

Training: Data Management – In depth (Ref DM-B01)		
<b>Date:</b> Apr 22-23 9.00-16.00	<b>Location:</b> Copenhagen (TBD)	<b>Cost:</b> 8.500 DKK
<b>Objective</b>	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.	
<b>Format</b>	Classroom training: lectures, discussion and exercises. Participants are welcome to submit or bring their own cases, examples and questions.	
<b>Teacher</b>	Anders Mortin, TriTiCon	
<b>Target Audience</b>	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.	
<b>Course scope</b>	<p><u>Day 1</u></p> <ol style="list-style-type: none"> <li>1. Data Management in the big picture: stakeholders, process and system touch points and dependencies.</li> <li>2. Data Management in depth; processes, interactions, related processes, dependencies, regulatory requirements and systems               <ol style="list-style-type: none"> <li>i. Trial set-up</li> <li>ii. Data collection and cleaning</li> <li>iii. Trial close-out and database lock</li> <li>iv. DM deliverables and closeout</li> </ol> </li> </ol> <p><u>Day 2</u></p> <ol style="list-style-type: none"> <li>3. Data Quality Management and Risk Management.               <ol style="list-style-type: none"> <li>i. What is quality of clinical data?</li> <li>ii. Overview and examples of data quality management activities</li> <li>iii. Risk Management in DM – Risk areas, suggested methods</li> </ol> </li> <li>4. Standards and Standards Management               <ol style="list-style-type: none"> <li>i. Overview of data management related standards</li> <li>ii. Strategic, tactical and practical use of standards, standards governance</li> </ol> </li> <li>5. Clinical Data Systems               <ol style="list-style-type: none"> <li>i. Systems overview, scope and dependencies</li> <li>ii. System validation– key requirements and basic methodology</li> <li>iii. Market overview – DM related systems</li> </ol> </li> <li>6. Summary and take-aways</li> </ol>	