

Challenges in Conducting Multi-Center Academic Trials

Nina R. Schooler, Ph.D.

Joanne B. Severe, M.S.

Academic Multi-Site Clinical Trials Workshop

- Participants
 - Nina Schooler
 - Joanne Severe
 - Barry Lebowitz
 - Andrew Leon
 - Gary Sachs



Goals

- To identify the challenges and solutions that are unique to academic trials as opposed to those characteristic of all clinical trials
-
-



ISCTM

THE INTERNATIONAL SOCIETY FOR CLINICAL TRIALS AND METHODOLOGY

Sources of Funding

- Federal (NIH) grants and contracts
 - Foundation for the NIH (FNIH)
 - Private foundations (e.g., Michael J Fox)
 - Targeted to specific diseases
 - Industry Investigator-initiated studies
 - Industry contributions of medication supplies
-
-

Leadership Models

- “First Among Equals”
 - Hierarchical
- 
-



ISCTM

THE INTERNATIONAL SOCIETY FOR
CLINICAL TRIALS AND METHODOLOGY

Characteristics of Functional Collaborations

- Shared passion for the question
 - Willingness to collaborate
 - Clear delineation of roles
 - Motivation
 - Experience/understanding of meeting regulatory and financial requirements of a study
 - Unique shared contributions
-

Technical Skills I

- Ability to formulate a compelling question and communicate it to relevant stakeholders
 - Collaborators
 - Grant funding agency
 - Reviewers
 - Gate keepers to the patient population
 - Subject participants
-
-

Technical Skills II

- Identification and creation of a collaborative network
 - Site performance (e.g., recruitment, retention)
 - History of prior collaboration
 - Strategy for engaging and identifying additional collaborators
 - Multiple PI's vs Sub-contracting
 - Performance sites vs Collaborators
-
-

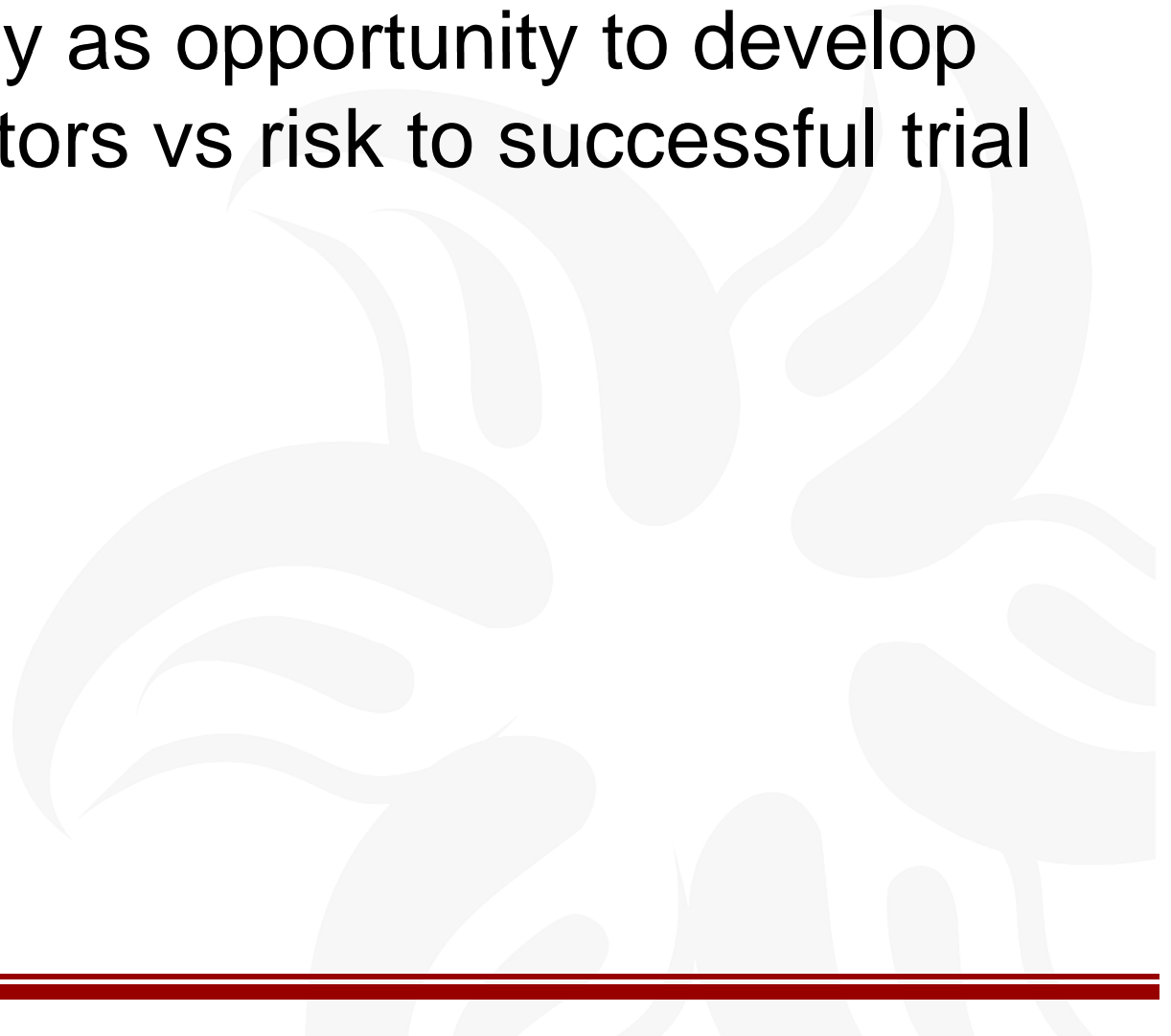


ISCTM

THE INTERNATIONAL SOCIETY FOR CLINICAL TRIALS AND METHODOLOGY

Unresolved Site Issue

- Multi-site study as opportunity to develop new investigators vs risk to successful trial completion



Generalizability

- NIH diversity policies (race, ethnicity, gender, age)
 - Should the sample size be large enough to conduct sub-group analyses OR
 - Moderator analyses to detect patient characteristics that moderate the treatment effect size
-