

Multi-Center Clinical Trials

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Multi-Center
Clinical Trials
but
First Let's Practice
Herding Kittens

Multi-Center
Clinical Trials:

Shoot Me Now!

Multi-Center Clinical Trials:

The Agony And The Ecstasy

Definition

A collaborative effort that involves more than one independent center for the tasks of enrollment, treating, and following study participants.

Rationale for Multi-Center Clinical Trials

Recruit adequate number of participants
within a reasonable period of time.

1. To address the research question within a reasonable period of time
2. To assure a more representative sample of the study population.
3. Scientific collaboration, to address a common problem.

Conduct of Multi-Center Trials

Multi-Center Trials are complex undertakings that entail agreement on following a common protocol by all participating centers.

This agreement is built on full and clear communication by the participating centers throughout all stages of Trial design and execution.

Conduct of Multi-Center Trials: A “How To” Guide

1. Establishment of an Organizing Group

- Organizes and oversees all phases of Trial.
- Comprised of leaders from funding source (e.g., government agencies, private research organizations), and science (recognized experts on subject matter).
- Must have necessary authority to operate.

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2. Determination of Trial Feasibility – Is the Trial Worth Doing?

- Review of literature and other key information.
- Sample size determination (UC event rate, tx effect size, anticipated adherence/drop-out) and population availability.
- Likely costs of the Trial

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2. Determination of Trial Feasibility – Is the Trial Worth Doing?

- Availability of competent / cooperative investigators
- Timeliness of the Trial
- Need for feasibility study?

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3. Identification / Selection of Trial Sites

- Recruitment sites:
 - Is there a sufficient recruitment population?
 - Is the investigator group experienced?
 - Is there institutional support?

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3. Identification / Selection of Trial Sites

- Coordinating Center
 - Assists in Trial Design.
 - Implements randomization scheme.
 - Data responsibilities.
 - Ongoing communication with all centers.
 - Staff must have wide ranging expertise.

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3. Identification / Selection of Trial Sites

- Laboratory Cores
 - Perform specialized activities
 - Expertise / capacity to perform activities
 - Required independence from Clinical Sites
 - Issues of maintenance of blind

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4. Protocol Development

- Development prior to selection of sites
- Development after selection of sites
 - Planning sessions
 - Working groups
- *It is essential that everyone be ‘on board’!*

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5. Establishment of Organizational Structure

- Data Monitoring Committee
- Executive Committee
- Steering Committee
 - Focused sub-committees
- Organizational structure governed by Trial size

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6. The Issue of ‘QA’

- Need for training and standardization
- Certification / remediation procedures
- Implementation before Trial begins
- Procedures for staff turnover
- Dovetails with organizational structure

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7. Monitoring / Oversight of Performance

- Recruitment
- Data quality
- Adherence to protocol
- Frequency of monitoring
- Remediation and adjustment

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8. Dissemination Policies

- Essential, since the “credit” must be shared by all.
- Issues surrounding commercial sponsorship.
- Processes for insuring quality and consistency
- Role of Coordinating Center.

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In Summary

- Communication, communication, communication
- Costs, costs, costs
- Collaboration and compromise