



# VA Precision Oncology Platform and Clinical Trials

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# VA Mission

- To fulfill President Lincoln's promise: "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans

# How Well Do You Know the VA?

- Veterans: 22 million, ~9% female, 22% minority
- VA composed of VHA, VBA, National Cemeteries
- VHA enrolled Veterans: 9.11 million (Aug '15)
- VA Hospitals: 144
- VA Outpatient sites: 1203
- ~50,000 new cancer cases per year
  - 3.5% of national total
- Well established, integrated EHR

# Quality of Care for Older Patients With Cancer in the Veterans Health Administration Versus the Private Sector

- CRC: diagnosed at earlier stage
- Colon: higher rate of curative-intent surgery
- DLBCL: higher rate of standard chemotherapy
- Myeloma: higher rate of bisphosphonate
- Prostate: lower use of IMRT or 3D-CRT
- 9 other measures: similar
- Conclusions:
  - VHA system generally similar to or better than care for fee-for-service Medicare beneficiaries
  - adoption of some expensive new technologies may be delayed in the VHA

# The VA National Precision Oncology Platform



- Turnkey processes established for molecular profiling
- National contracts to reduce costs and increase uniformity
- Molecular oncology consultation service to assist clinicians
- New drugs made available to patients through research partnerships
  - Clinical trials are often a standard of care in Oncology
- Patient data aggregated for learning and research purposes

# Goals

- Define and disseminate Precision Oncology best practices
- Provide standardized high quality care
  - Reduce disparities
  - Facilitate providers
  - Engage patients
- Utilize program data to:
  - Understand cost and effectiveness
  - Generate knowledge on what works and what does not
  - Provide opportunities for clinical trial participation
- Realize economies of scale for laboratory and drug costs

# Learning and Research in POP

- Interdependence of clinical care and research programs
  - Molecular profile has value only if targeted therapies exist
  - Targeted therapy development requires access to patients who have been profiled
- Large patient population critically enables a complete view of the full landscape of patient profiles:
  - Many profiles will have substantial numbers, speeding learning
  - For any clinical trial, can find patients with the appropriate profile
  - Good coverage of the space of profiles improves power of statistical modeling



# Traditional Research Opportunities

- Intramural and sponsored clinical trials opened nationally to enable broad patient access
  - Structure provided by the VA Cooperative Studies Program and the VA Central IRB
  - Intellectual capital provided by VA clinicians and external stakeholders
  - Patients matched to clinical trials through data repository
- Appeal to potential sponsors and partners
  - Rapid enrollment into clinical trials due to size of the VA
  - Cost effective participation given VA infrastructure and programs
  - Potential for participation in Cancer Moonshot Programs

