Presenter Disclosure Information

Fatema A. Legrand, PhD

The following relationships exist related to this presentation:

BN ImmunoTherapeutics, Salary, Warrants, Employee

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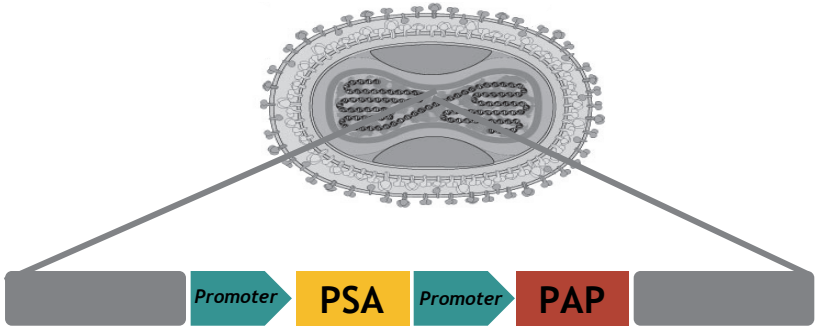
Phase I Dose Escalation Trial of MVA-BN®-PRO in Men with Non-Metastatic Castration Resistant Prostate Cancer



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MVA-BN®-PRO Clinical Trial Objectives

PRIMARY - Evaluate the safety and tolerability of multiple injections of MVA-BN®-PRO

SECONDARY – Evaluate the ability of MVA-BN®-PRO to generate humoral and cellular immune responses to prostate antigens PSA and PAP

EXPLORATORY – Evaluate anti-tumor activity of MVA-BN®-PRO

- PSA level: baseline, monthly, and 6 and 12 months after last vaccination
- Bone scan: baseline and 6 months after last vaccination

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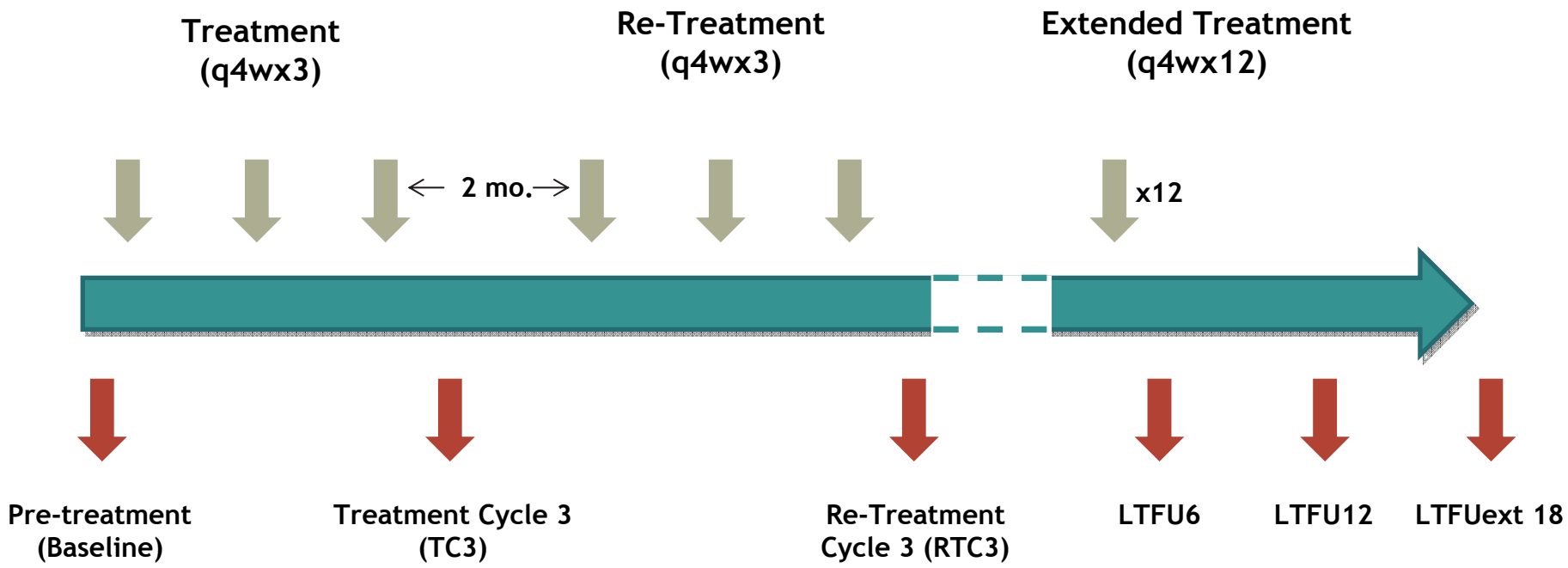
MVA-BN®-PRO Clinical Evaluation Plan



