AGENDA

CTTI Expert Meeting:
Stakeholder Perceptions of the Use of Mobile Technology in Clinical Trials
Jan. 9-10, 2018

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:

► Present findings from CTTI evidence gathering activities examining the perspectives of investigators and potential research participants on the use of mobile technology for collection of objective data in clinical trials.

► Discuss how this and additional evidence presented may be used to provide direction to the research enterprise for the appropriate utilization of mobile technology in clinical trials.

► Identify products that CTTI should develop to equip the clinical trials enterprise to address the barriers, preferences, and needs of investigative site personnel and potential research participants in regulatory submission trials using mobile technology.
9:00 a.m.  Welcoming Remarks

Welcome and Background  
Annemarie Forrest, CTTI  
- Brief Overview of CTTI and the Mobile Clinical Trials (MCT) Program.  
- Highlighted findings and recommendations from CTTI’s Novel Endpoints, Mobile Devices, and Legal & Regulatory Projects.  
- MCT Stakeholder Perceptions: Project overview and meeting objectives.

9:20 a.m.  Keynote Presentation  
John Wilbanks, Sage Bionetworks

9:40 a.m.  Session I: Presentation of Evidence on Potential Participant Perspectives of Mobile Technology in Clinical Trials

Session I Facilitator: Zachary Hallinan, CTTI  
Session I Objectives:  
- Present and discuss findings from CTTI survey of potential research participants.  
- Identify key themes that should be carried forward into project recommendations.

9:40 a.m.  Presentation and Discussion of Findings from the MCT Stakeholder Perceptions Survey of Potential Clinical Trial Participants  
Angie Botto-van Bemden, Arthritis Foundation  
Cindy Geoghegan, Independent Patient / Caregiver  
Les Jordan, Target Health

11:25 a.m.  Session II: Understanding and Incorporating Patient Perspectives into Trials using Mobile Technology

Session II Facilitator: Steve Morin, FDA, OCHA  
Session II Objective:  
- Understand related findings on patient perspectives of, and experiences with, mobile in clinical trials.

11:30 a.m.  Key Considerations for Patient Engagement in Clinical Trials  
Suzanne Schrandt, Arthritis Foundation

11:45 a.m.  Mobile in Clinical Trials: Landscape and Value Proposition  
John Hernandez, Verily Life Sciences

12:00 p.m.  Ethical and Privacy Considerations of Mobile Technology  
Camille Nebeker, University of California, San Diego

12:15 p.m.  Open Group Discussion
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2:00 p.m.  Session III: Using Mobile Technology to Collect Objective Trial Data—Implications for Traditionally Underrepresented Patient Populations

Session III Facilitator: Maria Ali, The George Institute for Global Health
Session III Objectives:
► Understand perspectives that underrepresented populations have of clinical trials and mobile technology.
► Discuss elements of underrepresented populations’ experience in clinical trials that could be enhanced via the use of mobile technology, focusing on collection of objective trial data and experiences after the time of initial consent.

Session III Panelists:
Luther Clark, Merck & Company
Martin Mendoza, FDA, OC
Silas Buchanan, Institute for eHealth Equity
Cindy Geoghegan, Individual Patient / Caregiver

3:30 p.m. Session IV: Presentation of Evidence on Investigator Perspectives of Mobile Technology in Clinical Trials

Session IV Facilitator: Virginia Nido, Genentech-a member of the Roche Group
Session IV Objectives:
► Present and discuss findings from CTTI interviews with investigators who have conducted trials involving mobile technology for objective data collection.
► Identify key themes that should be carried forward into project recommendations.

3:30 p.m. Findings from MCT Stakeholder Perceptions Investigator Interviews
Bill Wood, NC TraCS, University of North Carolina at Chapel Hill

4:15 p.m. Open Group Discussion

5:00 p.m. Adjourn to Dinner Reception
### JANUARY 10, 2018

**8:15 a.m.  Session V: Site Experiences with Mobile Technology in Clinical Trials**

**Session V Facilitator:** Petros Okubagzi, MedStar Health  
**Session V Objectives:**
- Present and discuss case study experiences of investigative sites in trials using sponsor-provided and patient-provided (BYOD) mobile devices.
- Contextualize the site experience with discussion of research sponsor experiences conducting trials with mobile technology.

**Session V Panelists:**  
David Morin, Holston Medical Group  
Elisha French, Genentech—a member of the Roche Group  
Evan Muse, Scripps Translational Science Institute

**9:30 a.m.  Session VI: Breakout Groups—Actionable Opportunities for Transformative Change**

**Session VI Objectives:**
- Discuss implications of mobile in clinical trials for both patients and sites.
- Identify key themes and tools required to support stakeholders in addressing the needs of research participants and investigative sites.

**Breakout Instructions and Directions**  
Zachary Hallinan, CTTI

1. **Training, Technical Support, and Site Budgets for Trials Using Mobile Technology**  
   *Facilitator:* Virginia Nido, Genentech—a member of the Roche Group

2. **Designing Trials with Mobile Technology to Meet Patient and Site Needs**  
   *Facilitator:* Les Jordan, Target Health

3. **Meeting Patient Expectations for Communication, Data Sharing, and Privacy**  
   *Facilitator:* Maria Ali, The George Institute for Global Health

**11:15 a.m.  Session VII: Plenary Discussions of Breakout Recommendations**

- **11:15 a.m.** Key Discussion Points: Training, Technical Support, and Site Budgets for Trials Using Mobile Technology
- **11:30 a.m.** Key Discussion Points: Designing Trials with Mobile Technology to Meet Patient and Site Needs
- **11:45 a.m.** Key Discussion Points: Meeting Patient Expectations for Communication, Data Sharing, and Privacy
- **12:00 p.m.** Highlights, Wrap-Up, & Next Steps

**12:30 p.m.  Adjourn**