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## **Eugene Dula, MD, FACS**

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### **CURRICULUM VITAE**

#### **Credentials:**

Medical License: G56131

2001 Diplomat - American Board of Urology  
1992 Diplomat - American Board of Urology

#### **Education:**

1975 - 1979 Bachelor of Science - Psychobiology, UCLA, Los Angeles, California  
1979 - 1984 Doctor of Medicine - Mount Sinai School of Medicine, New York,  
New York  
1984 - 1985 Internship, Surgery: Kaiser Foundation Hospital, Los Angeles, California  
1985 - 1986 Residency, Surgery: Kaiser Foundation Hospital, Los Angeles, California  
1986 - 1990 Residency, Urology: Kaiser Foundation Hospital, Los Angeles, California

#### **Work Experience:**

1992 - Present Medical Director - West Coast Clinical Research, Tarzana, California  
1991 - 2006 Partner - Western Urologic Associates Medical Group, Tarzana,  
California  
2 - Present Partner, San Fernando Valley Urological Associates, Tarzana, CA  
1989 - 1990 Chief Resident in Urology - Kaiser Foundation Hospital, Los Angeles,  
California

#### **Hospital Affiliations:**

2000 - 2002 Member, Executive Medical Committee, Valley Presbyterian Hospital, Van  
Nuys, California  
1999 - 2004 Member, Credentials Committee, Valley Presbyterian Hospital, Van Nuys,  
California  
1999 - Present Member, Ethical review board Tarzana Regional Medical Center  
1995 - 1996 Chairman, Medical Records Committee, Valley Presbyterian Hospital, Van  
Nuys, California

**Curriculum Vitae For:**  
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1993 - 2000	Member, Utilization Review Committee, Valley Presbyterian Hospital, Van Nuys, California
1993 - 1996	Chief, Department of Urology, Valley Presbyterian Hospital, Van Nuys, California
1991 - Present	Active Staff, Valley Presbyterian Hospital, Van Nuys, California
1990 - Present	Active Staff, West Hills Hospital, West Hills, California
1990 - Present	Active Staff, Tarzana Regional Medical Center, Tarzana, California

**Professional Affiliations:**

1999 - Present	Member, European Society of Impotence Research
1998 - Present	Member, International Society for the Study of Impotence Research
1997 - Present	Member, Sexual Medicine Society
1997 - 1999	Member, Association of Clinical Research Professionals
1996 - Present	Member, Society for Urodynamics and Female Urology
1995 - 1996	Committee Member, California Urologic Association
1993 - 1995	Member, Help for Incontinent People
1999 - Present	Member, International Society for the Study of Women's Sexual Health
1992 - Present	Fellow, American College of Surgeons
1990 - Present	Member, Western Section American Urologic Association
1986 - Present	Member, American Urologic Association

**Research Activities:**

**Cardiology - Acute Myocardial Infarction**

1. A Randomized, Double-Blind, Placebo Controlled Trial Of The Effect Of Weekly XXXXX on the Incidence of Coronary Artery Disease in Subjects With Evidence of Exposure to C.Pneumoniae.

**Cardiology - Angina**

2. A Phase III, Multicenter, International, Randomized, Double-Blind, Aspirin-Controlled Trial to Evaluate the Efficacy and Safety of Two Regimens With XXXXX, an Oral Platelet Glycoprotein IIb/IIIa Receptor Antagonist, As Therapy for the Long Term Prevention of Secondary Vascular Events In Patients after an Acute Coronary Syndrome.

**Cardiology - Atrial Fibrillation**

3. A Multicenter, Double-Blind, Placebo Controlled, Parallel Design Clinical Trial To Assess the Efficacy and Safety of 50 mg, 100 mg, and 125 mg of XXXXX For The Prophylactic Treatment of Symptomatic Atrial Fibrillation/Flutter And/Or Symptomatic Paroxysmal Sypraventricular Tachycardia.
4. A Multicenter, Open-Label Clinical Trial To Assess The Long-Term Safety Of 100mg Of XXXXX In Patients With Atrial Fibrillation/Flutter And/Or Symptomatic Paroxysmal Supraventricular Tachycardia.

**Cardiology - Hypertension**

5. A Randomized, Double-Blind, XXXXX And XXXXX Controlled Study Of XXXXX in Subjects With Mild To Moderate Hypertension.
6. A Randomized, Double-Blind, Active-Controlled Evaluation of the Antihypertensive Response to XXXXX in Subjects Uncontrolled on Calcium-Channel Blocker Therapy
7. A Randomized, Double-Blind, Active-Controlled Evaluation of the Antihypertensive Response to XXXXX in Subjects Uncontrolled on Ace Inhibitor Monotherapy.
8. XXXXX Cardiovascular Treatment Assessment Versus XXXXX

**Cardiology - Intermittent Claudication**

9. A Twenty-four Week, Randomized, Double-Blind Study of the Effects of XXXXX versus XXXXX and Placebo Administered Orally To Patients With Intermittent Claudication Secondary to Peripheral Arterial Disease
10. A Randomized, Double-Blind Study Of The Effects Of XXXXX Versus XXXXX Or Placebo In Patients With Intermittent Claudication Secondary To Peripheral Vascular Disease.

