CTTI 10 YEAR ANNIVERSARY

ONE DECADE OF IMPACT • ONE VISION AHEAD

The Clinical Trials Transformation Initiative 10 Year Anniversary

Draft Agenda of the Symposium on Feb. 6, 2018

DoubleTree by Hilton Hotel Bethesda-Washington, DC

8120 Wisconsin Ave., Bethesda, MD 20814

CTTI MISSION

To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- Discover how CTTI has influenced the clinical trials enterprise during the past decade.
- Hear from other organizations about the benefits of applying CTTI recommendations successfully.
- Learn how CTTI's current work will impact and shape clinical trials of the future.

FEBRUARY 6, 2018

8:30 a.m.	**Session I: Reflection**
	Session I Facilitator: Pamela Tenaerts, CTTI
8:30 a.m.	Welcome and Introduction to CTTI *Pamela Tenaerts, CTTI*
8:45 a.m.	Welcome from the Executive Committee *Jacqueline Corrigan-Curay, FDA*
8:55 a.m.	Keynote Address *Scott Gottlieb, FDA (TBC)*
9:30 a.m.	**Session II: Implementation and Impact – Quality by Design**
	Session II Facilitator: Martin Landray, University of Oxford
9:30 a.m.	Reflection on Quality by Design *Robert Temple, FDA, CDER* *Fergus Sweeney, European Medicines Agency (TBC)*
9:45 a.m.	Quality by Design Project Overview and Recommendations *Ann Meeker-O'Connell, Johnson & Johnson*
10:00 a.m.	Quality by Design Case Study *Julie Deitrich, Amgen*
10:20 a.m.	Discussion
10:45 a.m.	**Break and Poster Session**
11:15 a.m.	**Session III: Implementation and Impact – Patient Groups & Clinical Trials**
	Session III Facilitator: Nancy Roach, Fight Colorectal Cancer
11:15 a.m.	Reflection on Patient Engagement *Ken Getz, Tufts University*
11:25 a.m.	Patient Groups & Clinical Trials Project Overview and Recommendations *Bray Patrick-Lake, Duke Clinical Research Institute*
11:40 a.m.	Patient Groups & Clinical Trials Case Study *Ron Bartek, Friedreich's Ataxia Research Alliance* *Jeff Sherman, Horizon Pharma*
12:00 p.m.	Discussion
12:30 p.m.	**Lunch and Poster Session** *(Provided)*

FEBRUARY 6, 2018 *(Continued)*

1:30 p.m.	**Session IV: Implementation and Impact – Use of a Single IRB of Record**
	Session IV Facilitator: Joanne Less, FDA, OC
1:30 p.m.	Reflection on Use of a Single IRB of Record *Jerry Menikoff, Office for Human Research Protections*
1:40 p.m.	Central IRB Project Overview and Recommendations *Soo Bang, Celgene (TBC)*
1:55 p.m.	Use of a Single IRB of Record Case Study *Hallie Kassan, Feinstein Institute for Medical Research*
2:15 p.m.	Discussion
2:45 p.m.	**Break and Poster Session**
3:00 p.m.	**Session V: Envisioning the Future of Clinical Trials**
	Session V Facilitator: Rob Califf, Duke University
3:00 p.m.	The Future of Clinical Trials *Rob Califf, Duke University / Verily*
3:20 p.m.	Discussion
4:00 p.m.	**Summary & Adjournment** *Pamela Tenaerts, CTTI*