23 June 2023

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EUROPE
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CDISC 2023 Europe Interchange - Copenhagen

Brief Summary

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Day 1 Agenda

Session 2: Regulatory topics

- **PMDA presentation (*Yuki Ando*)**:
  - PMDA validation rules and changes in receiving study data;
  - Release of Data Standard Catalogue (include support for SDTM IG 3.3 starting on April 1 2023; end of support for Define xml 1.0 on March 31 2025).

- **FDA's study data policy framework and how CDISC properties are evaluated for inclusion (*Helena Sviling*)**:
  - FDA commitment to adoption of CDISC standards and its benefits clinical research;
  - Challenges and opportunities in CDISC standards implementation and how it's evaluated by FDA;

- **Data submission and evidence generation in Europe – an EMA update (*Eftychia-Eirini Psarelli*)**:
  - How RAW DATA analysis (e.g. CDISC SDTM) from clinical trials could support regulatory decision-making;

- **Regulatory Panel session**

Day 1 Agenda

Session 3 - 4: most interesting topics

- **To EC or not to EC, that is the Question (*Caroline Francis – Astrazeneca*)**:
  - Exposure as Collected SDTM domain has been implemented in 2013. As part of a review of data collection standards, Astrazeneca implemented this domain in 2022;
  - Description of this implementation with a focus on ECMOOD (SCHEDULED / PERFORMED for planned / actual treatments) variable, which leads to a change in EC structure (more vertical structure).
  - "Old" collection module and SDTM mapping were horizontal. Discussion on different options in order to minimise impact on processes, tools and trainings;

- **Automatic Defining ADaM for Clinical Studies using Machine Learning (*Thomas Rye Olsen and Henning P. Foh – Novo Nordisk*)**:
  - Use of ML in order to forecast the ADaM structure used for Clinical Trials;

Day 2 Agenda

Session 5 - 6 - 7: most interesting topics

- **Coming together – a Journey in the Harmonisation and Modernisation of Clinical Analysis Standards (*Warwick Benger – GSK*)**:
  - Implementation of a harmonized, simplified and connected e2e data standards by combining requirements of 3 group of stakeholders. More complicated if we consider the way of working of different TA;

- **Analysis result Standards Guidelines and Implementation using R Shiny (*Smriti Anand and Jayashree V. – Pfizer*)**:
  - Implementation of various standards safety reports that are sent for submission using R shiny application, which provides an interactive interface to create visualization and summaries;

- **Raising awareness for additional FDA Data Standards submission recommendations (*Angelo Tinazzi – Cytel*)**;
  - TAUG availability, which use is recommended by FDA;
  - Descriptions of other Guidances released by FDA to reduce variability in the interpretation;

Day 2 Agenda

Session 8: TMF Presentation

- **TMF presentation (*Karen Roy and Paul Fenton – TMF Reference Model*)**:
  - Trial Master File (TMF) is the collection of documents and information that serves as evidence that a clinical trial is conducted in adherence with good clinical practices (GCP). In addition proves that the integrity of the regulatory submissions data has been maintained;
  - TMF Reference Model was originally developed under DIA (Drug Information Association). Now is part of CDISC (Clinical Data Interchange Standards Consortium);
  - Last updates / news on TMF;

Useful links

- Personal work mail: federico.x.baratin@gsk.com

- CDISC EU presentations: https://www.cdisc.org/events/interchange/2023-europe-interchange/archive

Thanks for the attention

Questions?

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