Issue, Project Overview, and Meeting Objectives

Gerrit Hamre
Project Manager, Clinical Trials Transformation Initiative
# MCT Legal and Regulatory Issues Project Team

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<tr>
<th>Team Leaders</th>
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<th>Project Manager</th>
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<td>Linda Coleman (Yale)</td>
<td>David Babanian (Quorum Review/Kinetiq)</td>
<td>Gerrit Hamre (CTTI)</td>
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<td>Gary Grabow (Genentech)</td>
<td>Paul Conway (AAKP)</td>
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<td>Jan Hewett (FDA CDER)</td>
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<td>Barak Richman (Duke)</td>
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<td>Laura Podolsky (Science37)</td>
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**Social Science Lead**

Amy Corneli (CTTI)
Why Not Mobile?

**Project Purpose:**
- The project aims to propose recommendations to overcome the legal and regulatory barriers that inhibit widespread use of mobile technology in clinical trials

**Project Objectives:**
- Catalog and summarize laws, regulations, and associated organizations that affect the implementation of mobile clinical trials
- Identify perceived and actual legal and regulatory barriers to conducting mobile clinical trials
- Identify opportunities to clarify and inform policies that affect the implementation of mobile clinical trials
Definitions

Telemedicine
- Using remote delivery of healthcare to evaluate, treat or diagnose disease through use of a communication technology
- Telephone, email, online health record portals, fax, audio conferencing, live-video, or store-and-forward mobile device
- Delivered by physician, nurse practitioner, or other designated medical personnel

Clinical Trial Using Telemedicine
- Execution of a clinical trial protocol, including data collection and reporting for case report forms, where patient care relies partially or fully on telemedicine visits

Telehealth
- “Telemedicine” and “Telehealth” are interchangeable terms
Legal and Regulatory Issues

- Health Authority Receptivity/Readiness
- Good Clinical Practice
- Institutional Review Boards
- Privacy/Confidentiality
- Reimbursement
- Shipping and Receiving of Investigational Agents
- Telemedicine
Methods and Milestones

- Sponsor Interviews – Q4 2016
- Analysis of findings – Q1 2017
- Team F2F Meeting in D.C. – April 12, 2017
- **Expert Meeting – July 11-12 2017 Washington DC**
  - Remote Healthcare Providers, FDA, IRBs, GCP Monitors, Patients, Telemedicine Providers/Policy Experts, and Drug Supply Chain Experts
- Catalogue Summarizing Laws/Regs/Associations
- Recommendations
Meeting Objectives

- Present findings from evidence gathering activities
- Discuss how this evidence may be used to provide direction for the appropriate utilization of mobile technology in clinical trials
- Describe what products CTTI should develop to overcome the legal and regulatory barriers that inhibit more widespread use of mobile technology in clinical trials
THANK YOU.

www.ctti-clinicaltrials.org