**Endocrinology - Non-Insulin Dependent Diabetes Mellitus**

11. A Randomized, Double-Blind, Placebo Controlled, Thirty-Six Week Safety And Efficacy Trial Of XXXXX 0.5, 1 Or 2mg Three Times Daily In Elderly Type II Diabetes Mellitus Patients (Non-Insulin Dependent Diabetes Mellitus, NIDDM).
12. An Open-Label, Long Term Extension Study Of XXXXX In Type II Diabetes Mellitus (Non-Insulin Dependent Diabetes Mellitus, NIDDM).
13. A Randomized, Double-Blind, Placebo Controlled, Thirty-Six Week Safety And Efficacy Trial Of XXXXX 0.5, 1, Or 2 mg Three Times Daily In Elderly Type II Diabetes Mellitus Patients (Non-Insulin Dependent Diabetes Mellitus, NIDDM).
14. A Randomized, Double-Blind, Placebo Controlled, Thirty-Six Week Safety And Efficacy Trial Of XXXXX 0.5, 1, Or 2mg Three Times Daily In Elderly Type II Diabetes Mellitus Patients (Non-Insulin Dependent Diabetes Mellitus, NIDDM).

**Gastroenterology - Constipation**

15. A Multicenter, Randomized, Double-Blind, Placebo Controlled, Phase 2b Study Of Oral XXXXX for the Treatment of Opioid-Induced Constipation In Patients with Chronic, Non-Malignant Pain.

16. A Multicenter, Multinational, Open-Label Study Of Oral XXXXX Comparing Continuous Vs. Intermittent Treatment for Opioid-Induced Constipation In Patients with Chronic, Non-Malignant or Malignant Pain.

**Gastroenterology - Irritable Bowel Syndrome**

17. A Multicenter Non-Drug Study To Develop An Irritable Bowel Syndrome Quality Of Life Questionnaire and Diary.

**Gastroenterology - Non-ulcerative Dyspepsia**

18. A Study To Evaluate The Effects Of XXXXX 30 mg Or 15 mg QD Versus Placebo in Patients with Non-Ulcer Dyspepsia.

**Neuroscience - Pain Syndrome**

19. Phase III Assessment Of Safety And Tolerability Of Oral Sustained Release XXXXX Vs. Oral Immediate Release XXXXX In Patients With Chronic Non-Malignant Pain.

**Other - Chronic Renal Failure**

20. A Dose Ranging, Placebo Controlled, Parallel Group Study To Assess The Efficacy and Safety of XXXXX For Reduction Of Serum Phosphate In Chronic Renal Failure Patients Receiving Hemodialysis.

**Pulmonology - Pneumonia**

21. Comparative Safety And Efficacy Of XXXXX And XXXXX In The Treatment Of Community-Acquired Pneumonia.

**Rheumatology - Osteoarthritis/Rheumatoid Arthritis**

22. Clinical Protocol To Evaluate The Long-Term Safety Of XXXXX In Treating The Signs and Symptoms of Osteoarthritis and Rheumatoid Arthritis.
23. Clinical Protocol For A Multicenter, Double-Blind, Parallel Group Study Comparing the Incidence Of Gastroduodenal Ulcer Associated With XXXXX 200mg BID with That of XXXXX 75mg BID and XXXXX 80mg TID, Taken For 12-Weeks in Patients with Osteoarthritis or Rheumatoid Arthritis.
24. Clinical Protocol To Evaluate The Long-Term Safety Of XXXXX In Treating The Signs and Symptoms of Osteoarthritis and Rheumatoid Arthritis.

**Rheumatology - Rheumatoid Arthritis**

25. A Multicenter, Blinded, Randomized, Placebo Controlled Trial to Study the Ability of XXXXX to Retard Joint Destruction, and Evaluate the Long Term Safety of XXXXX, in Subjects with Rheumatoid Arthritis

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26. A Multicenter Double-blind Study to Evaluate the Safety and Efficacy of XXXXX in Subjects with Rheumatoid Arthritis using XXXXX
27. A Double-Blind, Placebo-Controlled, Randomized, Parallel Group Clinical Trial of XXXXX in Patients with Active RA failing Treatment with XXXXX
28. A Multi-Center Continuation Study of XXXXX Administered as a Subcutaneous Injection in Patients with Rheumatoid Arthritis
29. XXXXX Versus Placebo In The Treatment Of Rheumatoid Arthritis Patients Taking Second-Line Drugs.
30. Clinical Protocol For A Multicenter, Double-Blind, Placebo Controlled, Randomized Comparison Study of the Efficacy and Safety of XXXXX 10 Mg QD, XXXXX 20 Mg QD, XXXXX 40 Mg QD and XXXXX 500 Mg Bid In Treating the Signs and Symptoms of Rheumatoid Arthritis
31. A Multicenter, Randomized, Blinded, Placebo Controlled Study To Describe Long-Term Safety of Daily Subcutaneous Injections of XXXXX in Patients With Rheumatoid Arthritis
32. Clinical Protocol To Evaluate the Long-Term Safety of XXXXX in Treating the Signs and Symptoms of Rheumatoid Arthritis
33. A Multicenter Randomized Double-Blind Placebo-Controlled Study of the XXXXX in Rheumatoid Arthritis Patients Currently Receiving Treatment with XXXXX.

**Urology - Bacterial Prostatitis**

34. A Randomized, Multicenter, Double-Blind, Double-Dummy Comparative Trial Of XXXXX and XXXXX for the Treatment of Bacterial Prostatitis.

