EMWA Professional Development Programme

Clinical Study Reports: Mastering the Essential Skills

Drug development; Foundation; 7.5 hours (double workshop)

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Pre-workshop assignment

Objective

To familiarise attendees with International Council for Harmonisation (ICH) E3 guidelines for the structure and content required for clinical study reports (CSRs).

Content

1. Please look at the ICH E3 template outline provided and familiarise yourself with the corresponding ICH E3 guidelines. Do not feel you have to read the guidelines page-by-page; try to get a rough idea of how a CSR should look in terms of structure and content:
    - Our ICH E3 CSR template outline (overleaf, 4 pages)
    - ICH E3 Guidelines: Structure and Content of CSRs

2. Now briefly look at the questions and answers based on the ICH E3 guidelines and the launch paper for the CORE (Clarity and Openness in Reporting: E3-based) Reference:
    - ICH E3 Questions and Answers (R1)
    - CORE Reference launch paper (2016)

3. Please send an email to gaele.ducher@scinopsis.com and monica@aproposscience.com indicating:
    - How much experience you have in writing CSRs

Time required

1 hour

Related Workshops

A list of workshops related to specific aspects of CSR preparation is provided below for your information (details are provided in the EPDP Workshop Programme):

- DDF5 Clinical Study Report Appendices
- DDF6b From Protocol to Study Report: What's In-between?
- DDF11a Subject Narratives for Clinical Study Reports
- DDF22a Drug Safety for Medical Writers Part 1: Adverse Events and Concomitant Medications
- DDF23a Drug Safety for Medical Writers Part 2: Laboratory Data
- DDF35 Introduction to Writing about Efficacy
- DDF36 An Introduction to Clinical Trial Disclosure - the Regulatory Requirements, Industry Commitments, and Protection of Data Privacy and Company Confidential Information

- DDF38 CORE Reference – Clarity and Openness in Reporting: E3-based
- DDA24 Clinical Study Reports in Oncology
- PTA6 Scheduling and Proposal Writing: The Clinical Study Protocol and Report
- PTF1 Data Presentation I: Tables and Graphs
- PTF4 Medical Writing and Quality Control: Clinical Study Reports
- PTF29 How to Manage Your Writing Project

1. TITLE PAGE
2. SYNOPSIS
3. TABLE OF CONTENTS
4. LIST OF ABBREVIATIONS
5. ETHICS

5.1. INDEPENDENT ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD
5.2. ETHICAL CONDUCT OF THE STUDY
5.3. PATIENT INFORMATION AND CONSENT

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE
7. INTRODUCTION
8. STUDY OBJECTIVES
9. INVESTIGATIONAL PLAN

9.1. OVERALL STUDY DESIGN AND PLAN DESCRIPTION
9.2. DISCUSSION OF STUDY DESIGN, INCLUDING THE CHOICE OF CONTROL GROUPS
9.3. SELECTION OF STUDY POPULATION

9.3.1. Inclusion Criteria
9.3.2. Exclusion Criteria
9.3.3. Removal of Patients from Therapy or Assessment

9.4. TREATMENTS

9.4.1. Treatments Administered
9.4.2. Identity of Investigational Product(s)
9.4.3. Method of Assigning Patients to Treatment Groups
9.4.4. Selection of Doses in the Study
9.4.5. Selection and Timing of Dose for Each Patient
9.4.6. Blinding
9.4.7. Prior and Concomitant Therapy
9.4.8. Treatment Compliance

9.5. EFFICACY AND SAFETY VARIABLES

9.5.1. Efficacy and Safety Measurements Assessed and Flow Chart

9.5.1.1. Efficacy Measures

9.5.1.1.1. Primary Efficacy Variable
9.5.1.1.2. Secondary Efficacy Variable 1
9.5.1.1.3. Secondary Efficacy Variable 2

9.5.1.2. Safety Measures

9.5.1.2.1. Adverse Events
9.5.1.2.2. Safety Laboratory Assessments
9.5.1.2.3. Vital Signs
9.5.1.2.4. Physical Examination
9.5.1.2.5. Other Safety Variable

