	45		
795500992	2.6	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	24	18	46		
795500992	1.7	4	% of erections firm enough for intercourse[0,100]	Apomorphine 3	8	19	28		
795500992	2.7	4	% of erections firm enough for intercourse[0,100]	Apomorphine 4	8	19	36		
795501	1	8	% of erections firm enough for intercourse[0,100]	Apomorphine [2,4]	254 **		62		
795501	90	8	% of erections firm enough for intercourse[0,100]	Placebo [2,4]	253 **		55		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
VAS Duration									
750054	1	999	VAS Duration[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	13.59	39.44		
750054	2	999	VAS Duration[0,100]	40 mg phentolamine + 150mg papaverine 40	36	13.59	39.99		
750054	3	999	VAS Duration[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	13.59	40.53		
750054	4	999	VAS Duration[0,100]	sildenafil 100	36	13.59	42.46		
VAS Satisfaction									
750054	1	999	VAS Satisfaction[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	11.61	36.1		
750054	2	999	VAS Satisfaction[0,100]	40 mg phentolamine + 150mg papaverine 40	36	11.61	36.8		
750054	3	999	VAS Satisfaction[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	11.61	36.83		
750054	4	999	VAS Satisfaction[0,100]	sildenafil 100	36	11.61	40.3		

Appendix 3D - Other Scaled Data

Studies Including Apomorphine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
GAQ									
750054	1	999	GAQ[1,5]	40mg phentolamine + 6 mg apomorphine 40	36		2.92		
750054	2	999	GAQ[1,5]	40 mg phentolamine + 150mg papaverine 40	36		2.98		
750054	3	999	GAQ[1,5]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36		2.92		
750054	4	999	GAQ[1,5]	sildenafil 100	36		2.5		
750054	1	999	VAS Rigidity[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	16.61	44.53		
750054	2	999	VAS Rigidity[0,100]	40 mg phentolamine + 150mg papaverine 40	36	16.61	43.98		
750054	3	999	VAS Rigidity[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	16.61	44.63		
750054	4	999	VAS Rigidity[0,100]	sildenafil 100	36	16.61	46.12		
% of erections firm for intercourse-partner surv									
795500992	1	4	% of erections firm for intercourse-partner surv[0,100]	Apomorphine 3	102 **	26.1	51.3		
795500992	2	4	% of erections firm for intercourse-partner surv[0,100]	Apomorphine 4	102 **	26.1	51.7		
Anxiety about erectile function									
10297992	1	12	Anxiety about erectile function[,]	MUSE [125,1000]	81 **				0.536
10297992	90	12	Anxiety about erectile function[,]	Placebo	78 **				0.199

Appendix 3D - Other Scaled Data

Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Percent successful attempts at intercourse									
10035	1.1	3	Percent successful attempts at intercourse[0,100]	ICI alprostadil [,40]		68	82.2		
10035	2.1	3	Percent successful attempts at intercourse[0,100]	MUSE [,1000]		68	47.4		
10396992	1.1	4	% of injections resulting in intercourse[0,100]	MUSE [125,1000]			56		
10184	1	12	% of injections resulting in intercourse[0,100]	intracavernous PGE1 20		30	85		
10184	2	12	% of injections resulting in intercourse[0,100]	MUSE 100		30	55		
10396992	1	12	% of injections resulting in intercourse[0,100]	MUSE [125,1000]		78 **	51		
10396992	90	12	% of injections resulting in intercourse[0,100]	Placebo [125,1000]		81 **	7.5		
10396992	1.1	12	% of injections resulting in intercourse[0,100]	MUSE [125,1000]			65		
10396992	1.1	12	% of injections resulting in intercourse[0,100]	MUSE [125,1000]			61		

Appendix 3D - Other Scaled Data

Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
time to return to non-erect state (min)									
10644	1.1	0	time to return to non-erect state (min)[0,]	MUSE 125	1490		67		
10644	1.2	0	time to return to non-erect state (min)[0,]	MUSE 250	1492		70		
10644	1.3	0	time to return to non-erect state (min)[0,]	MUSE 500	1117		74		
10644	1.4	0	time to return to non-erect state (min)[0,]	MUSE 1000	1140		79		
10672	90	0	Duration of response (min.)[0,]	Placebo	66 *		7		
10672	1.1	0	Duration of response (min.)[0,]	MUSE 125	66 *		31.7		
10672	1.2	0	Duration of response (min.)[0,]	MUSE 250	66 *		38.5		
10672	1.3	0	Duration of response (min.)[0,]	MUSE 500	66 *		50.7		
10672	1.4	0	Duration of response (min.)[0,]	MUSE 1000	66 *		57		
Comfort (Vis. An. Scale)									
10672	90	0	Comfort (Vis. An. Scale)[0,100]	Placebo	66 *		93.1		
10672	1.1	0	Comfort (Vis. An. Scale)[0,100]	MUSE 125	66 *		86.7		
10672	1.2	0	Comfort (Vis. An. Scale)[0,100]	MUSE 250	66 *		83.4		
10672	1.3	0	Comfort (Vis. An. Scale)[0,100]	MUSE 500	66 *		82.7		
10672	1.4	0	Comfort (Vis. An. Scale)[0,100]	MUSE 1000	66 *		78.9		
10672	90	0	Ease of Administration (Vis. Ana. Scale)[0,100]	Placebo	66 *		92.8		
10672	1.1	0	Ease of Administration (Vis. Ana. Scale)[0,100]	MUSE 125	66 *		92.8		
10672	1.2	0	Ease of Administration (Vis. Ana. Scale)[0,100]	MUSE 250	66 *		91.1		
10672	1.3	0	Ease of Administration (Vis. Ana. Scale)[0,100]	MUSE 500	66 *		90.3		
10672	1.4	0	Ease of Administration (Vis. Ana. Scale)[0,100]	MUSE 1000	66 *		91.5		

Appendix 3D - Other Scaled Data

Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Patient satisfaction									
10035	1.1	3	Patient satisfaction[1,7]	ICI alprostadil [,40]		64	5.7		
10035	2.1	3	Patient satisfaction[1,7]	MUSE [,1000]		65	3.1		
10297992	1	12	Contentment (subdomain of personal wellness)[,]	MUSE [125,1000]		81 **			0.046
10297992	90	12	Contentment (subdomain of personal wellness)[,]	Placebo		78 **			-0.075
10297992	1	12	Personal wellness[,]	MUSE [125,1000]		81 **			0.054
10297992	90	12	Personal wellness[,]	Placebo		78 **			-0.083
10297992	1	12	Relationship with partner[,]	MUSE [125,1000]		81 **			0.343
10297992	90	12	Relationship with partner[,]	Placebo		78 **			-0.105
Penile Response (Vis. Anal. Scale)									
10672	90	0	Penile Response (Vis. Anal. Scale)[0,100]	Placebo		66 *	18.4		
10672	1.1	0	Penile Response (Vis. Anal. Scale)[0,100]	MUSE 125		66 *	41.8		
10672	1.2	0	Penile Response (Vis. Anal. Scale)[0,100]	MUSE 250		66 *	44.2		
10672	1.3	0	Penile Response (Vis. Anal. Scale)[0,100]	MUSE 500		66 *	47.8		
10672	1.4	0	Penile Response (Vis. Anal. Scale)[0,100]	MUSE 1000		66 *	54.3		
10297992	1	12	Quality of erection[,]	MUSE [125,1000]		81 **			0.706
10297992	90	12	Quality of erection[,]	Placebo		78 **			-0.008

Appendix 3D - Other Scaled Data

Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
time to maximal response (min)									
10644	1.1	0	time to maximal response (min)[0,]	MUSE 125	1490		21		
10644	1.2	0	time to maximal response (min)[0,]	MUSE 250	1492		7		
10644	1.2	0	time to maximal response (min)[0,]	MUSE 250	1492		22		
10644	1.3	0	time to maximal response (min)[,]	MUSE 500	11170		23		
10644	1.4	0	time to maximal response (min)[0,]	MUSE 1000	1140		24		
time to onset of response (min)									
10644	1.1	0	time to onset of response (min)[0,]	MUSE 125	1490		7		
10644	1.3	0	time to onset of response (min)[0,]	MUSE 500	1117		7		
10644	1.4	0	time to onset of response (min)[0,]	MUSE 1000	1140		7		
Self esteem (subdomain of personal wellness)									
10297992	1	12	Self esteem (subdomain of personal wellness)[,]	MUSE [125,1000]	81 **				0.059
10297992	90	12	Self esteem (subdomain of personal wellness)[,]	Placebo	78 **				-0.088

