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
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<th>Time</th>
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| 8:30  | 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  | 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 | 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**