Legal and Regulatory Issues Affecting the Adoption of Mobile Clinical Trials

Multi-Stakeholder Expert Meeting

Summary of the Meeting held July 11-12, 2017

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

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

Meeting materials, including agenda, participant list, and presentations are available on the Clinical Trials Transformation Initiative (CTTI) website at: https://www.ctti-clinicaltrials.org/briefing-room/meetings/legal-regulatory-issues-affecting-adoption-mobile-clinical-trials

Publication Date: October 11, 2017

MEETING OBJECTIVES

The goal of this meeting was to more fully understand the real and perceived legal and regulatory challenges with the design and conduct of mobile clinical trials (MCTs) through the following activities:

- 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 the Clinical Trials Transformation Initiative (CTTI) should develop to equip change agents to overcome the legal and regulatory barriers that may hinder more widespread use of mobile technology and methodology in clinical trials, including for the purposes of regulatory submission

MEETING BACKGROUND

Mobile clinical trials (MCTs), for the purposes of this project, are defined as decentralized or remote clinical trials that incorporate the use of mobile applications, electronic data capture and output, and/or nontraditional trial processes and procedures (e.g., telemedicine[1], mobile nursing, investigational drug shipment directly to the trial participant). The MCT model may provide trial participants with a greater amount of control, convenience, and comfort by offering at-home or local patient care and instant connectivity to trial staff and other participants. Sponsors may reap the benefits of an efficient trial model that increases participant recruitment, potentially reaches a more diverse population over a larger geographical area, and helps ensure trial participant retention throughout the trial. Although multiple sponsor companies have successfully designed and conducted MCTs, MCTs for regulatory submission purposes have yet to be adopted widely due in part to presumed legal and regulatory challenges in the United States (US).

The goal of the CTTI MCT Program is to increase the adoption and appropriate use of mobile technology in clinical trials. The MCT Program includes four projects dedicated to identifying and addressing specific challenges that may impede the adoption of these technologies: Legal and Regulatory Issues, Novel Endpoints, Stakeholder Perceptions, and Mobile Devices. This meeting was convened by the CTTI MCT Legal and Regulatory Issues Project Team, whose goal is to develop materials that address the current legal and regulatory challenges with MCTs and to support the appropriate adoption of processes that facilitate MCT design and conduct, including for the purposes of regulatory submission.

[1] For the purposes of this project, MCTs are defined as decentralized or remote clinical trials that incorporate the use of mobile applications, electronic data capture and output, and/or nontraditional trial processes and procedures (e.g., telemedicine, mobile nursing, investigational drug shipment directly to the trial participant).

An assumption of this project is that the design and conduct of MCTs may be hindered by actual and perceived State and Federal legal and regulatory challenges. It is essential that MCTs are efficiently and thoughtfully designed and conducted within the boundaries of laws and regulations; therefore, the overall goal of the expert meeting was to engage stakeholders in deep discussion, grounded in data and experience, to identify solutions to the legal and regulatory challenges with the widespread adoption of MCTs. As such, the Legal and Regulatory Issues Project dovetails with the other efforts within the MCT Program, and the recommendations and tools generated by the other projects may serve as support or context to the ones offered from this project.

MEETING EXECUTIVE SUMMARY

The CTTI MCT Legal and Regulatory Issues Project Team convened a meeting involving key stakeholders on July 11 and 12, 2017. The participants included industry sponsors, representatives from the Food and Drug Administration (FDA), investigators, representatives from telemedicine providers and policy bodies, institutional review board (IRB) members, and patient representatives experienced with MCTs. All meeting participants possessed knowledge of or experience with the perceived and actual legal and regulatory challenges associated with designing or conducting such trials.

The meeting opened with presentations about the project findings to date. These presentations highlighted the potential benefits that MCTs may afford trial participants. Presentations acknowledged the current legal and regulatory challenges with designing and conducting MCTs, which were identified by several stakeholders. The presentations closed with a call for experts' perspectives on the goals and needs of the medical community and a request to work together to develop recommendations on how to address MCT legal and regulatory concerns.