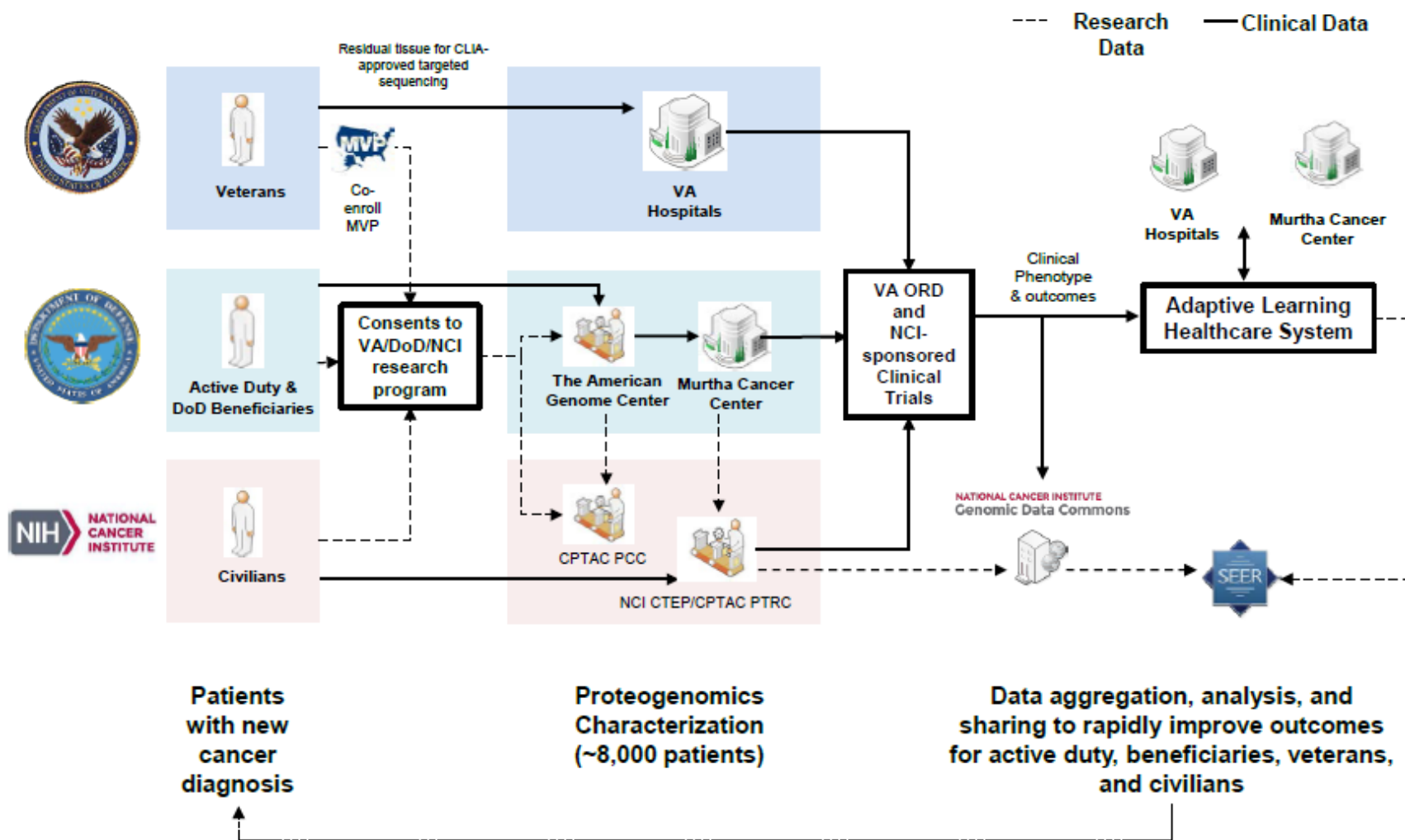


# Rapid Learning Opportunities

- Analytics applied to the data repository predict expected outcomes for patients based on past experience
- This knowledge will be used by providers, tumor boards, researchers and Program sponsors for:
  - Decision support
  - Practice guidelines refinement
  - Determination of Precision Oncology Program effectiveness
  - For publication if knowledge is generalizable

*The POP is an exemplar of a “Learning Healthcare System” where traditional clinical and research silos are replaced by systematic learning using scientific methodology in the clinical care ecosystem*

