

**SCDM 2019 EMEA CONFERENCE  
23- 25 OCTOBER 2019**

**Wednesday, 23 October 2019**

**SCDM Leadership Forum**

SESSION	PRESENTATION
<i>Lunch</i>	
<b>Leadership Forum</b> Emphasis on Strategy & Future	<i>Evolution of CDM : Submission failure topic?</i>
	<i>Emerging Regulatory requirements</i>
	<i>Audit trail review</i>
	<i>eCRF Review by Investigators</i>
	<i>Data source proliferation</i>
	<i>Panel discussion</i>
	<i>Coffee Break</i>
	<i>From CDM to Clinical Data Sciences</i>
	<i>Need for new technologies</i>
	<i>Panel discussion: From CDM to Clinical Data Sciences</i>
<b>Thursday, 24 October 2019</b>	
<b>EMEA 2019 CONFERENCE</b>	
<b>Session 1:</b> Emphasis on Operations & Present	<i>Experience ICH E6 R2</i>
	<i>What do regulators see here?</i>
	<i>Vendor oversight different approaches; what would/doesn't really work? Sponsor &amp; perspective; connect/ disconnect.</i>
	<i>Central Data Review/Statistical Monitoring approach</i>
	<i>Risk based quality management in CDM (Pharma/ Medidata)</i>
<b>Session 2:</b> New Regulations	<i>Essence &amp; impact of eSource Qualification opinion</i>
	<i>One last time: GDPR and CDM (real example) and site prespective (CRO...)</i>
	<i>Inspection readiness 2020</i>
<b>Sponsors Session</b>	<i>Sponsor Time</i>
	<i>Sponsor Time</i>
	<i>Sponsor Time</i>
<b>Session 3:</b> Application of AI & ML	
	<i>CRO Presentation</i>

	<i>Pharma presentation</i>
	<i>technology companies</i>
<b>Session 4: Emerging Technologies: between hype &amp; hope</b>	<i>Integrated discrepancy management approaches linking CRF and non-CRF data</i>
	<i>Developments in eCOA. Real World Data</i>
<b>Friday, 25 October 2019</b>	
	<i>grabing and keeping talent in CDM</i>
	<i>Practical experiences of changing responsibilities</i>
<b>Session 5: Evolution of the role of the Data Manager</b>	<i>Relevance of CDM qualification / certification</i>
	<i>Role of Clinical Data Management professional Organizations</i>
	<i>CDM moving towards ALSC &amp; DMW?</i>
	<i>Update on the revision of GCDMP document</i>
<b>Session 6: The future of CDM - where are we heading?</b>	<i>New trial designs, eTrials</i>
	<i>Data Reconciliation in 2025</i>
	<i>Panel discussion: DM-Topia, or what will the ideal DM world look like?</i>
<b>Sponsors Session</b>	<i>Sponsor time</i>
	<i>Sponsor time</i>
	<i>Sponsor time</i>
<b>Session 7: Other perspectives on Clinical Development</b>	<i>Site perspective</i>
	<i>Patient perspective</i>
	<i>Panel discussion</i>
<b>Closing Session</b>	<i>Closure</i>