Following the introductory presentations, there were seven additional sessions, including one breakout session, that focused on the following: designing and conducting MCTs (examples from the field), telemedicine and state licensing challenges, the drug supply chain of custody, engaging with pertinent stakeholders in the design and conduct of MCTs, and special site and investigator considerations in MCTs. Open group discussion occurred following each session, and two sessions were moderated group discussions with panelists. The primary goal of these discussions was to increase awareness and understanding regarding different stakeholders' perceptions of legal and regulatory challenges associated with the session topic. The breakout group sessions aimed to encourage a focused discussion among experts across stakeholder groups to reach consensus around key themes and to seek solutions on each specified topic.

Recurring themes throughout the meeting included the following:

- Current state laws and regulations are highly varied, including drug supply considerations with investigational and marketed products, and should be thoroughly understood and recorded in an accessible location that can be updated (e.g., public database).
- Guidance or modification to existing guidance is requested by investigative sites, sponsors, and Institutional Review Boards to delineate the PI's responsibilities regarding patient care and trial oversight and potential delegation of responsibilities.
    - Guidance from regulatory bodies is of particular interest.
- MCTs should not be held to different, higher standards than traditional trials, unless specific areas of concern are identified
- MCT trial designers should strive to engage trial participants and especially regulatory agencies in trial design early in development.
- Consensus is needed on definitions for terms that are central to MCT design and conduct. For example:
    - What defines an "investigative site" in an MCT?
    - What is included in "standard patient care," and how would this differ from "treatment" or "research?"
- Inspiration for the design and conduct of MCTs can be gleaned from current and previous successful remote clinical trials.
- Tasks or activities provided by third-party vendors may be leveraged when thoughtfully integrated in MCT design.

These themes and more specific solutions identified during the multi-stakeholder discussions will drive the development of recommendations and tools by the CTTI MCT Legal and Regulatory Issues Project Team to address the legal and regulatory challenges with designing and conducting MCTs.

MEETING SUMMARY

The meeting was organized into seven individual sessions: the first session was an overview of project findings to date, the following three sessions were focused topic presentations and open discussions that described experts' opinions and real-world experiences in the field, two sessions were moderated group discussions on specific topics that were led by panelists, and the final session included active breakout groups. Breakout groups were designed to capture key lessons learned and to determine the initial proposed framework for the development of project recommendations and tools.

Project Overview and Findings (Session I)

The introductory presentation set the tone of the meeting by providing anecdotes that described some of the inspiration for incorporating mobile technology in clinical trials, future possibilities with MCTs, and regulatory agency interest in

participating in the development of operational models. Following this, findings from sponsor interviews conducted between October 2016 and January 2017 were presented. The potential for collecting trial data offsite using mobile technology (i.e., the MCT model) holds several potential advantages based on interview responses:

- Trial participant ease and convenience
- Improved recruitment and retention of trial participants
- Increased geographical reach
- Continuous monitoring
- Collection of “real world” data
- The potential for identifying unexpected or hidden variables
- Leveraging objective data in favor of subjective data for increased data consistency
- The potential for developing novel endpoints
- Cost savings

Although the FDA has guidances describing the use and collection of electronically sourced data as well as trial oversight/monitoring, these do not specifically address MCTs, particularly in regard to the following legal and regulatory challenges that were identified by both interviewees and meeting attendees:

