



## **CTTI IND Safety Advancement Project**

Summary of the Multi-Stakeholder Meeting held July 21-22, 2015

DoubleTree by Hilton Hotel Washington, D.C. – Silver Spring, MD 20910

**CTTI MISSION:** To identify and promote 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://ctti-clinicaltrials.org/expert-meeting-ctti-ind-safety-advancement-project/>*

Publication Date: September 22, 2015

## MEETING BACKGROUND

On September 29, 2010, the US Food and Drug Administration (FDA) published a final rule, effective March 28, 2011, that clarified reporting requirements for serious and unexpected suspected adverse reactions occurring in clinical trials conducted under an investigational new drug application (IND) (CFR 21.312). The FDA issued a final guidance on December 20, 2012 in support of the revised regulations. The final IND safety reporting rule clarified that sponsors should not submit expedited safety reports for individual cases of serious and unexpected adverse events for which there is little reason to believe that the drug caused the event.

The final rule is intended to improve the overall quality of safety reporting by reducing the number of uninterpretable individual reports sent to FDA and clinical investigators, allowing them to focus resources on the assessment and communication of more meaningful data. The rule implicitly requires the sponsor to review safety data collected across all completed and ongoing studies in an IND, analyze these data in the aggregate, evaluate the available evidence, and make a judgment about the likelihood that the drug actually caused the serious adverse event. A previous CTTI IND Safety project issued recommendations that offer an approach for companies to monitor the safety of an investigational new drug throughout the development program. However, anecdotal reports indicated that problems with large numbers of uninterpretable individual safety reports remain, particularly in oncology clinical trials. This follow-on project addresses issues in oncology trials, with the hope that issued recommendations will also be generalizable to other therapeutic areas.

The IND Safety Advancement project objectives served as the foundation of this expert meeting, as follows:

- Evaluate the impact of FDA rule changes and original CTTI IND Safety project recommendations on the volume of submitted IND safety reports (“safety report”) in oncology trials
- Understand the sponsors’ challenges to full implementation of the safety reporting rule in oncology trials
- Understand the sponsors’ motivation to change their company practices of safety reporting in oncology trials to fully comply with the safety reporting rule
- Understand investigators’ challenges with receipt and management of safety reports at oncologic investigative sites and coordinating centers
- Explore FDA inspection findings related to safety reporting
- Facilitate adoption of best practices for communicating and managing safety reports consistent with FDA guidance, the IND safety rule and CTTI recommendations

Before the expert meeting, CTTI gathered evidence through the following methods:

- Analyzed the change in volume of safety reports in oncology trials submitted to FDA annually since publication of the safety reporting rule
  - Conducted surveys and interviews with investigators and sponsors to assess challenges and motivations to managing safety reporting processes
  - Assessed the volume of FDA warning letters issued that were related to safety reporting via FDA review and sponsor self-report
  - Analyzed findings from data-gathering activities
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## MEETING OBJECTIVES

The objectives of the multi-stakeholder meeting included the following:

- Present findings and conclusions from the project evidence-gathering activities
  - Discuss opportunities for improving the efficiency and value of the safety reporting process
  - Understand opportunities for educating stakeholders on safety reporting best practices
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## MEETING EXECUTIVE SUMMARY

The IND Safety Advancement Project convened a meeting involving stakeholders with expertise in this topic, on July 21 and 22, 2015. The participants included representatives from academia, nonprofit organizations, government agencies, institutional review boards (IRBs), industry, health systems, patient representatives, site representatives, and professional societies.

