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

Date: May 06 9.00-17.00	**Location:** Online	**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	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, 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	<u>Day 1</u> 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	