- The complexity in navigating differing state laws and regulations
- The need for physicians/PIs with licensing in multiple states
- Challenges with the drug supply chain of custody (e.g., shipping, receiving, and administering investigational products or approved commercial pharmaceuticals)
- Legal and regulatory responsibilities of the PI regarding trial oversight and patient care, and delegation of responsibilities related to patient care
- Legal responsibilities of local physicians who are not PIs but contribute data
- The role and responsibilities of mobile nurses
- The perception that challenges common to both traditional clinical trials and MCTs are often viewed as greater obstacles in MCTs, which may hinder use of the MCT model
- Appropriate and ethical use of products, activities, and processes provided by third-party vendors (eg, when using mobile nursing from a third-party vendor or when a separate agency provides patient care at the trial participant’s home, a communication plan may be needed to ensure that the information provided to the PI is timely, as the PI is still ultimately responsible for patient care)
- Data security and integrity given the unlimited information potentially generated by mobile technology

Experiences from the Field (Sessions II-IV)

Three sessions included presentations from stakeholders with experience designing and conducting MCTs, telemedicine opportunities and challenges, state licensing challenges, and drug supply chain of custody accountability. Key considerations with MCTs are the value of the virtual technology and the ability to leverage resources. Concepts explored in the presentations included timely access to diagnostics and treatment; communication among the care team (e.g., mobile nursing) and between the trial participant, the investigator, and the care team; remote monitoring concerns; the perspective of medical boards on telemedicine; the scope of "practice of medicine;" credentials and training of medical practitioners involved in MCTs; and the benefits of telemedicine.

Components integral to the success of a MCT were identified and included:

- Early and appropriate trial participant engagement
- Inclusion of willing and able investigative site coordinators in the MCT
- A supportive physician network that includes physicians who are licensed in numerous states
- A sophisticated and secure application preloaded on devices to connect with the team

In addition to the components mentioned above, it was emphasized that investing in early research activities prior to MCT initiation helps navigate challenges that may arise due to differing state laws and is essential to the trial's success. In situations where the sponsor may not be familiar with telemedicine laws and regulations, incorporating third-party vendors in the trial design may provide a solution and assist with certain operations because the vendor often already has the infrastructure and processes to address such considerations with telemedicine. Engaging with experts (e.g., state medical boards, third-party telemedicine vendors, telemedicine policy organizations) may help to streamline the trial and prevent obstacles from emerging during trial conduct. Successful MCTs tailor the protocol, including the mobile device use, to the trial participant's condition. The technology incorporated should support the trial rather than hinder it. Furthermore, the trial should not be designed around the available technology; rather, the technology should be incorporated as appropriate to support and enhance the trial.

Stakeholders involved in MCTs found that building trust, rapport, and effective communication between trial participants, investigators, and staff led to increased satisfaction of those involved and to better patient care. Ensuring trial participant-centricity is a primary consideration for MCTs. At-home or local care is convenient and comfortable for trial participants, which increases recruitment, retention, and trial participant satisfaction; however, meeting attendees acknowledged that many stakeholders are concerned about sufficient trial

oversight and safety monitoring. To ensure proper safety monitoring in MCTs, it is important that trial participants have easy access to trial staff and patient care. While this may seem like a straightforward assertion, meeting attendees expressed some confusion regarding the PI's ultimate responsibilities with oversight and patient care, especially in relation to the definition of "practice of medicine." This topic was explored in more detail during the moderated discussion sessions and is summarized in the next section of this document.

Finally, anecdotal evidence was provided by a trained and experienced pharmacist to illustrate how changing regulations and laws influence medical practice. One highly challenging aspect of the drug supply chain of custody in MCTs is the potential need for a single pharmacist to maintain licensing with 50 different state pharmacy boards and to track varied or conflicting requirements across those 50 states. Additional challenges and potential solutions related to drug handling in the setting of at-home care were discussed. Attendees were concerned about the scenario of a trial participant directly receiving a shipped drug without proper training on administration. In some cases, the drug can be shipped to a mobile nurse or other staff. With investigational products, drug accountability was another concern in MCTs. While it was suggested that some of the traditional trial methods for drug accountability may be appropriate, a more thoughtful approach needs to be considered for MCTs rather than just turning to traditional methods that may not be optimal or appropriate. It was also acknowledged that treatment compliance and drug accountability measures are imperfect in traditional trials and that MCTs should not be held to higher standards just because MCTs are new and unfamiliar.