Appendix 3D - Other Scaled Data

Studies Including MUSE

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Partner satisfaction									
10035	1.1	3	Partner satisfaction[1,7]	ICI alprostadil [,40]		59	5.3		
10035	2.1	3	Partner satisfaction[1,7]	MUSE [,1000]		60	2.8		
10297992	1	12	Contentment (subdomain-personal wellness)part surv[,]	MUSE [125,1000]		81 **			0.07
10297992	90	12	Contentment (subdomain-personal wellness)part surv[,]	Placebo		78 **			-0.05
10297992	1	12	Personal wellness (partner survey)[,]	MUSE [125,1000]		81 **			0.075
10297992	90	12	Personal wellness (partner survey)[,]	Placebo		78 **			-0.05
10297992	1	12	Relationship with partner (partner survey)[,]	MUSE [125,1000]		81 **			0.348
10297992	90	12	Relationship with partner (partner survey)[,]	Placebo		78 **			0.117
Quality of erection (partner survey)									
10297992	1	12	Quality of erection (partner survey)[,]	MUSE [125,1000]		81 **			0.477
10297992	90	12	Quality of erection (partner survey)[,]	Placebo		78 **			0
Self esteem (subdomain-personal wellness)part surv									
10297992	1	12	Self esteem (subdomain-personal wellness)part surv[,]	MUSE [125,1000]		81 **			0.08
10297992	90	12	Self esteem (subdomain-personal wellness)part surv[,]	Placebo		78 **			-0.045
Overall health (subdomain-pers wellness) part surv									
10297992	1	12	Overall health (subdomain-pers wellness) part surv[,]	MUSE [125,1000]		81 **			0.03
10297992	90	12	Overall health (subdomain-pers wellness) part surv[,]	Placebo		78 **			-0.085

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Sexual encounter profile									
750054	1	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	36	1.63	3.43		
750054	2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	36	1.63	3.23		
750054	3	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	1.63	3.37		
750054	4	999	Sexual encounter profile[0,6]	sildenafil 100	36	1.63	3.5		
750054	1.1	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	7	1.45	3.2		
750054	2.1	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	7	1.45	2.41		
750054	3.1	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	7	1.45	2.86		
750054	4.1	999	Sexual encounter profile[0,6]	sildenafil 100	7	1.45	2.53		
750054	1.2	999	Sexual encounter profile[0,6]	40mg phentolamine + 6 mg apomorphine 40	29	1.67	3.6		
750054	2.2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine 40	29	1.67	3.45		
750054	3.2	999	Sexual encounter profile[0,6]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	29	1.67	3.42		
750054	4.2	999	Sexual encounter profile[0,6]	sildenafil 100	29	1.67	3.69		

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Percent successful attempts at intercourse									
10035	1.1	3	Percent successful attempts at intercourse[0,100]	ICI alprostadil [,40]	68		82.2		
10035	2.1	3	Percent successful attempts at intercourse[0,100]	MUSE [,1000]	68		47.4		
10184	1	12	% of injections resulting in intercourse[0,100]	intracavernous PGE1 20	30		85		
10184	2	12	% of injections resulting in intercourse[0,100]	MUSE 100	30		55		
750054	1	999	Proportion of successful vaginal penetration[0,1]	40mg phentolamine + 6 mg apomorphine 40	36	0.13	0.58		
750054	2	999	Proportion of successful vaginal penetration[0,1]	40 mg phentolamine + 150mg papaverine 40	36	0.13	0.55		
750054	3	999	Proportion of successful vaginal penetration[0,1]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	0.13	0.59		
750054	4	999	Proportion of successful vaginal penetration[0,1]	sildenafil 100	36	0.13	0.58		
750054	1	999	Proportion of vaginal intercourse and orgasm[0,1]	40mg phentolamine + 6 mg apomorphine 40	36	0.06	0.46		
750054	2	999	Proportion of vaginal intercourse and orgasm[0,1]	40 mg phentolamine + 150mg papaverine 40	36	0.06	0.42		
750054	3	999	Proportion of vaginal intercourse and orgasm[0,1]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	0.06	0.45		
750054	4	999	Proportion of vaginal intercourse and orgasm[0,1]	sildenafil 100	36	0.06	0.44		

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
VAS Duration									
750054	1	999	VAS Duration[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	13.59	39.44		
750054	2	999	VAS Duration[0,100]	40 mg phentolamine + 150mg papaverine 40	36	13.59	39.99		
750054	3	999	VAS Duration[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	13.59	40.53		
750054	4	999	VAS Duration[0,100]	sildenafil 100	36	13.59	42.46		
Patient satisfaction									
10035	1.1	3	Patient satisfaction[1,7]	ICI alprostadil [,40]	64		5.7		
10035	2.1	3	Patient satisfaction[1,7]	MUSE [,1000]	65		3.1		
750054	1	999	VAS Satisfaction[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	11.61	36.1		
750054	2	999	VAS Satisfaction[0,100]	40 mg phentolamine + 150mg papaverine 40	36	11.61	36.8		
750054	3	999	VAS Satisfaction[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	11.61	36.83		
750054	4	999	VAS Satisfaction[0,100]	sildenafil 100	36	11.61	40.3		

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
GAQ									
750054	1	999	GAQ[1,5]	40mg phentolamine + 6 mg apomorphine 40	36		2.92		
750054	2	999	GAQ[1,5]	40 mg phentolamine + 150mg papaverine 40	36		2.98		
750054	3	999	GAQ[1,5]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36		2.92		
750054	4	999	GAQ[1,5]	sildenafil 100	36		2.5		
750054	1	999	VAS Rigidity[0,100]	40mg phentolamine + 6 mg apomorphine 40	36	16.61	44.53		
750054	2	999	VAS Rigidity[0,100]	40 mg phentolamine + 150mg papaverine 40	36	16.61	43.98		
750054	3	999	VAS Rigidity[0,100]	40 mg phentolamine + 150mg papaverine + 6mg apomorphine 40	36	16.61	44.63		
750054	4	999	VAS Rigidity[0,100]	sildenafil 100	36	16.61	46.12		
Mean # of full erections w/satisfactory sex/month									
790779	1	4	Mean # of full erections w/satisfactory sex/month[0,]	0.8% testosterone cream 2	42		4.05[1.8]		
790779	2	4	Mean # of full erections w/satisfactory sex/month[0,]	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2	42		6.46[2.7]		

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
Avg# of Gr 3 or 4 sex. stimulated erections per wk										
700015	1	4	Avg# of Gr 3 or 4 sex. stimulated erections per wk[0,]	sildenafil [25,75]T		44 **		2.4		
700015	90	4	Avg# of Gr 3 or 4 sex. stimulated erections per wk[0,]	Placebo [25,75]T		44 **		0.8		
704145	1	4	# of erections per week[0,]	Afrodex T		50	0.21	2.34		
704145	90	4	# of erections per week[0,]	Placebo T		50	0.37	0.46		
704145	1.1	4	# of erections per week[0,]	Afrodex T		28	0.21	2.41		
704145	90.2	4	# of erections per week[0,]	Placebo		28	0.54	0.42		
704145	1.2	4	# of erections per week[0,]	Afrodex T		22	0.19	2.25		
704145	90.1	4	# of erections per week[0,]	Placebo T		22	0.15	0.51		
Mean value of time between doses										
700015	1	4	Mean value of time between doses[0,]	sildenafil [25,75]T		44 **		50.2d		
700015	90	4	Mean value of time between doses[0,]	Placebo [25,75]T		44 **		56.7d		
700015	1	4	Minimum time between doses[0,]	sildenafil [25,75]T		44 **		23.9		
700015	90	4	Minimum time between doses[0,]	Placebo [25,75]T		44 **		32.7		
# of orgasms per week										
704145	1	4	# of orgasms per week[0,]	Afrodex T		50	0.16	1.25		
704145	90	4	# of orgasms per week[0,]	Placebo T		50	0.3	0.36		
704145	1.1	4	# of orgasms per week[0,]	Afrodex T		28	0.15	1.4		
704145	90.2	4	# of orgasms per week[0,]	Placebo		28	0.41	0.33		
704145	1.2	4	# of orgasms per week[0,]	Afrodex T		22	0.17	1.05		
704145	90.1	4	# of orgasms per week[0,]	Placebo T		22	0.15	0.4		