The findings and conclusions of CTTI's evidence-gathering methods were presented and discussed. Experts explored the reasons why the final rule has not been fully implemented, addressing the topic from the perspective of sponsors, the FDA, and investigators. Presentations and dialogue focused on challenges with implementation and consequences of non-adherence to the final rule, examples of successful changes in sponsor practices, and suggestions for how to improve the reporting system and incite a cultural change. Proposed recommendations for attributes of electronic reporting portals were also discussed. Much of the meeting centered on achieving an understanding between investigators, sponsors, regulators, and patients, and addressing the needs, goals, and concerns of each group. Experts discussed that the rule was not effectively being implemented on a large enough scale and that the system is slow to change. Suggestions to improve the system and change the culture of safety reporting included the following: direct sponsor-FDA interaction, additional guidance or education from the FDA, examples and case studies of successful

practice changes and enhanced communication between parties. Solutions to improve the electronic portal were suggested; however, experts discussed that improving the quality of safety reports was the paramount concern.

The IND Safety Advancement team is considering next steps to advance this project, as informed by the expert meeting discussions, and will revise the proposed recommendations for desired attributes of electronic portals for expedited safety reporting.

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## MEETING SUMMARY

### Presentation and Discussion Highlights: Session I

The first session began with the patient perspective on the current clinical research system and drug development; namely, that it is viewed as inefficient. Issues related to the high volume of safety reports contribute to this inefficiency. The presenter introduced the final rule and its purpose (ie, to decrease the number of uninterpretable safety reports in favor of higher quality, more understandable safety reports). Following this, the IND Safety project history and a general overview of safety reporting and current FDA guidance was presented. The IND Safety project history overview addressed CTTI's previous efforts to help with adherence to the final rule, summarizing previous recommendations that were created from the surveys, analyses, expert meetings, and workgroups from prior CTTI safety reporting-related projects.

The FDA expected approximately a 90% reduction in safety reports following issue of the final rule. An audit of safety reports submitted to the Office of Hematology and Oncology Products (OHOP), however, indicated that the mean number of safety reports submitted annually per IND actually increased after 2010 as compared to before 2010.

The CTTI IND Safety Advancement Project aims were presented. The project intends to improve safety reporting and increase successful implementation of the Final Rule by discussing motivations to change sponsor practices, challenges that sponsors face, and working to create a better understanding of what is expected with the Final Rule. This CTTI project focused specifically on oncology. Meeting objectives were to discuss:

- findings and conclusions from the CTTI's evidence-gathering activities,
- solutions to improve efficiency and value of the IND safety reporting processes, and
- suggestions to disseminate information covered in the meeting to a wider audience.

Emphasis was placed on discourse and collaboration to understand sponsor motivations, investigator concerns, FDA goals, and successful communication between all parties.

During the discussion period experts discussed the data on the volume of safety reports and agreed that non-adherence to the final rule is a problem in the clinical trial enterprise (CTE). Despite some statements from sponsors indicating that many have reduced the amount of safety reports since 2010, FDA audits show that up to 80% of reports are not compliant with the current reporting rule and thus uninformative. Experts discussed that the intention of the final rule was not being met. Sponsors indicated that without more direction and examples from the FDA describing reports that are not required to be expedited, implementation would continue to be challenging. Additionally, some meeting attendees cited the lack of harmonization between US and rest-of-world regulations as a challenge for operationalizing consistent reporting processes. Investigator representatives and patient advocates vocalized concerns that the high volume of safety reports make it difficult to identify that safety information that is relevant to care of individual study participants. . Regulators stressed that the purpose of individual expedited reports is to alert the agency to a meaningful, unique event.

### **Presentation and Discussion Highlights: Session II**

During the second session, project findings from the investigative site survey and interviews and the sponsor survey and interviews were presented. Results from the investigative site survey and interviews indicate that sites are still being inundated with non-compliant safety reports. Results also showed that investigators and staff do not always have familiarity with the final rule. In general, investigator respondents felt that most individual reports were of little value, lacked information, and were time-consuming, and that reports lacking actionable information were not used to improve trials or enhance patient safety in any way. Respondents were more interested in reports, either aggregate or individual, that result in protocol changes. Finally, investigator respondents indicated the lack of technical uniformity across electronic portals contribute to the burden on investigative sites in managing safety reports. .

