Pre-defined courses

Introduction to today's data management

Objectives: To provide participants with a basic understanding of the role and objectives of data management (DM) in today's clinical trials and help them establish a comprehensive base knowledge of Clinical Data Management.

Target Audience: Participants with little or no experience in DM, Intermediate Data Managers who want to expand and update their knowledge in this field.

Modules: A1, A2, A3, C1

Data Management for non-DMs

Objectives: To provide participants with a basic understanding of the role and objectives of data management (DM) in today's clinical trials and help them establish a comprehensive base knowledge of Clinical Data Management.

Target Audience: Non-Data Managers who are wanting to understand the basics of DM, for example Trial Managers, Statisticians, Safety, Medical monitors, QA and Vendor Management.

Modules: A2, A3, C1, C3

Data Management – In Depth

Objectives: To strengthen participants capability to independently lead and drive DM activities and interact with external stakeholders. Furthermore, to increase indepth understanding of DM processes and systems, to work with process and system improvement and to work with company/program level activities.

Target Audience: Data Managers who want to both widen and deepen their understanding of DM and develop their capability to lead DM teams, manage CROs and vendors or lead improvement and change initiatives within the company.

Modules: A2, A4, A5, A6. B1, B3, C1, C2

Managing Data Management

Objectives: To provide tools for managing and optimizing data management processes. To develop sourcing, processes and system strategies.

Target Audience: Senior Data Managers, DM team leads, Functional Managers and Line Managers with DM as an area of responsibility who are looking to develop their capability to lead and develop a DM unit and/or improve sourcing and oversight capabilities.

Modules: B1, B2, B3, B4, B5, B6, C1, C2, D1, D2, D3

Managing Clinical Systems

Objectives: To provide participants with a thorough understanding of the clinical systems landscape, the role of the different systems and overlaps and relations in functionality and system data scope. Further, to understand different options for how to design an overall company or trial solution. Finally, the typical service and system provider categories and key selection criteria will be discussed.

Target Audience: Clinical System Managers or similar roles. Data Managers, DM team leads, or Line Managers with a clinical systems responsibility or interest. IT Business partners or IT project Managers working with Clinical Systems.

Modules: A2, C1, C2, C3, C4, C6, D1

Introduction to eCOA / ePRO

Objectives: To provide a basic understanding of the processes, technology and regulatory requirements for eCOA/ePRO. To strengthen the participants ability to evaluate and select and manage ePRO/eCOA provider(s). Further, to give an end-to-end introduction to the typical sponsor/CRO role in eCOA/ePRO, with topics like good design principles, UAT, compliance management, monitoring and data handling.

Target Audience: Data Managers, Trial Managers and Vendor Managers wanting to improve their understanding of ePRO/eCOA process and technology in order to manage services/providers and/or develop or enhance related internal processes.

Modules: C1, C4, C5