Appendix 3D - Other Scaled Data

Studies Including Other

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
# of doses taken per week									
700015	1	4	# of doses taken per week[0,]	sildenafil [25,75]T	40		3.4[0.3e]		
700015	90	4	# of doses taken per week[0,]	Placebo [25,75]T	40		2.6		
Partner satisfaction									
10035	1.1	3	Partner satisfaction[1,7]	ICI alprostadil [,40]	59		5.3		
10035	2.1	3	Partner satisfaction[1,7]	MUSE [,1000]	60		2.8		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Anxiety (All)									
700025	90	6	Anxiety (All)[0,25]	Placebo [25,100]T	174	19.6	19.8		
700025	90	6	Anxiety (All)[0,25]	Placebo [25,100]T	174	19.6	20.3		
700025	1	6	Anxiety (Residual)[0,25]	sildenafil [25,100]T	174	19.4	20.2		
700025	1	6	Depression[0,10]	sildenafil [25,100]T	174	8.9	9		
700025	90	6	Depression[0,10]	Placebo [25,100]T	174	8.9	8.8		
700025	1	6	Impact of erectile problems[5,30]	sildenafil [25,100]T	174	20	24.5		
700025	90	6	Impact of erectile problems[5,30]	Placebo [25,100]T	174	20	20.9		
796190	1	6	ASEX - Arousal[,]	sildenafil [50,100]	44	3.6[1.1]	3[1]	0.7(0.2,1.2)	
796190	90	6	ASEX - Arousal[,]	sildenafil [50,100]	45	3.5[1]	3.6[1.2]		
796190	1	6	ASEX - Orgasm (ability)[,]	sildenafil [50,100]	44	4.5[0.9]	3.2[1.3]	1.3(0.8,1.9)	
796190	90	6	ASEX - Orgasm (ability)[,]	sildenafil [50,100]	45	4.5[1]	4.6[1.1]		
796190	1	6	ASEX - Orgasm (satisfaction)[,]	sildenafil [50,100]	44	3.7[1.4]	2.8[1.3]	1.1(0.5,1.7)	
796190	90	6	ASEX - Orgasm (satisfaction)[,]	sildenafil [50,100]	45	3.7[1.3]	3.8[1.5]		
796190	1	6	CGI-SF[,]	sildenafil [50,100]	44	4.1[1.4]	2.3[1.3]	1.7(1.1,2.1)	
796190	90	6	CGI-SF[,]	sildenafil [50,100]	45	4[1.2]	3.9[0.8]		
796190	1	6	MGH-SFQ - Arousal[,]	sildenafil [50,100]	44	3.7[1.4]	2.6[1.3]	1(0.5,1.6)	
796190	90	6	MGH-SFQ - Arousal[,]	sildenafil [50,100]	45	3.8[1.2]	3.7[1.3]		
796190	1	6	MGH-SFQ - Orgasm (ability)[,]	sildenafil [50,100]	44	4.3[0.9]	2.7[1.3]	1.7(1.1,2.3)	
796190	90	6	MGH-SFQ - Orgasm (ability)[,]	sildenafil [50,100]	45	4.5[1]	4.5[1]		
796190	1	6	MGH-SFQ - Total[,]	sildenafil [50,100]	44	20.5[3.7]	13.9[5.7]	5.8(3.5,8.3)	
796190	90	6	MGH-SFQ - Total[,]	sildenafil [50,100]	45	21.3[3.7]	20.6[4.3]		
200300	1	12	EDITS Score (defined in Methods)[0,100]	sildenafil [25,100]T	124		73.6[3.2e]		
200300	90	12	EDITS Score (defined in Methods)[0,100]	Placebo [25,100]T	121		48.4[3.2e]		
200300	1	12	Partner EDITS Score (defined in Methods)[0,100]	sildenafil [25,100]T	36		63.9[8.1e]		
200300	90	12	Partner EDITS Score (defined in Methods)[0,100]	Placebo [25,100]T	44		33.3[7.5e]		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
10028	1	26	Mean # of grade 3 erections per month[0,]	sildenafil 25	102 **		2.1d		
10028	2	26	Mean # of grade 3 erections per month[0,]	sildenafil 50	107 **		2.4		
10028	3	26	Mean # of grade 3 erections per month[0,]	sildenafil 100	107 **		3.1		
10028	90	26	Mean # of grade 3 erections per month[0,]	Placebo 25	216 **		2.4		
700018	1	26	# of grade 3 erections[0,]	sildenafil [25,100]T	159 **	0.44[0.1e]	1.67[0.11e]		
700018	1	26	# of grade 3 erections[0,]	sildenafil [25,100]T	159 **	0.44[0.1e]	1.67[0.11e]		
700018	90	26	# of grade 3 erections[0,]	Placebo [25,100]T	156 **	0.44[0.1e]	0.63[0.11e]		
700018	90	26	# of grade 3 erections[0,]	Placebo [25,100]T	156 **	0.44[0.1e]	0.63[0.11e]		
10730	1	999	Geo. mean dur (min) of rigidity >60% @ penis base[0,0]	sildenafil 10	10		25.9(11.7,56.8)		
10730	2	999	Geo. mean dur (min) of rigidity >60% @ penis base[0,0]	sildenafil 25	10		24.1(10.3,55.8)		
10730	3	999	Geo. mean dur (min) of rigidity >60% @ penis base[0,0]	sildenafil 50	10		31.8(14.4,69.6)		
10730	90	999	Geo. mean dur (min) of rigidity >60% @ penis base[0,0]	Placebo 50[,10]	10		3.2(1.1,7.9)		
10730	1	999	Geo. mean dur (min) of rigidity >60% @ penis tip[0,0]	sildenafil 10	10		19.1(9.8,36.8)		
10730	2	999	Geo. mean dur (min) of rigidity >60% @ penis tip[0,0]	sildenafil 25	10		26.3(13,52.7)		
10730	3	999	Geo. mean dur (min) of rigidity >60% @ penis tip[0,0]	sildenafil 50	10		26.5(13.7,50.8)		
10730	90	999	Geo. mean dur (min) of rigidity >60% @ penis tip[0,0]	Placebo 50[,10]	10		3(1.3,6.4)		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
Proportion of successful attempts										
10024	1	6	Proportion of successful attempts[0,100]	sildenafil [25,100]T	175 *			55		
10024	90	6	Proportion of successful attempts[0,100]	Placebo [25,100]T	174 *			0		
10223	1	12	% of attempts resulting in intercouse[0,100]	sildenafil [25,100]T	53			73[5e]		
10223	90	12	% of attempts resulting in intercouse[0,100]	Placebo [25,100]T	52			30[5e]		
105033	1	12	Percent successful attempts at intercourse[0,100]	sildenafil [25,100]T	163 **			65		
105033	1	12	Percent successful attempts at intercourse[0,100]	sildenafil [25,100]T	163 **			65		
105033	90	12	Percent successful attempts at intercourse[0,100]	Placebo [25,100]T	166 **			20		
105033	90	12	Percent successful attempts at intercourse[0,100]	Placebo [25,100]T	166 **			20		
105100	1	12	Percent successful attempts at intercourse[0,100]	sildenafil 25	93			64		
105100	2	12	Percent successful attempts at intercourse[0,100]	sildenafil 50	100			73		
105100	3	12	Percent successful attempts at intercourse[0,100]	sildenafil 100	93			73		
105100	90	12	Percent successful attempts at intercourse[0,100]	Placebo	84			25		
700003	1	12	% of attempts successful[0,100]	sildenafil [25,100]T	40	13.8		58.8(48,69)		
700003	90	12	% of attempts successful[0,100]	Placebo [25,100]T	82	13.8		14.4(8.6,23)		
700003	1.1	12	% of attempts successful[0,100]	sildenafil	40	14.1		48.6(34,63)		
700003	90.1	12	% of attempts successful[0,100]	Placebo	37	14.1		15.9(7.7,30)		
700003	1.2	12	% of attempts successful[0,100]	sildenafil	58	12.6		62(45,76)		
700003	90.2	12	% of attempts successful[0,100]	Placebo	40	12.6		16.8(8.2,31)		
700003	1.3	12	% of attempts successful[0,100]	sildenafil	45 *	18.6		63.1(45,79)		
700003	90.3	12	% of attempts successful[0,100]	Placebo	32 *	18.6		20.7(8.4,41)		
700003	1.4	12	% of attempts successful[0,100]	sildenafil	58 *	11.4		56.3(43,69)		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
700003	90.4	12	% of attempts successful[0,100]	Placebo	70 *	11.4		13.4(7.4,23)		
700009	1	12	% of successful attempts at intercourse[0,100]	sildenafil [25,100]T	110			62		
700009	90	12	% of successful attempts at intercourse[0,100]	Placebo [25,100]T	111			30		
796061	1	12	percent successful attempts at intercourse[0,100]	sildenafil [50,100]T	64 *			65		
796061	1	12	percent successful attempts at intercourse[0,100]	sildenafil [50,100]T	64 *			65		
796061	90	12	percent successful attempts at intercourse[0,100]	Placebo [50,100]T	72 *			35		
796061	90	12	percent successful attempts at intercourse[0,100]	Placebo [50,100]T	72 *			35		
796062	1	12	% successful attempts at intercourse[0,100]	sildenafil [25,100]T	67			62.46		
796062	90	12	% successful attempts at intercourse[0,100]	Placebo [25,100]T	66			26.47		
Median proportion of attempts at sexual intercours										
10169	1	6	Median proportion of attempts at sexual intercours[0,100]	sildenafil [25,100]T	168 *			55d		
10169	90	6	Median proportion of attempts at sexual intercours[0,100]	Placebo [25,100]T	168 *			0d		
200300	1	12	How often erections were satisfactory for intercou[0,5]	sildenafil [25,100]T	124 *			3.46		
200300	90	12	How often erections were satisfactory for intercou[0,5]	Placebo [25,100]T	121 *			1.78		
Erections lasting long enough										
10252	1.2	4	Erections lasting long enough[0,5]	sildenafil 50	12			2.71[0.51e]		
10252	90.2	4	Erections lasting long enough[0,5]	Placebo 50	11			1.49[0.61e]		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
durat. erection for pts with ?60% rigidity (min)										
10252	1.1	0	durat. erection for pts with ?60% rigidity (min)[0,]	sildenafil 50	17			3.5d		
10252	90.1	0	durat. erection for pts with ?60% rigidity (min)[0,]	Placebo 50	2			0d		
10021	91	0.012	Duration of erections >60% in minutes[0,]	Placebo 100	16			0.4		
10021	1	0.012	Duration of erections >60% rigid-RigiScan--minutes[0,]	sildenafil 100	16			2.5		
10021	90	0.012	Duration of erections 60% rigid-RigiScan--minutes[0,]	Placebo 100	16			0.5		
10021	2	0.024	Duration of erections >60% rigid-RigiScan--minutes[0,]	sildenafil 100	16			1.4		
700016	1	4	Duration[0,5]	sildenafil 10	90	1.5		2.6[0.3e]		
700016	2	4	Duration[0,5]	sildenafil 25	80	1.5		2.8[0.3e]		
700016	3	4	Duration[0,5]	sildenafil 50	75	1.5		3.2[0.3e]		
700016	90	4	Duration[0,5]	Placebo 999	91	1.5		2.1[0.3e]		
10021	1	999	Mean duration of Grade 3-4 erection in minutes[0,]	sildenafil 100	16			19.4		
10021	91	999	Mean duration of Grade 3-4 erection in minutes[0,]	Placebo 100	16			2.9		
10021	90	999	Mean duration of Grade 3-4 erections in minutes[0,]	Placebo 100	16			3.9		
10021	2	999	Mean duration of Grade 3-4 erections in minutes[0,]	sildenafil 100	16			13.9		
10161	1	999	Duration of rigidity (minutes)[0,]	sildenafil 25	8	8.9		17.9		
10161	90	999	Duration of rigidity (minutes)[0,]	Placebo 25	8	8.9		10.4		
10161	2	999	Duration of rigidity (minutes)[0,]	sildenafil 50	8	8.9		25.6		
10161	91	999	Duration of rigidity (minutes)[0,]	Placebo 50	8	8.9		13.5		
700023	1	999	Mean duration of rigidity (minutes)[0,]	sildenafil 25	15	7.9		23.1		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
700023	90	999	Mean duration of rigidity (minutes)[0,]	Placebo 25	15	7.9	8.7		
700023	2	999	Mean duration of rigidity (minutes)[0,]	sildenafil 50	15	7.9	28.9		
700023	91	999	Mean duration of rigidity (minutes)[0,]	Placebo 50	15	7.9	10.5		
Subject's satisfaction with sex life									
10252	1.2	4	Subject's satisfaction with sex life[0,5]	sildenafil 50	12		3.72[0.37e]		
10252	90.2	4	Subject's satisfaction with sex life[0,5]	Placebo 50	13		2.2[0.4e]		
796190	1	6	ASEX - Total[,]	sildenafil [50,100]	44	19.5[4.3]	14.8[4.8]	4.7(2.7,6.8)	
796190	90	6	ASEX - Total[,]	sildenafil [50,100]	45	19.6[3.7]	19.6[4.8]		
796190	1	6	MGH-SFQ - Overall satisfaction[,]	sildenafil [50,100]	44	4.6[0.8]	3[1.4]	1.3(0.7,1.9)	
796190	90	6	MGH-SFQ - Overall satisfaction[,]	sildenafil [50,100]	45	4.7[0.8]	4.3[1]		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Hardness									
700016	1	4	Hardness[0,5]	sildenafil 10	90	2	2.9[0.3e]		
700016	2	4	Hardness[0,5]	sildenafil 25	80	2	3[0.3e]		
700016	3	4	Hardness[0,5]	sildenafil 50	74	2	3.3[0.3e]		
700016	90	4	Hardness[0,5]	Placebo 999	91	2	2.4[0.3e]		
796190	1	6	ASEX - Erectile Function[,]	sildenafil [50,100]	44	4.2[1]	2.9[1.1]	1(0.5,1.5)	
796190	90	6	ASEX - Erectile Function[,]	sildenafil [50,100]	45	4.4[0.9]	4.1[1.1]		
796190	1	6	MGH-SFQ - Erectile Function[,]	sildenafil [50,100]	44	4.4[1.1]	3.1[1.6]	1.4(0.7,2.1)	
796190	90	6	MGH-SFQ - Erectile Function[,]	sildenafil [50,100]	45	4.7[1]	4.8[1.2]		
10161	1	999	Patient self-rating of erections[0,10]	sildenafil 25	8	3.4	5.8		
10161	90	999	Patient self-rating of erections[0,10]	Placebo 25	8	3.4	3.5		
10161	2	999	Patient self-rating of erections[0,10]	sildenafil 50	8	3.4	6.9		
10161	91	999	Patient self-rating of erections[0,10]	Placebo 50	8	3.4	3.8		
700023	1	999	Mean erectile score[0,10]	sildenafil 25	15	4	6		
700023	90	999	Mean erectile score[0,10]	Placebo 25	15	4	4.1		
700023	2	999	Mean erectile score[0,]	sildenafil 50	15	4	7.5		
700023	91	999	Mean erectile score[0,10]	Placebo 50	15	4	4.2		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Mean # of grade 3 or 4 erections									
10708	1	0.012	Mean # of grade 3 or 4 erections[0,]	sildenafil 25		12	1.6		
10708	90	0.012	Mean # of grade 3 or 4 erections[0,]	Placebo 25		12	0.3		
10708	1	0.024	Mean # of grade 3 or 4 erections[0,]	sildenafil 25		12	0.25		
10708	90	0.024	Mean # of grade 3 or 4 erections[0,]	Placebo 25		12	0.3		
10708	1	0.06	Mean # of grade 3 or 4 erections[0,]	sildenafil 25		12	1.2		
10708	90	0.06	Mean # of grade 3 or 4 erections[0,]	Placebo 25		12	0.85		
10708	1	0.071	Mean # of grade 3 or 4 erections[0,]	sildenafil 25		12	0.38		
10708	90	0.071	Mean # of grade 3 or 4 erections[0,]	Placebo 25		12	0		
10223	1	12	Mean # of erections sufficient for intercourse[0,]	sildenafil [25,100]T		53	6.9[0.9e]		
10223	90	12	Mean # of erections sufficient for intercourse[0,]	Placebo [25,100]T		52	2.4[0.9e]		
10028	1	26	Mean # of grade 4 erections per month[0,]	sildenafil 25		102 **	2.2		
10028	2	26	Mean # of grade 4 erections per month[0,]	sildenafil 50		107 **	4.2		
10028	3	26	Mean # of grade 4 erections per month[0,]	sildenafil 100		107 **	3.4		
10028	90	26	Mean # of grade 4 erections per month[,]	Placebo 25		216 **	0.7		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Freq. of erections when sexually stimulated

