Mastering Essential Records: Reviewing & Reporting

ONLINE COMPTENCY COURSE

TASK ACADEMY

ABOUT THIS **COURSE**

INTRODUCTION

Essential records are the backbone of every clinical trial - the documents that tell the story of how a study was designed, conducted, and validated. They serve as proof of compliance with Good Clinical Practice (GCP) and regulatory requirements, ensuring that data is credible and that the rights and safety of trial participants are protected. Without accurate, complete, and well-maintained essential records, no clinical trial can stand up to scrutiny.

Mastering Essential Records, a 2-part series of courses, is designed to give you a clear, practical understanding of the documentation that underpins high-quality research. Whether you in a monitoring role or part of the trial conduct team at site, you will gain the knowledge and confidence to manage essential records with accuracy and purpose.

COURSE OUTCOMES

In this part of the Mastering Essential Records Course series, you will learn how to:

- Define what essential records are and recognise which documents are typically classified as essential in clinical trials
- Conduct and document a comprehensive review of the ISF to verify that essential records are accurate, complete, and audit-ready
- Document and Report on the ISF Review.

By the end of this course, you'll be equipped to confidently manage essential records - strengthening both the quality and credibility of the trials you support.

WHO SHOULD TAKE THIS COURSE?

This course will benefit any role player involved in the collection, completion, and filing of essential records in clinical trials: i.e.

- Clinical Research Associates
- Regulatory Affairs Associates
- Project Managers
- Quality Assurance (QA) and Compliance Specialists
- Data Managers and Trial Administrators
- New Professionals, entering the industry.

DELIVERY AND DURATION

Our comprehensive online programme has the following features:

- An informative self-paced online session to competence - at your own time and pace, anywhere.
- **Branching scenario**: Apply your knowledge and test your competency reviewing and reporting of the Essential Records, found in the ISF, through an interactive Branching Scenario. This scenario, based on the TBCure story, will place you in realistic, monitoring visit challenges - allowing you to navigate common issues and demonstrate your understanding of essential records in clinical trials.
- **Assessment on Essential Records** in clinical research with multiple-choice questions.
- On achieving a pass mark of 80% (unlimited attempts), you can download your competency certificate from the LMS to your computer.
- **GROUP DISCOUNT:** Buy 5 seats for this course, get the 6th seat for free.

R 1 200,00 | USD 70,00

3 HOURS

REGISTER NOW

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