acdm

association for **clinical data management**

Training Course Guide

Association for Clinical Data Management Training

Our mission is to provide opportunities to constructively engage, collaborate and learn from the industry experts in Data Management, to equip members with the necessary skills to excel in their careers, so they can become the data management experts of the future.

Serving the data management community for over 30 years, we take pride in helping our members in their professional development journey by offering both in-house and online training courses.

In-House Courses

An ACDM Trainer can come to your organisation to deliver a course for you

All of our ACDM Training Courses can be delivered for a group of your employees at your location. Over the last 30 years the ACDM has become a leader in the delivery of clinical data management training. Our in-house courses range from one day 'Introduction' sessions through to more in depth training over several days. We have delivered training for a wide range of organisations including top 10 pharma, CROs, and non-commercial organisations.

Please contact us to discuss your training requirements and we will provide you with a comprehensive proposal including suggested content, trainer, pricing and timelines.
www.acdmglobal.org/training-courses/in-house-courses

Online Training

Online Training from the Association for Clinical Data Management are interactive voice and media based courses. Each course is broken down into sections and at the end of each section is a self assessment to allow you to check your understanding of the content. Once you have completed all the sections and the self assessments you can take the final examination. Once you have successfully completed the examination you can download your certificate of completion.

Each course consists of:

- Interactive voice and media presentation
- Self assessments
- Examination
- Certificate

All the online courses can be taken at a time to suit the user. The course can be paused at any time and returned to at a later date. The user can access the course as soon as payment has been made.

If you need to purchase for more than one user please contact us to discuss multi-user schemes. These simplify the managing of online learning and also you receive a discounted price. Contact ACDM for more information here: admin@acdmglobal.org

The following pages have details of all current courses available online.

Fundamentals of Clinical Data Management

In today's clinical trial environment with the increasing adoption of technology, roles are changing and a good understanding of clinical data management tasks is critical for the whole study team. This course provides an overview of the fundamentals of clinical data management, explaining the key tasks data managers perform, highlighting the important interactions between study team members and how to ensure high quality clinical data.

The course is suited to non-data management professionals wanting to understand what clinical data management involves, or data managers new to the role.

By the end of this course you will:

- Be able to describe the key clinical data management tasks in a clinical trial
- Understand which tasks are important for ensuring high quality clinical data
- Understand the critical interactions between clinical data management and other members of the study team

ECG & Holter Data

Regulatory authorities require cardiac safety data to be collected during all clinical phases of the development of a new drug.

This module will explain the types of cardiac safety data which the FDA and other regulatory authorities typically expect to be collected through ECGs and Holters.

By the end of this course you will be able to:

- Understand the terminology used in ECGs & Holters
- Explain what data is available from an ECG
- Explain what data is available from a Holter
- Understand the difference between an ECG & a Holter
- Be able to assess & appropriately evaluate the requirements stated in a protocol

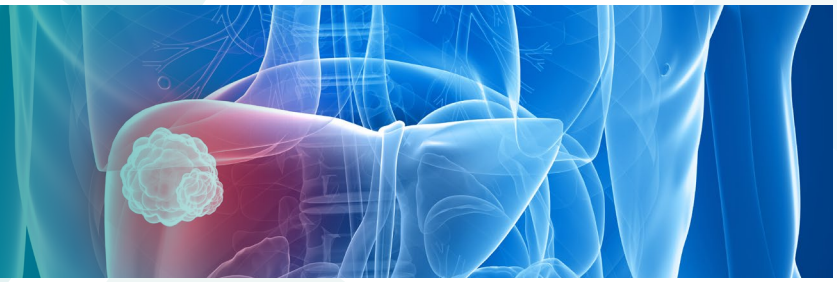
Management of Non-CRF Data

In this course you will learn about the different types of data commonly collected outside of the CRF, how this data should be managed and integrated with the CRF data and some of challenges faced with non-CRF data.

By the end of this module you will be able to:

- Identify different types of data that are captured outside of the CRF
- Describe the processes that occur during the set-up phase in relation to non CRF data
- Understand how to manage & integrate non CRF data
- List some of the data cleaning activities that non CRF data has to undergo

RECIST for Data Managers



This course provides data management professionals with the background and explanation of what RECIST is; and practical experience and recommendations for how the criteria are used in clinical trials along with tips to help aid RECIST data review.

In the course you will learn:

- What RECIST is
- The background of RECIST
- The different methods of measurement
- The types of lesions
- Response criteria
- Designing CRFs for RECIST data capture
- Example validation checks for RECIST data review
- CDISC Data Standards for RECIST
- iRECIST
- Efficacy endpoints in oncology

Building data management success in Sponsor CRO relationships

This course looks at both the Sponsor and CRO viewpoints on how to make sure outsourced Data Management is executed in a successful way, with all parties confident in the relationship between the Sponsor and the Data Management CRO.

The course covers the processes and best practices involved in establishing successful relationships including; roles and responsibilities, creating and maintaining communication channels, managing change, managing risk and examples of oversight.

Preparing for Regulatory Inspections

This course provides an overview of the critical preparation tasks required to ensure your inspection achieves the best possible outcome for your organisation. You will understand what regulatory authorities are and what they do, and then learn how they conduct inspections and the key information they are looking for.