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
10252	1.2	4	Freq. of erections when sexually stimulated[0,5]	sildenafil 50		12		3.68[0.59e]		
10252	90.2	4	Freq. of erections when sexually stimulated[0,5]	Placebo 50		11		2.57[0.74e]		
700015	1	4	Avg# of Gr 3 or 4 sex. stimulated erections per wk[0,]	sildenafil [25,75]T		44 **		2.4		
700015	90	4	Avg# of Gr 3 or 4 sex. stimulated erections per wk[0,]	Placebo [25,75]T		44 **		0.8		
700016	1	4	# of Grade 3 or 4 erections per week[0,]	sildenafil 10		86	1.8	2.8[0.2e]		
700016	2	4	# of Grade 3 or 4 erections per week[0,]	sildenafil 25		82	1.8	3[0.2e]		
700016	3	4	# of Grade 3 or 4 erections per week[0,]	sildenafil 50		76	1.8	3.6[0.2e]		
700016	90	4	# of Grade 3 or 4 erections per week[0,]	Placebo 999		92	1.8	2.1[0.3e]		
700016	1	4	Frequency of erections[0,5]	sildenafil 10		90	2.4	2.9[0.3e]		
700016	2	4	Frequency of erections[0,5]	sildenafil 25		85	2.4	3.1[0.3e]		
700016	3	4	Frequency of erections[0,5]	sildenafil 50		78	2.4	3.4[0.3e]		
700016	90	4	Frequency of erections[0,5]	Placebo 999		94	2.4	2.7[0.3e]		
700018	1	26	# of grade 4 erections[0,]	sildenafil [25,100]T		159 **	0.44[0.1e]	1.56[0.1e]		
700018	1	26	# of grade 4 erections[0,]	sildenafil [25,100]T		159 **	0.44[0.1e]	1.56[0.1e]		
700018	90	26	# of grade 4 erections[0,]	Placebo [25,100]T		156 **	0.44[0.1e]	0.64[0.12e]		
700018	90	26	# of grade 4 erections[0,]	Placebo [25,100]T		156 **	0.44[0.1e]	0.64[0.12e]		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
# of erections sufficient for intercourse									
10338	1	1.5	# of erections sufficient for intercourse[0,]	sildenafil		20	4.3		
10338	2	1.5	# of erections sufficient for intercourse[0,]	sildenafil		21	3.29		
10338	90	1.5	# of erections sufficient for intercourse[0,]	Placebo		21	1.33		
10252	1.2	4	Freq. of erections hard enough for intercourse[0,5]	sildenafil 50		12	2.75[0.56e]		
10252	90.2	4	Freq. of erections hard enough for intercourse[0,5]	Placebo 50		11	2.13[0.68e]		
10252	1.2	4	Number of erections/week sufficient for penetrat.[0,]	sildenafil 50		12	1.8		
10252	90.2	4	Number of erections/week sufficient for penetrat.[0,]	Placebo 50		14	0.4		
105033	1	12	Number of successful attempts at intercourse[0,]	sildenafil [25,100]T		163 **	5.9		
105033	1	12	Number of successful attempts at intercourse[0,]	sildenafil [25,100]T		163 **	5.9		
105033	90	12	Number of successful attempts at intercourse[0,]	Placebo [25,100]T		166 **	1.5		
105033	90	12	Number of successful attempts at intercourse[0,]	Placebo [25,100]T		166 **	1.5		
Mean value of time between doses									
700015	1	4	Mean value of time between doses[0,]	sildenafil [25,75]T		44 **	50.2d		
700015	90	4	Mean value of time between doses[0,]	Placebo [25,75]T		44 **	56.7d		
700015	1	4	Minimum time between doses[0,]	sildenafil [25,75]T		44 **	23.9		
700015	90	4	Minimum time between doses[0,]	Placebo [25,75]T		44 **	32.7		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
ASEX - Sexual Desire									
796190	1	6	ASEX - Sexual Desire[,]	sildenafil [50,100]	44	3.6[1.3]	2.9[1]	0.7(0.1,1.2)	
796190	90	6	ASEX - Sexual Desire[,]	sildenafil [50,100]	45	3.5[1.3]	3.5[1.3]		
796190	1	6	MGH-SFQ - Sexual Desire[,]	sildenafil [50,100]	44	3.5[1.3]	2.5[1.2]	0.6(0,1.2)	
796190	90	6	MGH-SFQ - Sexual Desire[,]	sildenafil [50,100]	45	3.6[1.4]	3.2[1.2]		
# of doses taken per week									
700015	1	4	# of doses taken per week[0,]	sildenafil [25,75]T	40		3.4[0.3e]		
700015	90	4	# of doses taken per week[0,]	Placebo [25,75]T	40		2.6		
SF-12 Mental Health									
700025	1	6	SF-12 Mental Health[0,100]	sildenafil [25,100]T	174	49.4	51.3		
700025	90	6	SF-12 Mental Health[0,100]	Placebo [25,100]T	174	49.4	50.1		
Quality of life: Sex life									
700008	1	10	Quality of life: Sex life[0,5]	sildenafil [25,100]T	14		4.21		
700008	90	10	Quality of life: Sex life[0,5]	Placebo [25,100]T	16		2.19		
700003	1	12	Quality of life: sexual life domain[1,6]	sildenafil [25,100]T	102 *		3.79		
700003	90	12	Quality of life: sexual life domain[1,6]	Placebo [25,100]T	103 *		2.55		
Positive well-being									
700025	1	6	Positive well-being[0,20]	sildenafil [25,100]T	174	12.4	13.4		
700025	90	6	Positive well-being[0,20]	Placebo [25,100]T	174	12.4	13		
700008	1	10	Whole life quality of life[0,5]	sildenafil [25,100]T	14		4.93		
700008	90	10	Whole life quality of life[0,5]	Placebo [25,100]T	16		4.69		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Partner's rating - achieving an erection

