



Medical Writing Training Course: Protocols, Clinical Study Reports and CTD Summaries



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Introduction:

Medical writing training on protocols, clinical study reports and CTD summaries is a 5-day course for medical writers and clinical research, regulatory and medical affairs staff that ends with a Draft Clinical Study Report Sections Package built from case trial data. Submissions and publications stall when protocols leave endpoints ambiguous, study reports attach statistical output without interpretation and summaries contradict their source tables. Nominees already author or review clinical documents, and the course works through case trial data, drafting rounds and peer review. CoreConcept Training Center delivers this medical writing course.

Course Objectives:

- Plan the clinical document set for a development programme and adapt scientific style to assessors, investigators, clinicians and lay readers
- Draft clinical trial protocol and investigator brochure sections with aligned objectives, endpoints and SPIRIT checklist items
- Write clinical study report sections to the ICH E3 structure, integrating statistical output with clinical interpretation
- Prepare patient narratives, in-text tables and figures that trace accurately to data listings
- Write CTD Module 2 clinical summaries, journal manuscripts, abstracts and plain language summaries in line with reporting guidelines such as CONSORT
- Run quality control, review rounds and sign-off for clinical documents and produce draft study report sections from case data

Target Audience:

- Medical writers who author protocols, clinical study reports and submission summaries
 - Clinical research staff who supply trial data and review study documents
 - Regulatory affairs staff who compile the clinical sections of submission dossiers
 - Medical affairs staff who prepare manuscripts, abstracts and scientific communications
 - Biostatistics and data management staff who produce tables, figures and listings for reports
 - Pharmacovigilance staff who contribute safety narratives and safety summaries
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Course Outline:

Day 1: Medical Writing Roles and Scientific Writing Style

- Clinical Development Document Map From Protocol to Submission
- Medical Writer Role Within Clinical and Regulatory Teams
- Audience Analysis for Assessors, Investigators, Clinicians and Patients
- Scientific Style Rules for Precision, Hedging and Consistency
- Document Gap Review of an Existing Clinical Report

Day 2: Trial Protocols, Investigator Brochures and Reporting Standards

- SPIRIT Checklist Applied to Clinical Trial Protocol Drafting
- Estimands, Endpoints and Objectives Alignment in Protocol Synopses
- Investigator Brochure Sections and Periodic Update Content Planning
- ICH E3 Clinical Study Report Section Architecture
- CONSORT Checklist and Participant Flow Diagram Requirements

Day 3: Clinical Study Report Drafting and Data Presentation

- CSR Synopsis Drafting With Key Numerical Results
- Efficacy Results Interpretation From Statistical Output Tables
- Safety Evaluation Writing for Adverse Events and Laboratory Shifts
- Patient Narrative Templates for Deaths and Serious Adverse Events
- In-Text Tables and Figures Design From Data Listings

Day 4: CTD Summaries, Publications and Document Quality Control

- CTD Module 2 Clinical Overview Benefit-Risk Argument Structure
- Summary of Clinical Safety Pooling and Integration Choices
- Journal Manuscript and Conference Abstract Structure for Trial Results
- Plain Language Summary Writing for Lay Readers
- Quality Control Checks, Review Rounds and Sign-Off Workflow

Day 5: Case Study on Drafting Clinical Study Report Sections

- Case Trial Data Package Review and Key Message Planning
 - Case CSR Synopsis and Efficacy Section Draft
 - Case Safety Section and Patient Narratives Draft
 - Peer Quality Control Review Against the ICH E3 Structure
 - Draft Clinical Study Report Sections Package Completion
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Skills You Will Gain:

- Clinical Document Planning
- Scientific Style Editing
- Protocol Synopsis Drafting
- Clinical Study Report Authoring
- Patient Narrative Writing
- Data Table Design
- Lay Summary Writing
- Document Quality Control

Why Attend This Course:

- Hand the clinical development or regulatory lead a Draft Clinical Study Report Sections Package with synopsis, efficacy and safety text and patient narratives built from case data
- Decide which results belong in in-text tables, which move to appendices and how much interpretation each results section needs
- Avoid extra review cycles, assessor questions and manuscript rejections caused by inconsistent numbers, ambiguous endpoints and unchecked drafts
- Share style sheets, narrative templates and quality control checklists with writing, statistics and clinical colleagues

Conclusion:

Back at work, the participant gives the clinical development or regulatory lead draft clinical study report sections and a set of templates that the writing team can reuse for protocols, CTD summaries and publications. The lead uses them to set authoring standards, plan review rounds and agree sign-off responsibilities before the next study report or submission. After the first document produced this way, the team should review the number of review cycles, quality control findings, data inconsistencies and reviewer queries against earlier documents.

Frequently Asked Questions FAQ:

What should participants know before the medical writing training course on clinical study reports?

Participants should already write or review clinical or regulatory documents and be able to read clinical trial results tables. Bringing an anonymised protocol, study report section or manuscript helps them apply the style rules, templates and quality control checks to their own documents.

How does medical writing training on protocols and clinical study reports differ from a regulatory affairs course?

Medical writing focuses on authoring the documents themselves: protocols, clinical study reports, narratives, summaries and publications. A regulatory affairs course focuses on submission strategy, registration routes, dossier management and post-approval changes, which this course touches only where they shape document content.

What does ICH E3 require from medical writing of clinical study reports?

ICH E3 sets the structure and content of a clinical study report, from the synopsis, ethics and investigational plan to patient disposition, efficacy and safety evaluation, discussion, tables and appendices. It expects one integrated clinical and statistical report rather than separate documents joined together.

What do participants take back from the medical writing course on protocols, clinical study reports and CTD summaries?

Participants take back draft clinical study report sections built from case data, with a synopsis, efficacy and safety text and patient narratives, plus style sheets, narrative templates and quality control checklists for protocols, CTD summaries and publications.