**Urology - Benign Prostatic Hypertrophy**

35. A Phase II/III, Double-Blind, Placebo Controlled, Dose Finding Study Of The Safety and Efficacy of XXXXX in Patients with Symptomatic Benign Prostatic Hyperplasia.
36. A Long-Term, Open-Label Clinical Study Evaluating the Safety and Efficacy of XXXXX in Subjects with Symptomatic Benign Prostatic Hyperplasia (BPH).
37. A Phase II/III, Double-Blind, Placebo Controlled, Dose-Finding Study Of The Safety and Efficacy of XXXXX in Patients with Symptomatic Benign Prostatic Hyperplasia (BPH).
38. A Study to Determine the Minimum Perceptible Difference for each of Five Quality of Life Questionnaires for Patients with Benign Prostatic Hyperplasia

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39. A Randomized, Double-Blind, Placebo Controlled, Two-Year, Parallel Group Study of the Efficacy and Safety of XXXXX 0.5mg in the Treatment And Prevention of Progression of Benign Prostatic Hyperplasia.
40. A Randomized, Double-Blind, Placebo Controlled, Parallel Group Study Of The Efficacy and Safety of XXXXX in the Treatment and Modification Of Progression of Benign Prostatic Hyperplasia.
41. XXXXX Versus Placebo In Patients With Irritative Symptoms Of Benign Prostatic Hyperplasia.
42. A Phase II/III, Double-Blind, Placebo Controlled, Dose-Finding Study Of The Safety and Efficacy of XXXXX in Patients with Symptomatic Benign Prostatic Hyperplasia (BPH).
43. A Double-Blind Placebo-Controlled, Parallel-Group Safety And Efficacy Study Evaluating Three Dose Regimens of XXXXX, A Selective Alpha-Adrenergic Antagonist, In the Treatment of Benign Prostatic Hyperplasia
44. The Efficacy, Onset Of Effect, And Safety Of XXXXX Once Daily In The Treatment of Lower Urinary Tract Symptoms of Benign Prostatic Hyperplasia: A Randomized, Placebo-Controlled Trial Using an Acute International Prostate Score
45. A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase II Clinical Trial to Evaluate the Efficacy and Safety of Two Dosing Regimens of XXXXX in Subjects with Symptomatic Benign Prostatic Hyperplasia.
46. A Three-Month, Double-Blind, Placebo Controlled, Randomized, Multicenter Study Of the Effects and Safety of XXXXX in Patients with Symptomatic Benign Prostatic Hyperplasia.
47. An Open-Label, Multicenter Study Of The Effects And Safety Of XXXXX In Patients with Symptomatic Benign Prostatic Hyperplasia.
48. A One-Year, Multicenter, Double-Blind Study Of The Effects Of Once-Daily Dosing With XXXXX 80 mg or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia.
49. A Three-Month, Double-Blind, Placebo Controlled, Randomized, Multicenter Study Assessing the Efficacy and Safety of XXXXX in Patients With Symptomatic Benign Prostatic Hyperplasia.
50. A One-Year Placebo-Controlled Efficacy Study and Long-Term Safety Assessment of XXXXX Intermittent IM Dosage Regimens in Patients with Symptomatic BPH.

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51. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multicenter Study to Evaluate the Urodynamic Effects of XXXXX Once a Day for 12 Weeks in Men With Signs and Symptoms of Benign Prostatic Hyperplasia.
52. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, 5-Group, Multinational Study to Evaluate the Efficacy, Dose Response, and Safety of XXXXX Once-a-Day Dosing for 12 Weeks in Men With Signs and Symptoms of Benign Prostatic Hyperplasia.
53. A Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of XXXXX, in Patients with Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hypertrophy.
54. A Randomized, Double-Blind, Placebo-Controlled, Parallel Design, Multinational Study to Evaluate the Efficacy and Safety of XXXXX 2.5 and 5 mg Once Daily Dosing for 12 Weeks for the Treatment of Erectile Dysfunction and Signs and Symptoms of Benign Prostatic Hyperplasia in Men with Both Erectile Dysfunction and Benign Prostatic Hyperplasia

**Urology - Bladder Cancer (CIS)**

55. Intravesical XXXXX In Patients With Carcinoma In Situ Of The Bladder Who Have Failed Or Have Recurrence Following Treatment With BCG.
56. A Phase II Study: Intravesical XXXXX In Patients With Transitional Cell Carcinoma of The Bladder.

**Urology - Bladder Cancer (Papillary)**

57. Phase III Randomized Study Of A Single Adjunctive Instillation Of Intravesical XXXXX versus No Adjunctive Therapy Immediately Following Transurethral Resection in Patients with Multiple Superficial (Ta/T1) Bladder Tumors.

**Urology - Complicated Urinary Tract Infection**

58. A Randomized, Double-Blind, Multicenter Trial Comparing XXXXX And XXXXX for the Treatment of Complicated Urinary Tract Infections.
59. Prospective, Non-Blinded, Multi-Center Trial To Evaluate The Efficacy And Safety of XXXXX Once-Daily (QD) Modified Release (XXXXX MR) 1000 Mg Tablets In The 7-14 Day Treatment Of Patients With Complicated Urinary Tract Infections (cUTI) or Pyelonephritis.
60. A Randomized, Double-Blind, Multicenter, Phase II/III Comparison Of XXXXX in the Treatment of Complicated Urinary Tract Infection And Pyelonephritis.

**Urology - Erectile Dysfunction**

61. A Randomized, Double-Blind, Parallel, Placebo-Controlled Study in Men with Erectile Dysfunction to Evaluate the Efficacy and Safety of XXXXX When Sexual Attempts Occur at Specific Time Points after Dosing
62. A Randomized, Double-Blind, Parallel, Placebo-Controlled Study To Evaluate The Efficacy And Safety Of XXXXX (2.5 mg and 5 mg) Administered Once Daily To Men With Erectile Dysfunction
63. XXXXX 2.5mg and 5mg Once a Day Compared to Placebo in Day of Onset of Efficacy

**Urology - Erectile Dysfunction (Organic)**

64. A Phase III, Long-Term, Open-Label, Flexible Dose, Safety Extension Study Of XXXXX Tablets in the Treatment of Male Erectile Dysfunction.
65. Open-Label Study Of The Efficacy And Safety Of An Aqueous XXXXX Topical Cream in the Treatment of Erectile Dysfunction.
66. A Randomized, Double-Blind, Parallel, Placebo-Controlled Study To Evaluate The Efficacy and Safety of XXXXX Administered "On Demand" To Men With Erectile Dysfunction.
67. A Phase III, Two-Year, Long Term, Open-Label, Flexible Dose, Safety Extension Study of XXXXX Tablets In The Treatment Of Male Erectile Dysfunction.