# Applied Proteogenomics Organizational Learning and Outcomes (APOLLO) Consortium VA/DoD/NCI



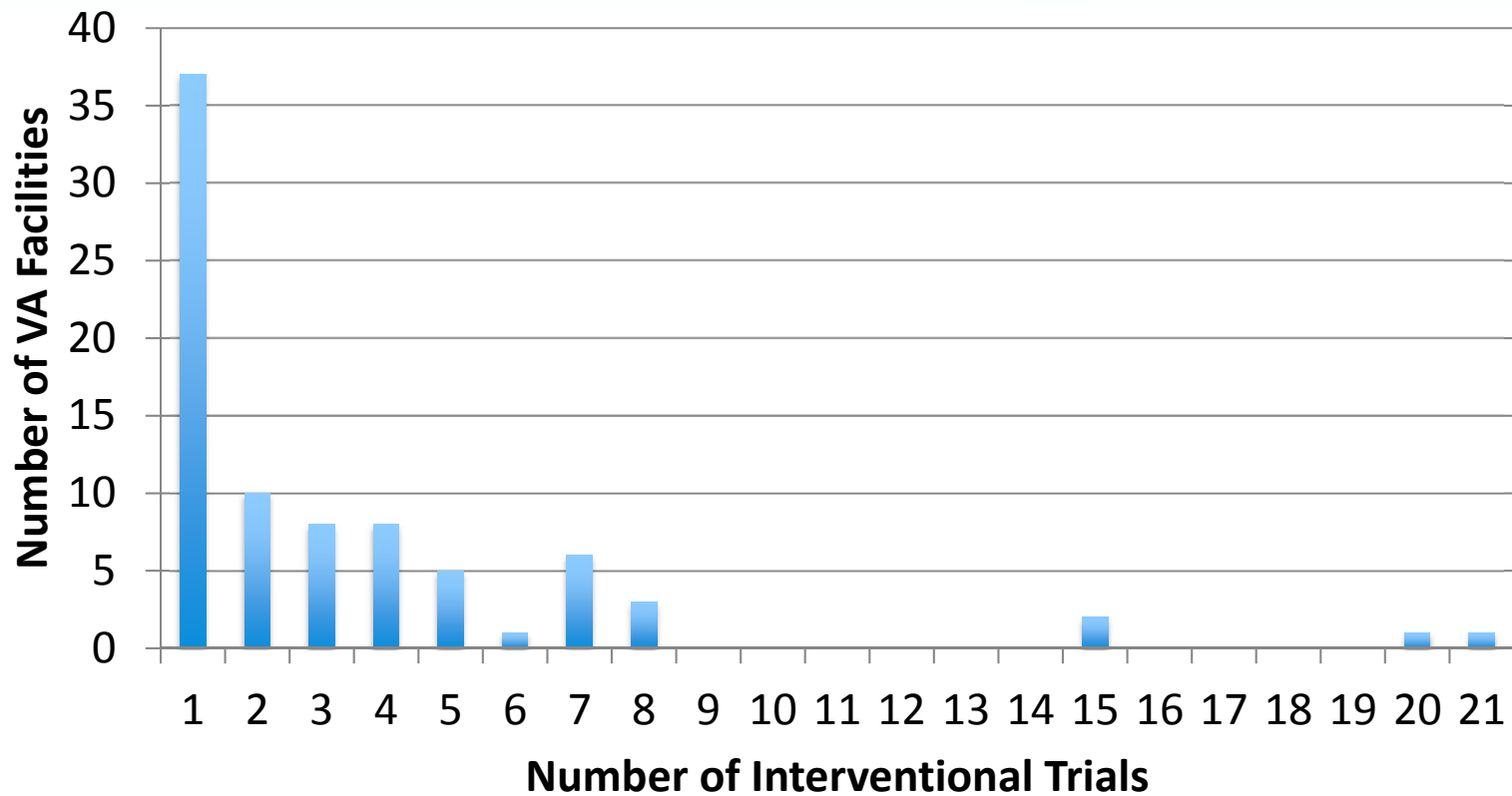
## RQ12A – Clinical Therapeutics and Evaluation Program (CTEP): Trial Participation Rates (Open and Closed)

- Participation rates in the VA system are statistically lower than the national rates when we look at **strictly males** (i.e., 0.74% vs 0.37%)
- Restricting the analysis to **only VA facilities enrolling patients**, the VA rate of participation increased substantially to 2.07% (exceeding the national rate of 1.8)

**Trial Participation Rates, overall and VA (Men Only) 2001-2003**

	Overall (US Population)	VA (all VA Hosps)	VA (only participating VA Hosps)
CRC	1.16%	0.30%	2.00%
Lung	0.67%	0.30%	1.40%
Prostate	0.70%	0.47%	2.50%
Myeloma	0.52%	0.74%	18.20%
NHL	0.15%	0.00%	0
Overall	0.74%	0.37%	2.07%