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
105033	90	12	Partner's rating - achieving an erection[0,5]	Placebo [25,100]T		38		1.9		
105033	90	12	Partner's rating - achieving an erection[0,5]	Placebo [25,100]T		38		1.9		
105033	1	12	Partner's rating - achieving erection[0,5]	sildenafil [25,100]T		34		3.5		
105033	1	12	Partner's rating - achieving erection[0,5]	sildenafil [25,100]T		34		3.5		
105100	1	12	Partner's rating ability to achieve erection[0,5]	sildenafil 25		128 **		2.64		
105100	2	12	Partner's rating ability to achieve erection[0,5]	sildenafil 50		132 **		3.59		
105100	3	12	Partner's rating ability to achieve erection[0,5]	sildenafil 100		127 **		3.55		
105100	90	12	Partner's rating ability to achieve erection[0,5]	Placebo		127 **		2.01		
200300	1	12	Partner rating of patient's erections[0,5]	sildenafil [25,100]T		31	2.2	3.8[0.5e]		
200300	90	12	Partner rating of patient's erections[0,5]	Placebo [25,100]T		25	2.2	1.7[0.5e]		
750205	2	12	Partner question # 1 (achieve erection)[0,5]	sildenafil [25,100]T		40 *	2.3	3.8		
750205	1	12	Partner question #1 (achieve erection)[0,5]	sildenafil [25,100]		229 *	2.4	3.3		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
Partner's rating - maintaining an erection										
105033	1	12	Partner's rating - maintaining an erection[0,5]	sildenafil [25,100]T		34		3.1		
105033	1	12	Partner's rating - maintaining an erection[0,5]	sildenafil [25,100]T		34		3.1		
105033	90	12	Partner's rating - maintaining an erection[0,5]	Placebo [25,100]T		38		1.2		
105033	90	12	Partner's rating - maintaining an erection[0,5]	Placebo [25,100]T		38		1.2		
105100	1	12	Partner's rating ability to maintain erection[0,5]	sildenafil 25		128 **		2.38		
105100	2	12	Partner's rating ability to maintain erection[0,5]	sildenafil 50		132 **		3.55		
105100	3	12	Partner's rating ability to maintain erection[0,5]	sildenafil 100		127 **		3.52		
105100	90	12	Partner's rating ability to maintain erection[0,5]	Placebo		127 **		1.84		
200300	1	12	Partner rating of maintained erections[0,5]	sildenafil [25,100]T		31	1.5	3.8[0.5e]		
200300	90	12	Partner rating of maintained erections[0,5]	Placebo [25,100]T		25	1.5	1.3[0.5]		
750205	1	12	Partner question # 2 (maintain erection)[0,5]	sildenafil [25,100]		229 *	1.7	3		
750205	2	12	Partner question # 2 (maintain erection)[0,5]	sildenafil [25,100]T		40 *	1.2	3		
Quality of sex life (partner's assessment)										
10252	1.2	4	Quality of sex life (partner's assessment)[0,5]	sildenafil 50		10		3.36[0.37e]		
10252	90.2	4	Quality of sex life (partner's assessment)[0,5]	Placebo 50		10		2.84[0.41e]		
200300	1	12	Partner rating of satisfaction w/ sexual intercour[0,5]	sildenafil [25,100]T		31	1.9	3.1[0.5e]		
200300	90	12	Partner rating of satisfaction w/ sexual intercour[0,5]	Placebo [25,100]T		25	1.9	1.2[0.5e]		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Quality of partner's erection									
10252	1.2	4	Quality of partner's erection[0,5]	sildenafil 50	10		3.78[0.45e]		
10252	90.2	4	Quality of partner's erection[0,5]	Placebo 50	9		2.84[0.5e]		
Partner response to IIEF Q3+Q4									
700018	1	12	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	43	2.2	4.1		
700018	1	12	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	43	2.2	4.1		
700018	1	12	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	36		2.2		
700018	1	12	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	36		2.2		
700018	1	26	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	46	1.7	3.8		
700018	1	26	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	39		1.7		
700018	1	26	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	46	1.7	3.8		
700018	1	26	Partner response to IIEF Q3+Q4[0,10]	sildenafil [25,100]T	39		1.7		

Appendix 3D - Other Scaled Data

Studies Including Sildenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
Ability to achieve erection (assessed by partner)										
10027992	2	6	Ability to achieve erection (assessed by partner)[0,5]	sildenafil [25,100]T		72		3.84		
10027992	90.2	6	Ability to achieve erection (assessed by partner)[0,5]	Placebo [25,100]T		73		2.64		
10027992	0.2	6	Ability to achieve erections (assessed by partner)[0,5]			178 **	2.25			
10027991	1	12	Ability to achieve erection (assessed by partner)[0,5]	sildenafil [25,100]T		34		3.52		
10027991	90.1	12	Ability to achieve erection (assessed by partner)[0,5]	Placebo [25,100]T		38		1.89		
10027991	0.1	12	Ability to achieve erections (assessed by partner)[0,5]			329 **	1.86			
Ability to maintain erection (assessed by partner)										
10027992	0.2	6	Ability to maintain erection (assessed by partner)[0,5]			178 **	1.46			
10027992	2	6	Ability to maintain erection (assessed by partner)[0,5]	sildenafil [25,100]T		72		3.25		
10027992	90.2	6	Ability to maintain erection (assessed by partner)[0,5]	Placebo [25,100]T		73		1.96		
10027991	0.1	12	Ability to maintain erection (assessed by partner)[0,5]			329 **	1.26			
10027991	1	12	Ability to maintain erection (assessed by partner)[0,5]	sildenafil [25,100]T		34		3.11		
10027991	90.1	12	Ability to maintain erection (assessed by partner)[0,5]	Placebo [25,100]T		38		1.18		