Results from the sponsor survey and interviews indicate a dichotomy in sponsor and FDA/investigator perception of final rule adherence. A total of 20 sponsor companies were polled in the survey. Many of the sponsor respondents believe that they made strides to reduce expedited safety reports, reducing individual reports by 40% to 75%. The sponsor respondents suggested that the main barrier to full implementation of the rule and achieving a 90% reduction in report volume was a lack of guidance and training. Other concerns reported by respondents included the following: lack of regulatory harmonization internationally, liability concerns with missed safety signals, unwillingness to overrule investigator determinations of relatedness, and difficulties defining thresholds for aggregate reporting. Results indicate that sponsors believe that the FDA has a role in helping/guiding sponsors. Sponsor respondents want clarity on thresholds for aggregate analysis and whether there would be consequences to a mistake or misjudgment. One-on-one meetings between sponsors and FDA, webinars and/or workshops were suggested as a solution to enhance clarity. Sponsors that received input and feedback from the FDA

regarding their strategies for reporting safety reports were better able to make changes to their reporting practices to adhere to the final rule.

Following the presentations in the second session, an open discussion among stakeholders explored the following issues: mechanisms for providing feedback to sponsors, investigator versus sponsor assessment of causality, guidance and education to increase adherence to the final rule, issues related to unmasking data, and the overall need for a cultural change at sponsor organizations regarding safety reporting (that is, a shift away from conservatism in determining which reports are expedited). Attendees discussed sponsors' integration of investigator and FDA feedback, issues with communication between investigators and sponsors when mediated by CROs, and how to best facilitate open communication between investigators and sponsors.

Experts discussed who is responsible for assessing drug relatedness. Although the final rule states that sponsors are ultimately responsible for determining relatedness to the investigational drug, certain sponsor representatives mentioned that they prefer to defer to the investigator's assessment of safety and are uncomfortable with disagreeing with the investigator. However, both the FDA and investigators urged sponsors to assume responsibility for determining causality based on their in-depth familiarity of their drug product, particularly their unique knowledge of the cumulative safety data. FDA representatives indicated that regulators rely on sponsors to know their drug and the potential safety concerns and expect sponsors to adhere to high pharmacovigilance standards.

### **Presentation and Discussion Highlights: Session III**

The third session focused on FDA inspection practices related to IND safety reporting. The objectives of this session were to clarify and discuss the conduct of FDA inspections for safety reports. The first presentation was about FDA policy, processes, and inspections. The presenter covered definitions of seriousness, expectedness, and causality. Because all safety information will be submitted to the FDA eventually (eg, IND annual reports, NDA submission, periodic benefit-risk evaluation reports), individual safety reports are not frequently warranted. Strategies that the FDA is exploring to influence change include more communication with sponsors opening an IND about expectations for safety reporting and also additional instruction to its field inspectors evaluating compliance with the IND reporting rule. Clarification on requirements for reporting during pre-marketing versus post-marketing was presented as well as the importance of documentation to avoid or respond to inspections. The second presentation discussed the cultural issues and barriers that may impede changing the IND safety reporting practices. There is a perception in industry that underreporting will lead to an inspection finding or worse (eg, a later adverse event that may be construed as sponsor negligence). The presenter questioned what type of education is needed to change practice and suggested that additional guidance and tools were necessary to spread best practices.

Discussion following the presentation touched on the differences in reporting responsibilities of the sponsor pre- and post-marketing (i.e., under 21 CFR 312

and under 21 CFR 314), how to improve report quality, how to respond to a 483 form, and potential training options to assist with medical judgments. In regard to judgments on whether or not to expedite a safety report, because the lack of objective criteria lead sponsors to take a conservative approach, some experts suggested that the FDA present different scenarios relating to medical decision-making with safety reports and examples of reports that are appropriate and inappropriate to submit according to the final rule. Attendees discussed that a culture of trust on all sides is needed to encourage changes in safety reporting processes and discussion focused on how to develop it.