**Urology - Erectile Dysfunction (Psychogenic)**

68. A Phase III, Long-Term, Open-Label, Flexible Dose, Efficacy And Safety Study Of XXXXX Tablets in The Treatment Of Male Erectile Dysfunction.

**Urology - Hypogonadism**

69. A Long-Term Study Of The Safety And Effectiveness Of The XXXXX For Hormonal Replacement in Hypogonadal Men.
70. A Two-Arm, Open-Label, Randomized, Multi-Center Pharmacokinetic and Long-Term Safety Study of Intramuscular Injections of 750 mg and 1000 mg XXXXX in Hypogonadal Men.

**Urology - Impotence**

71. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel Group, 3-Month Comparison Study to Investigate the Efficacy And Safety of XXXXX in Males with Erectile Dysfunction and Diabetes Mellitus.



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72. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Fixed-Dose, Parallel Group, 3-Month Comparison Study to Investigate Efficacy and Safety of XXXXX in Males with Erectile Dysfunction And Diabetes Mellitus.
73. A Randomized, Double Blind, Multi-Center, Fixed-Dose, Cross-Over Study To Investigate the Efficacy and Safety of 20mg of XXXXX Given On Demand In Comparison to 100mg of Sildenafil Given On Demand in Males with Erectile Dysfunction and a Diagnosis of Diabetes Mellitus And/Or Hypertension And/Or Hyperlipidemia
74. A Multicenter, Randomized, Placebo Controlled, Two Period (Clinic, Home) Efficacy and Safety Study of Intraurethral Administered XXXXX In The Treatment of Mild to Moderate Erectile Dysfunction.
75. A Phase III Efficacy And Safety Study Of Three Fixed Doses Of XXXXX Tablets versus Placebo in the Treatment of Male Erectile Dysfunction.
76. A Phase III, Long-Term, Open-Label, Flexible Dose, Efficacy And Safety Study Of XXXXX SL Tablets in the Treatment of Male Erectile Dysfunction.
77. A Phase III, Efficacy And Safety Study Of Four Fixed Doses Of XXXXX SL Tablets versus Placebo in the Treatment of Male Erectile Dysfunction.
78. A Randomized, Double-Blind, Placebo-Controlled Study to Assess Duration of Responsiveness to XXXXX in Patients with Erectile Dysfunction.
79. A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXXXX Administered "On Demand" to Patients with Male Erectile Dysfunction.
80. An Evaluation on Effect of XXXXX on Sperm Concentration in Normal Healthy Subjects or Subjects with Mild Erectile Dysfunction.
81. Phase III, Efficacy And Safety Of An Aqueous XXXXX Topical Cream In The Treatment of Erectile Dysfunction.
82. A Randomized, Double-Blind, 4-week, Two-Period Crossover Study to Evaluate Patient Preference for XXXXX versus XXXXX during the Initial Treatment Period for Erectile Dysfunction.
83. Phase II, Multicenter, Parallel, Randomized, Double-Masked, Placebo Controlled, Dose Ranging Study of XXXXX Inhibitor in Diabetic Patients with Erectile Dysfunction.
84. A Phase III, Double-Blind, Randomized Parallel Study Evaluating the Safety and Efficacy of XXXXX Sublingual (2 and 3 mg) in the Treatment of Male Erectile Dysfunction.
85. A Phase III, Twelve-Month, Open-Label, Flexible Dose, Safety Extension Study of XXXXX in the Treatment of Male Erectile Dysfunction.

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86. A Randomized, Placebo-Controlled, Double-Blind, Parallel Design Phase III Trial of the Efficacy and Safety of XXXXX in Male Patients with Erectile Dysfunction.
87. An Open-Label, Parallel Design, Twelve Month Phase III Trial of the Safety and Efficacy of XXXXX in Male Patients with Erectile Dysfunction.
88. A Placebo-Controlled, Randomized, Double-Blind, Crossover, Pilot Study to Evaluate the Efficacy and Safety of Intranasally Administered XXXXX In Patients with Mild-to-Moderate Male Erectile Dysfunction.
89. A Placebo Controlled, Parallel Group, Randomized, Double-Blind, Phase III Trial Of 40 mg and 80 mg Oral XXXXX in Patients with Erectile Dysfunction.
90. An Open-Label, 24-Month Trial Of 40 mg Oral XXXXX In Patients With Minimal Erectile Dysfunction.
91. An Open-Label, 13-Month Trial Of Oral XXXXX In Patients With Mild To Moderate Erectile Dysfunction.
92. A Phase III Crossover Study Evaluating the Efficacy and Safety of XXXXX (2, 3, 4 mg) in Combination with XXXXX (25 or 50 mg) in the Treatment of Male Erectile Dysfunction.
93. A Phase III Efficacy And Safety Study Of Three Fixed Doses Of XXXXX SL Tablets 2, 4, And 5 mg versus Placebo in the Treatment of Male Erectile Dysfunction.
94. A Phase III Efficacy and Safety Study of XXXX 3 mg Tablets Versus Placebo and XXXX 3 mg Tablets Versus XXXX 4 mg Tablets in the Treatment of Male Erectile Dysfunction.
95. A Phase III, Six-Month, Long-Term, Open-Label, Flexible Dose, Safety Extension Study of XXXXX Tablets (2, 3, and 4 mg) in the Treatment of Male Erectile Dysfunction.
96. A Phase III Study Evaluating the Safety and Efficacy of XXXXX (2, 3, or 4 mg) Compared to XXXXX (25, 50 or 100 mg) in the Treatment of Male Erectile Dysfunction.
97. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Dose-Response Study to Investigate the Efficacy, Safety and Dose-Response Relationship of XXXXX Given On-Demand for Twelve Weeks in Men With Erectile Dysfunction.
98. A Double-Blind, Twelve-Week Comparative Efficacy And Safety Study Of Oral XXXXX, Oral XXXXX Vs. Placebo In Patients With Erectile Dysfunction.
99. Screening Protocol For Identification Of Patients With Erectile Dysfunction For Participation in XXXXX (Twelve-Week, Double-Blind, Efficacy and Safety Study of Oral XXXXX, Oral XXXXX Vs. Placebo For The Treatment Of Erectile Dysfunction.)

