

General Chapters - Statistics Expert Committee Monday-Tuesday, October 9-10, 2017 8:30 a.m. – 5:00 p.m., 8:45 a.m. – 1:00 p.m. U.S., Rockville

Draft Agenda

Goals and Anticipated Outcomes

- To review progress of EC's 2015-2020 work plan
- · Review status of on-going chapter revisions
- Discuss new areas for possible consideration
- Set goals under each agenda item

Attendees

Attendee list provided on the day of the meeting

Day 1 October 9, 2017

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

8:30 a.m. 1. Procedural Matters and Standard of Conduct

Mr. Singer

- (Informational)
 - a. Call Meeting to Orderb. Establish Quorum
 - c. Identification of Observers and Confidential Information
 - d. Conflicts of Interest

END OF CLOSED SESSION

USP Head	lquarters
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8:45 a.m.	2.	Opening and	Procedural	Matters
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(Informational & Decision-making)

a.	Meetings Center Announcements	Ms. Hawkins
b.	Welcome	Mr. Singer
C.	Introductions	All
d.	Minutes of the Previous Meeting	Mr. Singer
e.	Approval of the Agenda	Mr. Singer
f.	Procedural Announcements	Mr. Freebern

9:00 a.m. 3. Review Work Plan

(Discussion)

a. Updates to 2015-2020 Statistics EC Work Plan Mr. Walfish

9:45 a.m. 4. Chapter Updates

a. <1010>	Mr. Schofield
b. Bioassay	Dr. Lansky
c. <1210>	Dr. Tan



10:45 a.m. **Break** 11:00 a.m. 5. Workshops and Education (Discussion) a. <1010> and <1210> Mr. Walfish b. Bioassay Chapters Mr. Walfish c. Bioassay Workshop Mr. Singer 12:00 p.m. **Group Photo** 12:05 p.m. Lunch 1:00 p.m. 6. Expert Panels and Subcommittees (Discussion & Decision Making) Timelines, deliverables and resourcing to be determined a. Content Uniformity in Large Sample Sizes Dr. Sandell Dr. Sandell b. Joint Committee on Data Analysis 3:00 p.m. **Break Expert Panels and Subcommittees continued** 3:30 p.m. c. Validation / Verification Ms. Weitzel 7. Discussion of Face to Face Date for 2018 ΑII 4:30 p.m. 8. General Chapter Decision Tree Mr. Walfish 4:45 p.m. (Discussion) 5:00 p.m. **Day 1 Meeting Adjournment** Day 2 October 10, 2017 8:30 a.m. 9. Subcommittee Working Sessions (Discussion & Decision Making) Mr. Schofield a. Comments to <1010> 10:30 a.m. Break 11:00 a.m. b. Bioassay Chapters Dr. Lansky 1:00 p.m. **Box Lunch and Adjournment**