



VA Research & Development Program

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VA Research Mission & Vision

VA Research is **unique in its focus** on the health, healthcare, and well-being of Veterans. We strive ***to relentlessly pursue knowledge and real-world innovations that benefit Veterans and the nation through focus, efficiency, and high-value partnerships.***

- Cover **the full research lifecycle**, from laboratory based science through clinical trials to the broad implementation of innovations.
- Attract, train, and retain the **highest quality investigators** and staff.
- Assure a culture of **professionalism, collaboration, and accountability** in research to assure safety of Veteran participants and their information.

Better Care, Better Outcomes

Biomedical and Lab RD

Discover New Treatments

Clinical Sciences R&D and Cooperative Studies

Translate Discovery into Effective Tx

Rehabilitation R&D

Speed Recovery of Injured Vets

Health Services R&D

Improve Care for Veterans

Regulatory Oversight – NPPO, CIRB, Animal

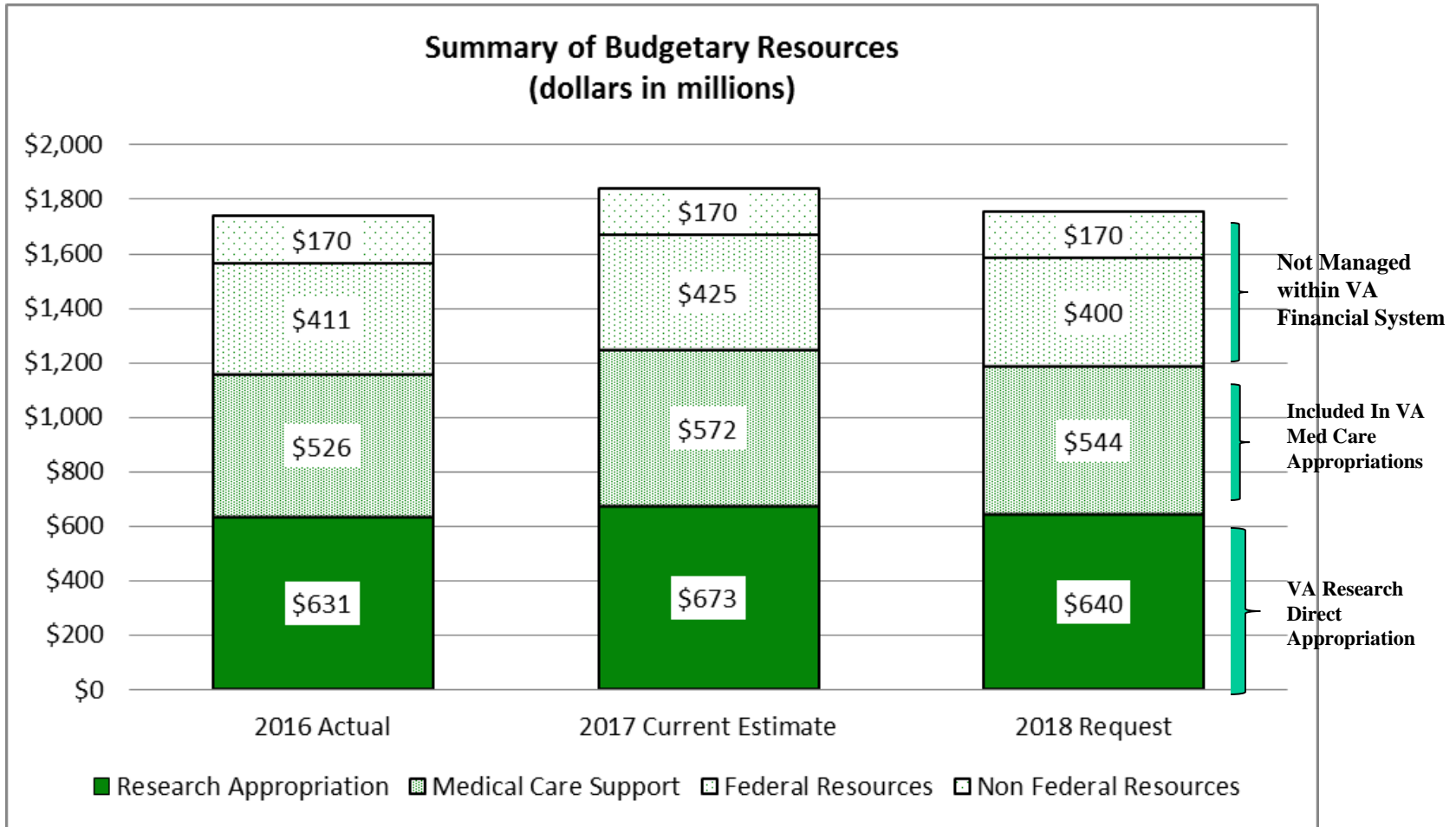
Data Infrastructure and IT

Genomic Research and Precision Medicine (MVP)

