

Landscape of the Use of Central Institutional Review Boards for Multicenter Clinical Trials

Soo Bang, Celgene Corporation

June 12-13, 2014



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE

Speaker Disclosure & Disclaimer

- Presenter is employed by Celgene Corporation
 - receives stock options as part compensation
 - does not hold private stocks in any single pharmaceutical/biotechnology company
- The views and opinions are those of the presenter and do not represent those of the speaker's employer or industry
- These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copy right laws of the United States of America and other countries. Use by permission. All rights reserved.

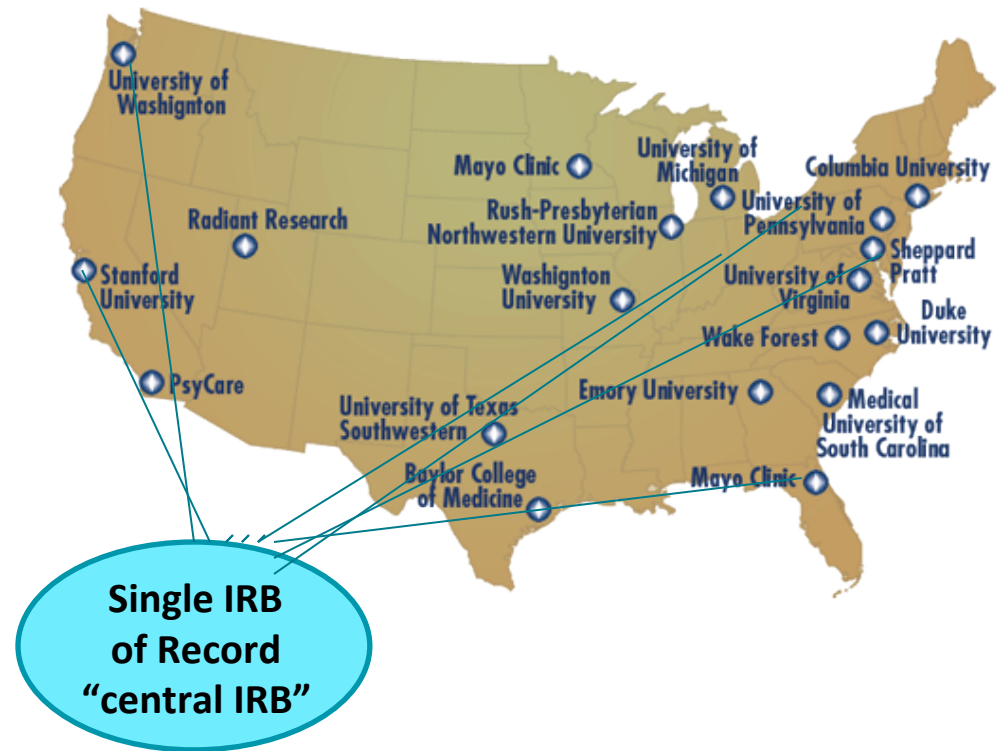
Common Misunderstanding of cIRB Concept

Barriers in realizing efficiencies of cIRB model – Concept Misunderstanding



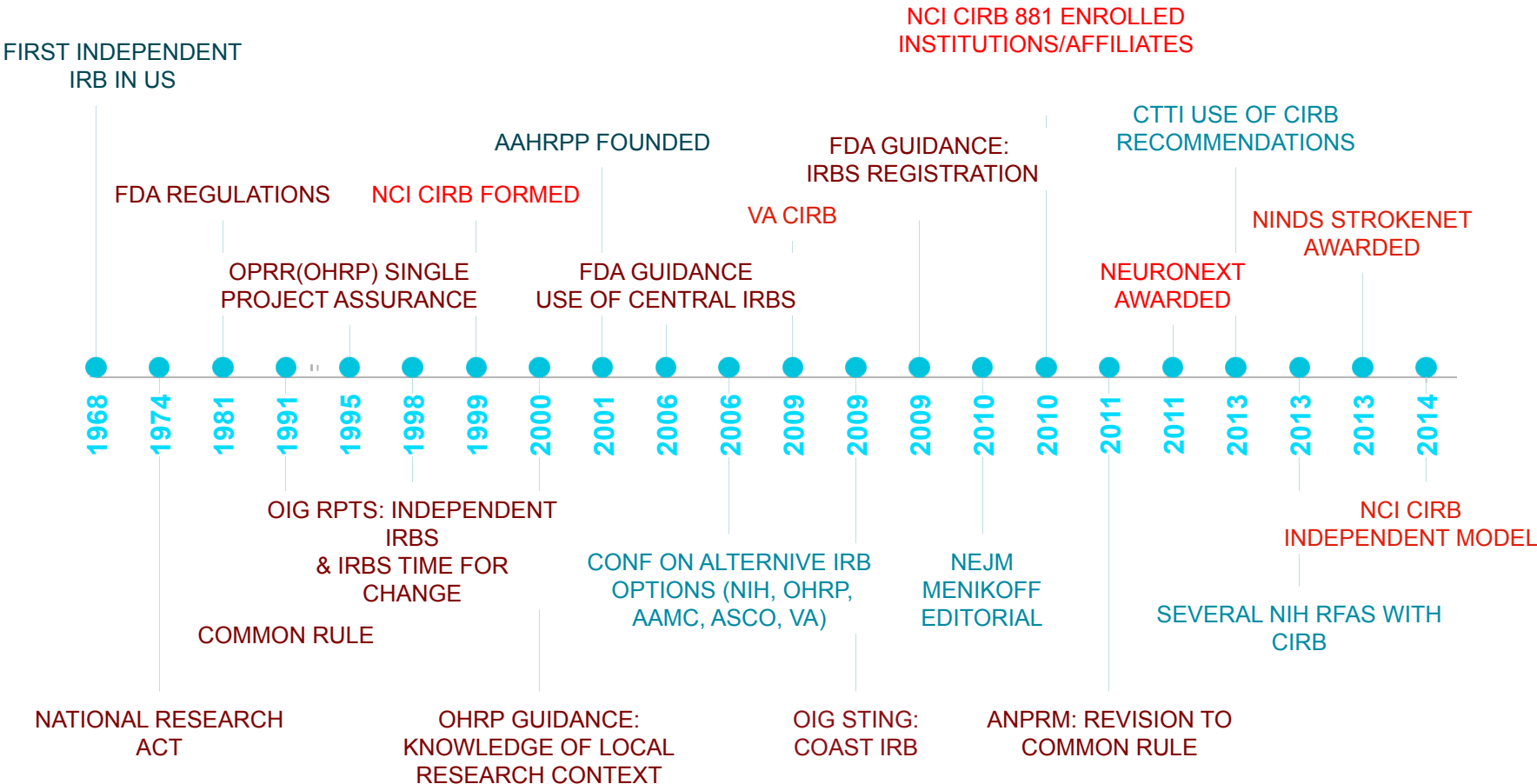
Institutional
IRB

Commercial
IRB



A "central IRB" can be a non commercial IRB, but used as a single IRB of record to which sites cede all regulatory responsibilities / scientific oversight and integrity of the protocol from initial review to termination , including ICF.

Historical Timeline



CTTI Project:

Use of Central IRBs for Multicenter Clinical Trials

Goal

Identify solutions to address barriers to the adoption of central IRBs for multicenter clinical trials

Objectives were to:

- Solicit current perceptions of barriers
- Develop a strategy to address the identified barriers
- Assess reactions to proposed solutions to remove these barriers

Methods

➤ Literature Review

➤ Expert Advisory Panel

- Institutional, federal, and commercial IRBs, industry, and regulatory agencies

➤ Semi-structured Interviews

- Stakeholders at six research institutions that did not typically use central IRBs

➤ Expert Meeting

- FDA, OHRP, federal and industry sponsors, independent IRBs, research institutions, and patient advocates

Results: Need to clarify terms

▶ Central IRB = Single IRB-of-record for a given protocol

