



Advancing the Use of Central IRBs for Multicenter Clinical Trials in the United States

Expert Meeting Agenda · June 12-13, 2014

Hilton Washington DC/Rockville Hotel & Executive Meeting Center
1750 Rockville Pike
Rockville, MD 20852

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

CTTI Definition of Central IRB: A single IRB of record for all sites participating in a multicenter clinical trial. A range of entities may serve as a central IRB (e.g. another institution's IRB, a federal IRB, or an independent IRB).

Meeting Objectives:

- Discuss practices, implementation strategies, and solicit additional suggestions for increasing the use of central IRBs for multicenter clinical trials
- Present findings from the CTTI Central IRB Advancement project's collection of IRB authorization agreements and standard operating procedures
- Obtain additional feedback to refine proposed IAA template and tools

DAY 1 – JUNE 12, 2014

- 7:30 AM** **Breakfast**
- 8:45 AM** **Welcoming Remarks**
Introduction to the Clinical Trials Transformation Initiative
Bray Patrick-Lake (CTTI)
- Session I** **Landscape of the Use of Central IRBs for Multicenter Clinical Trials**
8:55-10:30
- Session Facilitator: Soo Bang (Celgene Corporation)*
Session Objectives:
- Discuss past, present, and future of the use of central IRBs for multicenter clinical trials (including the outcomes of previous CTTI activities)
 - Review industry, federal, and academic examples of changing to centralized IRB review model
- 8:55 AM History of the Use of Central IRBs for Multicenter Clinical Trials
Soo Bang
- 9:10 AM Academic Institution Example
David Borasky (University of North Carolina – Chapel Hill)
- 9:30 AM Federal Central IRB Example
Jacquelyn Goldberg (National Cancer Institute – Central IRB)
- 9:50 AM Industry Sponsor Example
Soo Bang
- 10:10 AM Q&A and Discussion
- 10:30 AM** **Break**
- Session II** **Why Are We Still Talking About Local Context as a Barrier?**
10:45-11:45
- Session Facilitator: Cynthia Hahn (North Shore-LIJ Health System)*
Session Objectives:
- Identify and discuss the aspects of local context that remain problematic for central IRBs
 - Discuss how local context is handled by all parties when a central IRB is used for a multicenter clinical trial
- 10:45 AM Panel:
- Patrick McNeilly (FDA)
 - Kerrie Flynn (Neurological Clinical Research Institute)
 - Jane Perlmutter (Patient Representative)
 - David Forster (WIRB-Copernicus Group)
- 11:15 AM Q&A and Discussion (All Meeting Attendees)

Session III **Challenges and Solutions for Implementing Use of a Central IRB for Multicenter Clinical Trials: Breakout Sessions**
11:45-Noon

11:45 Introduction to post lunch breakout group activities
Sara Calvert (CTTI)

12:00 PM **Lunch (Provided)**

Session III **Challenges and Solutions: Breakout Sessions**
1:00-3:00

1:00 PM Workgroup Activity: Discuss biggest challenges to using centralized review and propose solutions to those challenges. Who are the people who are in a position to make changes? What information do they need? How do we get the required information to those who can make changes?

Montrose *Workgroup 1*
Wilson *Workgroup 2*
Truman *Workgroup 3*

Session III **Challenges and Solutions: Feedback**
2:00 -3:00

Session Objective: Presentation and discussion of the challenges and solutions from each working group

2:00 PM Report out by breakout groups (10 minutes each group)

- What were the top 3 challenges discussed by your group?
- What are the proposed solutions to these challenges?

