SCDM EMEA Conference, 23-25 October 2019, Berlin

EVOLVING CLINICAL DATA MANAGEMENT

Call for Abstracts

Dear Clinical Data Management Friends!

Save the Date! On 23-25 October of this year, the Society for Clinical Data Management (SCDM) Europe, Middle East & Africa (EMEA) Conference takes place in Berlin.

Clinical Data Management is typically one of these areas where continuous change has become the new normal. The theme of the meeting will be 'Evolving Clinical Data Management', and many of the changes - present & future - are slated to be discussed.

As always, the SCDM Conference will be characterized by *interaction*: the emphasis will be on the exchange of ideas & discussion. The target audience will be the seasoned CDM professionals & leaders, from Pharma, Regulators, CROs & Academia.

Since we want to have real-world stories, you are kindly invited to present from your day-to-day experience, ranging from strategizing & leading change management, to the ins and outs of actual implementation of new concepts.

Deadline: 10th of June 2019

The topics in our ever-changing world we would like to cover:

- Implementation of ICH E6 (R2)
  - Role of CDM in Risk Based Monitoring
  - Risk Based Monitoring from site perspective
  - Implementing Quality by Design: Risk Indicators & Quality Tolerance Limits
  - Risk Based Quality Management in CDM: where can we focus (and defocus)?
  - GCP at the site: challenges & opportunities of working with academia
- Insight Generation as a new function within CDM; first 'Citizen Data Scientists' spotted?
  - Experiences with Central Data Review
  - Using eHealth records, Real World Data, Registries
- Technology
  - End-to-end data solutions; any learning experiences to share?
  - Experience with AI & Machine Learning: is CDM 3.0 anywhere near?
  - Wearables & medical devices from a Site, Pharma & Regulator perspective

- Regulations:
    - Implementing the EMA, MHRA & FDA Data Integrity Guidelines
    - Impact of EMA's eSource Direct Data Capture qualification opinion
    - GDPR and CDM
    - IRB is not the enemy: retrospective studies the site perspective
- Experiences with Inspections & shifting regulatory focus
    - Ongoing eCRF review by investigators
    - Routine Audit Trail review
    - CRO oversight: where is the sweet spot?
- Any other hot & happening CDM topics you may be working on!

We look forward to welcome you in Berlin!