A Roadmap to Establishing Optimal CRO and Sponsor Relationships

CBINET Early Phase Clinical Trial Breakthroughs

March 2015
## Workshop Overview

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Identifying the Best CRO that fits your Early Clinical Development Strategy and Needs

- Identify what types of studies/programs are intended for outsourcing, which vary from organization to organization.
  - Begin by assessing the business need and the overall strategy of the compound/program under development.
    - For example, is it a compound which has been in-licensed?
    - Priority of compound in portfolio.
    - Complexity of program and studies.
- Take an inventory of the infrastructure and resources which the sponsor has in order to meet the development of the compound.
  - How large or small is the sponsor company developing the compound?
  - What type of CRO do we need to support development?
  - What services do we need them to provide?
- Review vendor qualification information and historical data when selecting for placement of a future clinical trial(s).
Identifying the Best CRO that fits your Early Clinical Development Strategy and Needs

• Determine the roles and responsibilities of the Sponsor and the CRO from study start up through regulatory inspection readiness.
  — Study Drug Release
  — ClinicalTrials.gov
  — Database Management
  — Medical Writing
  — Medical Monitoring and CRA Monitoring
  — Specialty Laboratories
  — Regulatory Submissions
  — Investigator Selections
  — Others?

*Always remember that subject safety is the highest priority.*
Identifying the Best CRO that fits your Early Clinical Development Strategy and Needs

Assess the capability of the CRO to successfully support and lead your trial/program

» Ensure subject safety – first and foremost!
» Ensure quality study data
» Avoid timeline disruption and study delay

Include Relevant Stakeholders:
• Vendor Relations
• Finance/Procurement
• Quality Assurance
• Statistics
• Data Management
• Drug Metabolism/PK
• Regulatory
• Monitoring/Ops, as needed

Establish Partnership Team that consists of reps from Sponsor and CRO:
• Study Specific Teams – meet routinely (wkly) and responsible for study progress
• Higher level team that meets (qrtly) to review portfolio, ongoing & upcoming studies and how best to utilize resources
• Innovate together!

Establish KPI (Key Performance Indicators):
• Which KPIs are important
• Evaluate progress over time
• Establish who will keep KPIs
• Collaborate and adjust, as needed
Identifying the Best CRO that fits your Early Clinical Development Strategy and Needs

- Understand considerations for working with large, medium or niche CRO providers.
  - Know up front what the limitations are for every CRO with which you collaborate.
  - Do not assume that the “larger” the CRO the more capabilities it has to offer.
  - Different paradigms can be utilized depending upon the objectives of the clinical study. For example:

  ![Diagram showing the different paradigms and activities]

  **All study management transferred to the CRO.**

  **Selected activities transferred to the CRO(s).**
Building a Strong and Lasting Relationship between Sponsor and CRO

**Learning to Speak the Same Language**
- Examples – need to define terms like SAS datasets, Functional Areas, Statistical and PK analysis, First Patient In, Risk Based Monitoring, Soft Lock, Database lock, Note to File, Amendment

**Executive Sponsorship**
- Sponsor and CRO - should be cascaded down throughout each functional area in both organizations (SME to SME)

**Approach to Outsourcing Paradigm**
- What is being outsourced and what is being provided by Sponsor
- Roles and Responsibilities
- Process – who is doing what and when
- What are deliverables and timelines

**Alignment and Agreement**
- Target Timelines – built for speed but adjusted based on experience
- Data Deliverables and Tracking
Building a Strong and Lasting Relationship between Sponsor and CRO

• Balancing needs
  – Management, CRO capacity/capabilities, Program teams

• What to do when we hit the wall?
  • Real Examples
    – Trial Master File or CSR Backlog
    – Data Management and Data Deliverables Misalignment
    – Inspection Readiness – who is responsible

• Resolution
  – Identification and prioritization of issues (safety first)
  – Communicate and have a plan- detailed discussions at appropriate levels
  – Takes work!

• Compromise and Communicate - always think about the safety and development of the compound (as the patients are waiting)
Key Elements to a Successful Partnership

- Sponsor and CRO Alignment, Commitment, and plain ole “hard work”
- Communication—Routine, Planned, & Ad Hoc - as often as necessary
- Maturity of Partnership and Experience – “doesn’t happen overnight”
- Approach to Issue Resolution – challenges will arise, it’s how they are handled
- Mutual “skin in the game” – has to be mutually beneficial
- Partnership has to be flexible and evolve in order to meet changing business needs
- Give feedback – bi-directional with candor and courage
- Continuing Innovation – how can we partner better?
Mutual Benefits of a Successful Partnership

Benefits to Sponsor

– Means to expand (and contract) with changing business demands
– Partnership willing to innovate and expand scope of work
– Reliable, flexible, responsive partnership that can navigate & mitigate challenges

Benefits to CRO

– Partnership willing to explore different business models and types of outsourcing
– Challenged to Innovate
– Rich scientific discussions and mutual learnings – scientific issues and drug development
Oversight and Governance

• Governance and Escalation Path to Senior Management (as an example)
  – Study Teams – meet routinely, as appropriate
  – Operational Governance Team - members of both organizations meet routinely
  – Executive Governance Meetings – quarterly

• Practical Oversight and Quality Assurance (QA)
  – Vendor Management Oversight Plan – includes each functional area
  – Quality Control Visits
  – Audits and Inspections – prepare together and share feedback

• Quality Document, Quality Agreement, or Operations Manual
Breakout Exercise and Readout

Instructions:
1. Select two questions from below and think about who, what, and why as you respond.
2. Appoint a Group Representative to summarize the output of each question to the broader community.
3. Output will be collated and posted after the workshop.

Key Questions:
- What are the key characteristics of a strong, successful sponsor/CRO relationship? Prioritize characteristics, if possible.
- What criteria should sponsors utilize to determine which CRO best fits their early phase development needs, inclusive of key internal functional areas?
- What considerations should a CRO taken into account when they take on a partnership with a sponsor?
- Outsourcing versus “inhouse” – what studies/tasks will we outsource? Discuss various models of outsourcing.
- How to best approach vendor management oversight, issue escalation, and mitigation solutions from sponsor and CRO perspectives.
Thank you!

Jim Nissel  
Celgene  
Jnissel@Celgene.com  
908-673-2485

Laura Vessey  
Merck  
Laura_Vessey@Merck.com  
(732) 594-1814