CTTI's Mobile Technologies Event Agenda

FDA White Oak Campus | Silver Spring, MD | July 16, 2018

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

MEETING OBJECTIVES:

Share practical examples and best practices for:

- Selecting mobile technologies for data capture that are appropriate to the trial.
- Capturing complete, attributable, and high-quality data.
- Managing the data generated by mobile technologies—including safety considerations, data integrity, and security issues.
- Designing and executing a protocol that uses mobile technologies for data capture.
- Preparing for FDA submission and inspection.

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9:30 a.m. Welcoming Remarks

9:30 a.m. Introduction to the Clinical Trials Transformation Initiative (CTTI)
Annemarie Forrest, CTTI

9:40 a.m. Introduction to CTTI's Mobile Clinical Trials (MCT) Program
Jennifer Goldsack, CTTI

10:00 a.m. Session I: Technology Selection

Review new CTTI recommendations and resources for selecting a mobile technology for data capture.

Aaron Coleman, Fitabase
John Hubbard, GenStar Capital
Barry Peterson, Independent Consultant
Linda Ricci, FDA, CDRH
Drew Schiller, Validic
Jeremy Wyatt, ActiGraph

11:05 a.m. Session II: Data Collection, Analysis, and Interpretation

Review new CTTI recommendations and resources for ensuring the capture of high-quality data using mobile technologies.

Brian Bot, Sage Bionetworks
Aiden Doherty, University of Oxford
Luca Foschini, Evidation Health
Nina Mian, AstraZeneca
Ken Skodacek, FDA, CDRH

12:40 p.m. Session III: Data Management

Review new CTTI recommendations and resources for managing the data generated by mobile technologies.

Bill Bates, Validic
Andy Coravos, Elektra Labs
Phil Coran, Medidata Solutions
Jennifer Goldsack, CTTI
Cheryl Grandinetti, FDA, CDER
Ashish Narayan, Mount Sinai Health System

1:40 p.m. Session IV: Optimizing Protocol and Design Execution

Review new CTTI recommendations and resources for optimizing protocol design and execution.

Abby Bronson, Parent Project Muscular Dystrophy (PPMD)
Eugene Patin, Novartis
Michele Russell-Einhorn, Advarra
Kaveeta Vasisht, FDA, CDER
Bill Wood, University of North Carolina

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2:50 p.m.	**Session V: Supporting FDA Submission and Inspection**
	Review new CTTI recommendations and resources for supporting sponsors who are preparing for FDA submission and inspection. *Jonathan Helfgott, Johns Hopkins University* *Matt Kirchoff, NIH, NIAID* *Tom Switzer, Genentech-a member of the Roche Group*
3:25 p.m.	**Session VI: Mobile Technologies in Perspective**
3:25 p.m.	EMA Experience with the Review of Digital Technology Proposals in Medicine Development Programs *Francesca Cerreta, European Medicines Agency (EMA)*
3:40 p.m.	The Future of Mobile Technologies in Clinical Trials *Francesca Cerreta, EMA* *Ray Dorsey, University of Rochester* *Pat Furlong, PPMD* *John Hubbard, Genstar Capital* *Leonard Sacks, FDA, CDER*
4:20 p.m.	Q & A
4:40 p.m.	Closing Comments
4:45 p.m.	**Adjourn**