- To which sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research including informed consent
- A range of entities may serve as a central IRB
 - e.g., independent IRBs, federal IRBs, another institution's IRB
- Implies that an institution not choosing to use the single IRB-of-record would not participate in that protocol

Results: Common themes

- Concerns seemed to be associated with conflation of the responsibilities of the institution with the ethical review responsibilities of the IRB
 - Developed “considerations document”
- Remaining discomfort due to lack of experience using centralized review

Recommendation #1

➤ CTTI recommends using a central IRB* (defined as a single IRB of record for all sites) to improve the quality and efficiency of multicenter clinical trials.

***CTTI's Definition of Central IRB:** A single IRB of record for all sites involved in a multi-center protocol. A range of entities may serve as a central IRB (e.g. another institution's IRB, a federal IRB, an independent IRB).

Recommendation #2

➤ To address blurred distinctions between responsibilities for ethics review and other institutional obligations, CTTI recommends that sites and IRBs use a CTTI-developed guide* to support communication and contractual relationships between institutions and a central IRB.

*Considerations Document

Recommendation #3

➤ CTTI recommends that sponsors in a position to require the use of central IRB review for multisite trial networks should do so 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 Central IRB Advancement Project

- Follow-on to original project
- 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
 - IAA Template
 - Publication and public posting of results

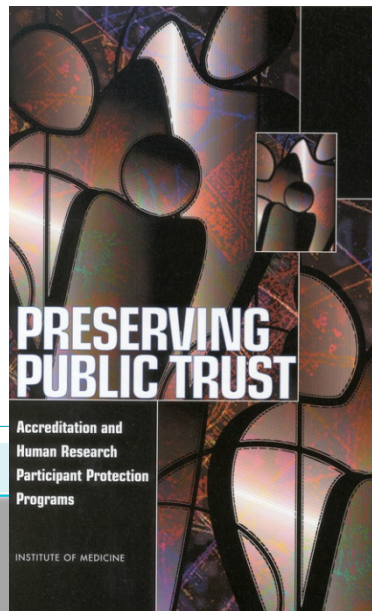
Meeting Objectives

- 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

Ensuring Human Research Protection



SAFEGUARDS



Protection of Human
Research Subjects

Thank you.



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE