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.
**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.
### Session II: An Evidence Driven Discussion—How can CTTI Findings Inform Solutions?

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<th>Time</th>
<th>Session</th>
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| 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.

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| 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                                                                             |
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