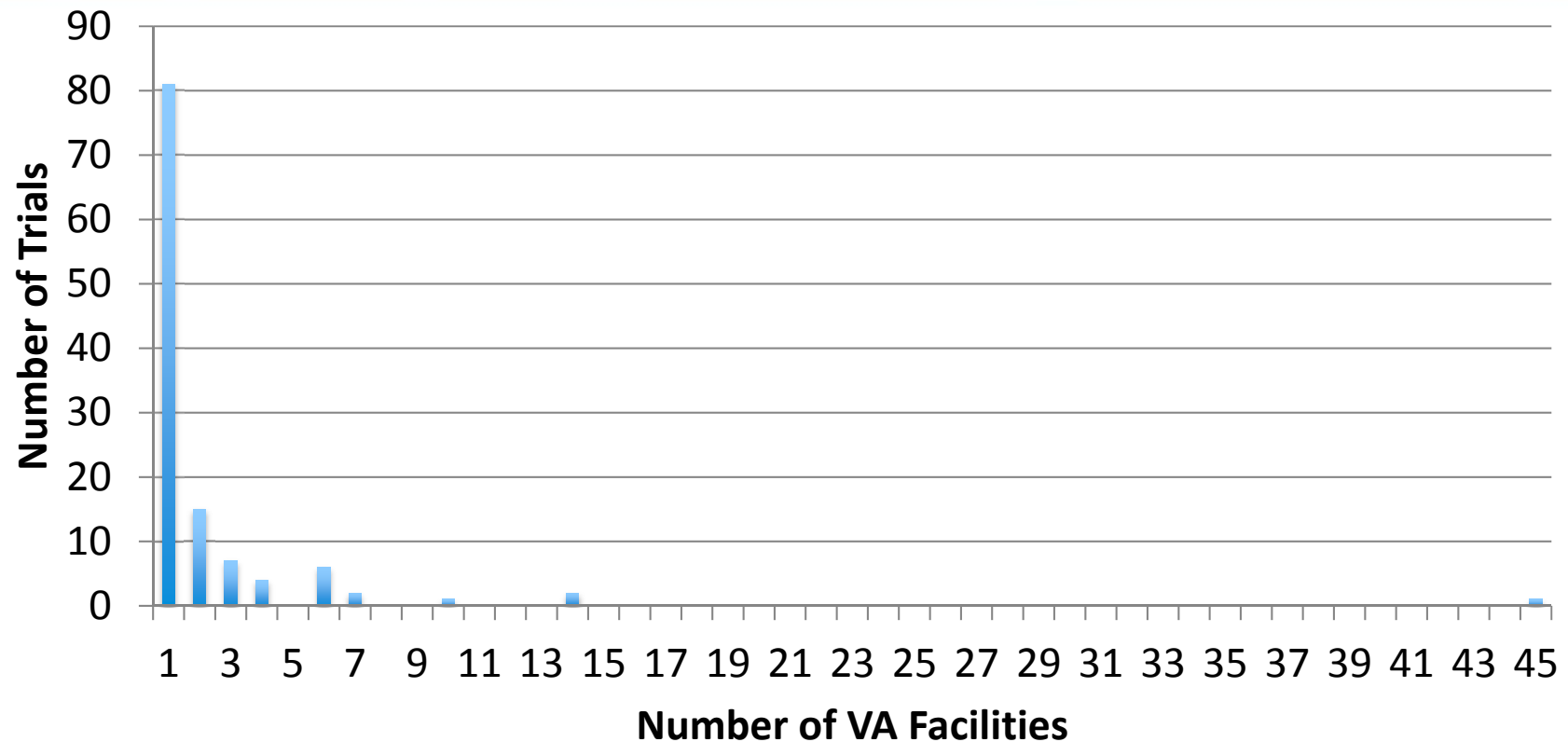
# Interventional Trials at VA Facilities: Open Trials per Site