Appendix 3D - Other Scaled Data

Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne		Follow-up	Chg. Points	Chg. Percent
Percentage of Successful intercourse attempts										
756005	1.1	3	Percentage of Successful intercourse attempts[0,100]	tadalafil 2		35 **		45.7		
756005	1.2	3	Percentage of Successful intercourse attempts[0,100]	tadalafil 5		37 **		61.7		
756005	1.3	3	Percentage of Successful intercourse attempts[0,100]	tadalafil 10		36 **		69.8		
756005	1.4	3	Percentage of Successful intercourse attempts[0,100]	tadalafil 25		36 **		70.2		
756005	90	3	Percentage of successful intercourse attempts[0,100]	Placebo		35 **	23	26.6		
SEP Q3 % success maintaing erection										
796036	1	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 2.5		74 **		37	20	
796036	1	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 2.5		74 **		37	20	
796036	2	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 5		151 **		40	22	
796036	2	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 5		151 **		40	22	
796036	3	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 10		321 **		58	34	
796036	3	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 10		321 **		58	34	
796036	4	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 20		258 **		70	39	
796036	4	12	SEP Q3 % success maintaing erection[0,100]	tadalafil 20		258 **		70	39	
796036	90	12	SEP Q3 % success maintaing erection[0,100]	Placebo		308 **		31	6	
796036	90	12	SEP Q3 % success maintaing erection[0,100]	Placebo		308 **		31	6	

Appendix 3D - Other Scaled Data

Studies Including Tadalafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
SEP diary Q2 percent successful at achieving erect									
796036	1	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 2.5		74 **	56	15	
796036	1	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 2.5		74 **	56	15	
796036	2	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 5		151 **	57	16	
796036	2	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 5		151 **	57	16	
796036	3	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 10		321 **	73	24	
796036	3	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 10		321 **	73	24	
796036	4	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 20		258 **	80	27	
796036	4	12	SEP diary Q2 percent successful at achieving erect[0,100]	tadalafil 20		258 **	80	27	
796036	90	12	SEP diary Q2 percent successful at achieving erect[0,100]	Placebo		308 **	48	2	
796036	90	12	SEP diary Q2 percent successful at achieving erect[0,100]	Placebo		308 **	48	2	
Mean # of full erections w/satisfactory sex/month									
790779	1	4	Mean # of full erections w/satisfactory sex/month[0,]	0.8% testosterone cream 2		42	4.05[1.8]		
790779	2	4	Mean # of full erections w/satisfactory sex/month[0,]	Cream: 0.8% testosterone, .06% co-dergocrinemesylate and .5% isosorbide dinitrate 2		42	6.46[2.7]		

Appendix 3D - Other Scaled Data

Studies Including Trazodone

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Baseline circumference base (cm) (Rigiscan)									
705000	1	4	Baseline circumference base (cm) (Rigiscan)[0,]	trazodone 200	14	6.8[0.5e]	7.2[0.8e]		
705000	90	4	Baseline circumference base (cm) (Rigiscan)[0,]	Placebo 200	14	7.1[0.6e]	7.1[0.6e]		
705000	1	4	Baseline circumference tip (cm) (Rigiscan)[0,]	trazodone 200	14	6.2[0.4e]	6.3[0.4e]		
705000	90	4	Baseline circumference tip (cm) (Rigiscan)[0,]	Placebo 200	14	6.3[0.6e]	6.3[0.5e]		
705000	1	4	Tumescence Base (cm) (Rigiscan)[0,]	trazodone 200	14	9[0.8e]	9.5[1e]		
705000	90	4	Tumescence Base (cm) (Rigiscan)[0,]	Placebo 200	14	10[1e]	9[0.9e]		
705000	1	4	Tumescence tip (cm) (Rigiscan)[0,]	trazodone 200	14	8[0.9e]	8[0.9e]		
705000	90	4	Tumescence tip (cm) (Rigiscan)[0,]	Placebo 200	14	8[1.4e]	8[1.5e]		
Duration of erection w / rigidty >/=60% in seconds									
705000	1	4	Duration of erection w / rigidty >/=60% in seconds[0,]	trazodone 200	16 **		513		
705000	90	4	Duration of erection w/ rigidty >/=60% in seconds[0,]	Placebo 200	17 **		157		
705000	1	4	Erection duration base [Rigiscan] (cm)[0,]	trazodone 200	14	42[46e]	50[40e]		
705000	90	4	Erection duration base [Rigiscan] (cm)[0,]	Placebo 200	14	40[42e]	43[34e]		
705000	1	4	Erection duration tip [Rigiscan] (cm)[0,]	trazodone 200	14	34[28e]	41[27e]		
705000	90	4	Erection duration tip [Rigiscan] (cm)[0,]	Placebo 200	14	35[34e]	31[18e]		
Index of sexual satisfaction									
705001	1	12	Index of sexual satisfaction[,]	trazodone 50	48 **	31.7	27.5		
705001	90	12	Index of sexual satisfaction[,]	Placebo 50	48 **	28.5	30.8		

Appendix 3D - Other Scaled Data

Studies Including Trazodone

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Mean desire score measured with VAS									
705000	1	0	Mean desire score measured with VAS[,]	trazodone 200		16 **	44		
705000	90	0	Mean desire score measured with VAS[,]	Placebo 200		17 **	27		
% Rigidity base (Rigiscan)									
705000	1	4	% Rigidity base (Rigiscan)[0,100]	trazodone 200		14	47[12e]	51[12e]	
705000	90	4	% Rigidity base (Rigiscan)[0,100]	Placebo 200		14	47[14e]	47[10e]	
705000	1	4	% Tumescence Base (Rigiscan)[0,100]	trazodone 200		14	37[8e]	34[10e]	
705000	90	4	% Tumescence Base (Rigiscan)[0,100]	Placebo 200		14	34[4e]	33[5e]	
% Rigidity Tip (Rigiscan)									
705000	1	4	% Rigidity Tip (Rigiscan)[0,100]	trazodone 200		14	43[13e]	43[12e]	
705000	90	4	% Rigidity Tip (Rigiscan)[0,100]	Placebo 200		14	41[10e]	38[11e]	
705000	1	4	% Tumescence Tip (Rigiscan)[0,100]	trazodone 200		14	30[9e]	30[10e]	
705000	90	4	% Tumescence Tip (Rigiscan)[0,100]	Placebo 200		14	29[7e]	29[11e]	

Appendix 3D - Other Scaled Data

Studies Including Vardenafil

Rigiscan rigidity activity units (tip)

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
758007	1	0.006	Rigiscan rigidity activity units (tip)[0,]	vardenafil 20		21	43.1[26.2]		
758007	2	0.006	Rigiscan rigidity activity units (tip)[0,]	vardenafil 40		21	46.1[20.4]		
758007	90	0.006	Rigiscan rigidity activity units (tip)[0,]	Placebo 20		20	13.9[13.8]		
758007	1	0.006	Rigiscan tumescence activity units (tip)[0,]	vardenafil 20		21	25.9[20.9]		
758007	2	0.006	Rigiscan tumescence activity units (tip)[0,]	vardenafil 40		21	24.7[12.1]		
758007	90	0.006	Rigiscan tumescence activity units (tip)[0,]	Placebo 20		20	7.9[9.1]		
758007	1	0.006	Rigiscan; rigidity activity units (base)[0,]	vardenafil 20		21	51[30.3]		
758007	90	0.006	Rigiscan; rigidity activity units (base)[0,]	Placebo 20		20	16.6[14.3]		
758007	1	0.006	Rigiscan; tumescence activity units (base)[0,]	vardenafil 20		21	28.3[18.7]		
758007	2	0.006	Rigiscan; tumescence activity units (base)[0,]	vardenafil 40		21	30.2[14.6]		
758007	90	0.006	Rigiscan; tumescence activity units (base)[0,]	Placebo 20		20	10.2[9.8]		
758010	1	0.006	Rigiscan; Rigidity activity units (base)[0,]	vardenafil 10		21	47.9[23.3]		
758010	2	0.006	Rigiscan; Rigidity activity units (base)[0,]	vardenafil 20		21	59.5[31.5]		
758010	90	0.006	Rigiscan; Rigidity activity units (base)[0,]	Placebo 10		21	27.4[20.6]		
758010	1	0.006	Rigiscan; Rigidity activity units (tip)[0,]	vardenafil 10		21	33.1[20.8]		
758010	2	0.006	Rigiscan; Rigidity activity units (tip)[0,]	vardenafil 20		21	43[29.6]		
758010	90	0.006	Rigiscan; Rigidity activity units (tip)[0,]	Placebo 10		21	16.6[17.2]		
758010	1	0.006	Rigiscan; Tumescence activity units (base)[0,]	vardenafil 10		21	25[14.1]		

Appendix 3D - Other Scaled Data

Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
758010	2	0.006	Rigiscan; Tumescence activity units (base)[0,]	vardenafil 20	21		35.5[25.9]		
758010	90	0.006	Rigiscan; Tumescence activity units (base)[0,]	Placebo 10	21		14.2[10.7]		
758010	1	0.006	Rigiscan; Tumescence activity units (tip)[0,]	vardenafil 10	21		17.9[12.4]		
758010	2	0.006	Rigiscan; Tumescence activity units (tip)[0,]	vardenafil 20	21		19.1[16.2]		
758010	90	0.006	Rigiscan; Tumescence activity units (tip)[0,]	Placebo 10	21		8.1[8.5]		
758008	1	12	Fugl-Meyer Score[,]	vardenafil 5	128 *			1.1	
758008	2	12	Fugl-Meyer Score[,]	vardenafil 10	123 *			1.5	
758008	3	12	Fugl-Meyer Score[,]	vardenafil 20	131 *			1.7	
758008	90	12	Fugl-Meyer Score[,]	Placebo	124 *			0.5	
%Successful intercourse attempts									
758008	1	12	%Successful intercourse attempts[0,100]	vardenafil 5	128 *	28.9	71.1		
758008	2	12	%Successful intercourse attempts[0,100]	vardenafil 10	123 *	26.1	70.9		
758008	3	12	%Successful intercourse attempts[0,100]	vardenafil 20	131 *	24.2	74.6		
758008	90	12	%Successful intercourse attempts[0,100]	Placebo	124 *	23.7	39.5		