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MVA-BN®-PRO Clinical Trial Summary

	№ Subjects
Cohort 1 (1 ×10^8 $TCID_{50}$)	8
Cohort 2 (2 ×10^8 $TCID_{50}$)	8
Cohort 3 (4×10^8 $TCID_{50}$)	8
Completed Treatment Phase (3 Vaccinations)	24
Completed Retreatment Phase (6 Vaccinations)	21
Extended treatment (Up to 18 Vaccinations) Median No. Vaccinations, Range	7 9 (6-12)

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MVA-BN®-PRO Clinical Trial Characteristics

Baseline Characteristics (n=24)	
Age (Median, Range)	70 (56-83)
ECOG Status (0/1)	21/3
Race (Caucasian/Black/Hispanic)	17/3/4
Previous Smallpox Vaccination (Yes/No/Unknown)	19/2/3
Prior Curative Intent Treatment for CRPC, n (%) Radical prostatectomy, external beam radiation, and/or brachytherapy	20 (83)
Adverse Events^ (Chills, Arthralgia, Fatigue, Peripheral Edema, Myalgia, Bladder spasms, Upper respiratory Tract Congestion)	3-4/(13-17)

^One serious AE, atrial tachycardia, was reported that was unrelated to study treatment.

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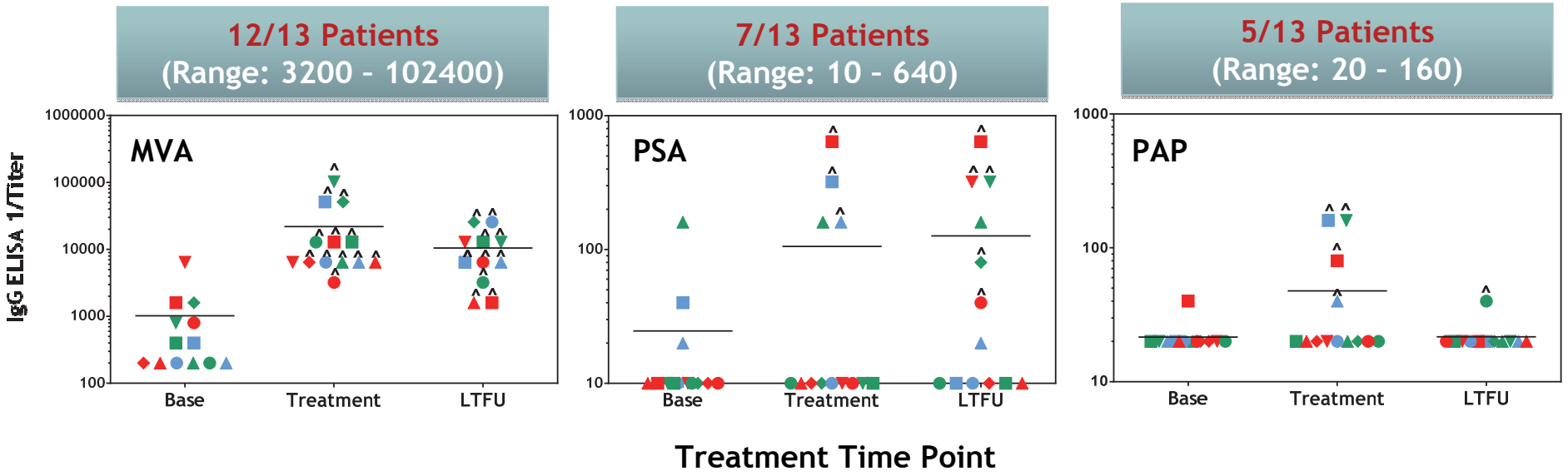
Vaccine Induced Humoral Responses to Standard MVA-BN®-PRO Treatment of up to 6 Injections



- No transgene specific humoral responses were detected in subjects receiving extended treatment.

