CDISC 2019 Europe Interchange

Amsterdam, Netherlands | 6-10 May


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2019 CDISC Europe Interchange
Amsterdam, Netherlands
8 - 9 May 2019 - Main Conference
6, 7, 10 May 2019 - Educational Courses
Register Now

E3C Current Members

- Andrea Rauch, Boehringer-Ingelheim, Germany
- Angelo Tinazzi, Cytel, Switzerland
- Jozef Aerts, Joanneum University, Austria
- Stijn Rogiers , SAS, Belgium
- Eanna Kiely, Clinbuild, Germany
- Silvia Faini, LivaNova, Italy
- Simon Lundberg, Astra Zeneca, Sweden
- Sujit Khune, Novo Nordisk, Denmark
- Malathi Hari, Larix, Denmark
- Nich de Donder, Business & Decision, Belgium
- Jörg Dillert, Oracle, Germany (Chair)

CDISC E3C Liaison

- Peter van Reusel, Innovion, Belgium

CDISC funded Support

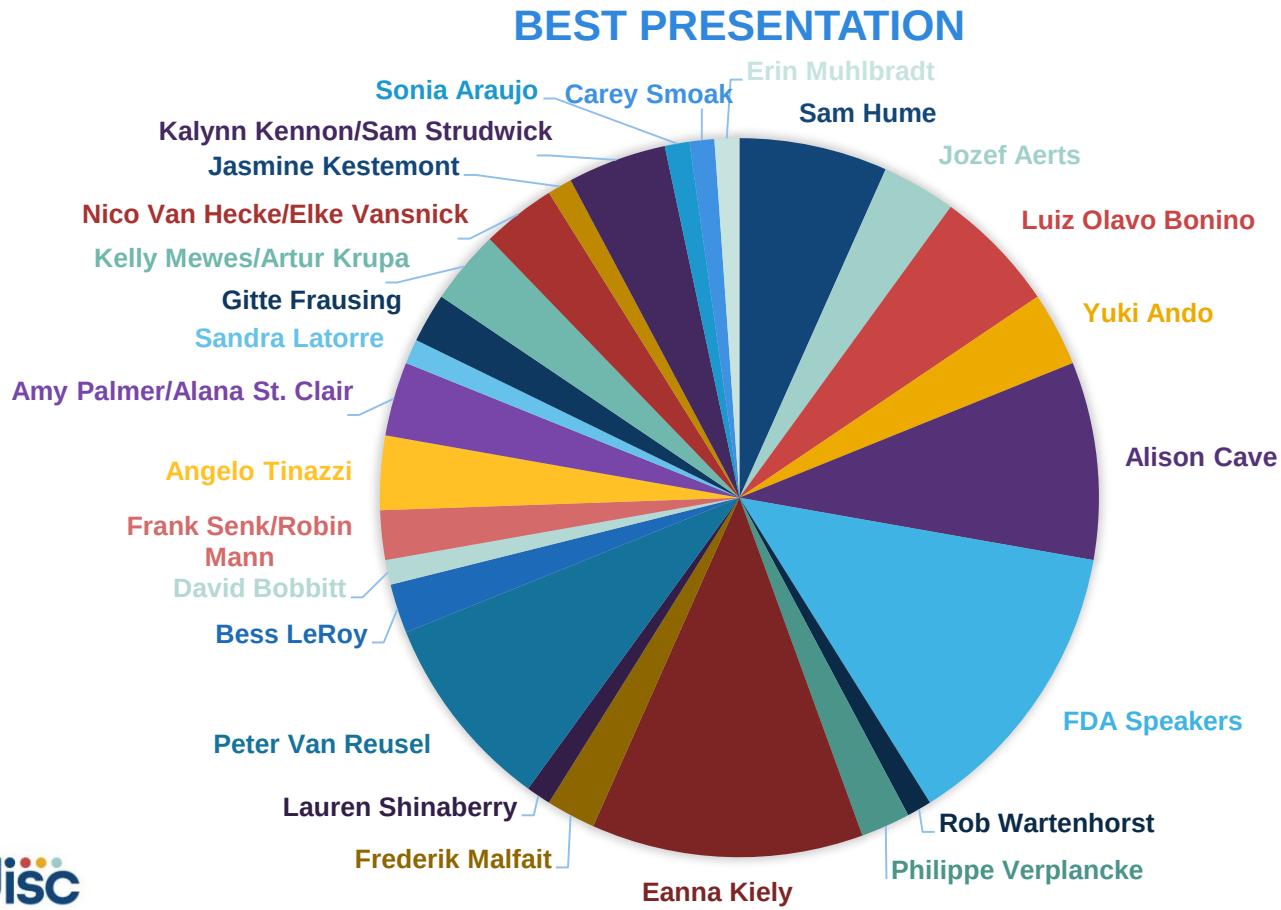
- Andrea Vadakin, CDISC,
  - European Interchange Program support
- Dominik Ruisinger
  - European Interchange Logistics