VETERANS HEALTH ADMINISTRATION  
Source: CT.gov; accessed 7/1/2016

Total = 82 VA facilities  
Mean ~3.4 trials/facility

# Interventional Trials at VA Facilities: Sites per Open Trial



VETERANS HEALTH ADMINISTRATION  
Source: CT.gov; accessed 7/1/2016

Total = 120 trials  
Mean ~2.3 facilities/trial

# NCI Trials in VA

- NCI-VA MOU to use NCI cIRB (June 2, 2015)
  - 4 sites have added NCI cIRB (Indianapolis, Atlanta, Durham, and West Haven)
  - 2 sites have started process (Buffalo, New Orleans)
- NCI PMI trials
  - MATCH: Durham (opening)
  - LungMAP: West Haven, East Orange, Indianapolis, Ann Arbor, Hines, Kansas City, Houston
  - ALCHEMIST: Brooklyn, Minneapolis
- Other NCI-sponsored studies: 49

PRESS RELEASE  
For Immediate Release  
Oct. 1, 2015



## **SWOG Pushes to Expand Access to Cancer Trials for U.S. Veterans**

PORTLAND, OR – As part of a major effort to expand access to cancer clinical trials for the nation’s military veterans, SWOG, the international cancer clinical trials network, and its charitable arm, The Hope Foundation, are providing \$125,000 to five U.S. Department of Veterans Affairs medical centers across the country.

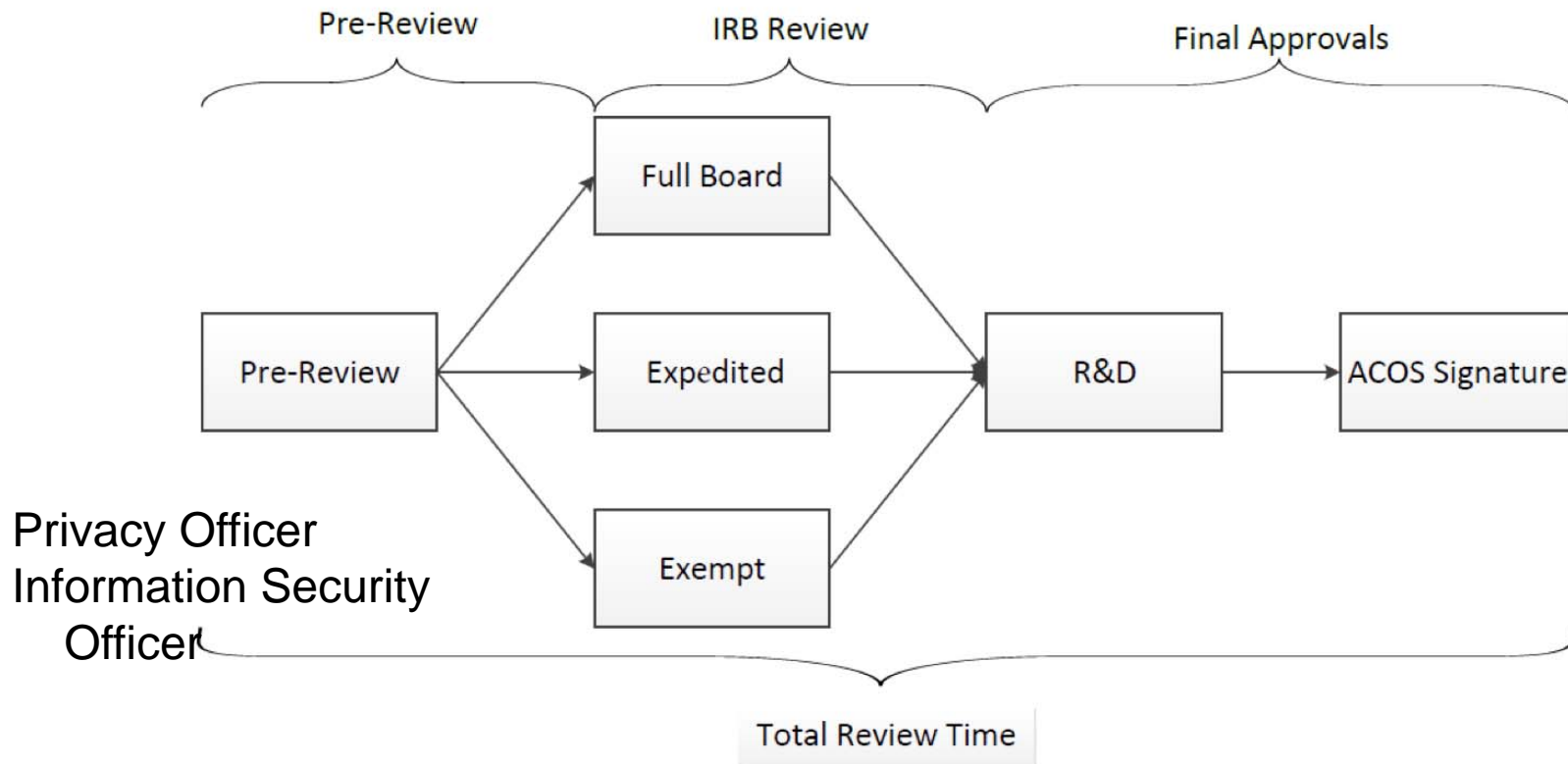
Under the new VA Integration Support Program, each VA medical center will receive \$25,000 in seed funding to help them enroll veterans in trials run by SWOG and other members of the National Cancer Institute’s National Clinical Trials Network (NCTN).

