Collaborations and Interactions with Industry for Clinical Trials

NCIC New Investigator Clinical Trial Course
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Contents

- Types of trials
- Approval processes
- Kinds of collaboration
- Cooperative groups
- Study planning
- Safety reporting

Two main types of trials

- Company-Sponsored
- Investigator-Sponsored

Two main types of trials (1)

Company-Sponsored

- May or may not be for registration
- Phase I-III
- Fully resourced by company (drug supplies, trial monitoring, regulatory filing, data collection, analysis and reporting)
- Company owns database and IP
- Centrally monitored to full regulatory standards
- Centres auditable at any time for medical or regulatory reasons
- Data publication infrequent and comprehensive

Two main types of trials (2)

Investigator-Sponsored

- Not for registration
- Phase II-IV
- Supported with drug, data management funds or both
- Investigator owns database – Institution may own IP
- Locally monitored (do not need to be monitored to full regulatory standards)
- Full safety reporting and drug accountability
- Centres auditable at any time for medical or regulatory reasons
- Frequent data communications (symposia, conferences)

Two different approval processes

- Company-Sponsored
- Investigator-Sponsored

Two different approval processes (1)

Company-Sponsored

- Idea originates internally
- Reviewed and sanctioned by multidisciplinary team
- Input from international steering committees
- Managed by strict timelines and project management groups (Clinical Operations)
- Often requires discussion (live or teleconference) with FDA
- Usually long protocol generation process (~ 6 mo) – Multiple review cycles
- Impact of protocol amendments critical
- Termination requires executive approval

Two different approval processes (2)

Investigator-Sponsored

- Proof of investigator-initiated proposals need to be in study files
- Protocol concept developed and peer-reviewed at company
- Concept needs to fit company strategy, ORQs
- Can be supported with drug, management funds, or both
- Reviewed monthly (CAC process)
- Can be terminated at the sole company's discretion at any time

Two kinds of collaboration

- Preclinical Studies and Early Trials
- ≥ Phase II Trials

Two kinds of collaboration (1)

Preclinical Studies and Early Trials

- Preclinical collaborations usually easy, cheaper and rapid to establish, in comparison with clinical trials
- Can access pipeline compounds before Phase I begins
- Highest risk for IP and discovery research disputes

Two kinds of collaboration (2)

≥ Phase II Trials

- Take months to implement, from concept generation to first patient dosed
- Long-term planning essential
- Continued and open communication between centres and company is critical (e.g., safety reporting)
- Centres subject to feasibility testing (if trial is company-sponsored) and may not qualify

Trials with Cooperative Groups (1)

- Assess structure of cooperative group proposing the trial
- Most important: History and track record of group
- Maximize reach-out and accessibility to investigators
- Tumour frequency
- Exposure and experience to treating community
- Faster accrual time
- Expertise of group + inter-group collaboration/expansion
- Explore new opportunities and potential avenues (based on local positive Ph.II results) not initially pursued
- Usually not a registration study

Trials with Cooperative Groups (2)

- How the group analyses the data: Different views and methods, CRA qualification/experience, etc... Win/win partnership
- Integrity and interpretation of database
- Quality of data: What is next?
- Owning the data (regulatory) & IP issues – legal aspect
- Investment level v Risk potential (control level v reliability and trust of group)
- Seen as objective, neutral and independent
- Win/win partnership

Planning for a Study with Pharma

- Begin with the end in mind
- Discuss your ideas within a Team before writing anything down (brainstorm)
- Involve a Statistician early in the process
- Don’t aim too high (do not be too ambitious)
- Be specific and concise (avoid verbosity and multiple iterations)
- Differentiate between a study for regulatory purposes and a study for medical purposes
- Use Protocol Templates whenever possible
- Make sure you have resources to do what you plan to do

Safety Reporting to Pharma

- All and any adverse event (study emergent or study-related) must be reported
- Inaccurate and incomplete safety reports are misleading and unfortunately extremely common
- Clarifications and queries must be made as close to real time to the event as possible
- Responsible follow-up must be exercised for unresolved events at the time of reporting
- Objective causality imputation requires, common sense, good semiology, and at times, the application of formal algorithms
- The importance of accurate safety reporting cannot be overemphasized

- A great man is he who does not lose his childlike heart!
  - Meng-Tse (372-289 B.C.)

Merci - Thank You !