Legal & Regulatory Issues Affecting the Adoption of Mobile Clinical Trials

Agenda of the Multi-Stakeholder Expert Meeting held July 11-12

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

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

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 equip change agents to overcome the legal and regulatory barriers that inhibit more widespread use of mobile technology in clinical trials, including for the purposes of regulatory submission
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Details</th>
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<tbody>
<tr>
<td>8:30 AM</td>
<td>Welcoming Remarks</td>
<td>Introduction to the Clinical Trials Transformation Initiative (CTTI)</td>
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<td>Annemarie Forrest, CTTI</td>
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<td>8:45 AM</td>
<td>Session I: Project Overview and Findings</td>
<td>Session I Facilitators: Leonard Sacks, FDA CDER Office of Medical Policy (OMP) and Vashali Popat, FDA CDER Office of New Drugs (OND)</td>
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<td>▶ Describe the CTTI Mobile Clinical Trials (MCT) Program and Legal &amp; Regulatory Issues Project</td>
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<td>▶ Present and discuss findings from project evidence gathering activities</td>
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<td>8:45 AM</td>
<td>Issue, Project Overview, and Meeting Objectives</td>
<td>Gerrit Hamre, CTTI</td>
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<td>9:00 AM</td>
<td>Qualitative Sponsor Interview Findings</td>
<td>David Babaian, Quorum Review, Kinetiq</td>
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<td>9:45 AM</td>
<td>Open Group Discussion</td>
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<td>10:45 AM</td>
<td>Session II: Conducting Decentralized Clinical Trials</td>
<td>Session II Facilitator: Gracie Lieberman, Genentech</td>
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<td>▶ Provide examples of decentralized clinical trials conducted using telemedicine, mobile nursing, and other methods for data capture</td>
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<td>▶ Discuss challenges and opportunities for conducting decentralized clinical trials</td>
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<td>10:45 AM</td>
<td>On the Ground and In the Cloud: Lessons Learned from Operating DCTs</td>
<td>Laura Podolsky, Science37</td>
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<td>11:00 AM</td>
<td>Combining Crowdsourced Protocol Design and Digital Study Execution</td>
<td>Marc Foster, Transparency Life Sciences</td>
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<td>11:15 AM</td>
<td>Advancing Patient-Centered Clinical Trials by Implementing At-home Study Visits</td>
<td>Gail Adinamis, Global Care Clinical Trials</td>
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<td>11:30 AM</td>
<td>Conducting Trials Remotely via Telehealth</td>
<td>Michael O’Brien, AMC Health</td>
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<td>11:45 AM</td>
<td>Open Group Discussion</td>
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<td>12:30 PM</td>
<td>Lunch</td>
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1:15 PM  Session III: Telemedicine and State Licensing Issues

Session III Facilitator: Barak Richman, Duke University
Session III Objectives:
► Facilitate informed discussion on opportunities and challenges related to greater utilization of telemedicine
► Propose mechanisms for change and key pressure points that may enable greater consistency to telemedicine state licensing issues

1:15 PM  Advancing Telehealth Care: State and Federal Legal and Regulatory Issues
Mario Gutierrez, Center for Connected Health Policy

1:30 PM  Telemedicine: Expanding Access, Protecting Patients
Lisa Robin, Federation of State Medical Boards (FSMB)

1:45 PM  Navigating State Telemedicine Laws
Ross Friedberg, Doctors on Demand

2:00 PM  Open Group Discussion

2:45 PM  Session IV: Drug Supply Chain of Custody

Session IV Facilitator: Jan Hewett, FDA CDER Office of Scientific Investigations
Session IV Objectives:
► Describe how drug supply chain of custody issues affect implementation of mobile technology in clinical trials, particularly remote trials
► Propose solutions, where appropriate, to legal and regulatory barriers to drug supply chain of custody issues when conducting remote clinical trials

2:45 PM  Overcoming Barriers to Innovation in Clinical Research
David Kazarian, Infuserv America

3:15 PM  Open Group Discussion

4:00 PM  Session V: Engaging with Pertinent Stakeholders in the Design and Conduct of Decentralized Clinical Trials

Session V Moderator: Marissa Stroo, Duke University
Session V Objective:
► Facilitate dialogue with various, pertinent stakeholders about engaging on the design and conduct of decentralized clinical trials

Session V Panelists:
Linda Coleman, Yale University
Alicia Staley, Patient Advocate
Vaishali Popat, FDA CDER OND

5:00 PM  End of Day One
## Session VI: Special Site and Investigator Considerations in Decentralized Clinical Trials

**8:30 AM**

*Session VI Moderator: Paul Conway, American Association of Kidney Patients*

**Session VI Objectives:**
- Discuss delegation of investigator responsibilities in remote clinical trials
- Identify safety monitoring challenges and opportunities within the context of remote clinical trials

**Session VI Panelists:**
- David Babaian, Quorum Review, Kinetiq
- Doug Pham, FDA CDER OSI
- Penny Randall, Quintiles IMS

## Session VII: Breakout Groups – Actionable Opportunities for Transformative Change

**9:30 AM**

*Breakout Instructions and Directions*

*Gerrit Hamre, CTTI*

**Breakout 1: Telemedicine and State Licensing Issues**

*Facilitator: Barak Richman, Duke University*

**Breakout 2: Drug Supply Chain Issues**

*Facilitator: Jan Hewett; FDA, CDER, OSI*

**Breakout 3: Protocol Design and FDA Interactions**

*Facilitator: Annemarie Forrest, CTTI*

## Session VII: Breakout Report Outs

**11:00 AM**

*Report Out: Telemedicine and State Licensing Issues*

*Open Group Discussion*

**11:15 AM**

*Report Out: Drug Supply Chain Issues*

*Open Group Discussion*

**11:30 AM**

*Report Out: Protocol Design and FDA Interactions*

*Open Group Discussion*

**11:45 AM**

*Highlights, Wrap-Up & Next Steps*

*Gerrit Hamre, CTTI*

**12:00 PM**

*Adjourn*