Winners of the VA Integration Support Program awards are:

- Central Arkansas Veterans Healthcare System, Little Rock, Ark.
- Cincinnati VA Medical Center, Cincinnati, Ohio
- Durham VA Medical Center, Durham, N.C.
- VA Eastern Colorado Health Care System, Denver, Colo.
- VA New York Harbor Healthcare System, Manhattan Campus, New York, N.Y.

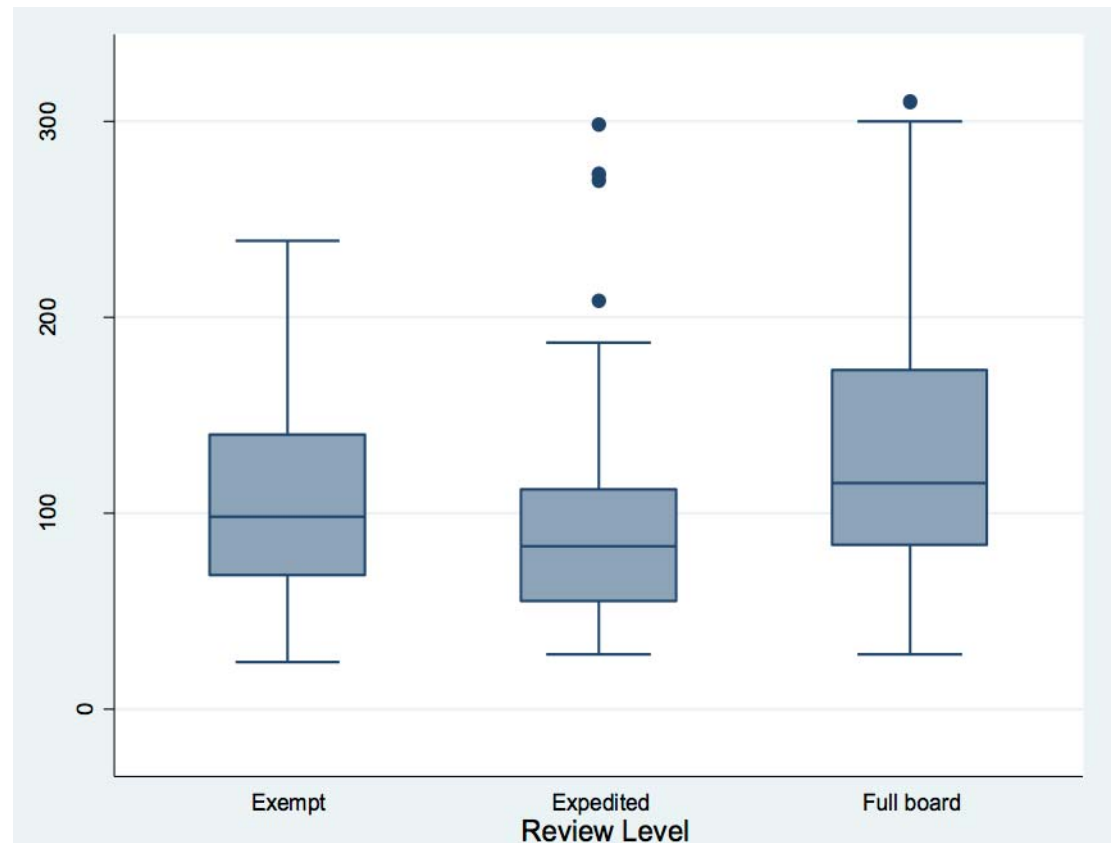


# VA Protocol Review Processes



# VA IRB Review Time

- 2010-2011
- 9 VA IRBs and the VA cIRB
- 139 full board review
  - 43 therapeutic interventional
  - Mean = 131 days
  - 10%  $\leq$  60 days
- 63 exempt
