

Department of Veterans Affairs (VA)
Office of Research and Development (ORD)
Clinical Science Research and Development Service (CSR&D)
Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)

The meeting was held at the American Association of Airport Executives (AAAE) Conference Center, 601 Madison Street, Alexandria, VA, on Thursday, December 12, 2013. The acting Chair, John Alexander, MD, MHS, presided.

CSSEC Members Present:

John Alexander, MD, MHS – Acting Chair	William Cushman, MD (teleconference)
Daniel Clauw, MD	John Powers, MD

Other Attendees Present:

Barry Davis, MD, PhD	Theodore Karrison, PhD
David Goldfarb, MD	Renee Martin, PhD
Debra Grady, MD, MPH	

VA Staff Present:

David Burnaska	Kelli Potter
Grant Huang, MPH, PhD – Designated Federal Official	Eric Schwinder
Timothy O’Leary, MD, PhD	Kathleen Swanson

Study Proponents Present: see attached agenda

Dr. Alexander opened the general session at 8:37 AM and welcomed the participants. Dr. Huang, Acting Director, Cooperative Studies Program (CSP), also welcomed the participants and briefly explained meeting logistics. He mentioned that Dr. Karl Kieburtz, the CSSEC Chair, has recently taken a new position at the University of Rochester and is unable to chair this meeting. Therefore, Dr. Alexander would serve as the acting Chair in his absence. Dr. Huang noted that CSP is continuing to perform well but needs to focus further on overcoming study recruitment challenges. He also reminded participants to complete their conflict of interest forms.

Dr. Alexander thanked the participants and commented that CSP conducts important studies for both Veterans and the general public. After the committee introduced themselves, he explained the review process: the reviewers meet in executive session to give brief synopses of their comments on the proposal before the Committee; study proponents are then brought in, apprised of reviewer comments and asked to make brief presentations and responses to the Committee; an interactive discussion with CSSEC ensues. A closed Executive Session follows to discuss recommendations for the proposal and to score it.

Dr. O’Leary, VA Acting Chief Research and Development Officer (CRADO), thanked the participants for their effort and the gift of their time. He commented that CSSEC’s input has been vital to improving the studies that CSP conducts. Dr. O’Leary discussed the

budgetary uncertainties and remarked that any potential budget increase would unlikely keep pace with the increasing costs of running clinical trials. He described two CSP observational studies that focused on Vietnam Era Veterans, one exclusively on women, as well as a study on Vietnam Veterans conducted under a contract with VA. He explained that ORD is working to develop stronger relationships with other VA program offices, such as the Office of Public Health, and with the Department of Defense. He also noted that support for the VA research program from the Office of Management and Budget remains strong.

Dr. Huang closed the public session of the meeting at 9:15 AM to begin the study review portion.

The study review portion of the meeting proceeded as scheduled, with two new submissions and one resubmission reviewed.

New Submissions:

CSP #594 "Comparative Effectiveness in Gout: Allopurinol vs. Febuxostat"
CSP #596 "Optimal Treatment for Recurrent Clostridium difficile Infection"

Resubmission:

CSP #592 "Efficacy and Safety of ICD Implantation in the Elderly"

The meeting concluded at 2:19 PM on December 12, 2013.

Submitted,

 JHA 12/16/13
John Alexander, MD, MHS
Acting Chair CSSEC

DEPARTMENT OF VETERANS AFFAIRS
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE
COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE (CSSEC)
AGENDA

December 12, 2013

Thursday, December 12, 2013

8:30 – 8:45 AM Opening of General Session & Welcoming Remarks
Timothy J. O’Leary, MD, PhD
Acting Chief Research & Development Officer

8:45 – 9:00 AM Overview of Review Procedures
John Alexander, MD, MHS
Acting CSSEC Chair

1st Proposal **CSP #594 – “Comparative Effectiveness in Gout: Allopurinol vs. Febuxostat”**

9:00 – 9:15 AM **Briefing Session**

9:15 – 9:30 AM **Study Team Presentation**
James R. O’Dell, MD – Principal Proponent
Mary Brophy, MD, MPH – Study Director
Robert Lew, PhD – Study Biostatistician
Ryan E. Ferguson, ScD, MPH – CSPCC Acting Director

9:30 – 10:15 AM **CSSEC Review**

10:15 – 10:30 AM **Executive Session**

10:30 – 10:45 AM	Break
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2nd Proposal **CSP #592 – “Efficacy and Safety of ICD Implantation in the Elderly”**

10:45 – 11:00 AM **Briefing Session**

11:00 – 11:15 AM **Study Team Presentation**
Steven Singh, MD – Principal Proponent
Merritt Raitt, MD – Study Consultant
Michael Wininger, PhD – Study Biostatistician
Peter Guarino, MPH, PhD – CSPCC Director

11:15 – 12:00 PM CSSEC Review

12:00 – 12:15 PM Executive Session

12:15 – 12:45 PM Lunch (working lunch, if needed)

3rd Proposal **CSP #596 – “*Optimal Treatment for Recurrent Clostridium difficile Infection*”**

12:45 – 1:00 PM Briefing Session

1:00 – 1:15 PM Study Team Presentation
Stuart Johnson, MD – Co-Principal Proponent
Dale Gerding, MD – Co-Principal Proponent
Derrick Kaufman, MS – Study Biostatistician
Domenic Reda, PhD – CSPCC Director

1:15 – 2:00 PM CSSEC Review

2:00 – 2:15 PM Executive Session

2:30 PM **MEETING ADJOURNMENT**