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Webinar on

Trial Master File – Clinical Data Systems

Learning Objectives

- *Trial Master File (TMF) background and rationale*
- *The essential documents to include in a TMF*
- *Organizing and maintaining a TMF*
- *Standard Operating Procedure required to support TMF*
- *Inspection of TMF records*
- *Q&A*

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This webinar, includes all of the documentation that a sponsor must record to demonstrate that they have met their obligations for the conduct of a clinical trial.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, animal health, tobacco, e-cigarette/e-liquid and other FDA-regulated industries. During her career, Carolyn worked directly, or on a consulting basis, for many of the larger pharmaceutical companies in the US and Europe.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

Companies engaged in the conduct of human clinical trials must adhere to specific government regulatory requirements. Certain documents, content, and images related to a clinical trial must be stored and maintained, and depending on the regulatory jurisdiction, this body of information may be stored in a trial master file (TMF).

This seminar will help you understand in detail the new requirements for trial master files. Companies engaged in the conduct of human clinical trials must adhere to specific government regulatory requirements. Certain documents, content, and images related to a clinical trial must be stored and maintained, and depending on the regulatory jurisdiction, this body of information may be stored in a trial master file (TMF).

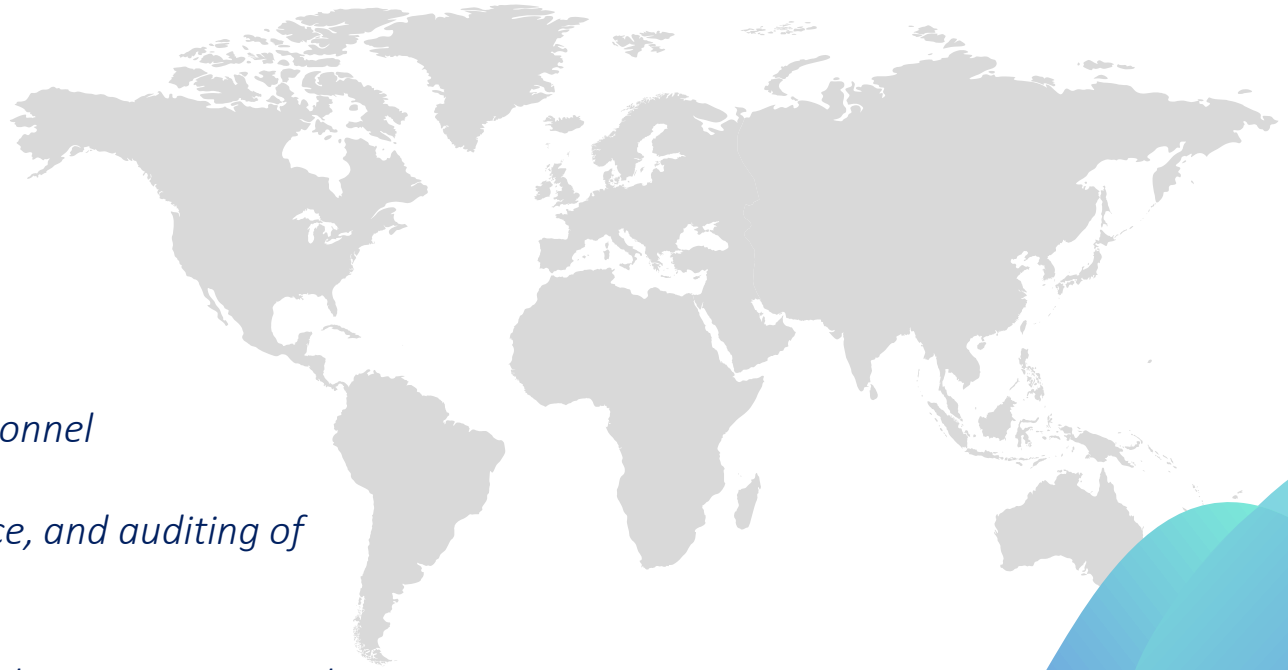
The TMF includes all of the documentation that a sponsor must record to demonstrate that they have met their obligations for the conduct of a clinical trial. The Code of Federal Regulations states in 21 CFR 312.50: “Sponsors are responsible for… ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.” The European Directive 2005/28/EC states: “…trial master file shall consist of essential documents, which enable both the conduct of a clinical trial and the quality of the data produced to be evaluated.”

ICH GCP, Section 8.1 describes “essential documents” as those that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

A consolidated guidance for industry on Good Clinical Practice (GCP) in 1996 was published by the International Conference on Harmonization (ICH). The objective was to provide a unified standard for the United States, European Union, and Japan to facilitate mutual acceptance of clinical data by the regulatory authorities in these global jurisdictions. The ICH document provided guidance for companies in all ICH regions to establish trial master files that contain key documents that enable the evaluation of the conduct of a trial and the quality of data produced uniformly by all jurisdictions involved.

In the US, there is no specific requirement from FDA for companies to prepare a trial master file, but if the regulatory authority requires ICH GCP to be followed, then there is consequently a requirement to create and maintain a trial master file. Documents contained in the TMF must be available for inspection by the appropriate regulatory authorities at any time during and after the conduct of a clinical trial and must be submitted to support the request for product approval. This is true for pharmaceuticals, biologics and medical devices.

Who Should Attend ?



Lead CRAs, CRA Managers

Project and/or Study Managers

Project and/or Clinical Trial Assistants

Clinical Operations Administrators, Quality Assurance Personnel

Sponsor and CRO personnel involved in set up, maintenance, and auditing of the Trial Master File for sponsors

Auditors engaged in the internal inspection of clinical trial documentation and practices

Consultants working in the life science, tobacco and related industries who are involved in computer system implementation, validation and compliance would also benefit.

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