- 117 expedited



## Strawman Model for VA Cancer Clinical Trials

- Maximize use of VA and NCI cIRB, regardless of sponsor
  - VA cIRB now accepting pharma-sponsored and other non-VA sponsored trials
- Prioritization of clinical trials by disease group steering committees
  - Align with clinical care priorities, including Precision Oncology
  - Access to VA cIRB governance
- Leverage VA Clinical Studies Program support
- Partner with NCI, industry, non-profit foundations

## Extra Slides

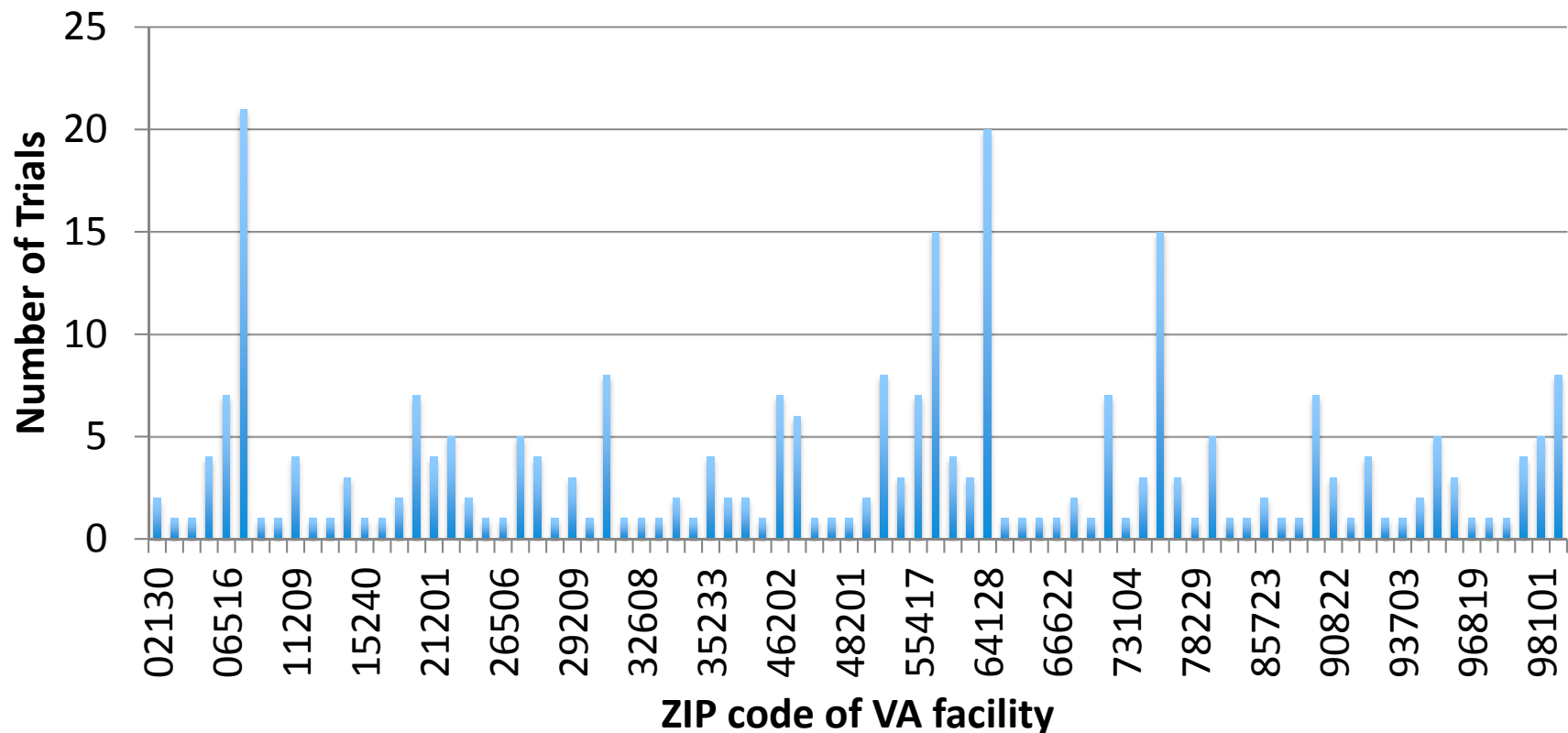
# VA Facilities Near NCI-Designated Cancer Centers

