

Clinical Research Fellowship Learning Objectives

Department of Emergency Medicine

Denver Health Medical Center, Denver, Colorado

1. Identification of Area of Focus

2. Hypothesis Generation

3. Research Design

- 3.1 Definition of Study Population or Model System
- 3.2 Definition of Endpoints
 - 3.2.1 Relevance
 - 3.2.2 Reliability
 - 3.2.3 Validity
- 3.3 Experimental and Quasi-Experimental Designs
- 3.4 Observational Designs
- 3.5 Sample Size Determination / Power Analysis
- 3.6 Planned Comparisons and Analyses
 - 3.6.1 Primary Endpoint
 - 3.6.2 Multiple Endpoints versus Composite Endpoints
 - 3.6.3 Subgroup Analyses
 - 3.6.4 Adjustment for Covariates
 - 3.6.5 Modeling

4. Data Collection Methods

- 4.1 Data Collection Instrument (DCI) and Case Report Form (CRF) Design
- 4.2 Testing and Revision of DCIs and CRFs
- 4.3 Database Design
- 4.4 Data Verification and Query Resolution

5. Data Monitoring and Interim Data Analysis

- 5.1 Data Monitoring Committees
- 5.2 Statistical Aspects of Interim Data Analysis / Efficacy Monitoring
- 5.3 Safety Monitoring

6. Data Analysis

- 6.1 Verification of Data Quality
- 6.2 Verification of Data Assumptions
 - 6.2.1 Quality of Randomization
 - 6.2.2 Characteristics of Study Population
 - 6.2.3 Sample Size Assumptions
- 6.3 Data Analysis
 - 6.3.1 Independent Variables
 - 6.3.2 Primary and Secondary Dependent Variables
 - 6.3.3 Advanced Methods
 - 6.3.3.1 Multivariable Linear and Logistic Regression Techniques
 - 6.3.3.2 Classification and Regression Tree Analysis
 - 6.3.3.3 Decision Analysis
 - 6.3.3.4 Cost Analysis
 - 6.3.3.5 Sensitivity Analysis
 - 6.3.4 Exploratory Data Analysis
 - 6.3.4.1 Data-Motivated Analyses

7. Presentation of Research

- 7.1 Abstract Preparation and Submission
- 7.2 Oral Presentation of Research Results
- 7.3 Poster Presentation of Research Results

<p>8. Manuscript Preparation, Submission, and Revision</p> <ul style="list-style-type: none"> 8.1 Manuscript Outline 8.2 Manuscript Preparation 8.3 Manuscript Revision and Interaction with Editors 8.4 Responding to “Letters to the Editor”
<p>9. Grant Preparation, Submission, and Revision</p> <ul style="list-style-type: none"> 9.1 Grant Preparation 9.2 Grant Submission 9.3 Grant Revision
<p>10. Project Management</p> <ul style="list-style-type: none"> 10.1 Budget Management 10.2 Personnel Management 10.3 Progress Reports 10.4 Interaction with External Agencies
<p>11. Ethical Aspects of Medical Research</p> <ul style="list-style-type: none"> 11.1 Institutional Review Board 11.2 Human Subject Protection <ul style="list-style-type: none"> 11.2.1 Elements of Informed Consent 11.2.2 Elements of HIPAA 11.3 Uses of Animal Subjects 11.4 Research Fraud and Misconduct
<p>12. Informatics</p> <ul style="list-style-type: none"> 12.1 Personal Productivity Software <ul style="list-style-type: none"> 12.1.1 Word Processing and Data Management 12.1.2 Scientific Tables and Figures 12.1.3 Personal Information Management 12.2 Scientific Graphics 12.3 Poster Creation 12.4 Web Page Design 12.5 Database Design and Translation 12.6 Statistical Software
<p>13. Teaching Skills</p> <ul style="list-style-type: none"> 13.1 Clinical Supervision 13.2 Lecture Preparation
<p>14. Career Development</p> <ul style="list-style-type: none"> 14.1 Skill Development 14.2 Development and Maintenance of Collaborative and Mentored Relationships 14.3 Time Management 14.4 Requirements for Academic Promotion