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100. A Phase III, Efficacy And Safety Study Comparing Escalating Doses Of XXXXX to 5 mg or 6 mg Doses of XXXXX or Placebo in the Treatment Of Male Erectile Dysfunction.
101. A Drug Interaction Study To Evaluate The Safety And Pharmacodynamic Effects Of XXXXX (5mg) Tablets and Antihypertensives or Nitrates.
102. Randomized, Placebo-Controlled, Double-Blind, Parallel Design Trial Of The Efficacy and Safety of XXXXX in Male Patients with Mild to Moderate Erectile Dysfunction
103. Randomized, Placebo-Controlled, Double-Blind, Parallel Design Trial Of The Efficacy and Safety Of XXXXX In Male Patients With Mild To Moderate Erectile Dysfunction
104. A Phase III Evaluation Of The Safety And Efficacy Of XXXXX For Hormonal Replacement in Hypogonadal Men.
105. A Double-Blinded, Randomized Evaluation Of The Safety And Efficacy Of XXXXX in Subjects with Erectile Dysfunction
106. A Phase 2, Randomized, Double-Blind, Twelve Week, Dose-Ranging Efficacy And Safety Study Of XXXXX of 10 mg, 25mg, 50 mg, 200 mg, XXXX 50 mg, Each versus Placebo in Subjects with Erectile Dysfunction

**Urology – Nocturia**

107. A Randomized, Double-Blind, Placebo-Controlled, Three-Arm, Parallel-Group, Fixed-Dose, Multi-Center Study To Assess Efficacy and Safety of Daily Oral Administration of 5 Mg Or 10 Mg of XXXXX versus Placebo in Male And Female Subjects with Nocturia.
108. A Double-Blind, Placebo-Controlled, Randomized US Study To Evaluate The Effect of XXXXX on Nocturia in Patients with Symptoms of Overactive Bladder.
109. A Multi-Center Extension Study Investigating the Long Term Efficacy and Safety of a XXXXX Formulation of XXXXX for the Treatment of Nocturia in Adults.
110. A Randomized, Double Blind, Placebo Controlled, Parallel Group, Multi-Center Study with a Double Blind Extension Investigating the Efficacy and Safety of a XXXXX Formulation of XXXXX for the Treatment of Nocturia in Adults.

**Urology - Non-bacterial Prostatitis**

- 111. A Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of XXXXX in the Treatment of Chronic Nonbacterial Prostatitis.
- 112. A Prospective, Randomized, Double-Blind, Controlled, Multicenter Comparative Trial to Evaluate the Clinical Effects of XXXXX versus XXXXX Versus Placebo in the Treatment of Non-Bacterial Prostatitis.

**Urology - Premature Ejaculation**

- 113. A Placebo-Controlled, Double-Blind, Randomized, Crossover Study of the Efficacy and Safety of XXXX in the Treatment of Rapid Ejaculation.
- 114. Placebo-Controlled, Double-Blind, Randomized, Parallel Study Of The Efficacy and Safety of XXXXX in the Treatment of Rapid Ejaculation.
- 115. An Open-Label Study Of The Long Term Safety Of XXXXX In The Treatment Of Rapid Ejaculation.
- 116. A Phase 2b Multi-Center, Double-Blind, Placebo-Controlled, Parallel Group Dose Response Study to Assess the Efficacy and Safety of Oral XXXXX In Men with Premature Ejaculation.
- 117. A Phase 2 Multi-Center, Open-Label Extension Trial To Assess The Safety And Sustained Efficacy of Oral XXXXX Administered As Required In Adult Men With Premature Ejaculation.
- 118. A Placebo-Controlled, Double-Blind, Randomized, Parallel Study Of The Withdrawal Effects of Chronic Daily and As Needed Dosing With XXXXX In The Treatment of Premature Ejaculation.
- 119. A Phase 2b, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study, With Open-Label Follow On, To Evaluated the Efficacy, Safety and Tolerability of XXXXX in Subjects with Premature Ejaculation.

**Urology - Prostate Cancer**

- 120. A Phase III, Multicenter, Open-Label Randomized Study of XXXXX vs. XXXXX In Patients with Prostate Cancer Who Are Candidates for Initial Hormonal Therapy
- 121. A Rollover, Multicenter, Open-Label, Maintenance Study of Patients with Prostate Cancer Who Were Previously Treated with XXXXX 50 mg or 100 mg IM
- 122. Long-Term Follow-Up of Patients Treated with XXXXX
- 123. Long Term Follow-up of Patients Exposed to XXXXX Gene Therapies