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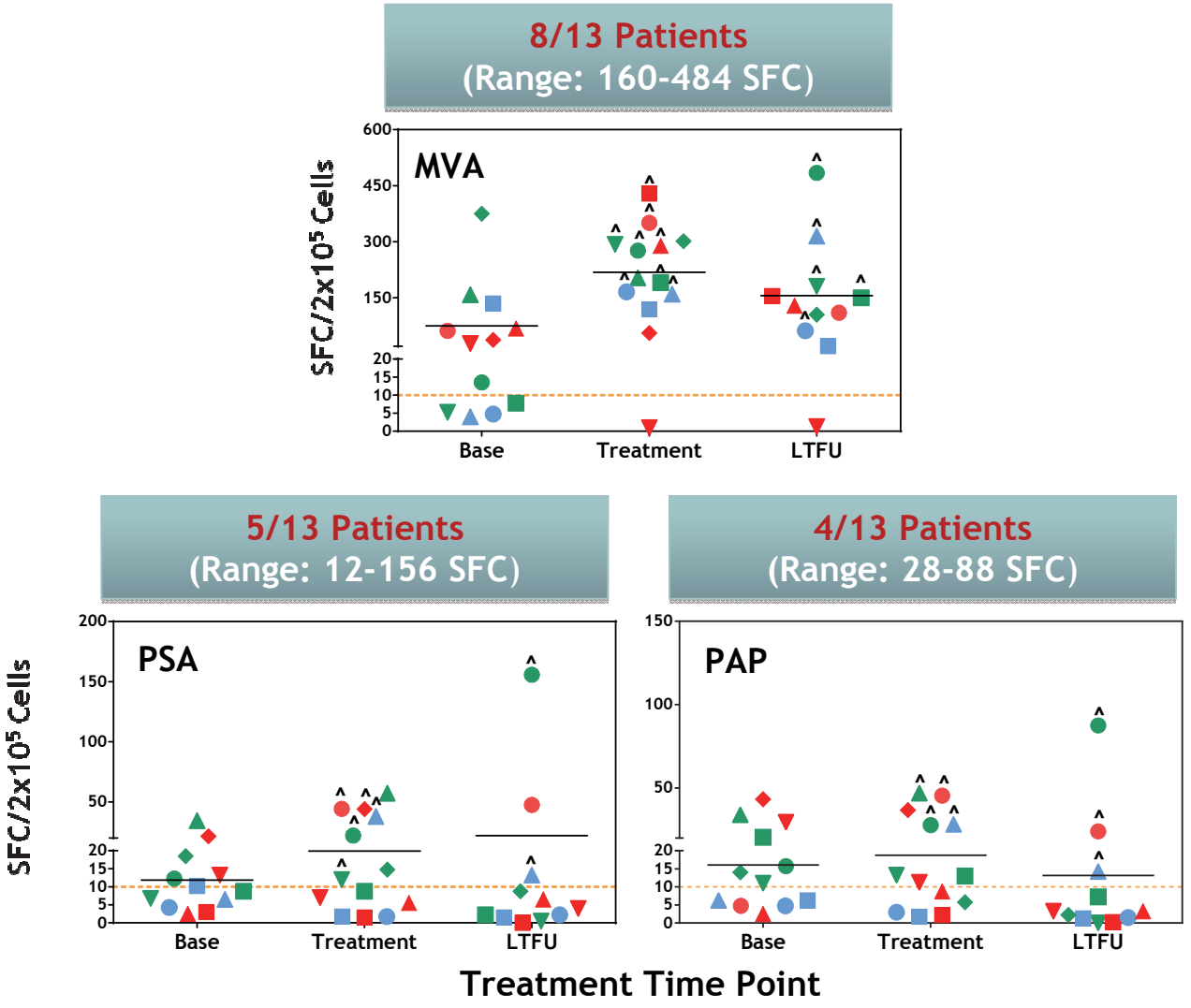
Augmented T-Cell ELISPOT Responses to Standard MVA-BN®-PRO Treatment of up to 6 Injections



