

SOCIETY FOR CLINICAL DATA MANAGEMENT SCDM LEADERSHIP FORUM & EMEA CONFERENCE

23–25 OCTOBER 2019 BERLIN, GERMANY

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WELCOME TO THE SCDM LEADERSHIP FORUM & EMEA CONFERENCE 2019!

Dear Clinical Data Management Colleagues and Friends,

It is with great excitement that we welcome you to our fourth 2019 SCDM Leadership Forum & EMEA Conference in Europe!

Save the date!



Continuing in the success of our previous EMEA meetings in Leiden, Uppsala and London – the SCDM EMEA Steering Committee is delighted to welcome you to the 2019 SCDM leadership Forum & EMEA Conference in Berlin, Germany by kind invitation of Bayer.

The **2019 SCDM Leadership Forum & EMEA Conference**, is an exclusive event where CDM Leadership in Pharma, CROs, Regulators and Academia – meet to discuss the current and future state of the Data Management Industry, as to prepare and position our organizations for the future. The emphasis being on 'Strategy and Future' and how it feeds into an evolving DM landscape. This will be an interactive meeting, with short introductions followed by a guided panel discussion – involving the audience.

"Thanks to big data, machines can now be programmed to the next thing right.

But only humans can do the next right thing." (Dov Seidman)

This year the SCDM Leadership Forum will be followed by a two-day SCDM EMEA Conference, themed: "Evolving Clinical Data Management" and thought leaders will discuss many of the changes – present and future. The topics are targeting experienced Clinical Data Management Professionals – we encourage you to use this event and actively engage in the discussions on the key challenges that this evolution will bring!

We look forward to spending the next few days with you and wish you an insightful and enjoyable **2019 SCDM EMEA** Leadership Forum & EMEA Conference!

SCDM EMEA Steering Committee



PROGRAM

WEDNESDAY, 23 OCTOBER 2019 SCDM LEADERSHIP FORUM 12:00 - 13:00 Welcome Lunch CRO OVERSIGHT: WHERE IS THE SWEET SPOT? Session chair: **PETER STOKMAN** • CRO Oversight, Benedikt Egersdoerfer, Global Data Sciences and Analytics, Bayer AG, Germany 13:00 - 15:00 • The Sweet Spot – multiple sponsor's taste, Pieter Voermans, Clinical Data Management Team Lead, Immunology, Infectious Disease, Ophthalmology & Neuroscience, Roche, Switzerland • CRO perspective, Tanya du Plessis, Vice President, Data Strategies and Solutions, Bioforum, South Africa Panel Discussion 15:00 - 15:30 Coffee Break 15:30 - 17:00 TALENT, PEOPLE, VIRTUAL TEAMS Session chair: TANYA DU PLESSIS Building a successful virtual team, Céline Pernet, Manager, Clinical Data Management, PRA Health Sciences, France Adaptability by Design – The Importance and Value of a Lead Data Manager, Lee Polley-Loughrey & Sherraine Hurd, Leads Data Manager, PRA Health Sciences, UK • Shared Learning and feedforward: leading the way to Clinical Data Managers future, Laura Pinzon, Senior Clinical Data Manager, MSD GDMS-GDO, Colombia Panel Discussion Location: Titanic Hotel - Room Frankfurt SCDM EMEA Leadership Forum Dinner 19:00 - 21:00 sponsored by Covance Chausseestraße 30 | D-10115 Berlin **THURSDAY, 24 OCTOBER 2019 EMEA CONFERENCE** 08:30 - 10:00 **EVOLUTION OF CDM** Session chair: JOANNA SIENNICKA • Evolution of CDM, Bernd Heinrich, VP, Head Data Management, Acquisition and Review, Bayer AG, Germany • The future of Clinical Trials, Jennifer Duff, Managing Director, Accenture Life Sciences, USA • Evolution of CDM role in terms of moving towards a Central Data Management System, Urszula Bulkowska, Manager, MSD, Poland Panel Discussion 10:00 - 10:30 Coffee Break sponsored by Roche 10:30 - 12:00 **TECHNOLOGY, AI, ML** Session chair: KARIM OUAKKAS • Using eSource to Bridge the Clinical/DM Divide, Jonathan Andrus, Chief Business Officer, Clinical Ink, USA • The digital transformation of clinical trials, Ross Rothmeier, Vice President, Technology Solutions and Innovation Labs, Medidata Solutions, USA Artificial Intelligence and Clinical Trials, Massimo Beccaria Managing Director, Alpha Technologies International, Italy Panel Discussion

