Documentation and Document Management

Documentation and Document Management

Clinical research documentation involves a variety of documents from various sources and is authored by several individuals. We will first look the general purpose of clinical care documentation and then focus on clinical research documentation. It is important to understand that a subset of this documentation will be used for data collection and analysis. This overview module is divided into 2 required components and 1 recommend video. Once you have completed all required parts, please link to the evaluation after which you will be directed to a certificate of completion for your education records.

Module Objectives

At the conclusion of this module, learners will be able to:

- Describe best practices for clinical research documentation.
- Define source documentation.
- Discuss how to handle discrepancies among various source documents.
- Describe the purpose of the regulatory file/binder.
- List the essential elements of the regulatory file/binder.
- Describe when it is appropriate to centralize essential documents.

Required				
Part 1	Documentation in Clinical Research (23 minutes)	Part 1 Handout	Resources	Evaluation
Part 2	Regulatory File (20 minute)	Part 2 Handout Regulatory File Checklist		
Recommended				
Video: • Clinical Trial Compliance: Using Notes to File to Document Variation (4 minutes)				