### **Presentation and Discussion Highlights: Session IV**

Session four presentations described an overview of expedited IND safety reporting and the challenges and opportunities related to aggregate reporting of safety reports. In the overview, the purpose of the safety report was emphasized (ie, providing interpretable information), and the role of sponsors and FDA was addressed. Following this, representatives from Merck and Eli Lilly presented on sponsors' experience with implementing the FDA's final rule, providing examples of successful changes made to company practices. Practices and elements that contributed to Merck's success in reducing IND safety reports by 90% included the following: a well-supported recruitment effort to recruit physicians who supported implementation of new processes; a critical review of past safety reports; clear definitions of the relevancy of follow-up reports; extensive training on causality thresholds, documentation, and final rule criteria; and open dialogue about particular cases. Eli Lilly's approached the final rule by updating processes as needed, in particular to address problematic areas. Examples included: 1) development teams evaluate the safety risks and document when assessments will be performed, and 2) a separate team that is unaffiliated with the trial team is responsible for evaluating the distribution of events across treatment arms This led to a reduction in safety reports by 50-80%. Finally, the investigators' perspective on safety reports was presented. The presenter suggested that physicians want concise and actionable information that provides pertinent drug behavior or informs treatment decisions. The presenter re-iterated the problem of the high volume of safety reports diluting safety signals and that electronic databases have not streamlined the process of evaluating safety reports because functionality issues remain.

Key themes and proposals from the discussion among attendees following the presentations included:

1. the need for senior management buy-in and active support to change company practices
2. the importance of investigator satisfaction to sponsors, so continued communication between investigators and sponsors is encouraged
3. safety report submission only when there is a protocol/consent change with other means of communication used for non-urgent safety information
4. sponsors should implement an approach to safety reporting that includes aggregate safety data

5. the importance of following up with the clinical site to fully evaluate the details of the case prior to any safety report submission
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### **Presentation and Discussion Highlights: Session V**

The objective of session five was to gather feedback on the proposed recommendations for the ideal attributes of electronic reporting portals for safety reports. Draft recommendations were presented, which included the following properties: user-friendly, operating system- and browser-independent, high performing, intuitive report-management and report-analysis capabilities (e.g., printing, filtering), flexible notification options (e.g., batching), and portal-specific education/training. Attendees suggested changes to the draft recommendations.

### **Presentation and Discussion Highlights: Session VI**

The sixth session concentrated on alternative methods other than IND safety reports for reporting safety information and communicating safety data to FDA. An FDA representative described existing alternative mechanisms, such as use of Investigator Brochures, IND annual reports, information amendments, and DSURs, to communicate safety data that is not required to be expedited. Following this, Pfizer and Eli Lilly representatives presented separate presentations on the sponsors' experience with periodic reporting to investigators. Methods employed by Pfizer included clinical trial safety update reports at 6-month intervals, blinded clinical trial safety update report line listings for investigators, and newsletters. Eli Lilly has changed practices based on investigator feedback: a 6-month safety report line listing report is distributed worldwide to investigators, and those individual case safety reports that comply with the final rule are also distributed to investigators. Some countries can "opt in" to receive all individual case reports. Additional changes to enhance the quality of safety information being communicated include highlighting important points, shortening reports, and consolidating results. The last presentation focused again on the investigators' perspective on safety reports and emphasized the bigger picture of serving the needs of patients and redirecting reporting concerns to address the overall goal of adequately communicating meaningful safety signals. Suggestions on how to proceed to achieve this goal included many topics previously discussed in the meeting, including detailing clear objectives, enhancing communication and education, addressing fears, and improving feedback mechanisms.

During the discussion period, attendees noted that ensuring appropriate action is taken to protect the public is the primary objective of the safety reporting system. Attendees noted that the proposed goal of a 90% reduction in safety report volume is at best a surrogate benchmark of an improved safety reporting system; the true goal is to ensure patient safety by enhancing report quality and eliminating uninformative safety reports, which some believe will correlate with approximately a 90% reduction in the volume of safety reports. Some attendees suggested that proactive planning by sponsors during protocol development should be exercised to ensure meaningful safety information is communicated to



investigators and regulators during conduct of the trial. Sponsors acknowledged that changing internal processes related to safety reporting has been challenging and may require the support of C-suite senior management. A CEO roundtable discussion with FDA representatives was suggested.

