Living Textbook Update

Kevin Weinfurt

Coordinating Center Communications staff

Proposed Organization

- Introduction

- Design

- Conduct

- Reporting/Dissemination

Introduction

- What is a Pragmatic Clinical Trial?

- Engaging Stakeholders and Building Partnerships to Ensure a Successful Trial

Design

- Sample Selection
- Intervention and Comparison Groups
- Randomization Schemes: Choosing Between Individual and Cluster Designs
- Choosing and Specifying Endpoints
- Statistical Considerations/Analysis Plan
- Ethics & Regulatory Considerations in Identifying and Enrolling Participants
- Data Access and Collection
- Planning for Data Safety and Monitoring
- Registration With ClinicalTrials.gov

Conduct

- Startup

- Recruitment

- Data Collection

  - Potential Changes That Might Occur

- Data Safety and Monitoring

  - Monitoring for Stability of Intervention and Comparison Groups

- Data Analysis

Reporting/Dissemination

- Reporting Findings From PCTs

- Special Considerations for Reporting PCTs

- The PCT Reporting Template

  - Examples

- Data Sharing and Promoting Transparency

- Dissemination Strategies for Different Stakeholders