Tech Transfer Program



Medical and Prosthetic Research Budget Summary



VA Office of Research and Development Research Priorities

ORD PRIORITIES

- Expand Veterans' access to high quality clinical trials
- Increase substantial real-world impact of VA research
- Transform VA data into a national resource

VETERAN-RELATED TOPIC PRIORITIES:

- PTSD
- Suicide prevention
- Opioid/pain management
- Traumatic brain injury



Precision Medicine & Big Data Research

- Million Veteran Program (MVP) is the largest genomic cohort of its kind in the world, with a database of health, lifestyle, military exposure and genetic data
 - 640,000 Veterans enrolled at this time.
- Partnership with Department of Defense to enroll active duty members in MVP and to enhance the dataset with active military data.
- Eight scientific projects using MVP data underway within a secure, central computing infrastructure within the VA (called GENISIS).
- Partnership established with Department of Energy to expand computing capability, leverage supercomputing expertise, and make data available more broadly to researchers within and outside VA while ensuring high security.
- New study (PRIME Care) will test impact of returning pharmaco-genomic test results to Veterans and their clinicians in choosing treatment for depression.

Posttraumatic Stress Disorder

- PTSD is a research priority for VA Research with much activity centered on supporting studies to advance treatment for this condition
- During FY17, approximately \$33 million supporting over 150 projects was dedicated to PTSD, which includes co-funding a PTSD clinical trials consortium with DoD (Consortium to Alleviate PTSD)
- Much important collaborative activities takes place with other federal agencies, stakeholders and industry
- ORD is developing a dedicated roadmap to help direct efforts focused on new medication treatments, the PTSD Psychopharmacology Initiative (PPI)

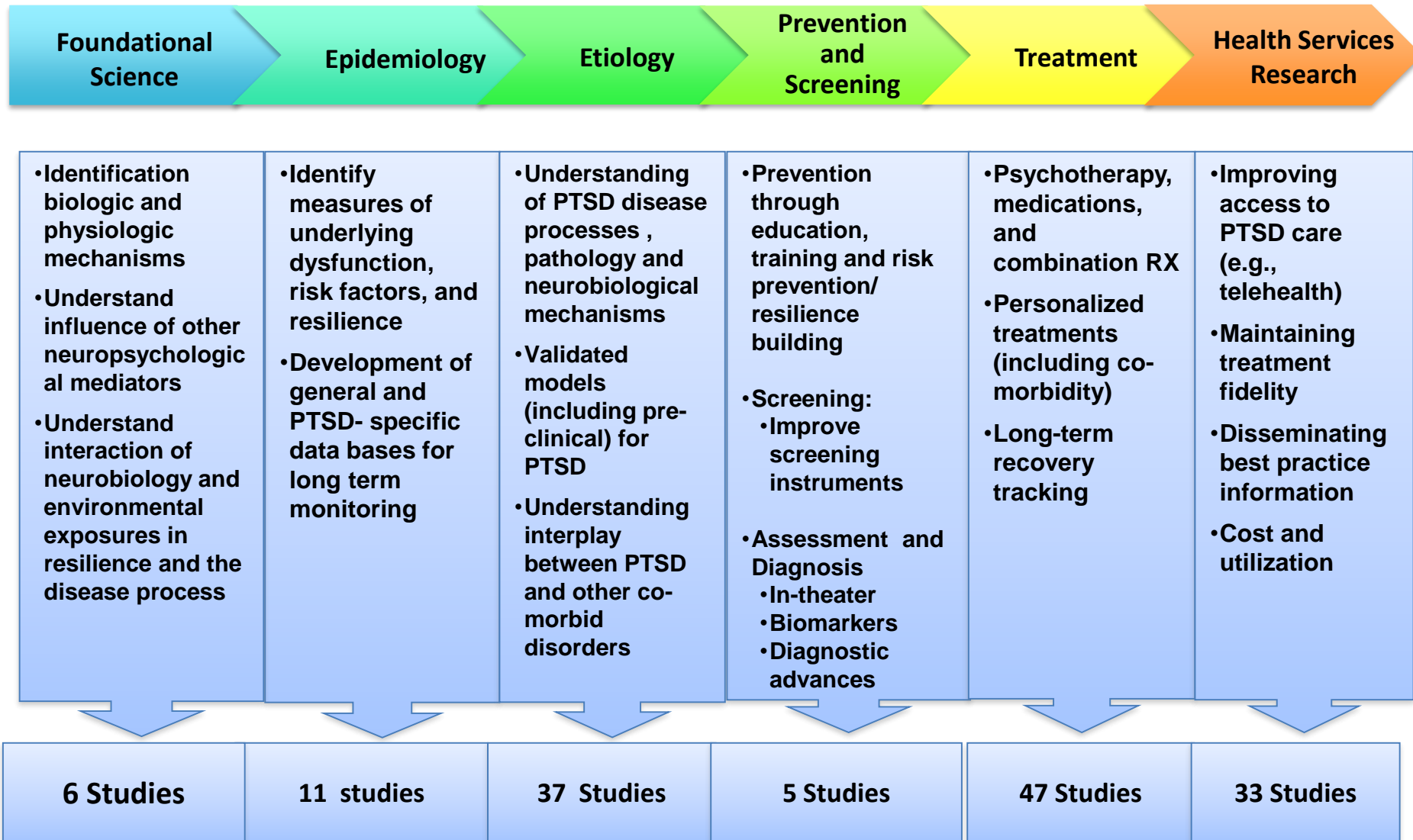
PTSD PSYCHOPHARMACOLOGY INITIATIVE (PPI)