City	NCI-designated cancer center
Boston	Dana-Farber Cancer Institute
White River Junction	Dartmouth-Hitchcock Medical Center
West Haven	Yale University School of Medicine
New York	?
Bronx	College of Physicians & Surgeons Columbia University
Brooklyn	?
Buffalo	Roswell Park Cancer Institute
Pittsburgh	University of Pittsburgh Cancer Institute
Philadelphia	University of Pennsylvania
Baltimore	University of Maryland
Richmond	Virginia Commonwealth University
Durham	Duke University Medical Center
Salisbury	Wake Forest University Health Sciences
Charleston	Medical University of South Carolina
Atlanta	Winship Cancer Institute of Emory University
Tampa	Moffitt Cancer Center
Birmingham	University of Alabama at Birmingham
Nashville	Vanderbilt University
Memphis	St. Jude Children's Research Hospital
Lexington	University of Kentucky
Cleveland	Case Western Reserve University
Indianapolis	Indiana University Melvin & Bren Simon Cancer Center
Ann Arbor	University of Michigan

City	NCI-designated cancer center
Detroit	Wayne State University School of Medicine
Iowa city	University of Iowa
Madison	University of Wisconsin Carbone Cancer Center
Minneapolis	University of Minnesota
Hines	? Northwestern or Univ of Chicago
Chicago	? Northwestern or Univ of Chicago
Saint Louis	Washington University School of Medicine and Barnes-Jewish Hospital
Kansas City	University of Kansas
Omaha	University of Nebraska Medical Center
Dallas	University of Texas Southwestern Medical Center
Houston	Baylor College of Medicine
San Antonio	University of Texas Health Science Center at San Antonio
Denver	University of Colorado Cancer Center
Salt Lake City	University of Utah
Tucson	University of Arizona
Albuquerque	University of New Mexico, Albuquerque
Los Angeles	University of California at Los Angeles
San Diego	University of California, San Diego
San Francisco	University of California, San Francisco
Palo Alto	Stanford University
Portland	Oregon Health & Science University
Seattle	Fred Hutchinson Cancer Research Center

N = 45

# Interventional Trials at VA Facilities: Facilities by ZIP Code



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