

**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 Hamilton Crowne Plaza, Washington, DC, on Tuesday, December 20, 2011. The Chair, Karl Kieburtz, MD, MPH, presided.

CSSEC Members Present:

Karl Kieburtz, MD, MPH - Chair
Daniel Clauw, MD
Barry Davis, MD, PhD
Ted Karrison, PhD

Sheryl Kelsey, PhD
Laura Mauri, MD, MSc
John Powers, MD

Other Attendees Present:

David Aron, MD, MS
William Cushman, MD
Joel Gelfand, MD, MSCE

Thomas Sharp, MD
Daniel Simon, MD
Frank Selke, MD

VA Staff Present:

David Burnaska
Grant Huang, MPH, PhD
Timothy O'Leary, MD, PhD

Kelli Potter
Matthew Verna
Stuart Warren, JD, PharmD

Study Proponents Present: see attached agenda

Dr. Kieburtz opened the general session at 8:07 AM and welcomed the participants.

Dr. O'Leary, VA Deputy Chief Research and Development Officer and Director, CSR&D, thanked the participants for their time and effort reviewing the proposals. He noted the significant impact the committee has had on clinical research by helping to determine what and how VA clinical research studies would be conducted. He commented that VA's fiscal year 2012 approved research budget demonstrates support for the overall research program, including the Cooperative Studies Program (CSP), particularly in light of the overall budget situation. He mentioned that CSP continues to seek collaborative opportunities with other agencies, as evidenced by one of the proposals to be reviewed, and that future funding continues to be uncertain. He also provided an update on the Million Veterans Program (MVP).

Dr. Kieburtz also thanked the reviewers. He noted that this committee is a very interesting one to participate on, and that the heterogeneity of backgrounds makes it different from study sections like those at the National Institutes of Health (NIH). He commented that the ability to interact with the study team during the review is both a unique and enjoyable feature of the committee. He further 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 the CSSEC ensues. A closed

Executive Session follows to discuss recommendations for the proposal and to score it. He also explained that one application involving a proposed collaboration with the National Heart, Lung, and Blood Institute (NHLBI), needed to be scored on both the VA CSP and NIH scales.

Dr. Huang, Deputy Director, CSP, thanked the CSSEC members for meeting so close to the holidays. He reminded members to sign the conflict of interest form. He explained that the VA Chief of Staff, John Gingrich, was coming to the meeting to thank the committee for its work. He provided background on the proposed NHLBI collaboration in one of the studies and discussed the NIH scoring system. He mentioned that the CSP statistical coordinating centers would undergo ISO audits soon. He described the CSP Network of Dedicated Enrollment Sites (NODES) pilot initiative, noting that the proposals were reviewed in November and that the next step is to conduct site visits of the top scoring applicants. He also provided a status report on CSP's electronic data capture (eDC) system implementation initiative..

VA Chief of Staff, John Gingrich, arrived and thanked the committee for its efforts in ensuring that VA conducts the highest quality clinical research. He commented on the committee's critical role in VA performing several landmark studies. Mr. Gingrich encouraged the group to continue to set the bar high to help ensure that Veterans receive the best health care possible.

Dr. Huang closed the public session of the meeting at 9:30 AM to continue with the study review portion. The study review portion of the meeting proceeded as scheduled, with three new submissions and one midterm review.

New Submissions:

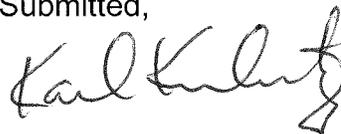
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|-------------|---|
| CSP #465-F | "VA Diabetes Trial Follow-up Study (VADT-FS)" |
| CSP #586 | "P2Y12 Receptor Antagonist and Aspirin vs. Aspirin Treatment and Impact on Outcomes of Coronary Artery Bypass Grafting (PAATRIOT CABG)" |
| CSP #517-FS | "ROOBY Trial Follow-up Extension" |

Midterm Review:

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| CSP #562 | "The VA Keratinocyte Carcinoma Chemoprevention Trial" |
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The meeting concluded at 2:45 PM on December 20, 2011.

Submitted,



Karl Kiebertz, MD, MPH
Chair CSSEC

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

December 20, 2011

The Hamilton Crowne Plaza
1001 14th Street, NW
Washington, DC 20005

Tuesday, December 20, 2011

8:00 – 8:30 AM Opening of General Session & Welcoming Remarks
Timothy J. O’Leary, MD, PhD
Deputy Chief Research & Development Officer
Director, Clinical Science R&D Service

8:30 – 8:45 AM Overview of Review Procedures
Karl Kieburtz, MD, MPH
CSSEC Chair

1st Proposal **CSP #465-F – “VA Diabetes Trial Follow-up Study (VADT-FS)”**

8:45 – 9:00 AM **Briefing Session**

9:00 – 9:30 AM VA Chief of Staff Remarks <i>John R. Gingrich</i> <i>Chief of Staff</i>

1st Proposal **CSP #465-F – “VA Diabetes Trial Follow-up Study (VADT-FS)**
(cont’d)

9:30 – 9:45 AM **Study Team Presentation**
Peter D. Reaven, MD – Co-Principal Proponent
Nicholas Emanuele, MD – Co-Principal Proponent
Rodney Hayward, MD – Co-Principal Proponent
Gideon Bahn, PhD – Study Biostatistician
Domenic Reda, PhD – CSPCC Director

9:45 – 10:00 AM **CSSEC Review**

10:00 – 10:15 AM **Executive Session**

10:15 – 10:30 AM Break

2nd Proposal **CSP #586 – “P2Y12 Receptor Antagonist and Aspirin vs. Aspirin Treatment and Impact on Outcomes of Coronary Artery Bypass Grafting (PAATRIOT CABG)”**

10:30 – 10:45 AM **Briefing Session**

10:45 – 11:00 PM **Study Team Presentation**

Faisal G. Bakaeen, MD – Co-Principal Proponent
Deepak L. Bhatt, MD, MPH – Co-Principal Proponent
Peter Peduzzi, PhD – Senior Biostatistician
Katherine Kirkwood, MS – Study Biostatistician
Peter Guarino, MPH, PhD – Acting CSPCC Director

11:00 – 11:45 PM **CSSEC Review**

11:45 – 12:00 PM **Executive Session**

12:00 – 12:45 PM Lunch (working lunch, if needed)
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3rd Proposal **CSP #517-FS – “ROOBY Trial Follow-up Extension”**

12:45 – 1:00 PM **Briefing Session**

1:00 – 1:15 PM **Study Team Presentation**

A. Laurie Shroyer, PhD – Co-Principal Proponent
Frederick Grover, MD – Co-Principal Proponent
Brack Hattler, MD – Study Co-Investigator
Joseph F. Collins, ScD – Biostatistician & CSPCC Director

1:15 – 1:45 PM **CSSEC Review**

1:45 – 2:00 PM **Executive Session**

2:00 – 2:15 PM Break

4th Proposal **CSP #562 – “The VA Keratinocyte Carcinoma Chemoprevention Trial” – MIDTERM REVIEW**

2:15 – 2:30 PM **Briefing Session**

2:30 – 2:45 PM **Study Team Presentation**

Martin Weinstock, MD, PhD – Study Chair
Robert Lew, PhD – Study Biostatistician
Louis Fiore, MD, MPH – CSPCC Director

2:45 – 3:15 PM

CSSEC Review

3:15 – 3:30 PM

Executive Session

3:45 PM

MEETING ADJOURNMENT