Training: Introduction to today's data management (Ref DM-A01)

Date: Apr 01-02 9.00-16.00	Location: Copenhagen (TBD)	Cost: 8.500 DKK
Objective	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.	
Format	Classroom training: lectures, discussions and exercises. Participants are welcome to submit or bring their own cases, examples and questions.	
Teacher	Anders Mortin, TriTiCon	
Target Audience	Participants with little or no experience in DM, Intermediate Data Managers who want to expand and update their knowledge in this field, Non-Data Managers who are wanting to understand the basics of DM for example sourcing, trial management, line management or QA activities.	

Course scope	Day 1
	
	1. Data Management in context: Clinical trials and DM, roles and objectives.
	   i. The role of clinical trial data collection and analysis in clinical development
	   ii. The role and objectives of Data Management activities
	   iii. Overview of a typical organization including internal and external stakeholders
	2. Data Management overview: End-to-end process introduction
	   i. Data Management process: Steps, inputs and outputs
	   ii. Pre DM activities, post DM activities and interacting activities
	   iii. Systems and data-flow overview
	   iv. Essential ICH requirements and other legislations
	
	Day 2
	
	3. Processes, systems, requirements and standards:
	   i. Trial set up
	   ii. Data collection and cleaning
	   iii. Trial close-out and database lock
	   iv. Data Management deliverables and closeout
	4. Summary and takeaways	

Training: Data Management – In depth (Ref DM-B01)

Date: Apr 22-23 9.00-16.00	Location: Copenhagen (TBD)	Cost: 8.500 DKK
Objective	To strengthen participants capability to independently lead and drive DM activities and interact with external stakeholders. Furthermore, to increase in-depth understanding of DM processes and systems, to work with process and system improvement and to work with company/program level activities.	
Format	Classroom training: lectures, discussion and exercises. Participants are welcome to submit or bring their own cases, examples and questions.	
Teacher	Anders Mortin, TriTiCon	
Target Audience	Data Managers who want to both widen and deepen their understanding of DM plus develop their capability to lead DM teams and manage CROs. Furthermore, those who want to initiate improvement and change initiatives within the company.	
Course scope	Day 1	

Course scope (continued)

Day 1
1. Data Management in the big picture: stakeholders, process and system touch points and dependencies.
2. Data Management in depth; processes, interactions, related processes, dependencies, regulatory requirements and systems
   i. Trial set-up
   ii. Data collection and cleaning
   iii. Trial close-out and database lock
   iv. DM deliverables and closeout

Day 2
3. Data Quality Management and Risk Management.
   i. What is quality of clinical data?
   ii. Overview and examples of data quality management activities
   iii. Risk Management in DM – Risk areas, suggested methods
4. Standards and Standards Management
   i. Overview of data management related standards
   ii. Strategic, tactical and practical use of standards, standards governance
5. Clinical Data Systems
   i. Systems overview, scope and dependencies
   ii. System validation– key requirements and basic methodology
   iii. Market overview – DM related systems
6. Summary and take-aways

Training: Introduction to eCOA/ePRO (Ref DM-C01)

Date: May 06 9.00-17.00	**Location:** Copenhagen (TBD)	**Cost:** 5.000 DKK
Objective	To provide a basic understanding of the processes, technology and regulatory requirements for eCOA/ePRO plus an overview of the service/provider options on the market today. To strengthen the participants ability to evaluate and select a provider/sourcing model plus evaluate, select and manage ePRO/eCOA provider(s).	
Format	Classroom training: lectures, discussion and exercises. Participants are welcome to submit or bring their own cases, examples and questions.	
Teacher	Anders Mortin, TriTiCon	
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.	

Course scope	Day 1
	1. Definitions and terminology
	2. eCOA/ePRO processes and technology – similarities and differences compared to the eCRF/EDC
	   a. Working with validated instruments
	   b. Patient facing material – translations, submission requirements
	   c. Technology – components and data-flow
	   d. The patient as a user
	3. Process and services - Scope, deliveries, challenges and best practice
	   a. Instrument licensing
	   b. COA/PRO design and set-up
	   c. Supportive material
	   d. Translation handling
	   e. Testing, UAT, validity and usability
	   f. Logistics and help-desk
	   g. Timings and dependencies for trial set-up
	4. Data Handling of patient reported data
	   a. Integration and reconciliation
	   b. Compliance and data quality
	   c. Data review, checks and changes
	5. Solutions and service options – models, considerations and market overview
	   a. Specialized providers
	   b. EDC system add-on providers
	   c. Service-package providers
	   d. Sub-service providers
	6. Summary and takeaways	

Training: Managing Data Management (Ref DM-D01)

Date: Jun 10-11 9.00-16.00	**Location:** Copenhagen (TBD)	**Cost:** 9.500 DKK

Objective	To provide tools for managing and optimizing data management processes. To develop sourcing, processes and system strategies.
Format	Classroom training: lectures, discussion and case work. Participants are welcome to submit or bring their own cases, examples and questions.
Teacher	Anders Mortin, TriTiCon
Target Audience	Sr 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.

Course scope	Day 1
	
	1. Current and future DM – Trends, challenges and changes
	   i. Business (organizational, trial designs, sourcing)
	   ii. Regulatory focus and expectations
	   iii. The role of data management, key skills, processes, technology
	2. Data Management Business Planning
	   i. The role of a department/team business plan
	   ii. Suggested components and considerations
	3. Action planning – Part I
	   i. Facilitated work / team-work with individual example/case/challenge (If preferred, a case will be provided)
	4. Sourcing options, strategies and vendor relationship set-up
	   i. System and service sourcing options and considerations
	   ii. Sourcing strategies and vendor selection
	   iii. Relationship set-up and management
	   iv. Oversight – responsibilities and activities
	
	Day 2
	
	5. Systems Strategies and Management
	   i. System components overview
	   ii. Sourcing and hosting
	   iii. System ownership, requirements and validation
	6. Risk Management in Data Management
	   i. Risk Management, ICH requirements in DM context
	   ii. Risk areas and suggested methods
	7. Action planning – Part II
	   i. Facilitated work / team-work with individual example/case/challenge
	8. Optimizing data management
	   i. Processes monitoring and continuous improvement methods
	   ii. Measurements and methods - KPIs, KQIs, RBM
	   iii. Quality Management
	9. Summary and takeaways