12:00 - 12:30	SPONSORS SESSION	Session chair: DAVIDE GAUDESI
	 PRA and SCDM Corporate PartnershipWhy? Michael Goedde, VP, Global Data Operations, PRA Health Sciences, USA Automating the Frustrations Out of Clinical Data Management, Sue Huxtable, Director, Data Management and Standards, Covance, USA Building an interoperable eCRF: Facilitating data capture by transmitting electronic source data from EHR, ePRO and medical devices, Elena Kochova, Customer Success Manager, Castor EDC, The Netherlands 	
12:30 - 13:30	Lunch sponsored by ED Castor EDC	
13:30 - 15:00	DATA SOURCE DIVERSIFICATION	Session chair: TANYA DU PLESSIS
	 Emerging Technologies - between hype & hope, Bruce Hellman, CEO & Co-Founder, -uMotif, UK Wearables & the development of end points, Bill Byrom, Vice President of Product Strategy and Innovation, Signant Health, UK Panel Discussion 	
15:00 - 15:30	Coffee Break	
15:30 - 17:30	INSIGHT GENERATION	Session chair: RICHARD YOUNG
	 Defining the Journey from RBM to RBX to RBQT, Richard Young, Vice President, Vault CDMS Strategy, Veeva Systems, UK RAVEN as a Central Data Review platform, Sacha Baulan, Senior Project Manager, Bayer AG, Germany Need for new technologies? Richard Davies, Vice President, Solution Expert, CluePoints, UK Panel Discussion 	
18:00 - 20:00	SCDM EMEA Leadership & EMEA Conference Networking Reception sponsored by PRA	Location: Bayer - Kasino
	FRIDAY, 25 OCT EMEA CONFI	
08:30 - 10:00	RBQM IN CDM	Session chair: CLAUDE PRICE
	 Emphasis on Operations & Present, Andy Lawton, Consultant, Risk Based Approach Ltd, UK Risk based quality management in CDM: evaluating the efficacy of queries, Peter Stokman, Business Lead Clinical Data Reporting & Review Environment, Bayer AG, Germany The Clinical Data Manager and the rise of RBM, Rafael Hernandez, Associate Director, MSD, Colombia Panel Discussion 	
10:00 - 10:30	Coffee Break	
10:30 - 12:00	DATA MANAGEMENT PROCESS QUALITY	Session chair: DOROTHY B. DOROTHEO
	 Clinical Data Manager: hybrid role and essential asset for a successful Risk Based Monitoring, Daphné Pestourie, Senior Lead Clinical Data Manager, PRA Health Sciences, France End to End Data Solution – Implementation of a Metadata Repository, Andrea Rauch, Head of Clinical Data Standards and Business Capabilities, Boehringer Ingelheim GmbH & Co. KG, Germany Inspection Readiness – Prepare or Bust, Dorothy B. Dorotheo, Director & Head of Clinical Data Management Acerta Pharma, USA Panel Discussion 	
12:00 - 12:30	POP-UP SESSION	
12:30 - 13:30	Lunch	
13:30 - 15:30	DIFFERENT PERSPECTIVES ON CDM	Session chair: IRINA SHER
	 The impact of amendments in clinical trials on dru Cuore Don Calabria, Italy Challenges of Establishing Good Clinical Data Man Robert Cartwright, Clinical Data Manager and SAS Panel Discussion 	
15:30 - 16:00	CLOSING SESSION SCDM - Society Highligts, SCDM Executive Committee members	

THANK YOU FOR ATTENDING
THE SCDM 2019 LEADERSHIP FORUM & EMEA CONFERENCE



SCDM EMEA STEERING COMMITTEE MEMBERS

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Business Lead Clinical Data Reporting & Review Environment
BAYER

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Ashish Bagde

Consultant, EXCELYA DATA

ABOUT SCDM

Non-Profit Professional Organization Founded in 1994

Serving Clinical Data Management and Research Professionals Education and Certification Provider

OUR MISSION

"Connect and inspire professionals managing global health data with global education, certification and advocacy"

OUR VISION

"Leading innovative clinical data science to advance global health research and development"

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