Conference Characteristics

% of Respondents Rank the Following “Very Good” or “Excellent”

Registration Process	Conference Content	Food & Beverage	Conference Organization & Management
90%	84%	74%	96%
• Registration and Conference websites easy to use, updated often • Request to pay in euros • Library Workshop was rescheduled late; created issues for travel and hotel booking	• Very new and interesting content • Regulatory & CDISC presentations important • Request for more presentations on SEND and more foundational standards information, specifically SDTM/CT	• "Excellent” • Lack of vegetarian options; too much bread	• "Seamless” • "Excellent” • Need more practice on sticking to 30-min timeslots

Presentation Feedback



Additional Attendee Feedback

Presenter / Speaker Performance Positives / Negatives	Topics Attendees Would Like to See	Mobile App Feedback Positives / Negatives	Overall Impressions Positives / Negatives
• 360 Presentations were very interesting • Many people enjoyed Éanna's presentation • Enjoyed updates from regulators, especially FDA and EMA	• Hands-on CDISC Library & 360 • Foundational content – SDTM, CDASH, ODM, CT • More information about what is coming down the pipeline • Session for Academia/SMEs on implementation challenges • Include NMPA with other regulators • More of: Linked data/end-to-end, RWE/RWD, LOINC, Define-XML • Technical Conformance Guide • Device standards & CDRH	**81% of respondents used the Mobile App** • "Best conference app I have ever seen" and compared it to PhUSE's • "Much better than a printed schedule"	• "Great networking opportunity." • "Better than prior years." • "More of a coordinated theme than previous Interchanges" • "Evening Event was nicely organized."
• FDA video may have been too long, and would like more interaction • 360 presentations may have been too technical for entire audience • Incorrect information given by a couple presenters		• Navigation needs to be easier to understand • Would like to rank presentations, rather than sessions • Networking with attendees through app needs work • Would like to be able to plan schedule by presentation, not session	• "Venue was a bit far from the city." • "Exhibitor area was too far away from sessions."

Key Plenary presentations

TOWARDS THE INTERNET OF FAIR DATA AND SERVICES

2019 CDISC Europe Exchange – Amsterdam, May 8, 2019

Luiz Bonino

luiz.bonino@go-fair.org

CDISC 360:
Evolution of the CDISC Standards

Peter Van Reusel, CSO, CDISC
Sam Hume, DSc, VP Data Science, CDISC
08-May-2019

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Big Data – Challenges and Opportunities

Moving forward with recommendations from the HMA-EMA Joint Big Data taskforce

Dr Alison Cave

Principal Scientific Administrator

Pharmacovigilance and Epidemiology Department

- **CDISC European Exchange May 2019**

FDA reviewers video

- https://www.youtube.com/watch?v=brtRroX8Ezw

EUC 2020 is knocking on the door

- US Interchange is coming
- Call for Abstracts – topics overworked last week in our E3C meeting
- Topics ...

Session Topics and Presentations Suggestions

International submissions

MDR session - Metadata guide v2.0

Use cases
- **are still important: provide examples to have more use cases.**

Network and break-out session
- **take topics from the conference, instead of panel discussion, with CDISC representative sitting there.**

Rules and tools

End-to-End / CDISC 360 updates
- **Experiences / progress from the working groups**

Standards governance
- **how to handle CDISC versions before submission/across standards**

Outcome from user or working groups
- **ex. CRF annotation – from the German user group**

Experience with TAUGs

Efficiency of standards usage / Management KPIs

RWE
- **to be continued with EMA**

Medical Devices
- **(beside the request to get something form the FDA)**
- **Is the model/standards are still valid today?**
- **What has changed over the years**

CDISC core
- **SDTM v3.3 – DefineXML v2.1 clearly mention them in the CfA**
- **ADaMIG v1.2 and ADaM for Integration guidelines (which are going to be published)**

Artificial Intelligence / Mobile devices

CDISC standards usage in academia

CDISC Library API

Laboratory/LOINC topics

OTHER TOPICS TOWARDS CDISC STANDARDS

You are welcome to submit an abstract on any CDISC model experience, its implementation and associated planning. Related use cases are encouraged. We want to hear your success stories even if they do not fit into the topic areas mentioned. CDISC is an open and multidisciplinary standard which interface with many areas and we are eager to hear about your experiences working with standards.

Deadline 29-Nov-2019

Our challenges – our selection and preparation period

- Selection period and challenges in Europe
  - (years end, January – March / April / May)

- next year time is short – need the community
  - 30st March – 3rd April 2020 in Berlin, Titanic Hotel
  - Regulatories, please mark your diaries: PMDA, EMA, FDA

  - Please be ready to send abstracts in September / October / November time 2019

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Thank you and see you in Berlin

30st March – 3rd April 2020