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.

Data Management related courses:

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

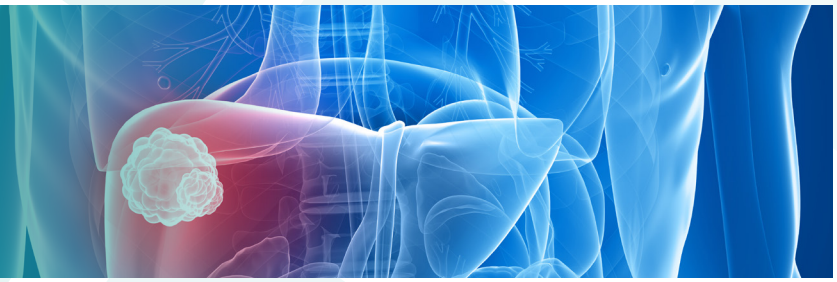
Management of Non-CRF Data

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

General courses:

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

Data Integrity

This course provides an overview of data integrity. As our data sources change, with decentralized trials and external data being used more in the clinical trial space we need to ensure data integrity.

Data integrity has always been fundamental to new drug development programs and a key objective of regulatory GCP inspections, is to reconstruct the study based on the data to confirm its data integrity.

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

Pricing:

Individuals

Non member

£50

Member

£40

Prices shown exclude VAT

Multi-User Scheme

Non member

1-4 Users - £50 per user

5-49 Users - 10% off: £45 per user

50-99 Users - 20% off: £40 per user

>100 Users - 25% off: £37.50 per user

Member

(20% member discount also applied)

1-4 Users - £40 per user

5-49 Users - 10% off: £36 per user

50-99 Users - 20% off: £32 per user

>100 Users - 25% off: £30 per user

Prices shown exclude VAT

Frequently Asked Questions

Is there discount available if I purchase multiple courses?

Yes, if you purchase modules through a multi-user scheme there are discounts available. The level of discount is determined by the number of courses purchased.

Can I mix-and-match the different courses in a multi-user scheme?

Yes. If you purchase multiple courses it is up to you how to assign these. You can assign these as any of the currently available courses. So for example if you purchased 25 courses you could assign 5 different users to 3 different courses, 3 users to 2 different courses, and 4 users to a single course.

How do I give my team access?

Once payment has been received you will receive a login that allows you to create users, assign courses and review progress. All you need to do is login through any web browser.

Are there any special apps/software needed?

No. Everything can be accessed through any standard web browser.

Are there any expiry dates on courses?

No. Once a user has been assigned to a course they can take the course at a time to suit them. There is no expiry of courses and also no expiry date of unassigned courses.

How long does it take to complete a course?

The average time taken to complete a course is 2 hours. Some are slightly longer and some are slightly shorter. A user can stop the course at any time and return to it.

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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