

Training: Introduction to today’s data management (Ref DM-A01)		
Date: Apr 01-02 9.00-16.00	Location: On-line	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	Online training: Webinar with discussions and exercises. Some of exercises will potentially be submitted electronically for post-course review and feedback by the teacher. 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	<p><u>Day 1</u></p> <ol style="list-style-type: none"> 1. Data Management in context: Clinical trials and DM, roles and objectives. <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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 <p><u>Day 2</u></p> <ol style="list-style-type: none"> 3. Processes, systems, requirements and standards: <ol style="list-style-type: none"> 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 	