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124. A Phase II Manufacturing Bridging Study of XXXXX and an Evaluation of XXXXX Plus Chemotherapy in Patients with Metastatic Hormone Refractory Prostate Cancer.
125. A Phase I Dose Escalation Study of XXXXX in Patients with Hormone-Refractory Prostate Cancer.
126. Phase I/II Dose Escalation and Efficacy Trial of XXXXX in Patients with Metastatic Hormone-Refractory Prostate Cancer.
127. Phase I/II Dose Escalation and Efficacy Trial of XXXXX in Patients with Metastatic Hormone-Refractory Prostate Cancer.
128. Phase I/II Study of a Prime-Boost Schedule of XXXXX in Hormone-Naïve Prostate Cancer Patients
129. Phase I/II Study of a Prime-Boost Schedule of XXXXX in Hormone-Refractory Prostate Cancer
130. A Multicenter, Phase 2b, Four Arm, Dose Finding, Randomized, Placebo-Controlled Study to Determine the Long Term Prostate Cancer Chemoprevention Efficacy and Safety of 20 mg, 40 mg & 60 mg Daily of XXXXX in Men with High Grade Prostate Intraepithelial Neoplasia (PIN)
131. A Phase I/II Study Evaluating the Safety, Tolerability, and Maximally Tolerated Dose of XXXXX Administered Once Every 3 Weeks.
132. A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXXXX mg XXXXX in Men with Non-Metastatic, Hormone-Refractory Prostate Cancer
133. A Phase III Extension Study to Evaluate the Safety of XXXXX mg XXXXX in Men with Hormone-Refractory Prostate Cancer
134. A Phase III, Multicenter, Open-Label, Randomized Study of XXXXX Vs. XXXXX, In Patients with Prostate Cancer Who Are Candidates for Initial Hormonal Therapy.
135. A Multicenter Study Of XXXXX In Patients With Prostate Cancer In Whom GnRH Agonists Are Contraindicated.
136. A Randomized, Prospective Study Comparing Intermittent Vs. Continuous Androgen Deprivation with XXXXX in Clinical Stage D2 Prostate Cancer.
137. A Randomized Double-Blind Comparative Trial Of XXXXX Versus Placebo In Patients with Early Prostate Cancer.

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138. A Phase B Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial To Assess The Safety And Efficacy Of XXXXX In Delaying The Systematic Progression Of Prostate Cancer In Patients With Intermediate To High Risk Of Recurrence With Rising PSA Levels After Prostatectomy, Prostatectomy And Radiotherapy Or Radiotherapy Alone For Localized Disease.
139. A Four-Year Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study Of The Efficacy And Safety Of XXXXX Administered Orally Once Daily To Reduce The Risk Of Biopsy-Detectable Prostate Cancer.
140. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Of Efficacy And Safety Study Of XXXXX For The Prevention Of Bone Fractures In Men With Prostate Cancer On Androgen Deprivation Therapy.
141. A Randomized, Double-Blind, Placebo-Controlled Study To Evaluate XXXXX In The Treatment of Bone Loss in Subjects Undergoing Androgen Deprivation Therapy For Nonmetastatic Prostate Cancer.
142. An Open-Label, Multi-Center, Extension Study Investigating the Long-Term Safety and Tolerability of XXXXX One-Month Depots in Patients with Prostate Cancer.

**Urology - Prostatic Disease**

143. Evaluation Of Biomarkers In The Diagnosis And Management Of Prostate.

**Urology - Semen Analysis**

144. A Randomized, Double-Blind, Parallel Group Comparison of the Safety of XXXXX and Placebo in Male Subjects with Respect to Testicular Function.
145. An Evaluation on Effect of 20 mg XXXXX on Sperm Concentration in Normal Healthy Subjects or Subjects with Mild Erectile Dysfunction.
146. An Evaluation Of Semen-Characteristics After 40 Weeks Dosing With 20 mg of XXXXX.
147. A Randomized, Double-Blind, Placebo-Controlled, Parallel Arm, Multi-Center Assessing the Effect of Daily Treatment of XXXXX or XXXXX Compared To Placebo on Spermatogenesis Mean Sperm Concentration Count, Morphology, Motility and Reproductive Hormones in Healthy Males Or Males With Mild Erectile Dysfunction.
148. A Multicenter Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Spermatogenesis in Healthy Male Subjects During Administration of XXXXX.
149. A Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of XXXXX Extended Release Tablet on Spermatogenesis in Human Males.
150. Prospective Randomized Double-Blind Study of Sperm Production In Healthy Volunteers Receiving XXXXX or Placebo

**Urology - Stress Urinary Incontinence**

151. XXXXX to the Submucosa of the Bladder Outlet and Proximal Urethra for the Treatment of Stress Urinary Incontinence.
152. Efficacy and Safety of XXXXX Compared with Placebo in Subjects with Stress Urinary Incontinence.
153. Long Term Monitoring of Safety in Subjects Treated with XXXXX for Stress Urinary Incontinence.
154. Efficacy And Safety Of XXXX In Women Of Different Demographic Characteristics and Co-Morbidities with Stress Urinary Incontinence.
155. A 8 Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study Evaluating the Efficacy, Tolerability and Safety Of XXXXX for Women with Stress Urinary Incontinence.

**Urology - Urge Urinary Incontinence**

156. Comparison of the Efficacy and Tolerability of XXXXX and XXXXX in the Treatment of Overactive Bladder.
157. A Randomized Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study to Assess Efficacy and Safety of Daily Oral Administration of XXXXX versus Placebo in Male and Female Subjects with Overactive Bladder.
158. An Open-Label, Long-Term Tolerability Study Of Daily Oral Administration Of XXXXX in Male and Female Subjects With Overactive Bladder.
159. Clinical Efficacy And Safety Of XXXXX As Compared To XXXXX And Placebo. A Phase III, Randomized, Double-Blind, Multinational Study In Patients with Detrusor Over-activity and Symptoms Of Frequency, Urge Incontinence and Urgency.
160. Long-Term Safety, Tolerability and Clinical Efficacy of XXXXX. A Phase III Open, Multinational Study In Patients With Detrusor Over-activity, Symptoms Of Frequency, Urge Incontinence And/Or Urgency.
161. A 6-Week, Double-Blind, Placebo Controlled, Randomized, Parallel Group, Multicenter, Multidose Study of the Efficacy and Safety of XXXXX in Patients with Overactive Bladder Symptoms of Increased Urinary Frequency, Urgency and Urge Incontinence.
162. A Phase IIIB Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of XXXXXX in Subjects with Overactive Bladder, Study XXXXXXXX.