2:30 PM Full group discussion

3:00 PM **Break**

Session IV **Process of Implementing Central IRB: Operations Model**
3:15- 4:15

Session Facilitator: *Petra Kaufmann*

Session Objectives:

- Discuss changes in institutional business model when transitioning from using in-house institutional IRB only to outside central IRB(s) for multicenter clinical trials
- Consider strategies to overcome institutional challenges of accepting ethical review from multiple outside IRBs

3:15 PM Panel:

- Hallie Kassan (North Shore-LIJ Health System)
- George Gasparis (Peer Consulting Group)
- Carol Pech (University of Wisconsin-Madison)
- Eric Mah (University of California, San Francisco)

3:45 PM Q&A and Discussion

Session V: IRB Authorization Agreement Data Collection

4:15-5:00

Session Facilitator/Presenter: Cynthia Hahn (North Shore-LIJ Health System)

Session Objectives:

- Discuss rationale for IRB Authorization Agreement template creation
- Review findings from data collection and synthesis of IAA agreements and standard operating procedures

5:00 PM Day 1 Wrap Up

6:00 PM Reception

DAY 2 – JUNE 13, 2014

8:00 AM Breakfast

Session VI Feedback and Refinement of IRB Authorization Agreement (IAA) Template

9:00-1:00

Session Facilitator: Cynthia Hahn (North Shore-LIJ Health System)

Session Objectives:

- Present and solicit feedback on proposed IAA Template
- Discuss what criteria are used to determine the type of reliance agreement (i.e. simple vs. complex) is required in different situations

9:00 AM Presentation and feedback on IAA template and propose criteria for selecting reliance agreement type

10:00 AM Q&A and Discussion

10:30 AM Break

10:45 AM Group discussion and decisions on IAA template and complexity criteria

12:00 PM Working Lunch (Boxed Lunch Provided)

Summarize decisions and next steps

1:00 PM Adjourn

Appendix A. Meeting Background

CTTI USE OF CENTRAL IRBs FOR MULTICENTER CLINICAL TRIALS PROJECT

The Clinical Trials Transformation Initiative (CTTI) conducted a project to determine the barriers to using central IRBs for multicenter clinical trials in the United States and to formulate potential solutions to overcome these barriers.

Methods: Review of the literature, discussions with IRB experts, interviews with representatives of research institutions, and an expert meeting in April 2012.

Results:

- Definition of central IRB was needed as many thought it referred only to an independent or commercial IRB. CTTI defines a central IRB as a single IRB of record to which sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research, including review of informed consent. A range of entities may serve as a central IRB (e.g. another institution's IRB, a federal IRB, an independent IRB).
- Many perceived barriers relate to conflating responsibilities of the institution with the ethical review responsibilities of the IRB.
- There was also a lack of comfort and trust with central IRB review. One of the most frequently cited barriers was the ability of a central IRB to address concerns of local context.
- A summary of CTTI's findings, along with potential solutions to address barriers to the use of central IRB review, was published in January 2013 (Flynn KE, et al. *PLoS One* 2013; 8(1): e54999).

Recommendations:

1. A central IRB be used to improve the quality and efficiency of multicenter clinical trials.
2. Sites and IRBs use a CTTI-developed guide to support communication and contractual relationships between institutions and a central IRB to address blurred distinctions between responsibilities for ethics review and other institutional obligations.
3. Sponsors require the use of central IRB review for multisite trial networks in order for relevant stakeholders to gain experience with central IRB review. The resulting experiences may foster greater comfort and trust with the central IRB model.

CTTI ADVANCING THE USE OF CENTRAL IRBs for MULTICENTER CLINICAL TRIALS PROJECT

Objectives:

- To assess and propose solutions for remaining areas of concern for using single IRBs of record for multicenter clinical trials
- To advance the use of central IRBs for multicenter clinical trials

Deliverables:

- Webinar series
- Expert meeting to discuss areas of concern, best practices, and finalize IAA template
- White paper and public posting of IAA template/additional tools

Appendix B. Meeting Participants

Central IRB Advancement Project Team

Team Leaders:

Soo Bang (Celgene)
Cynthia Hahn (NS-LIJHS)
Petra Kaufmann (NIH)

Team Members:

John Buse (UNC)
Cami Gearhart (Quorum IRB)
Cheryl Grandinetti (FDA)
Yvonne Higgins (WIRB-Copernicus Group)
Hallie Kassan (NS-LIJHS)
Patrick McNeilly (FDA)
Jane Perlmutter (Patient Advocate)
Andy Womack (BIO)

Project Manager:

Sara Calvert (CTTI)

Meeting Attendees

Our workshop 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 and dialogue both days.