

Programme

- 08:00 Registration and coffee
- 09:00 *Welcome and introductions*
Jon Wood, Chair, ACDM
- 09:10 **Keynote 1: ICH E6 (GCP) Addendum – The impact on Pharma and CDM**
Andy Lawton, Risk Based Approach Ltd
- 09:40 Real-world data for post marketing surveillance in eight European countries: How using an eCRF helped Stentys, a mid-size medical device company streamline his non-interventional study? How was data security handled in the Cloud?
Bertrand Le Bourgeois, Medsharing, France
- 10:00 Standardised CRF design in non-interventional studies
Alastair Simpson, Gilead Sciences, UK
- 10:20 **Coffee, tea and exhibition viewing**
- 10:50 BMS Centralized Monitoring dedicated team – Lessons learned after a year in effect
Yiannis Karageorgos, Bristol-Myers Squibb, International Network of Clinical Data Management Associations (INCDMA), Belgium
- 11:05 Risk-Based Monitoring, Remote Monitoring and eSource: The Unattainable Trilogy of Monitoring?
Stephanie Langouet, Cmed
- 11:20 Implementing Risk-Based Monitoring: Supporting tools
Marika Zanin, CROS NT GmbH, Germany
- 11:35 Big Data to Smart Data
Srinivas Karri, Oracle Health Sciences
- 11:50 **Panel discussion chaired by ACDM Board Member**
- 12:20 **Lunch and exhibition viewing**
- 13:20 **Keynote 2: Médecins Sans Frontières (MSF) / Doctors Without Borders**
- 13:50 Design Clinical Data Management KPIs - The S.M.A.R.T Way
Priya Hari, Kelly OCG
- 14:10 **AGM**
- 14:40 **Coffee, tea and exhibition viewing**
- 15:10 eSource beyond EDC and data management
Mathias Poensgen, Aris Global GmbH
- 15:30 GxP and Regulatory Considerations for Cloud Implementations
Anil Dhiri, Oracle Health Sciences
- 15:50 Transforming data to knowledge and the Question: Is Clinical Data Big (Data)?
Oliver Herrmann, Q-FINITY Quality Management
- 16:10 Chairs closing remarks
Jon Wood, Chair, ACDM
- 16:15 Conference close