Appendix 3D - Other Scaled Data

Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Mean success rate (ability to penetrate) per patie									
901052	1	12	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 5	189	42.8	65.5		
901052	2	12	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 10	194	45.4	75.5		
901052	3	12	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 20	182	40.9	80.5		
901052	90	12	Mean success rate (ability to penetrate) per patie[0,100]	Placebo	171	46	51.7		
901052	1	26	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 5	189	42.7	65.9		
901052	2	26	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 10	194	45.3	75.6		
901052	3	26	Mean success rate (ability to penetrate) per patie[0,100]	vardenafil 20	182	40.8	81.1		
901052	90	26	Mean success rate (ability to penetrate) per patie[0,100]	Placebo	172	45.6	51.9		
Mean success rate (duration sufficient for interco									
901052	1	12	Mean success rate (duration sufficient for interco[0,100]	vardenafil 5	188	14	50.6		
901052	2	12	Mean success rate (duration sufficient for interco[0,100]	vardenafil 10	194	14.6	64.5		
901052	3	12	Mean success rate (duration sufficient for interco[0,100]	vardenafil 20	182	14.7	64.5		
901052	90	12	Mean success rate (duration sufficient for interco[0,100]	Placebo	171	14.9	32.2		
901052	1	26	Mean success rate (duration sufficient for interco[0,100]	vardenafil 5	188	14	51.7		
901052	2	26	Mean success rate (duration sufficient for interco[0,100]	vardenafil 10	194	14.6	64.7		
901052	3	26	Mean success rate (duration sufficient for interco[0,100]	vardenafil 20	182	14.7	66.7		
901052	90	26	Mean success rate (duration sufficient for interco[0,100]	Placebo	172	14.8	32.7		

Appendix 3D - Other Scaled Data

Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Rigiscan time with base>60% rigidity (min)									
758007	1	0.006	Rigiscan time with base>60% rigidity (min)[0,]	vardenafil 20	21		58.1[35.3]	42.9	
758007	2	0.006	Rigiscan time with base>60% rigidity (min)[0,]	vardenafil 40	21		64.5[26.4]	49.3	
758007	90	0.006	Rigiscan time with base>60% rigidity (min)[0,]	Placebo 20	20		13.6[15.2]		
758010	2	0.006	Rigiscan; time at base >60% rigid (min)[0,]	vardenafil 20	21		66.9[38.5]		
758010	90	0.006	Rigiscan; time at base >60% rigid (min)[0,]	Placebo 10	21		30.6[23.5]		
758010	1	0.006	Rigiscan; time with base > 60% rigidity (min)[0,]	vardenafil 10	21	54.1	[26.6]		
Rigiscan; time with tip >60% rigid (min)									
758007	1	0.006	Rigiscan; time with tip >60% rigid (min)[0,]	vardenafil 20	21		48.7[30.4]		
758007	2	0.006	Rigiscan; time with tip >60% rigid (min)[0,]	vardenafil 40	21		48.7[26.7]		
758007	90	0.006	Rigiscan; time with tip >60% rigid (min)[0,]	Placebo 20	20		12.8[15.1]		
758010	1	0.006	Rigiscan; Time at tip >60% rigid (min)[0,]	vardenafil 10	21		39.2[26.3]		
758010	2	0.006	Rigiscan; Time at tip >60% rigid (min)[0,]	vardenafil 20	21		44.6[36]		
758010	90	0.006	Rigiscan; Time at tip >60% rigid (min)[0,]	Placebo 10	21		17.1[19.8]		

