Landscape of the Use of Central IRBs for Multicenter Clinical Trials

Sponsor’s experience: Challenges of Implementation

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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

AAHRP (Accreditation of Human Research Protection) Accredited

Unique criteria of Institution or Company
- Business, QA, Risk categorized and weighted

IRB Performance
- Quality, Speed, Costs
- SOPs

Final Selected IRBs
(Preferred and Non-Preferred Provider status)

Operational Efficiencies with implementation
- Systems, tools, and trainings
- Central Point of Contact
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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