Moderated Discussions on MCT Design and Site/Investigator Considerations (Sessions V-VI)

IRB Implications

The first topic for moderated discussion was on engaging pertinent stakeholders in the design and conduct of MCTs. Much of the discussion focused on the responsibilities of IRB members to evaluate trial protocols and their level of knowledge about unique considerations for MCTs. Attendees indicated that many IRB members are unlikely to be familiar with MCTs in general and may lack the technological understanding necessary to evaluate the use of mobile devices and concerns related to data integrity and security. It was suggested that a guidance document be developed to instruct IRB members on how to evaluate MCTs. It was also suggested that IRBs consider incorporating members who have a background in information technology. As data integrity and security are topics of discussion within the CTTI MCT Mobile Devices project, these were not discussed at length at the Legal and Regulatory Issues meeting.

Trial Participant Engagement

Patient groups may be engaged to assist with developing a document (eg, guidance, points to consider) for IRB members. It was mentioned that many IRB members may be uncomfortable with unfamiliar methods that rely on mobile technology, telemedicine or mobile nursing. As trial participants may have more practical experience with alternate means for trial recruitment and data collection than IRB members, they could offer their personal experience to address IRB members' concerns. Additionally, trial participants and patient groups may assist in MCT protocol design. Important items to include in an MCT protocol include a detailed communication plan and instructions for mobile device use. The communication plan will serve to address trial participant-staff/care team contact, provide trial participants with emergency contact information, and to describe escalation plans when problems with communication arise. The instructions will provide trial participants, caregivers, and healthcare providers (HCPs) with information on the appropriate use of mobile technology to help ensure data quality and integrity.

Investigator Oversight

The main topic of the second moderated discussion was special investigative site and investigator considerations in MCTs, and attendees largely focused on PI oversight as a practical concern and current regulatory concern in MCTs. In cases where the investigational product may demonstrate some toxicity or abuse potential, it was stressed that PIs should be within a reasonable proximity to the trial participant. Even with this level of support, such drugs may not even be appropriate for MCTs; sponsors should take additional care in MCTs to assess the appropriateness of study drugs.

The current FDA regulations require that at least one investigator sign Form 1572 to oversee trial participant safety and ensure appropriate safety monitoring in a trial. In the MCT model in which the "investigative sites" are not likely to be clinics or hospitals, sponsors may choose to have one central PI (i.e., an investigator who is responsible for multiple sites or a lead PI who is supported by regional subinvestigators or local HCPs) named on the 1572 form. Attendees recognized this choice is often unrealistic considering an individual's capabilities and places too heavy of a burden on one investigator.

Suggested solutions to alleviate the burden included increased delegation of certain activities and consultation with other medical experts as needed. Depending on the specific circumstances, appropriate delegated activities may include allowing mobile nurses to record AEs or facilitating the trial participant to contact their local HCP for advice regarding nonserious AEs. Ultimately, the PI must still maintain appropriate oversight during the trial and be compliant with the protocol. Attendees suggested that sponsors could draw inspiration from other industries and organizations to help develop solutions if the burden on the PI becomes too great (e.g., implementation of a hub-and-spoke model or defining a hierarchy of responsibilities for investigators, subinvestigator, and the PI).

Terminology Challenges

A closing thought from this session returned to the request for clearer language and definitions for MCTs and telemedicine operations. While meeting attendees agreed that consensus on definitions at this time would help initially with navigating laws, regulations, and considerations unique to MCTs, it was acknowledged that the language will evolve over time as the space evolves. A salient example of this is how radiology practices from the 1950s evolved into modern practices; when the modern practices were new, the language used to describe modern practices was “teleradiology.” As modern practices became standardized and the norm, these practices were no longer described as “teleradiology.” Attendees agreed that this phenomenon is likely to take place with telemedicine (i.e., telemedicine practices that seem novel today will become commonplace in several years); however, in order for such a future to come to fruition, guidance and clear direction is needed now.