CSR&D established PPI to focus efforts on new drug treatments for PTSD and has included:

- Biological Psychiatry article framing the crisis
- 2016 CSR&D Industry Day with industry partners
- New call for study proposals focused on PTSD medications with submission from qualified VA investigators
- PTSD Pharmacotherapy Clinical trial training workshop for 18 VA investigators 2017
- 6 new studies have been planned and funded to date; goal is to test many more potential compounds by 2020



PTSD Research Along the Continuum





Rehabilitation Research and Development

- **RR&D mission:** generate knowledge and innovations to advance the rehabilitative health and care of Veterans and the nation. In support of this mission, RR&D strives to effectively integrate preclinical, clinical and applied rehabilitation research and translate research results into practice.
- **Scientific Program areas:**

Behavioral Health and Social Reintegration

Sensory Systems and Communication Disorders

Brain Injury: TBI/Stroke

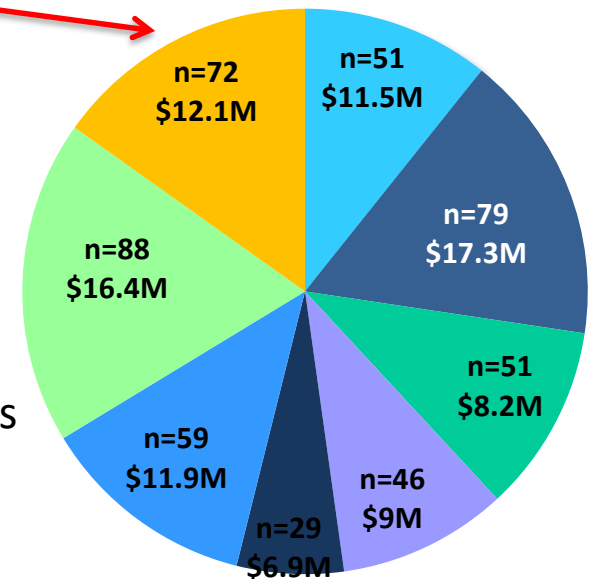
Aging and Neurodegenerative Disorders

Spinal Cord Injury/Disorders and Pain

Regenerative Medicine

Rehabilitation Engineering, Prosthetics/Orthotics

Musculoskeletal and Medical Co-morbidities



FY17 distribution



Cooperative Studies Program (CSP)

- CSP is a national infrastructure for sponsoring, developing & executing:
 - Multi-site clinical trials
 - Epidemiological & population research
 - Genomic medicine research
- First Cooperative Study conducted in 1940s on streptomycin for treating tuberculosis in WWII veterans
 - Program formally established in 1972
- Nearly **200** clinical trials and observational studies completed including landmark studies in cardiovascular disease / cardiovascular surgery, infectious diseases, surgery, gastroenterology, mental health, oncology, and endocrinology.



CSP Mental Health Studies

CSP #590 - Lithium for Suicidal Behavior in Mood Disorders

CSP #591 - Comparative Effectiveness Research in Veterans With PTSD (CERV-PTSD)

- Womens Enhanced Recruitment Process

CSP #575B - Genomics of Posttraumatic Stress Disorder Among Veterans

CSP #589 - Veterans Individual Placement and Support Towards Advancing Recovery (VIP-STAR)

CSP #256 – Vietnam Era Twins Registry

SD – PTSD – Can Service Dogs Improve Activity and Quality of Life in Veterans With PTSD?



Office of Research and Development

Three Strategic Priorities



**Access to High Quality
Clinical Trials**
*Increase Veterans' access to
clinical trials.*

Greater choice for Veterans.