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163. Clinical Efficacy And Tolerability/Safety Of XXXXX Prolonged Release Capsules and XXXXX Immediate Release Tablets Vs. Placebo. A Randomized, Double-Blind, Placebo Controlled, Multinational Study in Patients With Symptoms of Overactive Bladder.
164. Safety And Efficacy Of XXXXX Tablets In Men With Bladder Over-activity And Coexisting Bladder Outlet Obstruction. A Multinational, Randomized, Double-Blind and Placebo Controlled, 12-Weeks Study.
165. Long-Term Safety and Efficacy of XXXXX Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder.
166. Randomized, Double-Blind, Placebo-Controlled, Parallel Study to Evaluate the Effects of XXXXX, a 5-HT<sub>4</sub> Receptor Antagonist, in Women, 40-75 Years of Age, with Overactive Bladder.
167. Placebo Controlled Randomized, 12-Week, Dose-Ranging, Double-Blind Study Versus Placebo Using XXXXX as a Study Calibrator, to Evaluate Efficacy and Safety of XXXXX in Women with Overactive Bladder Including

**Urology - Urge Urinary Incontinence**

168. The Maximum Tolerated Dose And Minimum Effective Dose Of XXXXX Compared To XXXXX in the Treatment of Patients with Urge or Mixed Urinary Incontinence.
169. Comparison of the Efficacy and Tolerability of XXXXX and XXXXX in the Treatment of Overactive Bladder.
170. A 52-Week Extension Study to Evaluate Long-Term Safety of Oral XXXXX in Subjects with Overactive Bladder.
171. A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Study to Evaluate the Safety and Efficacy of XXXX in the Treatment of Adult Patients with Overactive Bladder.
172. Long-Term Safety, Tolerability and Clinical Efficacy of XXXXX. A Phase III, Open, Multinational Study in Patients with Detrusor Over-activity And Symptoms of Frequency, Urge Incontinence and Urgency.
173. A Multicenter, Open-Label Study of 20 mg, XXXXX, Twice Daily, for Up to 9 Months to Characterize the Population Pharmacokinetics in Patients with Overactive Bladder Participating in the Open-Label Treatment Phase of Study XXXXX.
174. Double-Blind, Placebo Controlled Study of XXXXX in Subjects with Symptoms of Overactive Bladder of Urgency, Frequency and Urinary Incontinence.
175. A Multi-Center, Double-Blind, Placebo-Controlled Dose Titration Study Of XXXX In Patients with Overactive Bladder.



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176. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial To Investigate the Efficacy, Tolerability and Safety of XXXXX Sustained Release In Subjects with Overactive Bladder Syndrome.
177. Long-Term, Open-Label Extension Trial For Subjects Completing Phase 3 Trial of XXXXX for the Treatment of Overactive Bladder Syndrome.
178. Open-label Extension Study of Sustained Release XXXXX in Subjects with Symptoms of Overactive Bladder.
179. A Long-Term, Open Label, Multicenter Study of XXXXXX in Subjects With Overactive Bladder.
180. A Multicenter, Double-Blind, Placebo-Controlled Study of 20 mg, Twice Daily XXXXX for 12 Weeks Followed by a 9-Month, Open-Label Treatment Phase in Patients with Overactive Bladder.
181. A 12-Week Safety And Efficacy Study Of XXXX Versus Placebo In Subjects With Overactive Bladder.
182. A Methodology Trial To Assess The Reproducibility Of Non-Invasive Measurements Used In the Diagnosis and Assessment of Treatment Outcome For Subjects with Abnormal Voiding.
183. A Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multicenter Study to Assess the Efficacy and Safety of the XXXXX in Subjects with Symptoms of Overactive Bladder.
184. A Randomized, Double-Blind, Parallel Group, Active Controlled, Multicenter Long-term Study to Assess the Safety and Efficacy of the XXXXX in Subjects with Symptoms of Overactive Bladder.

**Women's Health - Female Sexual Dysfunction**

185. A Randomized, Double-Blind, Placebo-Controlled, Fixed Dose, Multi-Center Study to Evaluate the Efficacy, Safety and Toleration of Oral XXXXX Administered For 12 Weeks to Post-Menopausal Women Who Have Been Diagnosed With Female Sexual Arousal Disorder
186. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Fixed Dose, Multi-Center Study To Evaluate the Efficacy, Safety and Toleration of Oral XXXXX Administered For 12 Weeks to Premenopausal Women Who Have Been Diagnosed With Female Sexual Arousal Disorder.
187. Prospective, Randomized, Double-Blind, Placebo-Controlled Evaluation of XXXXX Administered at Home for the Treatment of Women with Female Sexual Arousal Disorder (FSAD).

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188. A Phase 3, Twenty-Four Week, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of XXXXX 25 mg Twice Daily and 50 mg Once and Twice Daily in Premenopausal Women With Hypoactive Sexual Desire in North America.

189. A Phase 3, Twelve Month, Open-Label, Safety Trial of XXXXX 50 mg to 100 mg Daily in Women with Hypoactive Sexual Desire Disorder.

