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

Date:	Location:	Cost:
Sep- 16-17 9.00-16.00	On-line	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	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	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	<u>Day 1</u> 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 <u>Day 2</u> 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