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Clinical Trials and Industry Partnerships

A practical Primer for Research Administrators

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Objectives

- Understand the basic structure and purpose of clinical trials, including the major phases and regulatory requirements.
- Explain how industry partnerships work in clinical research, focusing on the roles of sponsors, CROs, and sites.
- Identify key components of clinical trial budgeting, contracting, and compliance unique to industry-sponsored studies.
- Recognize common administrative challenges and strategies to support efficient and compliant trial management.

Definition

- Clinical Trial
  - This is typically defined as a study where one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. However, certain regulatory bodies, funding sources, and medical journals have either more broad or more specific definitions (e.g., FDA, ICMJE, NIH, OHRP, etc.).*

*Specific definitions can be found on the ClinicalTrials.gov website.

Purpose

- Clinical Trials are designed to answer health or behavioral related questions regarding investigational treatments, novel surgical methods, innovative disease prevention strategies, experimental screening and diagnostic methods or technologies, and new methods or technology that improve comfort and quality of life.

Trial Design

- Interventional vs. Observational
  - Interventional: Studying the effect of a specific intervention (e.g., drug, device, behavior change) assigned to participants.
    - Examples: Randomized Controlled Trials, Non-randomized Trials, Open-Label Trials, Blind/Double-Blind Trials, Crossover Trials.
  - Observational: Observing health or health-related behavioral outcomes without intervention.
    - Examples: Cohort Studies, Case Studies, Cross-Sectional Studies.
- Single Site vs. Multi-Site vs. Decentralized
  - Single Site: Conducted at one specific site, by one team, under one protocol.
  - Multi-Site: One protocol at two or more independent, geographically distinct locations or institutions.
  - Decentralized: Non-traditional (e.g., homes, local labs, telemedicine, etc.)

Phases of Trials

- Drugs/Biologics
  - Phase 1: Safety and dosage (small sample size)
  - Phase 2: Efficacy and side effects (moderate sample size)
  - Phase 3: New treatment vs. established treatments (large sample size)
  - Phase 4: Post-marketing studies (dependent on FDA and similar products)

- Medical Devices
  - Traditional Feasibility: Preliminary safety and effectiveness data (small sample size)
  - Pivotal: Definitive evidence of safety and effectiveness (large sample size)
  - Post-market: Post-marketing studies (dependent on FDA and similar products)

Regulatory Requirements

- Required Training
  - Good Clinical Practice (GCP)
- Registration
  - Specific mandatory timeline determined by agency/organization requiring registration.
  - Not required for all trials (OHRP).
  - ClinicalTrials.gov or another registry (ICTRP).
- Annual Verification
  - Only required for trials registered.
- Posting Informed Consent
  - Required for most trials (not required by ICMJE).
  - Mandatory timeline (if required): after trial is closed to recruitment to no later than 60 days after the last study visit).
- Posting Results
  - Not required for all trials (not required by ICMJE or OHRP).
  - Mandatory timeline (if required): Within 12 months after the last study visit.
- Additional FDA Requirements
  - 21 CFR Parts: 11, 50, 56, 312, 812

Key Sponsorship Types

- Commercial (Industry)
  - Pharmaceutical, biotechnology, or medical device companies
- Non-Commercial (Academic/Non-Profit)
  - Academic Institutions, hospitals, or non-profits that initiate studies (likely focused on disease understanding, public health, independent research)
- Investigator-Sponsored Trials
  - Trials that are initiated and managed by a researcher or research team rather than a company.
- (Federal) Governmental Agencies
  - NIH, DoD, VA, etc.

Industry Partnerships

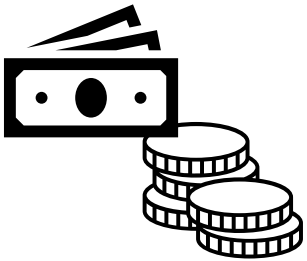
- Sponsors
  - Company who is responsible for initiating, managing, and financing a clinical trial.
    - Academic institutions can also trial sponsors.
  - Ultimate legal responsibility
    - Scientific integrity
    - Regulatory compliance
    - Participant safety
  - Operational and financial responsibilities
  - Can transfer some or most responsibility to a CRO via agreement.

Industry Partnerships

- Contract Research Organization (CRO)
  - Contracted specialized service provider hired by the Sponsor to perform specific activities to help carry out the trial.
  - Can be contracted to perform any of the following activities:
    - Clinical trial management, site management, patient recruitment, clinical monitoring, safety monitoring, data management, regulatory compliance and submissions, etc.
- Clinical Sites
  - Contracted locations where the trial is being performed (e.g., hospitals, clinics, specialized research centers).
  - Responsibilities include:
    - Patient recruitment, human subjects protection, protocol adherence, safety monitoring, data integrity, investigational product management, etc.

