



Strengthening the Investigator Site Community Project

Formerly Known as the Investigator Turnover Project

Agenda of the Multi-Stakeholder Expert Meeting April 5, 2017

Sheraton Silver Spring Hotel
8777 Georgia Avenue
Silver Spring, MD 20910

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

MEETING OBJECTIVES:

- ▶ Present findings from CTTI's Strengthening the Investigator Site Community Project: Expert Interviews and Survey
- ▶ Receive feedback on identified challenges experienced by principal investigators and strategies to overcome these challenges
- ▶ Identify essential elements necessary to strengthen and grow the community of productive, experienced site investigators
- ▶ Develop strategies and best practices to promote the growth and strengthening of the community of experienced site investigators
- ▶ Identify barriers to strategy implementation and propose solutions

WEDNESDAY APRIL 5, 2017

8:30 9:00 Introduction and Background

- 8:30 Introduction to the Clinical Trials Transformation Initiative
Gerrit Hamre, Clinical Trials Transformation Initiative (CTTI)
- 8:40 Issue, Project Overview, and Meeting Objectives
Diana Foster, Society for Clinical Research Sites (SCRS)

9:00 10:30 Session I: Presentation of Project Findings

Session I Facilitator: Diana Foster, SCRS

Session I Objectives:

- ▶ Present findings from One and Done survey
- ▶ Present findings from Active Investigator interviews
- ▶ Discuss findings, barriers, and solutions

- 9:00 One and Done Survey Design and Findings
Christopher Fordyce, University of British Columbia
- 9:30 Active Investigator Interview Findings
Terri Hinkley, Association of Clinical Research Professionals (ACRP)
- 10:00 Open Group Discussion

10:45 12:15 Session II: Identifying Essential Themes and Proposing Solutions

Session II Facilitator: Matthew Roe, Duke Clinical Research Institute (DCRI)

Session II Objectives:

- ▶ Examine high level themes established from collected data
- ▶ Identify essential elements to strengthen and grow participation of productive, experienced principal investigators
- ▶ Discuss generalizability and actionable solutions

- 10:45 Key Elements for Site Investigator Success: Infrastructure, Training, Staff Support, and Formalized Mentorship
Matthew Roe, DCRI
- 11:00 Fiscal Responsibility and Discipline: Budgets, Negotiation, Payment Schedules, and Terms
Kaitlin Malone, Amgen
- 11:15 Optimizing Trial Execution and Conduct: Recruitment, Protocol Eligibility, and FDA Reporting
Robin Douglas, QuintilesIMS
- 11:30 Investigator Perspective: My Approach / Why Do I Remain Involved?
David Whellan, Jefferson Clinical Research Institute
- 11:45 Open Group Discussion

WEDNESDAY APRIL 5, 2017 (Continued)

1:00 2:00 Session III: FDA Perspective and Feedback

Session III Facilitator: David Ciavarella, CR Bard, Inc.

Session III Objectives:

- ▶ Provide FDA tools to help investigators succeed
- ▶ Examine FDA identified concerns and areas for improvement

1:00 A Primer in FDA Resources for Clinical Investigators
Bridget Foltz; FDA, Office of Good Clinical Practice

1:15 FDA Observations Related to Investigator Participation
David Burrow; FDA, Office of Scientific Investigations

1:45 Open Group Discussion

2:15 2:45 Session IV: Panel Discussion Feedback from Participating Investigators

Session IV Facilitator: Matthew Roe, DCRI

Session IV Objectives:

- ▶ Receive feedback from investigators on presented data and proposed suggestions to strengthen and grow the investigator community

Panel Participants:

Principal Investigator Expert Meeting Attendees (TBD)

2:45 3:20 Session V: Panel Discussion Identifying Potential Implementation Barriers to Overcome and Necessary Change Agents

Session V Objectives:

- ▶ Identify strategies necessary to drive adoption of project recommendations
- ▶ Examine potential barriers to implementation and chart course to proactively address those barriers

Panel Participants:

Terri Hinkley, ACRP

Diana Foster, SCRS

Matthew Roe, DCRI

3:20 3:30 Session VI: Call to Action and Wrap up

3:20 Closing Statements

3:30 Adjourn