

Draft Guidance for Industry and Food and Drug Administration Staff;
Guidance for the Use of Bayesian Statistics in Medical Devices
July 27, 2006 – 8:30 a.m. – 5:00 p.m. EST
The Universities of Shady Grove, 9630 Gudelsky Drive, Rockville, MD

- 7:30 a.m. **Registration**
- 8:30 a.m. **Welcome and Introductory Remarks**
- Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA
 - Donna-Bea Tillman, Ph.D., Director, Office of Device Evaluation, CDRH, FDA
 - Susan Gardner, Ph.D., Director, Office of Surveillance and Biometrics, CDRH, FDA
- 9:00 a.m. **FDA Presentations about the draft guidance document “The Use of Bayesian Statistics in Medical Device Clinical Trials”**
- 10:05 a.m. **20 Minute Break**
- 10:25 a.m. **Additional FDA Presentations**
- 11:40 a.m. **Morning Wrap-Up**
- 11:45 – 1:15 p.m. **Lunch On Your Own**
- 1:15 p.m. **Panel I: Planning Considerations**
Panel and Floor Discussion
- Moderator:** Larry Kessler, Sc.D., Director, Office of Science and Engineering Laboratories, CDRH, FDA
- Panelists:**
- Susan Alpert, Ph.D., M.D., Senior Vice President, Chief Quality and Regulatory Officer, Medtronic
 - Donald Berry, Professor and Chairman, Department of Biostatistics and Applied Mathematics, MD Anderson Cancer Center, University of Texas
 - Barbara Buch, M.D., Deputy Director, Division of General, Restorative and Neurological Devices, CDRH, FDA

- Bailey Lipscomb, Ph.D., Vice President, Clinical Affairs, Medtronic Sofamor Danek
- Janet Trunzo, Executive Vice President, Technology and Regulatory Affairs, Advanced Medical Technology (AdvaMed)

2:45 p.m.

15 Minute Break

3:00 p.m.

Panel II: Practical Issues

Panel and Floor Discussion

Moderator: Greg Campbell, Ph.D., Director, Division of Biostatistics, CDRH

Panelists:

- Bradley P. Carlin, Ph.D., Mayo Professor of Public Health, Division of Biostatistics, University of Minnesota, Biostatistics, School of Public Health
- Ralph D'Agostino, Ph.D., Professor, Department of Mathematics and Statistics, Boston University, Mathematics and Statistics Department
- Steven Goodman, M.D., Ph.D., Professor of Oncology, Pediatrics, Biostatistics and Epidemiology, Johns Hopkins University
- Gerald J. Prud'homme, Partner, Hogan and Hartson LLP
- Roseanne White, Statistics Fellow, Guidant-Abbott Vascular
- Bram Zuckerman, M.D., Director, Division of Cardiovascular Devices, CDRH, FDA

4:45 p.m.

Afternoon Wrap-Up

5:00 p.m.

Adjournment