Department of Veterans Affairs (VA)
Office of Research and Development (ORD)
Cooperative Studies Program (CSP)

Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)
The meeting was held via videoconference on Thursday, January 18, 2024. The Chair, Hermes Florez, MD, PhD, presided.

CSSEC Members Present:
Hermes Florez, MD, PhD – Chair
Lisa Brenner, PhD
Richard Chappell, PhD
Stuti Dang, MD
Patrick O'Malley, MD
Michael Shilpak, MD, MPH
Brittany Zwischenberger, MD, MHSc

Other Attendees Present:
John Concato, MD, MS, MPH – US FDA
Ramin Ebrahimi, MD
Timothy Morgan, MD
Jonathan Yabes, PhD

VA Staff Present:
David Burnaska, MPA – Designated Federal Official (DFO)
Amanda Garcia, MPH – Alternate DFO
Stephen Bartlett, RPh, MSPH
Grant Huang, MPH, PhD
Rachl Ramoni, DMD, ScD
Leonardo Tamariz, MD
Elizabeth Willis (contactor)
Don Workman, PhD

Study Proponents Present: see attached agenda

Mr. Burnaska called the meeting to order at 1:00 PM. He thanked the reviewers for submitting their pre-review conflict of interest statements and reminded them to submit their post-review statements after the meeting. He mentioned that committee members would soon be receiving a poll to help with scheduling the next meeting and discussed some potential topics for that meeting.

Dr. Florez welcomed the participants and thanked them for their service. He explained that the overarching goals of the meeting are to advise ORD on what is the best science to help advance care for Veterans and what are ways to improve studies in general given the committee members' expertise in clinical trials. He then congratulated Dr. Huang, VA Deputy Chief R&D Officer-Enterprise Optimization, and Director, CSP, on receiving the Veterans Health Administration John D. Chase Award for Executive Excellence in Health Care.

Dr. Huang thanked Dr. Florez for the recognition, as well as the other participants for their time and effort. He commented that the committee was a key reason that allowed someone from VA Research to receive an award for achievements by helping to ensure that VA funds only the highest caliber research. He noted recent VA research

accomplishments, including the Million Veteran Program (MVP) enrolling its 1 millionth participant. He described the recently enacted Fiscal Responsibility Act of 2023, tightening federal budgets across the board, and commented that it may result in slowing down current research projects and delaying new studies. But he also stated that it presents an opportunity to further explore partnerships with other agencies and research sponsors, like the partnership with the Food and Drug Administration (FDA) on one of the studies under review that day, CSP #2037. He then introduced Dr. Concato, Associate Director for Real-World Evidence Analytics, Office of Medical Policy, Center for Drug Evaluation and Research (CDER), FDA.

Dr. Concato also congratulated Dr. Huang on his award. He discussed FDA's interest in and enthusiasm for the CSP #2037 treatment trial and how that partnership developed. He described FDA's activities around the use of real-world evidence more generally. He also noted the importance of novel trial designs, such as the VA's Diuretic Comparison Project, CSP #597.

Dr. Ramoni, the VA Chief Research & Development Officer, thanked Dr. Concato for his comments and for the opportunity to collaborate with FDA. She mentioned the budget constraints and how VA research is expanding collaborations with other research sponsors as a result. She discussed some new VA research activities underway, including the recent creation of a coordinating center for Alzheimer's Disease and Related Dementias. She noted the interest from the National Institute on Aging and the Alzheimer's Association to partner with the center. She described the VA research enterprise transformation activities, calling them a foundational restructuring of the VA research program to shift it to an integrated enterprise. Dr. Ramoni then mentioned VA's increased focus on research related to women's health and possible partnerships with the Department of Defense (DoD) in this area. Finally, she, too, congratulated Dr.
Huang on his award, and commented that it was the first time someone from the research program had received it.

Mr. Burnaska noted that no members of the public were in attendance and closed the public session of the meeting at 1:26 PM to begin the study review portion.

Dr. Florez then outlined the review meeting procedures for the day.

The study review portion of the meeting proceeded as indicated on the attached agenda with 1 new submission and 1 study that was discussed as a follow-up item from the previous meeting.

New Submission:

CSP #2037	"Veterans Affairs Learning Health System Initiative to Assess Novel Screening vs. Usual Care and Treatment with Apixaban vs. Rivaroxaban in Veterans with Atrial Fibrillation (VALIANT-AF) Trial"

Follow-up Discussion:

CSP #2036	"VA Randomized Trial of Surveillance Intervals after Transurethral Resection of High-Grade Bladder Tumors (VATSIT)"

The meeting concluded at 4:16 PM on January 18, 2024.

Submitted,

/s/
Hermes Florez, MD, PhD
CSSEC Chair

DEPARTMENT OF VETERANS AFFAIRS (VA) COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE (CSSEC)
AGENDA

January 18, 2024
(via teleconference/web conferencing platform)

Thursday, January 18, 2024 (all times Eastern)

1:00 – 1:10 PM Opening of General Session & Chair's Welcoming Remarks
David Burnaska, MPA
Designated Federal Official
Hermes Florez, MD, PhD
CSSEC Chair

1:10 – 1:15 PM Overview of Studies to be Reviewed
Grant Huang, MPH, PhD
Deputy Chief Research & Development Officer – Enterprise Optimization
Director, Cooperative Studies Program

1:15 – 1:20 PM Comments from FDA
John Concato, MD, MS, MPH
Associate Director for Real-World Evidence Analytics
Office of Medical Policy, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

1:20 – 1:30 PM Overview of Review Procedures
Hermes Florez, MD, PhD
CSSEC Chair

1st Proposal **CSP #2037 – *"Veterans Affairs Learning Health System Initiative to Assess Novel Screening vs. Usual Care and Treatment with Apixaban vs. Rivaroxaban in Veterans with Atrial Fibrillation (VALIANT-AF) Trial"***

1:30 – 1:45 PM **Briefing Session**

1:45 – 2:00 PM **Study Team Presentation**
William E. Boden, MD – Co-principal Proponent
Cara N. Pelligrini, MD – Co-principal Proponent
Paul A. Heidenreich, MD – Co-principal Proponent
Gheorghe Doros, PhD – Study Biostatistician
Paul Monach, MD – Study Director
Ryan Ferguson, ScD, MPH – CSPCC Director

2:00 – 2:45 PM **CSSEC Review**
2:45 – 3:00 PM **Executive Session**

3:00 – 3:15 PM Break / CSP Follow-up with Study Team

2nd Proposal **CSP #2036 – *"VA Randomized Trial of Surveillance Intervals after Transurethral Resection of High-Grade Bladder Tumors (VATSIT)" (REVISION)***

3:15 – 3:25 PM **Briefing Session**

3:25 – 3:35 PM **Study Team Presentation of Revisions**
Florian Schroeck, MD, MS – Principal Proponent
Zhibao Mi, PhD – Study Biostatistician
Kousick Biswas, PhD – CSPCC Director
3:35 – 3:50 PM **CSSEC Review**
3:50 – 4:00 PM **Executive Session**

4:00 PM **Meeting Adjournment**