U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Hilton Washington DC North/Gaithersburg

AGENDA

October 11 and 12, 2017

DAY 1—October 11, 2017

12:30 p.m.	Chair Opening of the Advisory Committee Meeting
12:45 p.m.	Opening Remarks, Scott Gottlieb, MD, *Commissioner of Food and Drugs, FDA*
12:55 p.m.	Opening Remarks, Jeffrey Shuren, MD, JD, *Director CDRH, FDA*
1:05 p.m.	Clinical Trials and Medical Devices, Owen Faris, PhD, *CDRH Clinical Trials Program Director*
1:25 p.m.	Patient Engagement Efforts with the Clinical Trial Enterprise - Bray Patrick-Lake, MFS, *Director of Stakeholder Engagement, Duke Clinical Research Institute* - Ken Getz, MBA, *Founder and Board Chair, Center for Information & Study of Clinical Research Participation (CISCRP)*
1:55 p.m.	Open Committee Discussion
2:10 pm	BREAK
2:25 pm	Open Public Hearing
2:55 p.m.	Round Table Topic #1: Patient Involvement in the Design of Clinical Trials
3:20 p.m.	Summary of Round Table Topic #1: Committee Discussion
3:45 p.m.	Round Table Topic #2: Patient Recruitment, Enrollment, and Retention
4:10 p.m.	Summary of Round Table Topic #2: Committee Discussion
4:35 p.m.	BREAK

4:50 p.m. Round Table Topic #3: Dissemination of Trial Data and Results to Participants and Other Patients

5:15 p.m. Summary of Round Table Topic #3: Committee Discussion

5:40 pm Open Committee Discussion

5:55 p.m. Closing Remarks

6:00 p.m. Adjourn

DAY 2 – October 12, 2017

8:00 a.m. Opening of the Advisory Committee Meeting

8:10 a.m. CDRH Patient Engagement Efforts, Katie O'Callaghan, *Assistant Director of Strategic Programs, CDRH*

8:20 a.m. Recap of Meeting Day 1, Michelle Tarver, MD, PhD, *Acting Assistant Director of Strategic Programs, CDRH*

8:35 a.m. **Topic 1: Patient Involvement in the Design of Clinical Trials**
- Faye S. O'Brien, *Outsourcing Programme Director, AstraZeneca*
- John Freimuth, MA, *Office of Advocacy Relations, National Cancer Institute*
- Anna McCollister-Slipp, *Chief Advocate for Participatory Research, Scripps Translational Science Institute*

9:20 a.m. Open Committee Discussion

9:40 a.m. **Topic 2: Patient Recruitment, Enrollment, and Retention**
- Elise Felicione, MPH, MBA, *Senior Director, Janssen Clinical Innovation* & Amy Loescher, *Director, Clinical Program Operations, Johnson & Johnson*
- Kenneth Stein, MD, FACC, FHRS, *Senior Vice President & Chief Medical Officer, Cardiac Rhythm Management and Global Health Policy, Boston Scientific*
- Kristin Carman, MA, PhD, *Director of Public and Patient Engagement, Patient Centered Outcomes Research Institute (PCORI)*
- Paul Melmeyer, *Director of Federal Policy, National Organization for Rare Diseases (NORD)*

10:40 a.m. Open Committee Discussion

11:00 a.m. BREAK

11:15 a.m. **Topic 3: Communication of Study Results to Trial Participants**
- Deborah Zarin, MD, *Director, ClinicalTrials.gov*
- John Wilbanks, *Chief Commons Officer, Sage Bionetworks*

11:45 a.m. Open Committee Discussion

12:05 p.m. Lunch

1:05 p.m. Open Public Hearing

2:35 p.m. BREAK

2:50 p.m. Committee Discussion of FDA Questions

4:50 p.m. Chair Closing Comments

5:00 p.m. Adjourn

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