Budgeting

- Fees and Costs
  - Start-up fees
  - Per-patient costs
  - Personnel costs
  - Administrative costs
  - Pass-through costs
  - Closeout costs



- Process
  - Analyze the protocol
  - Develop a Cost Matrix
  - Include all applicable fees
  - Negotiate with the Sponsor

Contracting

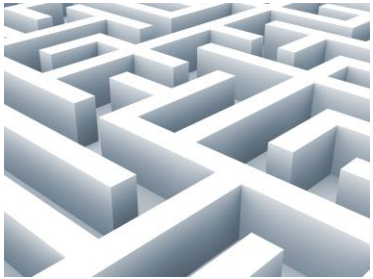
- Clinical Trial Agreement (CTA)
  - Legally binding contract between the sponsor, study site, and any applicable parties (CRO) to define the scope, payment terms, legal and regulatory responsibilities, and IP.
  - Key components:
    - Scope of Work
    - Budget and financial terms*
    - Responsibilities of parties
    - Regulatory compliance
    - IP
    - Publication
    - Indemnification and Insurance
    - Termination
    - Disputes

Compliance

- PRS Administrator
  - Manages the organization's ClinicalTrials.gov accounts and oversees the accuracy and timeliness of the data submitted in ClinicalTrials.gov.
- Institutional Review Board
  - Ensures the rights and welfare of the human research participants are protected.
- Audits and Inspections
  - Oversight mechanism (internal or external) to ensure the protection of human research subjects, compliance with applicable laws and regulations, and maintain data integrity.

Common Administrative Challenges

- Confusing administrative landscape
  - Information is hard to find or is not provided.
- Timelines
  - Delays in meeting goals, requirements, and planning.
- Budget and financial issues
  - Overruns, inaccurate financial planning, etc.
- Regulatory, IRB, and Site delays
  - Approval process may be more complex than originally thought.



Best Practices

- Communication
  - Early discussions help prevent confusion and bottlenecks.
  - Identify clear goals, timelines, and responsibilities early.
- Guidance
  - Clear guidance regarding each step of the process.
    - Identify the office/person to contact for each step of the process.
    - Identify the timeframe for each step in the process.
- Training
  - Campus-wide and/or targeted training regarding the process, requirements, and expectations help prepare administrators and study personnel for success.

Conclusion

- Clinical trials are initiated to investigate the effect of an intervention on health or behavioral-health outcomes.
- Federal laws, regulations, and policies from multiple organizations federal agencies regulate how trials are registered, conducted, and reported.
- Sponsors have the ultimate legal responsibility for all aspects of the trial.
- Budgeting, contracting, and compliance are critical roles in the process of initiating and conducting a clinical trial.
- Proper communication, guidance, and training can help clarify the clinical trial process amongst all parties and lead to successful partnerships.

Questions?

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Additional Information: Key Terms

- Clinical Trial Agreement
- ClinicalTrials.gov
- Contract Research Organization (CRO)
- Individual Participant Data (IPD) Sharing
- National Clinical Trial (NCT) Number
- Principal Investigator
- Protocol Registration and Results System (PRS)
- PRS Administrator
- Record
- Registry
- Responsible Party
- Sponsor

Additional Information: ClinicalTrials.gov - Registration

- Who needs to register?
  - If the study meets the definition of a clinical trial per one of the sources below, the responsible party is required to register the clinical trial on a public registry (e.g., ClinicalTrials.gov).
    - CMS*, FDA, ICMJE, NIH, PCORI, VA, and WHO
    - Note: OHRP does not require registration.
- When do I need to register?
  - FDA ("Applicable Clinical Trials") and NIH (Final Rule): 21 days after the first subjects has been enrolled.
    - CMS, IMCJE, PCORI, and WHO: Prior to enrollment
    - VA: Registration timeline is deferred to either to the FDA's or ICMJE's depending on which applies.

Additional Information: ClinicalTrials.gov - Maintenance

- Do I need to update the record?
  - All registered trials must be updated at least annually ("Annual Verification") to ensure that all the information has been verified as accurate.
  - Any changes or updates to the trial must be reflected in the record.

- When do I need to update the record?
  - Changes to overall recruitments status, recruitment status at any study site, and last follow-up date for the primary outcome measure must be made within 30 days of the change.
  - All other changes or updates to the record must be made at least every 12 months.

Additional Information:
ClinicalTrials.gov - Informed Consent Posting

- Do I need to post a consent form?
  - Yes, all clinical trials, other than those defined by ICMJE, area required to post a consent form used in the trial.
- Where do I post the consent form?
  - All registered trials must post within the record.
  - Clinical Trials defined by OHRP that were not registered must post on a dedicated website identified by OHRP.
- When do I need to post the consent form?
  - All consent forms that are required to be posted must be posted no later than 60 days after the last study visit.

Additional Information: ClinicalTrials.gov - Reporting Results

- Do I need to submit results?
  - If the study is defined as a clinical trial by CMS, FDA, NIH, PCORI, VA, or the WHO, the posting of results is required.
    - Note: ICMJE and OHRP clinical trials do not require results to be posted.
- When do I need to submit results?
  - Results must be submitted and made public (approved by the registration system) within 12 months after the last study visit.