Several attendees made the call for FDA guidances to be developed to specifically address the current ambiguity surrounding various MCT concepts (e.g., what constitutes an MCT “investigative site” and how often should trial participants physically and/or virtually visit with the PI). Because guidances may take considerable time to develop, FDA representatives suggested that sponsors interested in designing and conducting MCTs engage the FDA early in their MCT plans and also that sponsors share lessons learned with the FDA during the trial and after the trial has ended.

Breakout Group Discussions and Reports (Session VII)

Following the presentations and discussions of evidence for each topic area, the meeting attendees split into three different breakout sessions, each focused on a subset of the key challenges.

- Telemedicine and State Licensing
- Drug Supply Chain Custody
- Protocol Design and FDA Interactions

Each breakout group was composed of multi-stakeholder participants, experienced in a variety of backgrounds related to telemedicine, drug supply, and protocol design. Breakout groups concentrated on understanding the current landscape and brainstorming strategies to overcome the presumed legal and regulatory challenges with each topic.

Common themes emerged throughout these sessions, including the need for clarification of state medical regulations/laws as well as the need for a central location to record, update, and store such information; identification of points of contact for pertinent stakeholders and entities (e.g., national pharmacy boards, major patient advocacy groups); increased interaction and sharing of knowledge

among stakeholders (e.g., sponsors communicating with state medical boards); development of common language and template documents for MCTs; identification of a clear chain of responsibility/accountability within MCTs; and additional guidance and input from the FDA on MCT protocol design choices.

Ultimately, the evidence gathered by the MCT Legal and Regulatory Issues Project Team was greatly enriched by the high-quality discussions at the meeting. Multi-stakeholder expert engagement provided clear direction to the Project Team regarding recommendations and tools that would best drive this field forward, bringing us closer to the wider adoption and implementation of MCTs that adhere to the relevant federal and state regulations and laws. Following this meeting, the Project Team is developing a suite of recommendations and tools that are expected to be released in 2018.

FUNDING STATEMENT

Funding for this meeting was made possible, in part, by the FDA through grant R18FD005292. Views expressed in this publication do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organizations imply endorsement by the U.S. government. Partial funding was also provided by pooled membership fees from CTTI's member organizations.

ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership to identify and promote practices that will increase the quality and efficiency of clinical trials. The CTTI vision is a high-quality clinical trial system that is trial participant-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options.

Appendix A. Meeting Agenda

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

JULY 11, 2017

8:30 AM	**Welcoming Remarks**
8:30 AM	Introduction to the Clinical Trials Transformation Initiative *(CTTI)* *Annemarie Forrest, CTTI*
8:45 AM	**Session I: Project Overview and Findings**
	Session I Facilitators: Leonard Sacks, FDA CDER Office of Medical Policy (OMP) and Vashali Popat, FDA CDER Office of New Drugs (OND) *Session I Objectives*: ► Describe the CTTI Mobile Clinical Trials (MCT) Program and Legal & Regulatory Issues Project ► Present and discuss findings from project evidence gathering activities
8:45 AM	Issue, Project Overview, and Meeting Objectives *Gerrit Hamre, CTTI*
9:00 AM	Qualitative Sponsor Interview Findings *David Babaian, Quorum Review, Kinetiq*
9:45 AM	Open Group Discussion
10:45 AM	**Session II: Conducting Decentralized Clinical Trials**
	Session II Facilitator: Gracie Lieberman, Genentech *Session II Objectives*: ► Provide examples of decentralized clinical trials conducted using telemedicine, mobile nursing, and other methods for data capture ► Discuss challenges and opportunities for conducting decentralized clinical trials
10:45 AM	On the Ground and In the Cloud: Lessons Learned from Operating DCTs *Laura Podolsky, Science37*
11:00 AM	Combining Crowdsourced Protocol Design and Digital Study Execution *Marc Foster, Transparency Life Sciences*
11:15 AM	Advancing Patient-Centered Clinical Trials by Implementing At-home Study Visits *Gail Adinamis, Global Care Clinical Trials*
11:30 AM	Conducting Trials Remotely via Telehealth *Michael O'Brien, AMC Health*
11:45 AM	Open Group Discussion