The learning outcomes for the course are as follows:

- Recap on the basics of ICH GCP focusing on the R2 addendum
- Gain a knowledge of the cascade of regulations that exist
- Understand the responsibilities of the regulatory authorities
- Recognise the different types of inspection and what the inspectors inspect against
- Understand the general inspection process
- Understand what an inspection dossier and inspection plan is
- Understand how to assure compliance to regulations
- Recognise what you must do to prepare for an inspection
- Know how to prepare your work area before the Inspector arrives
- Understand how to interact with the Inspector
- Recognise some of the typical Data Management findings from inspections

Medical Coding

In the context of clinical trials, medical coding is essential for:

- **Data Standardization:** Ensuring that data from various sources is consistent and comparable.
- **Regulatory Compliance:** Meeting regulatory requirements and ensuring accurate reporting.
- **Data Analysis:** Facilitating the efficient and accurate analysis of clinical trial data.

By understanding and effectively implementing medical coding practices, we can ensure the reliability and validity of clinical trial data. This course dives into the critical role that medical coding plays in clinical trials, exploring its significance, processes, and best practices.

Risk Based Monitoring

This course provides an overview of risk based monitoring. In today's clinical trial environment with the adoption of technology, traditional onsite monitoring with 100% SDV has been replaced by a leaner approach where the type and frequency of monitoring is driven by the risks associated with the trial. This course explains how to take a risk based approach to monitoring.

By the end of this course you will:

- Understand the different types of monitoring; on-site, remote and centralised
- Learn what the regulations are when it comes to taking a risk based approach to monitoring
- Know what to consider when performing a risk assessment
- Recognise how to identify critical data and processes
- Understand how centralised monitoring and data visualisation dashboards can be used
- Recognise the benefits of risk based monitoring

Understanding Laboratory Data

For data managers laboratory data can prove to be frustrating, complex and time consuming. This course gives an explanation of what laboratory data consists of, why labs provide data in the way that they do, and gives practical advice to the data manager about how to handle this data and key points to consider. The course is intended for a data manager with little or no previous experience with working with laboratory data.

By the end of this course you will:

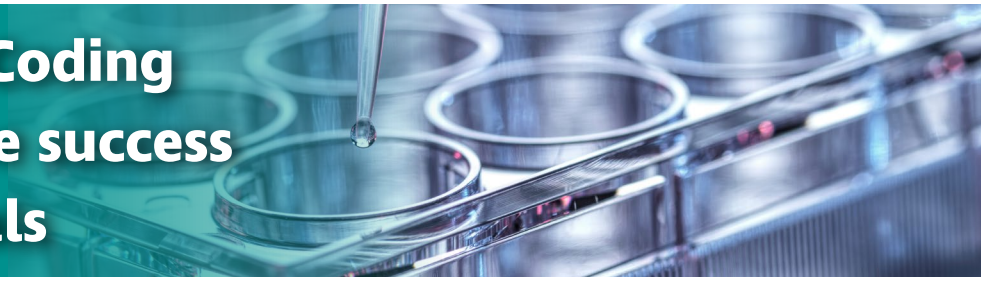
- Understand the fundamentals of laboratory data
- Recognise the different types of tests and how samples are prepared
- Understand the use of different units and normal ranges
- Realise why laboratories supply information in the way they do and where some of the challenges occur
- Understand the difference between a central lab and a local lab and why they are used
- Appreciate what should be considered during the set-up of a trial when lab data is being collected
- Understand different methods of collecting lab data for a trial
- Specify what should be checked during the validation of lab data

Pharmacokinetics

Understanding the Clinical Pharmacology of an Investigational Medicinal Product, is fundamental in drug development. Pharmacokinetics is a a branch of Clinical Pharmacology with the aim of understanding what the 'body does to the drug' primarily by measuring absorption, distribution, metabolism and excretion.

This short course provides an 'Introduction to Pharmacokinetics' and considerations within Data Management.

How Clinical Coding can ensure the success of clinical trials



This training provides an overview of how Clinical Coders can ensure the success of clinical trials.

Data Validation and Effective Query Writing

Within Clinical Data Management our ultimate goal is to ensure that all data collected within a clinical study is clean, clear, concise and appropriate. This course provides an introduction to the principles of data validation by explaining the why, who, what and when components of data validation. The course then moves on to fundamentals of effective query writing by highlighting the dos and don'ts of composing query message text to ensure queries are appropriate and are not leading.

The course is suited to data managers new to the role and also non data managers who are involved in validation and query management.

By the end of this course you will:

- Be able to describe why data is validated, who is responsible for data validation and where data validation takes place
- Understand the importance of data validation
- Understand the Dos and Don'ts of writing query message text
- Appreciate that queries can be mitigated by using other tools

ACDM Hot Topics

From Artificial Intelligence to the Art and Science of Data...

ACDM Hot Topics are 'discussions' held online focussing on a topic in Data Management.

ACDM Conferences

The ACDM Annual Conference has been running for over 30 years.

Enabling sponsors & exhibitors to maximise their exposure and opportunities, networking is an itegral part of ACDM Conferences.

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