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
### 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
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