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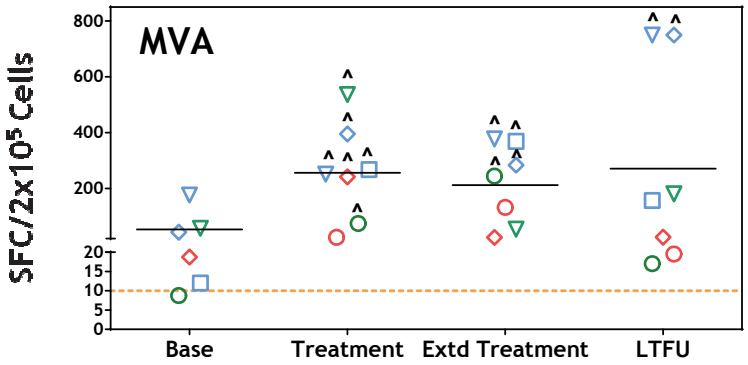
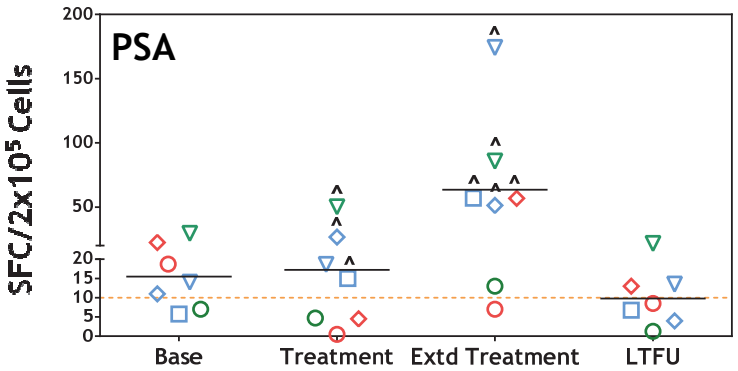
Increased T-Cell ELISPOT Responses to Extended MVA-BN®-PRO Treatment of up to 18 Injections

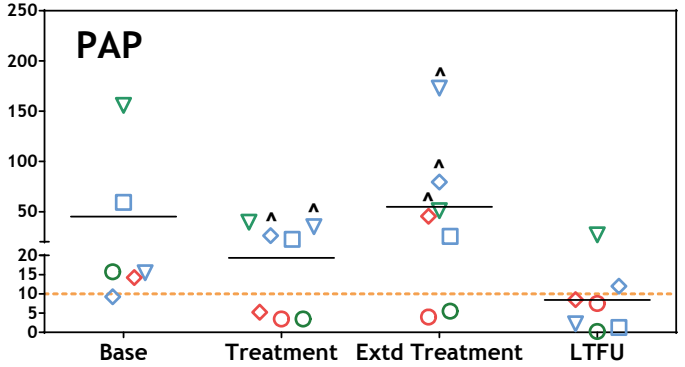
6/7 Patients
(Range: 74-750 SFC)



5/7 Patients
(Range: 15-174 SFC)



3/7 Patients
(Range: 26-173 SFC)