Modernizing our system.

Focus resources more efficiently.

Access.



Substantial Real-World Impact
*Increase the real-world impact of
VA research.*

Modernizing our system.

Focus resources more efficiently.



VA Data as a National Resource
*Increase the good that
VA Data can do.*

Modernizing our system.

Focus resources more efficiently.



Stakeholder Summit

Enabling Access
to Clinical Trials

APRIL 12 | WASHINGTON, DC

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PATRIOTIC

RESPECT

ALWAYS

COUNTRY

SEMPER

DEFEND

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Cohen Veterans
Bioscience



- Two-year partnered effort involving industry, CROs, VA Central Office and field leaders, and patient advocacy groups
- Goal: Reduce the time for industry-sponsored trials to be initiated in VA
 - Emphases: Partnership initiation, Business Processes (contracts / agreements), Regulatory/Policy



Commercial Partnerships: with VA Funds

Industry partner identifies
VA investigator(s) for Collaboration

*VA Investigator(s) must be
eligible to receive ORD
Funding*

Initial discussion regarding commitment from
partners (drug, protocol development, etc.)

Parties reach consensus on content of the Cooperative
Research and Development Agreement (CRADA)

VA Medical Center research office submits application
for funding to the Office of Research and Development

*The submission must be in
response to a published
RFA*

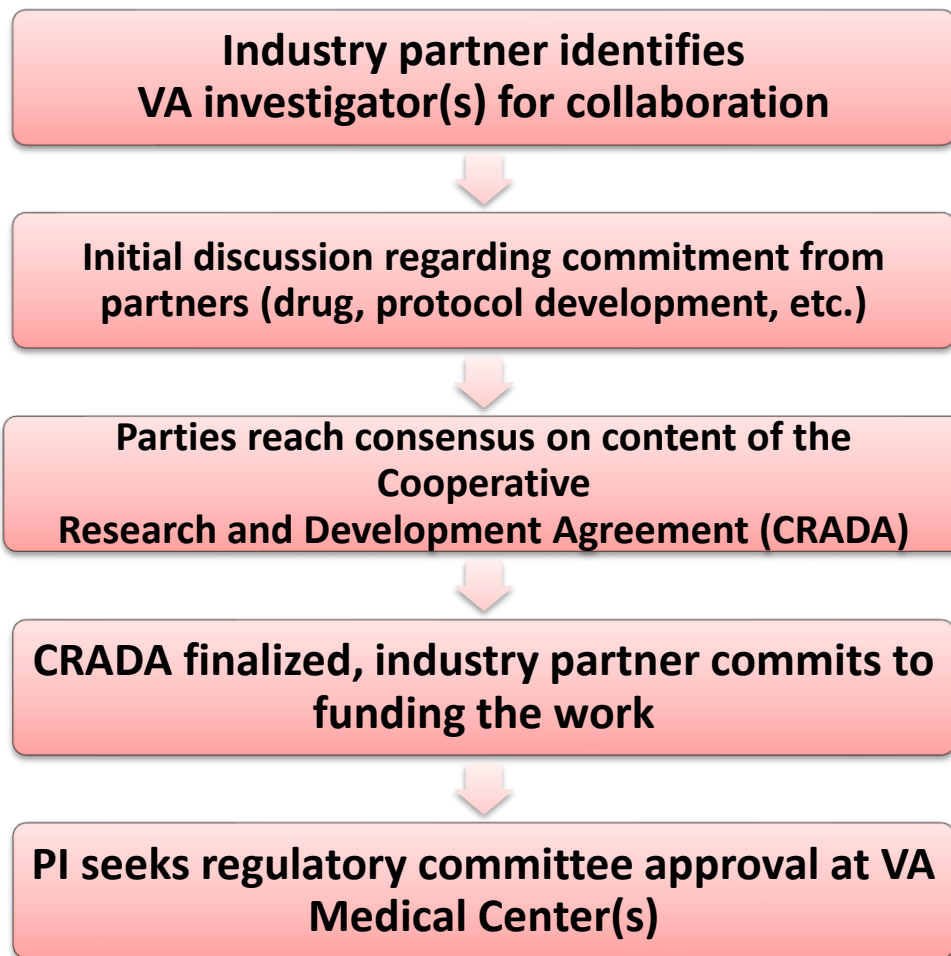
ORD Conducts scientific peer review

If a funding decision is favorable, PI seeks regulatory
committee approval at VA Medical Center(s)



Commercial Partnerships:

Industry/Partner Funds Only



Initial contact may be via the Nonprofit Corporation (NPC) or directly with the VA investigator

NPC is involved in these discussions regarding CRADA