



Who is the course suited to?

It is suitable for anyone carrying out or involved in clinical research who needs to gain knowledge of essential documents and an understanding of their importance during each stage of a clinical trial.

Course Contents

- Defining essential documents and their purpose.
- Types of essential documents.
- Essential documents before, during and after a Clinical Trial.
- ICH GCP E6 R2 and its requirements in regards to essential documents.
- The purpose of the Trial Master File (TMF).
- eTMF systems and their place in accurate storage and retrieval of essential documents.
- The roles and responsibilities of a monitor, sponsor and investigator regarding essential documents.
- How to archive essential documents according to ICH GCP standards.

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the optional links you choose to view.



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