

Important Documents



This module presents an overview of the key regulatory and operational documents that constitute the foundation of any clinical trial. Each of these documents is essential for maintaining scientific quality, protecting ethical standards, meeting regulatory requirements during the study and provide standardized procedures that enable valid, reproducible outcomes.

Collectively, they serve as the backbone of a clinical trial, providing the necessary framework for effective oversight and transparent conduct. These documents are maintained throughout the stages of a clinical trial, from planning and conduct to completion and are essential for audits and regulatory inspections.

Original and amended versions of documents such as the Protocol, Investigator's Brochure, Informed Consent Form and Case Report Form are submitted to Ethics Committees and Regulatory Authorities in accordance with applicable local regulations and guidelines. Relevant stakeholders also maintain corresponding documentation, including both original and revised versions, as required by local requirements.

This topic will detail these documents and outline the critical roles they play within a clinical research setting.