At the end of the meeting, stakeholders summarized key points and suggestions: more aggressive implementation of the “reasonable relatedness” criterion of the final rule, enhanced communication between sponsors, the FDA and clinical investigators, rigorous training programs for sponsor pharmacovigilance staff, further FDA guidance and/or education on safety reporting including direct sponsor-FDA interactions, and sharing of case studies and examples of successful changes in sponsor practices. CTTI closed the meeting by thanking the experts for their participation that would inform the next steps in this project.

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## FUNDING STATEMENT

Funding for this meeting was made possible, in part, by the Food and Drug Administration through grant R18FD005292, as well as CTTI membership fees. 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.

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## 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 patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options.

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*For more information, contact the IND Safety Advancement Project Manager Annemarie Forrest at [Annemarie.forrest@duke.edu](mailto:Annemarie.forrest@duke.edu) or visit <http://www.ctti-clinicaltrials.org>.*

## CTTI IND Safety Advancement Project

Agenda of the Multi-Stakeholder Meeting held July 21-22,  
2015

DoubleTree by Hilton Hotel Washington, D.C. – Silver Spring  
8727 Colesville Road, 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 and conclusions from the project evidence gathering activities
- ▶ Discuss opportunities for improving the efficiency and value of the expedited IND safety reporting process
- ▶ Understand opportunities for educating stakeholders on expedited IND safety reporting best practices

## Tuesday July 21<sup>st</sup>, 2015

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- 8:00am**      **Breakfast (Provided)**
- 9:00am**      **CTTI Introduction**  
*Pamela Tenaerts (CTTI)*
- Session I**    **Project History and Overview**  
*Session Facilitator: Nancy Roach (Fight Colorectal Cancer)*  
*Session Objectives:*
- ▶ Understand past and current efforts to improve the efficiency of expedited IND safety reporting
- 9:15am**      **Patient Perspective on Safety Reporting**  
*Nancy Roach*
- 9:25am**      **CTTI Project History and Current Guidance**  
*Jose Vega (Merck)*
- 9:40am**      **Expedited IND Safety Reports Submitted to FDA's Office of Hematology and Oncology Products**  
*Sean Khozin (FDA)*
- 9:55am**      **Project Overview and Meeting Objectives**  
*Michael Jones (Eli Lilly)*
- 10:10am**     **Discussion**
- 10:30am**     **Break**
- Session II**   **Presentation of Project Findings**  
*Session Facilitator: Raymond Perez (University of Kansas)*  
*Session Objectives:*
- ▶ Present and discuss findings and conclusions from the project evidence gathering activities
- 10:50am**     **Investigative Site Survey and Interview Findings**  
*Raymond Perez*
- 11:10am**     **Sponsor Survey and Interview Findings**  
*Robert Goodwin*
- 11:30am**     **Discussion**
- 12:15pm**     **Lunch (Provided)**

## Tuesday July 21<sup>st</sup>, 2015 (Continued)

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### Session III **Impact of FDA Inspection Practices on Expedited IND Safety Reporting**

*Session Facilitator: Robert Goodwin*

*Session Objectives:*

- ▶ Clarify and discuss conduct of FDA inspections for expedited IND safety reporting
- ▶ Understand forces that have shaped the culture around expedited IND safety reporting
- ▶ Understand cultural issues sponsor organizations face in changing expedited IND safety reporting processes

