CLINICAL TRIALS TRANSFORMATION INITIATIVE

AGENDA

CTTI Expert Meeting:
Qualifying Investigators to Conduct Sponsored Clinical Trials

Dec. 13-14, 2017

Hyatt Regency Bethesda
1 Bethesda Metro Center, Bethesda, MD 20814

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

MEETING OBJECTIVES:

- Report evidence gathered on:
  - Critical tasks associated with clinical investigators' conduct of clinical trials.
  - Gaps and redundancies in training for preparing clinical investigators to conduct clinical trials.
  - Suggested knowledge and skills necessary for the quality conduct of clinical trials.
- Evaluate proposed framework of characteristics within control of clinical investigator sites that define the quality conduct of a clinical trial.
- Discuss how preparing clinical investigators for the quality conduct of a clinical trial could be optimized.
- Identify the recommendations and tools that sponsors and investigators could implement to better prepare clinical investigators for the quality conduct of a clinical trial. Also, pinpoint the barriers—and solutions—to implementing these recommendations.

WEDNESDAY, DEC. 13, 2017

Welcome and Opening Remarks

9:00 a.m. Welcome and Review of Aligned CTTI Work
Annemarie Forrest, CTTI

9:15 a.m. The CTTI Investigator Qualification Project and Meeting Goals
Jennifer Goldsack, CTTI

Session I: Defining the Problem, Opportunity, and Goal

Session I Moderator: Jennifer Goldsack, CTTI
Session I Objectives:

- Define the challenges associated with the current approach to preparing investigators and their delegates for the quality conduct of a clinical trial.
- Identify other activities in the ecosystem that create a unique opportunity for this work to be particularly impactful.
- Describe the "goal state", or how we would characterize a landscape where investigators and their delegates are qualified for the quality conduct of clinical trials.

9:30 a.m. Defining the Problem
Michael J. Koren, ENCORE Research Group
Sabrina Comic-Savic, The Medicines Company
Cindy Geoghegan, Patients and Partners
Jean Mulinde, FDA

9:40 a.m. Open Group Discussion

10:00 a.m. A Changing Ecosystem – A Brief Review of ICH GCP Renovations Planned and Currently Under Way
Theresa Mullin, FDA

10:10 a.m. Open Group Discussion

10:30 a.m. Proposed Framework of Characteristics that Define the Quality Conduct of a Clinical Trial
Janette Panhuis, Population Health Research Institute (PHRI)

10:40 a.m. Open Group Discussion

11:00 a.m. Break

Session II: An Evidence Driven Discussion How can CTTI Findings Inform Solutions?

Session II Moderator: Janette Panhuis, PHRI
Session II Objectives:

- Report and discuss evidence gathered by CTTI Investigator Qualification Project Team.
- Discuss the significance of this information and supplement the findings with viewpoints and experiences of other stakeholder groups.
- Identify how the evidence and additional information discussed drives solutions to the challenges of effectively and efficiently preparing investigators and their delegates for the quality conduct of clinical trials.

WEDNESDAY, DEC. 13, 2017

Session II:	An Evidence Driven Discussion How can CTTI Findings Inform Solutions?
11:20 a.m.	Evidence Gathering: Our Approach to Data Collection *Teri Swezey, CTTI*
11:25 a.m.	Critical Tasks that our Evidence Suggests Should be Well Executed to Drive the Quality Conduct of a Clinical Trial *David Ciavarella, CR Bard*
11:35 a.m.	Open Group Discussion
12:10 p.m.	Perceived Risks to the Quality Conduct of Clinical Trials *Kate Haratonik, Genentech-a member of the Roche Group*
12:25 p.m.	Open Group Discussion
2:00 p.m.	Knowledge and Skills our Evidence Suggests may be Needed to Perform Critical Tasks and Mitigate Risks to Quality Trial Conduct *Catherine Dillion, Medical University of South Carolina*
2:15 p.m.	Open Group Discussion
2:45 p.m.	Evaluating Current Approaches to Preparing Investigators and Their Delegates: What is working, what is not, and what is missing? *Patricia Hurley, American Society of Clinical Oncology*
3:00 p.m.	Open Group Discussion
Session III:	**Approaches Beyond Training for Preparing Investigators to be Qualified for the Quality Conduct of Clinical Trials**
	Session III Moderator: Kate Haratonik, Genentech *Session III Objective:* ► Determine what knowledge should be communicated to investigators and their delegates through non-didactic approaches.
3:35 p.m.	Building a Learning Ecosystem *Tina Chuck, Northwell Health*
3:45 p.m.	Case Study of an Investigator Mentoring Program *Emily Lemons, PMG Research*
4:00 p.m.	Open Group Discussion
5:00 p.m.	**Adjourn Day One**

THURSDAY, DEC. 14, 2017

8:15 a.m. Opening Remarks
Jennifer Goldsack

Session IV: Training Approaches to Preparing Investigators

Session IV Moderator: Sabrina Comic-Savic, The Medicines Company
Session IV Objectives:

- Describe current training approaches from the perspective of both the trainer and the learner.
- Determine what knowledge should be communicated to investigators and their delegates through training approaches.
- Define how training approaches may be optimized.

8:25 a.m. Delivering Effective Training to Investigators and Their Delegates
Tina Chuck, Northwell Health

8:35 a.m. An Investigator's Reflections on Training in the Conduct of Clinical Research
Christine Hildebrand, Amici Clinical Research

8:45 a.m. FDA's Perspective on GCP Training
Bridget Foltz, FDA

8:55 a.m. Open Group Discussion

Session V: Driving Change

Session V Moderator: Ronnie Todaro, Parkinson's Foundation
Session V Objectives:

- Define what aspects of current practices for preparing investigators and their delegates for the quality conduct of clinical trials need to change.
- Identify practical approaches to affecting these changes.

10:15 a.m. Open Group Discussion

Session VI: An Overview of Next Steps

Session VI Moderator: Jennifer Goldsack, CTTI
Session VI Objectives:

- Identify what successful completion of this project should look like.
- Define next steps.

12:45 p.m. Adjourn and Departures