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, Infuserve 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**
4:00 PM	*Session V Objective*: ▶ Facilitate dialogue with various, pertinent stakeholders about engaging on the design and conduct of decentralized clinical trials
5:00 PM	**End of Day One**

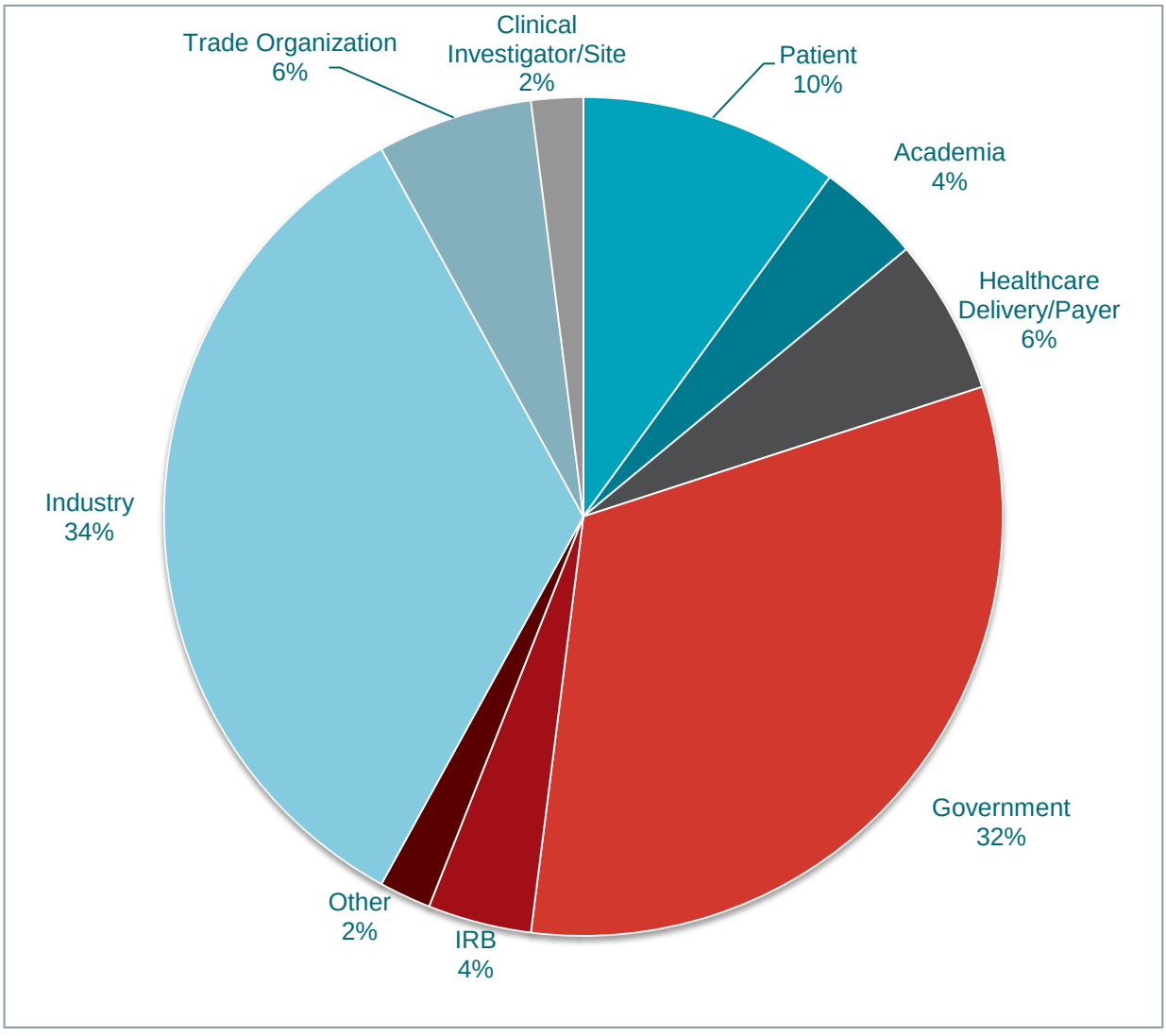
JULY 12, 2017

8:30 AM	**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*
9:30 AM	**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*
11:00 AM	**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**

Appendix B. Meeting Participants

Our expert meeting participants include representatives from a broad cross-section of the clinical trial enterprise including regulators, government sponsors of clinical research, academia, industry, patient advocates, clinical investigators, and other interested parties. Participants are expected to be actively engaged in dialogue both days.

Stakeholders Represented



Meeting Participants

Participant	Participant Affiliation
Gail Adinamis	GlobalCare Clinical Trials
Wayne Amchin	Food & Drug Administration (CDER)
Maria Apostolaros	PhRMA
David Babaian	Quorum Review IRB / Kinetiq
Matthew Bryant	Amgen
Catherine Clements	Eli Lilly & Company
Linda Coleman	Yale University
Paul Conway	American Association of Kidney Patients
Kristin Dolinski	PhRMA
Melody Eble	JJ / Janssen
Molly Flannery	Food & Drug Administration (CDER)
Jeff Florian	Food & Drug Administration (CDER)
Marc Foster	Transparency Life Sciences
Ross Friedberg	Doctor on Demand
Amnon Gavish	American Well
