# Landscape of the Use of Central IRBs for Multicenter Clinical Trials

## Sponsor's experience: Challenges of Implementation

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

# Sponsor - Central IRB - 2009

- Supported large pharmaceutical commitment to Human Research Subject Protection and commitment to AAHRPP accreditation
  - Aligns with (New SOP) – states commitment to Human Research Protection and IRB that will review sponsored research will be AAHRPP accredited
  - Address  IRB events “Coast” OIG Sting Operation
- Formalized Sponsor’s relationship with Master Agreements (7 Masters with 5 Preferred IRBs)
  - Better legal protection moving forward
  - Measure performance with quality metrics
  - Utilize based on more precise expertise in certain Therapeutic Areas
- Process of selecting of high quality Central IRBs through a transparent, audit-ready sourcing process based upon:
  - Quality: Evaluation with AAHRPP accreditation standards
  - Speed:  Cycle times
  - Costs (low on evaluation scoring)

# Contractual Performance Metrics

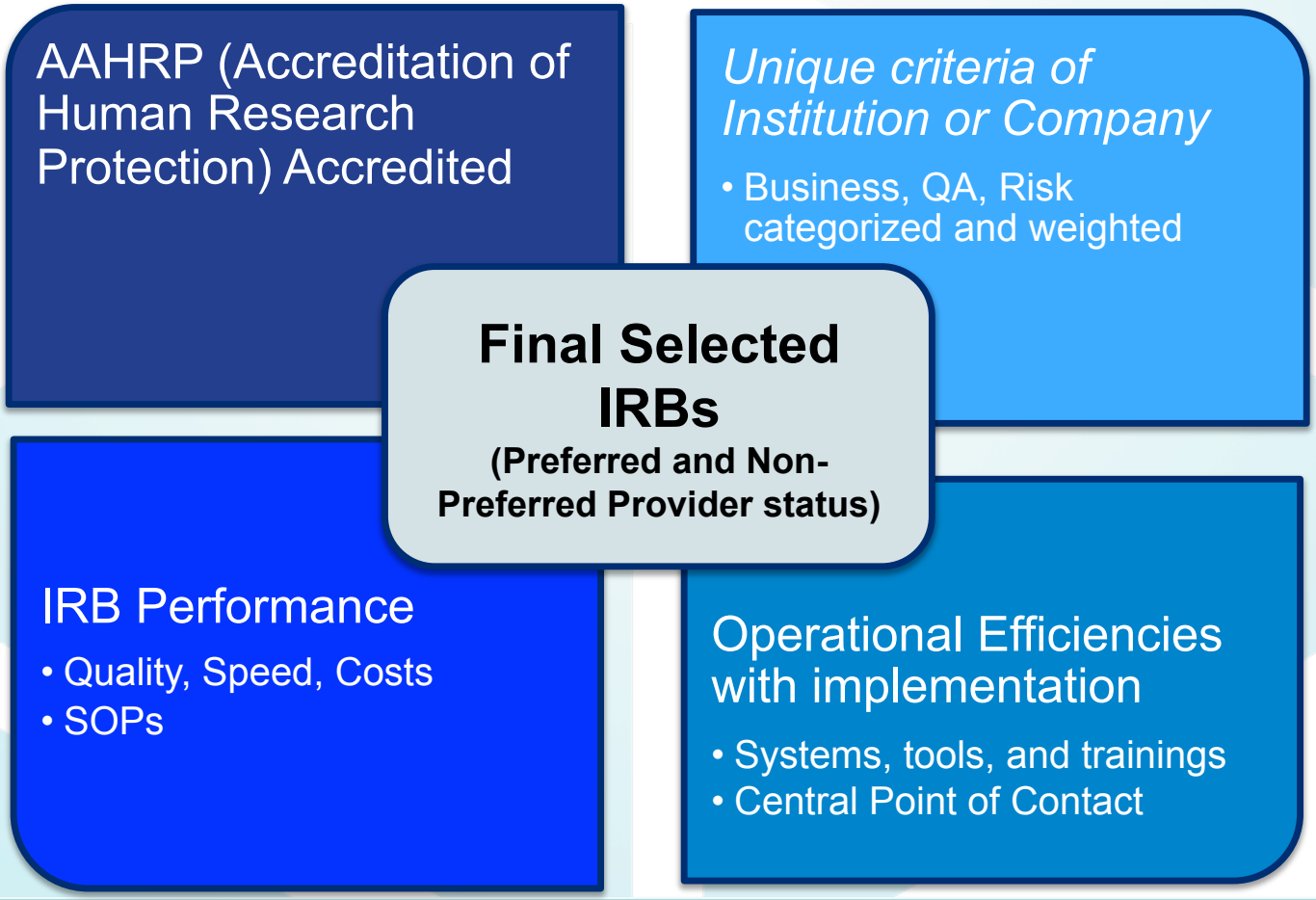
Quality

- Electronic Transmission/ IRB submission portal
- Communication Follow-up
- Accuracy of Approval Documents
- AAHRPP Accreditation Standing
- Staff Attrition/Retention

Speed

- Sponsor Submission Receipt to Review issued
- Investigator Site Submission to Review issued
- Protocol review Cycle Time
- Informed Consent Review Cycle time/ Revisions

# Industry Sponsor's Development of Criteria for Selection



# Journey to Change


# Big Hurdles / Barriers

*Overcoming perceptions, challenges with communication on model*

# 2012 Central IRB Initiative - Celgene

- Sponsor's selection process of adapting to new paradigm in the US for IRB review
  - Cross functional, multi-faceted selection process (Clinical Research & Development Operations, Legal, and Quality Assurance)
  - Project Managed by Global Site Contracts

- Adoption of  CTTI recommendations: Selection process for cIRB; implemented through upcoming multi-centered studies
  - Implementation Plan
  - Master Contract & ICF Negotiations
  - Communication with Our sites

# Implementation - Key Take Aways

- Communication, Communication, Communication
  - Internal Stakeholders (complete list)
  - Sites & Institutional Officials (Informational letter to sites)
    - *How to work with selected IRB*
  - CROs and vendor partners
- Training & Awareness
  - Train the Trainer, Line function champions, Clinical / TA leadership
  - Wide spread communication plan (including RMLs/CRAs)
- IRB – Sponsor Dialogue / Collaboration
  - On going Training, Feedback and Guidance

# Key Take Aways

- Establish and Maintain Key IRB relationships
  - Expert consultation / counsel / advisor
    - FDA Final Guidance on IRB Responsibilities
    - Sounding Board: Subject Reimbursement, Pediatric Studies, ICFs
- Feedback on Sponsor Protocols & Other related documents & IRBs
  - Lines of communication
  - Routine Performance Evaluation Review
  - Distribution of work among selected cIRBs
  - Feedback from CRO Partners & Sites
- Sponsor adoption - May foster Comfort and Trust
  - *Change the paradigm of our current system*

# Journey

- The first step toward change is awareness. The second step is acceptance.
  - Nathaniel Branden

- *Be the champion in your organization*

# Additional Information & Resources

- PLOS ONE Peer Reviewed Article
- CTTI Recommendation Slide Deck
- Dr. Weinfurt Central IRB Recommendations
- Dr. Weinfurt Duke Medicine Interview
- CTTI Central IRB Expert Panel Mtg April 2012

# Thank you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