**Publications:**

1. Eric J. Small, Natalie Sacks, John Nemunaitis, Walter J. Urba, Eugene Dula et al. Granulocyte Macrophage Colony-Stimulating Factor—Secreting Allogeneic Immunotherapy for Hormone-Refractory Prostate Cancer. *Clin Cancer Res* 2007;13(13), 3883
2. Eugene Dula, Stan Bufkozer, Renee Perdok, Michael George and The Apomorphine Study Group. "Double Blind, Crossover Comparison of 3mg Apomorphine SL with Placebo and with 4mg Apomorphine SL in Male Erectile Dysfunction", *Eur Urol*, 39:558-564, 2001
3. Eugene Dula "Safety and Efficacy of a Testosterone (T) Gel in a Geriatric Population"; *Journal of Urology*, Vol. 167, 4 Supplement, 1104, Apr, 2001
4. Eugene Dula ,William Keating, Paul F Siami et al "Efficacy and Safety of Fixed-Dose and Dose-Optimization Regimens of Sublingual Apomorphine Versus Placebo in Men with Erectile Dysfunction"; *Urology*, Volume 56,Number 1, Jul, 2000
5. Eugene Dula ,Susan Buttler, Renee Perdok, Kari Agre 1 " Efficacy and Safety of Apomorphine SL vs. Placebo for Erectile Dysfunction in Patients with Coronary Artery Disease"; *The Journal of Urology*", Vol. 163, Apr, 2000
6. Circulation Cross-Sectional Echocardiography. *Circulation*; "Circulation", Vol. 61, Jun, 1980
7. The Etiology of Primary Spontaneous Pneumothorax.; *Mount Sinai Journal of Medicine*", Vol. 52, Jul, 1985
8. The Role of the Urologist in the Diagnosis of Multiple Sclerosis.; *Urology*", Vol. 37, Apr, 1991
9. "Capitation, How much is enough?"; *California Urologic Association Report*", 1996

**Abstracts:**

1. Eugene Dula, "Efficacy and Safety of Apomorphine SL vs. Placebo for erectile dysfunction in patients with Coronary Artery Disease"; *International Journal of Impotence Research*", Vol. 13, supplement 1, S21, Apr, 2001
2. J. Curtis Nickel et al. "Effects of Rofecoxib in patients with chronic nonbacterial prostatitis: A Placebo Controlled Pilot Study"; *J. Urol.*165, 5, 114, Vol. 114, May, 2001
3. Eugene Dula, "Efficacy and Safety of Apomorphine SL vs. Placebo for Erectile Dysfunction in Diabetic Patients"; *International Journal of Impotence Research*, Vol. 12,,Suppl 3 ,S74 B5, Sep, 2000

**Curriculum Vitae For:**  
Eugene Dula, MD, FACS

4. Phase II Trial of a GM-CSF Gene-Transduced Prostate Cancer Cell Line Vaccine in Hormone Refractory Prostate Cancer: Ando, D et al, J. Urol.169, 4, 1479 April 2003.
5. Analysis of the long-term effects of vardenafil on semen characteristics in healthy men, and men with erectile dysfunction, Keith Jarvi, Eugene Dula, Margaret Drehobl, et al. Fertility and Sterility, Volume 88, Supplement 1, September 2007, Pages S388-S389

**Presentations:**

1. "Efficacy and Safety of Apomorphine SL vs. Placebo for Erectile Dysfunction in Patients with Coronary Artery Disease" To: Poster Session at the American Urology Association Jan 2000. Atlanta, Georgia
2. "Efficacy and Safety of Apomorphine SL vs. Placebo for patients with Coronary Artery Disease" To: International Society for Impotence Research Nov 2000. Perth Podium Presentation
3. "Efficacy and Safety of Fixed-Dose and Dose-Optimization Regimens of Sublingual Apomorphine Versus Placebo in Men with Erectile Dysfunction" To: Annual Conference of the European Society of Impotence Research Jan 2000. Barcelona Presentation
4. "The role of the Urologist in the Diagnosis of Multiple Sclerosis" To: Western Section of the American Urologic Association Jan 1987. San Francisco, California
5. "The Urologic Presentation of Multiple Sclerosis" To: Southern California Chapter of the American College of Surgeons Jan 1989. Palm Springs, California
6. "Prostate Cancer Update--1992" To: Medical Staff at NuMed Hospital Canoga Park, California
7. "Prostate Cancer Update--1992" To: Medical Staff at Valley Presbyterian Hospital Jan 1992. Van Nuys, California
8. "Incontinence in Women" To: Seniors Group Jan 1993. Canoga Park, California
9. "Men's Health" To: Rotary Club Jan 1994. Van Nuys, California
10. "Prostate Cancer" To: Golden Vitality Senior Group Jan 1994. Van Nuys, California
11. "Incontinence In Women" To: Golden Vitality Senior Group Jan 1994. Van Nuys, California
12. "Prostate Cancer Update--1994" To: Medial Staff At Valley Presbyterian Hospital Jan 1994. Van Nuys, California
13. "Use of Adjuvant Casodex in the Treatment of Localized Prostate Cancer" To: Prostate Cancer Group Jan 1996. Culver City, California
14. "Incontinence in Women" To: Golden Vitality Senior Group Jan 1996. Van Nuys, California

***Curriculum Vitae For:***  
Eugene Dula, MD, FACS

15. "Female Urinary Incontinence" To: Medical Staff at Valley Presbyterian Hospital Jan 1996. Van Nuys, California
16. "Efficacy and Safety of Apomorphine SL vs. Placebo for Erectile Dysfunction in Diabetic Patients" To: Second Fall Meeting Society for the study of Impotence Sep 2000. Cleveland, Ohio

**Awards:**

University of California, Los Angeles - Cum Laude, Dean's Honor List  
Eliot Corday Research Foundation Scholarship, 1978