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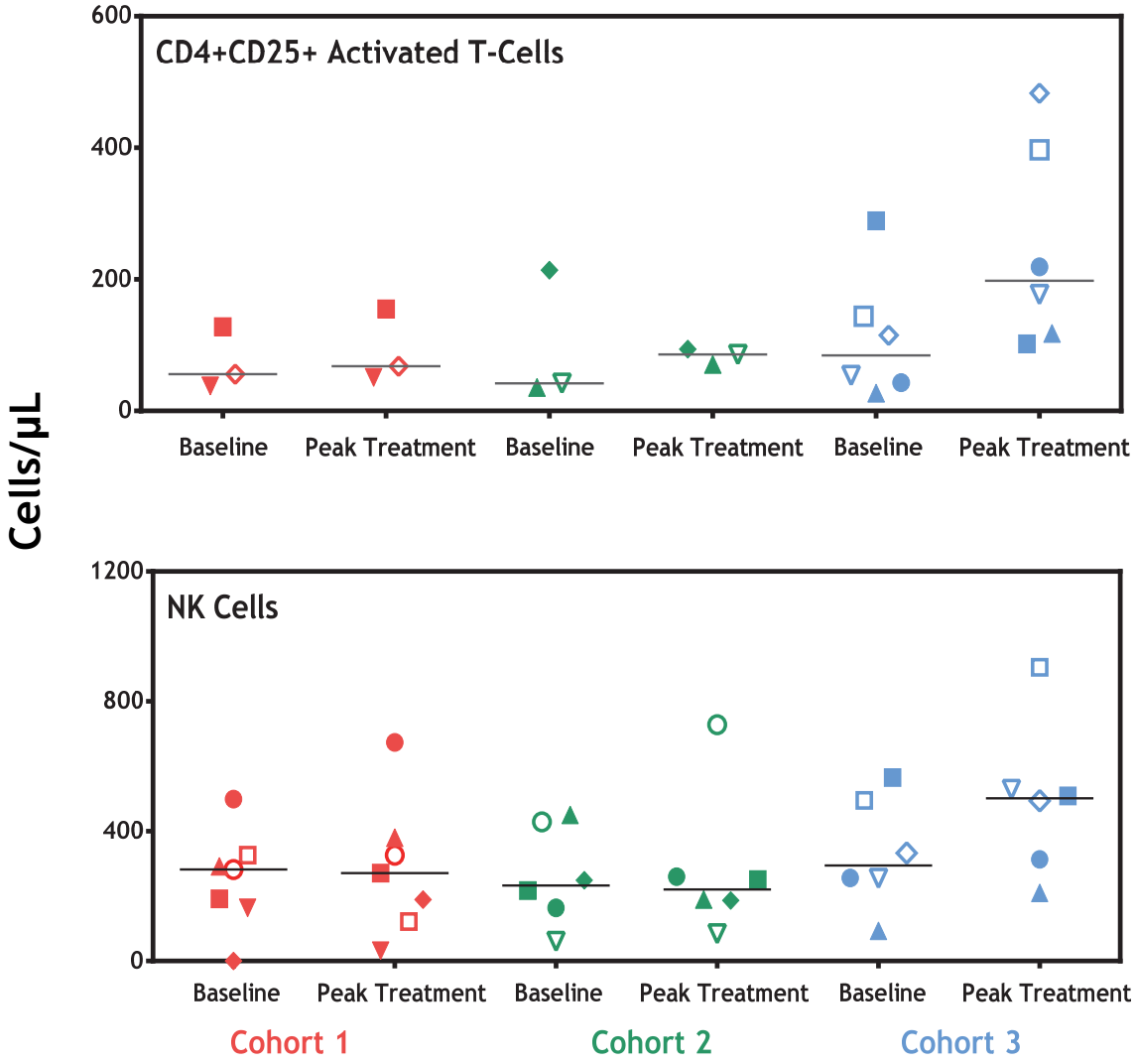
T-cell Activation and Upregulation of Innate Immune Responses with MVA-BN®-PRO Treatment



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Clinical Responses to MVA-BN®-PRO Treatment

	Pre-Study	Post-Treatment	Post-Extended Treatment
PSA-DT (Mean, months)	9.0	12.4	12.1
Subjects with Stable/Slowing PSA-DT, n (%)	NA	14/21 (67)	5/7 (71)

Bone Scan Response	Cohort 1	Cohort 2	Cohort 3	Extended Treatment
Stable disease, n (%)	4 (50)	7 (88)	8 (100)	6 (86)
Progression, n (%)	4 (50)	1 (13)	0	1 (14)

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Summary

- MVA-BN®-PRO treatment
  - Extended PSA-DT and
  - Delayed disease progression by bone scan

- Stronger and broader immune responses (innate, cell-mediated and humoral)
  - were induced with higher doses as well as total number of doses
  - and may correlate with greater clinical benefit

- Extended treatment may be beneficial in some patients

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Reiner Laus

BNIT Departments
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Manufacturing
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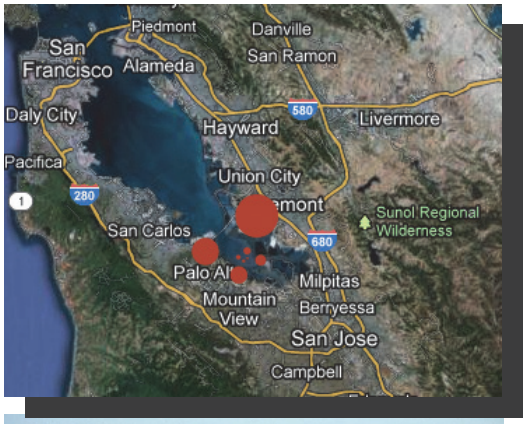
Clinical Centers and Patients
Walter Reed Army Medical Center
Urology Associates P.C.
South Florida Medical Research
Urology Centers of Alabama P.C
Urology Clinics of North Texas
Presbyterian Hospital Center for Cancer Research
Urology Associates of South Texas
Lawrenceville Urology



PROSTVAC Phase III Enrollment
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