Appendix 3D - Other Scaled Data

Studies Including Vardenafil

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Rigiscan time with base>80% rigidity (min)									
758007	1	0.006	Rigiscan time with base>80% rigidity (min)[0,]	vardenafil 20		21	29.8[25.5]		
758007	2	0.006	Rigiscan time with base>80% rigidity (min)[0,]	vardenafil 40		21	39.1[25.7]		
758007	90	0.006	Rigiscan time with base>80% rigidity (min)[0,]	Placebo 20		20	6[10.6]		
758010	1	0.006	Rigiscan; time at base >80% rigid (min)[0,]	vardenafil 10		21	25.2[24.5]		
758010	2	0.006	Rigiscan; time at base >80% rigid (min)[0,]	vardenafil 20		21	31.6[33.4]		
758010	90	0.006	Rigiscan; time at base >80% rigid (min)[0,]	Placebo 10		21	15.7[19.2]		
Rigiscan; time with tip >80% rigid (min)									
758007	1	0.006	Rigiscan; time with tip >80% rigid (min)[0,]	vardenafil 20		21	18.5[21.6]		
758007	2	0.006	Rigiscan; time with tip >80% rigid (min)[0,]	vardenafil 40		21	22.6[21.7]		
758007	90	0.006	Rigiscan; time with tip >80% rigid (min)[0,]	Placebo 20		20	5.2[8.7]		
758010	1	0.006	Rigiscan; Time at tip >80% rigid (min)[0,]	vardenafil 10		21	9.4[13.2]		
758010	2	0.006	Rigiscan; Time at tip >80% rigid (min)[0,]	vardenafil 20		21	21.5[29.5]		
758010	90	0.006	Rigiscan; Time at tip >80% rigid (min)[0,]	Placebo 10		21	6.9[13.5]		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
VAS orgasm									
10631	1	3.6	VAS orgasm[0,100]	yohimbine 36	29 **	79	82		
10631	90	3.6	VAS orgasm[0,100]	yohimbine 36	27 *	79	79		
704037	1	4	# of night erections per month[0,0]	yohimbine [5,10]	11	8.1[1.9e]	8.4[3.2e]		
704037	91	4	# of night erections per month[0,0]	Placebo [5,10]	11	8.1[1.9e]	9.1[3.2e]		
704037	2	4	# of night erections per month[0,0]	yohimbine [5,10]	15	14[2.2e]	17.5[2.1e]		
704037	92	4	# of night erections per month[0,0]	Placebo 10[,5]	15	14[2.2e]	14.9[2.1e]		
704037	1	4	Sexual arousal with intercourse (Diary)[1,10]	yohimbine [5,10]	11		7.1[0.6e]		
704037	91	4	Sexual arousal with intercourse (Diary)[1,10]	Placebo [5,10]	11		7[0.6e]		
704037	2	4	Sexual arousal with intercourse (diary)[1,10]	yohimbine [5,10]	15		7.8[0.2e]		
704037	92	4	Sexual arousal with intercourse (diary)[1,10]	Placebo 10[,5]	15		8[0.3e]		
704037	1	4	Sexual arousal with masturbation (Diary)[1,10]	yohimbine [5,10]	11		5.8[1.4e]		
704037	91	4	Sexual arousal with masturbation (Diary)[1,10]	Placebo [5,10]	11		4.5[1.1e]		
704037	2	4	Sexual arousal with masturbation (diary)[1,10]	yohimbine [5,10]	15		7.7[0.3e]		
704037	92	4	Sexual arousal with masturbation (diary)[1,10]	Placebo 10[,5]	15		7.6[0.3e]		
10400	1	999	Odds rati for treatment effect of yohimbine[0,]	yohimbine [5,5.4]	419		3.85(6.67,2.22)		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Able to get erection									
704037	1	4	Able to get erection[1,7]	yohimbine [5,10]	11	2.2[0.6e]	2.6[0.5e]		
704037	91	4	Able to get erection[1,7]	Placebo [5,10]	11	2.2[0.6e]	2.4[0.6e]		
704037	2	4	Able to get erection[1,7]	yohimbine [5,10]	15	6.7[0.2e]	6.9[0.1e]		
704037	92	4	Able to get erection[1,7]	Placebo 10[,5]	15	6.7[0.2e]	6.4[0.1e]		
704037	1	4	Able to keep erection[1,7]	yohimbine [5,10]	11	2.4[0.5e]	2.2[0.5e]		
704037	91	4	Able to keep erection[1,7]	Placebo [5,10]	11	2.4[0.5e]	2.5[0.5e]		
704037	2	4	Able to keep erection[1,7]	yohimbine [5,10]	15	6.5[0.1e]	6.5[0.2e]		
704037	92	4	Able to keep erection[1,7]	Placebo 10[,5]	15	6.5[0.1e]	6.5[0.1e]		
VAS duration of erection									
10631	1	3.6	VAS duration of erection[0,100]	yohimbine 36	29 **	60	47		
10631	90	3.6	VAS duration of erection[0,100]	yohimbine 36	27 *	60	40		
VAS rigidity of penis									
10631	1	3.6	VAS rigidity of penis[0,100]	yohimbine 36	29 **	49	59		
10631	90	3.6	VAS rigidity of penis[0,100]	yohimbine 36	27 *	49	58		
704037	1	4	Firmness of erection with intercourse (Diary)[1,10]	yohimbine [5,10]	11		6.4[1e]		
704037	91	4	Firmness of erection with intercourse (Diary)[1,10]	Placebo [5,10]	11		6[1.1e]		
704037	2	4	Firmness of erection with intercourse (diary)[1,10]	yohimbine [5,10]	15		9.1[0.4e]		
704037	92	4	Firmness of erection with intercourse (diary)[1,10]	Placebo 10[,5]	15		9.2[0.3e]		
Ejactulation when desired									
704037	2	4	Ejactulation when desired[1,7]	yohimbine [5,10]	15	6.2[0.3e]	6.8[0.4e]		
704037	92	4	Ejactulation when desired[1,7]	Placebo 10[,5]	15	6.2[0.3e]	6.2[0.3e]		
704037	1	4	Ejaculation when desired[1,7]	yohimbine [5,10]	11	4.1[0.6e]	6.2[1.1e]		
704037	91	4	Ejaculation when desired[1,7]	Placebo [5,10]	11	4.1[0.6e]	4.6[0.7e]		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
Firmness of erection with masturbation (diary)									
704037	2	4	Firmness of erection with masturbation (diary)[1,10]	yohimbine [5,10]	15		9.2[0.3e]		
704037	92	4	Firmness of erection with masturbation (diary)[1,10]	Placebo 10[,5]	15		9.1[0.3e]		
704037	1	4	Firmness of erections with masturbation (Diary)[1,10]	yohimbine [5,10]	11		7[0.6e]		
704037	91	4	Firmness of erections with masturbation (Diary)[1,10]	Placebo [5,10]	11		5.3[0.8e]		
# of erections per week									
704145	1	4	# of erections per week[0,]	Afrodex T	50	0.21	2.34		
704145	90	4	# of erections per week[0,]	Placebo T	50	0.37	0.46		
704145	1.1	4	# of erections per week[0,]	Afrodex T	28	0.21	2.41		
704145	90.2	4	# of erections per week[0,]	Placebo	28	0.54	0.42		
704145	1.2	4	# of erections per week[0,]	Afrodex T	22	0.19	2.25		
704145	90.1	4	# of erections per week[0,]	Placebo T	22	0.15	0.51		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
# intercourse per month									
704037	1	4	# intercourse per month[0,0]	yohimbine [5,10]	11	3.2[1e]	3.4[1.1e]		
704037	91	4	# intercourse per month[0,0]	Placebo [5,10]	11	3.2[1e]	2.4[1.3e]		
704037	2	4	# intercourse per month[0,0]	yohimbine [5,10]	15	5.1[0.7e]	5.3[1.1e]		
704037	92	4	# intercourse per month[0,0]	Placebo 10[,5]	15	5.1[0.7e]	4.5[1.1e]		
704037	1	4	# intercourse per week (Diary)[0,0]	yohimbine [5,10]	11		4[1.3e]		
704037	91	4	# intercourse per week (Diary)[0,0]	Placebo [5,10]	11		2.7[1e]		
704037	2	4	# intercourse per week (diary)[0,0]	yohimbine [5,10]	15		3.8[0.9e]		
704037	92	4	# intercourse per week (diary)[0,0]	Placebo 10[,5]	15		3.5[0.9e]		
704037	1	4	# of erections with sex per month[0,0]	yohimbine [5,10]	11	3.1[0.7e]	5.1[1.4e]		
704037	91	4	# of erections with sex per month[0,0]	Placebo [5,10]	11	3.1[0.7e]	2.6[0.7e]		
704037	2	4	# of erections with sex per month[0,0]	yohimbine [5,10]	15	14.9[2.4e]	13.3[1.8e]		
704037	92	4	# of erections with sex per month[0,0]	Placebo 10[,5]	15	14.9[2.4e]	13[1.4e]		
# of ejaculations per month									
704037	1	4	# of ejaculations per month[0,0]	yohimbine [5,10]	11	3.2[1.1e]	6[1.6e]		
704037	91	4	# of ejaculations per month[0,0]	Placebo [5,10]	11	3.2[1.1e]	3.7[1.1e]		
704037	2	4	# of ejaculations per month[0,0]	yohimbine [5,10]	15	14.9[2.8e]	12.5[1.8e]		
704037	92	4	# of ejaculations per month[0,0]	Placebo 10[,5]	15	14.9[2.8e]	13.1[1.9e]		
704145	1	4	# of orgasms per week[0,]	Afrodex T	50	0.16	1.25		
704145	90	4	# of orgasms per week[0,]	Placebo T	50	0.3	0.36		
704145	1.1	4	# of orgasms per week[0,]	Afrodex T	28	0.15	1.4		
704145	90.2	4	# of orgasms per week[0,]	Placebo	28	0.41	0.33		
704145	1.2	4	# of orgasms per week[0,]	Afrodex T	22	0.17	1.05		
704145	90.1	4	# of orgasms per week[0,]	Placebo T	22	0.15	0.4		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
# sexual fantasies per week									
704037	2	4	# sexual fantasies per week[0,0]	yohimbine [5,10]		15	8.1[1.1e]		
704037	92	4	# sexual fantasies per week[0,0]	Placebo 10[,5]		15	9.2[1.2e]		
704037	1	4	# sexual fantasies per week (Diary)[0,0]	yohimbine [5,10]		11	4.8[1.3e]		
704037	91	4	# sexual fantasies per week (Diary)[0,0]	Placebo [5,10]		11	4[0.8e]		
VAS libido									
10631	1	3.6	VAS libido[0,100]	yohimbine 36		29 ** 74	75		
10631	90	3.6	VAS libido[0,100]	yohimbine 36		27 * 74	72		
704037	1	4	Interest in sex[1,7]	yohimbine [5,10]		11 4[0.7e]	4.4[0.6e]		
704037	91	4	Interest in sex[1,7]	Placebo [5,10]		11 4[0.7e]	3.9[0.5e]		
704037	2	4	Interest in sex[1,7]	yohimbine [5,10]		15 5.3[0.7e]	4.7[0.4e]		
704037	92	4	Interest in sex[1,7]	Placebo 10[,5]		15 5.3[0.7e]	5[0.3e]		
704037	1	4	Sexual fantasies[1,7]	yohimbine [5,10]		11 3[0.7e]	3.5[0.6e]		
704037	91	4	Sexual fantasies[1,7]	Placebo [5,10]		11 3[0.7e]	2.9[0.4e]		
704037	2	4	Sexual fantasies[1,7]	yohimbine [5,10]		15 4.1[0.4e]	4.3[0.4e]		
704037	92	4	Sexual fantasies[1,7]	Placebo 10[,5]		15 4.1[0.4e]	4.3[0.3e]		

Appendix 3D - Other Scaled Data

Studies Including Yohimbine

Ref#	Grp #	Wks	Outcome measure	Treatment	Patients	Baselilne	Follow-up	Chg. Points	Chg. Percent
# masturbations per month									
704037	1	4	# masturbations per month[0,0]	yohimbine [5,10]	11	3.3[1.5e]	3.4[1.7e]		
704037	91	4	# masturbations per month[0,0]	Placebo [5,10]	11	3.3[1.5e]	3.2[1.3e]		
704037	2	4	# masturbations per month[0,0]	yohimbine [5,10]	15	11.1[2.7e]	8.5[1.4e]		
704037	92	4	# masturbations per month[0,0]	Placebo 10[,5]	15	11.1[2.7e]	7.3[1.3e]		
704037	1	4	# of masturbations per week (Diary)[0,0]	yohimbine [5,10]	11		2.8[1.1e]		
704037	91	4	# of masturbations per week (Diary)[0,0]	Placebo [5,10]	11		2.4[0.8e]		
704037	2	4	# of masturbations per week (Diary)[0,0]	yohimbine [5,10]	15		3.5[0.6e]		
704037	92	4	# of masturbations per week (Diary)[0,0]	Placebo 10[,5]	15		3.5[0.7e]		

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AUA Guideline on the Management of Erectile Dysfunction: An Update

This document was written by the Erectile Dysfunction Guideline Update Panel of the American Urological Association Education and Research, Inc., which was created in 2000. The Practice Guidelines Committee (PGC) of the AUA selected the committee chairs. Panel members were selected by the chairs. Membership of the committee included urologists with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the management of erectile dysfunction. This document was submitted for peer review to 80 urologists and other health care professionals. After the final revisions were made based upon the peer review process, the document was submitted to and approved by the PGC and the Board of Directors of the AUA. Funding of the committee was provided by the AUA. Committee members received no remuneration for their work. Each member of the committee provided a conflict of interest disclosure to the AUA.

This report is intended to provide medical practitioners with a consensus of principles and strategies for the management of erectile dysfunction. The report is based on current professional literature, clinical experience and expert opinion. Some of the medical therapies currently employed in the management of ED have not been approved by the U.S. Food and Drug Administration (FDA) for this specific indication. Thus, doses and dosing regimens may deviate from that employed for FDA-approved indications, and this difference should be considered in the risk-versus-benefit assessment. This document does not establish a fixed set of rules or define the legal standard of care and it does not pre-empt physician judgment in individual cases.

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