

National Priorities for Clinical Trial Research in PTSD

Timothy O'Leary, MD, PhD
**Director of VA Clinical Science
Research and Development
(VA CSR&D)**

VA Guidelines for PTSD Treatment Trials

- In 2007, the Institute of Medicine (IOM) was commissioned by the VA to assess the scientific evidence on treatment modalities for PTSD.
- In 2008, the IOM published Treatment of Posttraumatic Stress Disorder: An Assessment of the Evidence (National Academies Press, Washington, D.C.)
- In 2008, the VA, DOD, and NIMH convened “*Advancing Research Standards for PTSD Interventions: Suggested Approaches for Designing and Evaluating Clinical Trials*” to evaluate and respond to the OIM report
- The meeting summary describes recommendations for design and analysis of randomized controlled trials for PTSD

<http://www.research.va.gov/programs/csrd/default.cfm>

2008/2009 Research Funding Initiatives

- VA launches the Cooperative Clinical Trial Award (CCTA) Program to support smaller scale clinical trials, resourcing with Coordinating Center expertise
 - VA established Central DMC to monitor smaller scale clinical trials
 - DOD (USAMRMC) issues 150M budget for PTSD and TBI research, including PTSD/TBI Clinical Trials Coordinating Center, PTSD Research Consortium, intramural and extramural programs
 - In joint collaboration with the NIMH, VA CSR&D announced a new opportunity for funding, "Clinical Pharmacotherapy for PTSD: Single and Collaborative Studies" (R34). VA is coordinating with other federal funding agencies, additional joint solicitations are planned
 - Growing interest from Pharmaceutical Industry in Phase II and III studies for the treatment of PTSD
-

Challenges

- Preclinical investigations in PTSD are not leading to new therapeutic modalities or development of PTSD-specific molecular entities.
- Trying to use pharmacologic interventions optimized for other conditions may not be optimal.
- Need to deal with comorbid conditions more effectively.