#### **1:15pm FDA Policy, Processes and Inspections: Expedited IND Safety Reporting**

*Chrissy Cochran (FDA)*

#### **1:30pm Cultural Issues and Barriers to Changing Reporting Practice: Sponsor Perspective**

*Robert Goodwin*

#### **1:45pm Discussion**

#### **2:30pm Break**

### Session IV **Implementation of the FDA Final Rule on Expedited IND Safety Reporting**

*Session Facilitator: Patrick Archdeacon (FDA)*

*Session Objectives:*

- ▶ Understand challenges and opportunities related to aggregate reporting of expedited IND safety reporting
- ▶ Describe some sponsor methods for determining what/when/how to submit expedited ICSR or aggregate reports
- ▶ Discuss what is needed in reports to be valuable and interpretable to FDA and investigators
- ▶ Identify future opportunities for educating sponsors

#### **2:45pm Overview of Expedited IND Safety Reporting**

*Patrick Archdeacon*

#### **2:55pm Sponsor Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting**

*Nina Stuccio (Merck)*

#### **3:15pm Sponsor Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting**

*Kenneth Lipetz (Eli Lilly)*

#### **3:35pm Investigator Perspective on Expedited IND Safety Reporting**

*Jeffrey Infante (Tennessee Oncology Physicians)*

## Tuesday July 21<sup>st</sup>, 2015 (Continued)

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**3:45pm** **Round Table Discussion – Challenges with Implementing the FDA Final Rule on Expedited IND Safety Reporting**

**5:00pm** **Adjourn to Dinner Reception**

## Wednesday July 22<sup>nd</sup>, 2015

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**8:30am** **Welcoming Remarks**  
*Raymond Perez (University of Kansas)*

**Session V Reporting** **Desired Attributes of Electronic Portals for Expedited IND Safety Reporting**

*Session Facilitator: Raymond Perez*

*Session Objectives:*

- ▶ Solicit feedback on proposed recommendations for ideal attributes of electronic reporting portals for expedited IND safety reporting

**8:45am** **Presentation of Proposed Recommendations**  
*Krupa Patel (Merck)*

**9:00am** **Small Group Discussion of Proposed Recommendations**

- ▶ Would these recommendations solve your current challenges with Sponsor safety mailing systems/processes? If not, what other recommendations would you like to have considered?
- ▶ How would these recommendations work with your organization's current processes/procedures?
- ▶ What are some of the benefits you see for your organization if these recommendations were implemented?

**9:30am** **Large Group Discussion**

**10:00am** **Break**

## Wednesday July 22<sup>nd</sup>, 2015 (Continued)

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### Session VI Innovative Opportunities for Communicating Safety Information

*Session Facilitator: Michael Jones (Eli Lilly)*

*Session Objectives:*

- ▶ Consider alternative methods for reporting of IND safety information, including related challenges and opportunities
- ▶ Understand alternate safety reporting processes that would be of value to investigators