9.5.2. Appropriateness of Measures
9.5.3. Primary Efficacy Variable(s)
9.5.4. Drug Concentration Measurements

9.6. DATA QUALITY ASSURANCE
9.7. STATISTICAL METHODS AND DETERMINATION OF SAMPLE SIZE

9.7.1. Determination of Sample Size

9.8. CHANGES IN THE CONDUCT OF THE STUDY OR THE PLANNED ANALYSES

9.8.1. Changes in the Conduct of the Study
9.8.2. Changes in the Planned Analysis

10. STUDY PATIENTS

10.1. DISPOSITION OF PATIENTS
10.2. PROTOCOL DEVIATIONS

11. EFFICACY EVALUATION

11.1. DATA SETS ANALYSED
11.2. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS
11.3. MEASUREMENTS OF TREATMENT COMPLIANCE
11.4. EFFICACY RESULTS AND TABULATIONS OF INDIVIDUAL PATIENT DATA

11.4.1. Analysis of Efficacy

11.4.1.1. Primary Efficacy Endpoint
11.4.1.2. Secondary Efficacy Endpoint 1
11.4.1.3. Secondary Efficacy Endpoint 2

11.4.2. Statistical/Analytical Issues

11.4.2.1. Adjustments for Covariates
11.4.2.2. Handling of Dropouts or Missing Data
11.4.2.3. Interim Analysis and Data Monitoring
11.4.2.4. Multicentre Studies
11.4.2.5. Multiple Comparisons/Multiplicity
11.4.2.6. Use of an 'Efficacy Subset' of Patients
11.4.2.7. Active-Control Studies Intended to Show Equivalence
11.4.2.8. Examination of Subgroups

11.4.3. Tabulation of Individual Response Data
11.4.4. Drug Dose, Drug Concentration and Relationship to Response
11.4.5. Drug-Drug and Drug-Disease Interactions
11.4.6. By-patient Displays
11.4.7. Efficacy Conclusions

12. SAFETY EVALUATION

12.1. EXTENT OF EXPOSURE
12.2. ADVERSE EVENTS

12.2.1. Brief Summary of Adverse Events
12.2.2. Display of Adverse Events
12.2.3. Analysis of Adverse Events

12.2.3.1. Adverse Events by System Organ Class and Preferred Term
12.2.3.2. Adverse Events by Severity
12.2.3.3. Adverse Events by Relationship to Treatment

12.2.4. Listing of Adverse Events by Patient

12.3. DEATHS, OTHER SERIOUS ADVERSE EVENTS AND OTHER SIGNIFICANT ADVERSE EVENTS

12.3.1. Listing of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.3.1.1. Deaths
12.3.1.2. Other Serious Adverse Events
12.3.1.3. Other Significant Adverse Events

12.3.2. Narratives of Deaths, Other Serious Adverse Events and Certain Other Significant Adverse Events
12.3.3. Analysis and Discussion of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

12.4. CLINICAL LABORATORY EVALUATION

12.4.1. Listing of Individual Laboratory Measurements by Patient and Each Abnormal Laboratory Value
12.4.2. Evaluation of Each Laboratory Parameter

12.4.2.1. Haematology

12.4.2.1.1. Laboratory Values over Time
12.4.2.1.2. Individual Patient Changes

12.4.2.2. Clinical Chemistry

12.4.2.2.1. Laboratory Values over Time
12.4.2.2.2. Individual Patient Changes

12.4.2.3. Urinalysis

12.4.2.3.1. Laboratory Values over Time
12.4.2.3.2. Individual Patient Changes

12.4.2.4. Individual Clinically Significant Abnormalities

12.5. VITAL SIGNS, PHYSICAL EXAMINATION FINDINGS AND OTHER OBSERVATIONS RELATED TO SAFETY

12.5.1. Vital Signs
12.5.2. Physical Examinations
12.5.3. Other Safety Variable 1
12.5.4. Other Safety Variable 2

12.6. SAFETY CONCLUSIONS

13. DISCUSSION AND OVERALL CONCLUSIONS

14. STATISTICAL TABLES, FIGURES AND GRAPHS

14.1. DEMOGRAPHIC DATA
14.2. EFFICACY DATA
14.3. SAFETY DATA

15. REFERENCE LIST
16. APPENDICES