Bradford Gay	American Well
Cindy Geoghegan	Patient and Partners
Cheryl Grandinetti	Food & Drug Administration (CDER)
Jerold Grupp	CRF Health
Mario Gutierrez	Center for Connected Health Policy
Jan Hewett	Food & Drug Administration (CDER)
Amy Hummel	Alexion
Bhanu Kannan	Food & Drug Administration (CDER)
David Kazarian	Infuserve America
Eeshan Khandekar	National Academies of Sciences
Richard Knight	American Association of Kidney Patients
Phillip Kronstein	Food & Drug Administration (CDER)
Grazyna Lieberman	Genentech
Diane Maloney	Food & Drug Administration (CDER)
Ann Martin-Myers	Eli Lilly & Company
Patricia McGovern	Novartis
Amy McKenzie	Virta Health
Kristen Miller	Food and Drug Administration (CDER)
Michael O'Brien	AMC Health
Doug Pham	Food & Drug Administration (CDER)
Laura Podolsky	Science 37
Vaishali Popat	Food & Drug Administration (CDER)
Sesquile Ramon	BIO
Penny Randall	Quintiles IMS
Barak Richman	Duke University
Lisa Robin	Federation of State Medical Boards
Sarah Rowe	Quintiles IMS

Michele Russell-Einhorn	Schulman IRB
Leonard Sacks	Food & Drug Administration (CDER)
Ken Skodacek	Food & Drug Administration (CDRH)
Alicia Staley	Individual Patient/Caregiver
Juli Tomaino	Food and Drug Administration (CDER)
Kaveeta Vasisht	Food & Drug Administration (CDER)
Angela Walker	Eli Lilly & Company
Nicole Wolanski	Food & Drug Administration (OC)

For more information, contact the MCT Legal and Regulatory Issues Project Manager, Gerrit Hamre (gerrit.hamre@duke.edu) or visit https://www.ctti-clinicaltrials.org/projects/legal-and-regulatory