**10:15am Describe and Discuss Different Types of Safety Communication**  
*Patrick Archdeacon*

**10:30am Sponsor Experience with Periodic Reporting**  
*Maria Luisa Bonura (Pfizer)*

**10:45am Sponsor Experience with Periodic Reporting**  
*Marsha Millikan (Eli Lilly)*

**11:00am Investigator Perspective on Periodic Reporting**  
*Mohamed Salem (Georgetown)*

**11:10am Round Table Discussion**

**12:15pm Wrap Up**

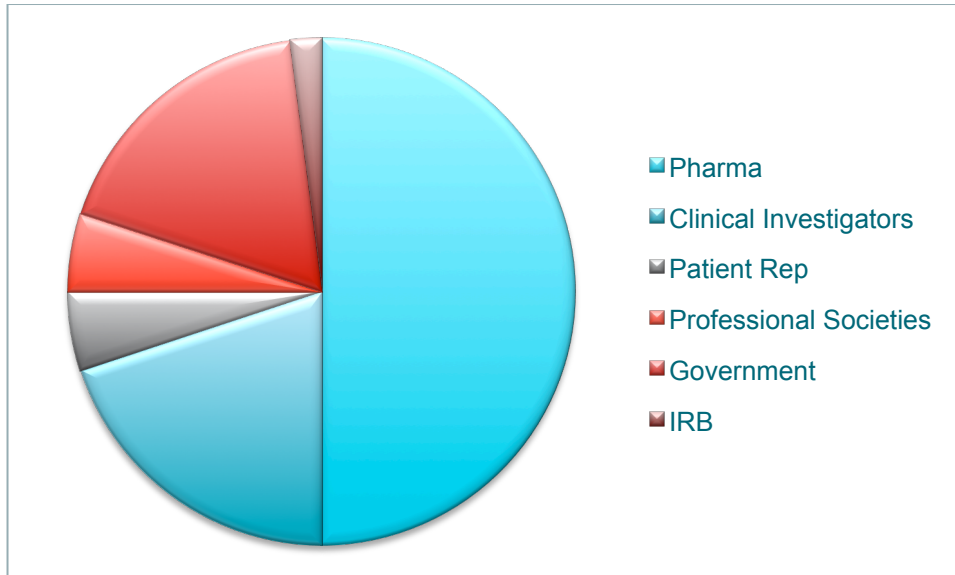
**12:30pm Adjourn (Boxed Lunch Provided)**

## Appendix B. Meeting Participants

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Our 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 CO-CHAIRS

Patrick Archdeacon, Food & Drug Administration  
Robert Goodwin, Pfizer, Inc.  
Jonathan Jarow, Food & Drug Administration  
Michael Jones, Eli Lilly and Company  
Raymond Perez, The University of Kansas Cancer Center  
Nancy Roach, Fight Colorectal Cancer

### MEETING ATTENDEES

Greg Ball, Merck & Co., Inc.  
Ely Benaim, Rexahn Pharmaceuticals  
Maria Luisa Bonura, Pfizer, Inc.  
Michele Britto, North Shore University Health System  
Lauri Carlile, Chesapeake IRB  
Chrissy Cochran, Food & Drug Administration  
Deborah Collyar, Patient Advocates In Research (PAIR)  
Connie Cullity, Food & Drug Administration

Theresa Cummings, University of Maryland  
Jeremy Day, US Oncology  
Wei Dong, Genentech/Roche  
Sutton Edlich, Rexahn Pharmaceuticals  
Marsha Fahrer, Bayer Healthcare  
Mary Jean Fusco, Janssen R&D  
Natalie Gearhart, Janssen Pharmaceuticals  
Janie Hofacker, American Association of Cancer Institutes (AACI)  
Jeffrey Infante, Sarah Cannon Research Institute/Tennessee Oncology  
Ni Khin, Food & Drug Administration  
Sean Khozin, Food & Drug Administration  
Steven Lemery, Food & Drug Administration  
Robert Lindblad, Society of Clinical Trials  
Kenneth Lipetz, Eli Lilly and Company  
Jaishri Meer, Genentech/Roche  
Marsha Millikan, Eli Lilly and Company  
Jean Mulinde, Food & Drug Administration  
Krupa Patel, Merck & Co., Inc.  
Christine Peterson, Rexahn Pharmaceuticals, Inc.  
Rachel Phipps, UNC Lineberger Comprehensive Cancer Center  
Janet Roepke, Eli Lilly and Company  
Mohamed Salem, Lombardi Comprehensive Cancer Center  
Dawn Sanderson, Sanofi  
Daniel Sargent, Mayo Clinic  
Rebecca Selle, Medical College of Wisconsin  
Ajay Singh, GlaxoSmithKline  
Reneé Smith, SCRI  
Nina Stuccio, Merck Research Laboratories  
Deepak Taneja, Janssen Pharmaceuticals  
Jose Vega, Merck & Co., Inc.  
Bill Wang, Merck Research Laboratories

## **STAFF**

Annemarie Forrest, CTTI  
Kelly Kilibarda, Whitsell Innovations, Inc.  
Kimberley Smith, CTTI  
Tacole Wood, Kelly Services