



2026 CDISC Europe Interchange

20 – 21 May | Milan, Italy
Thank you for being here with us!





Ruby



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Conference Essentials



#cdisc2026europe

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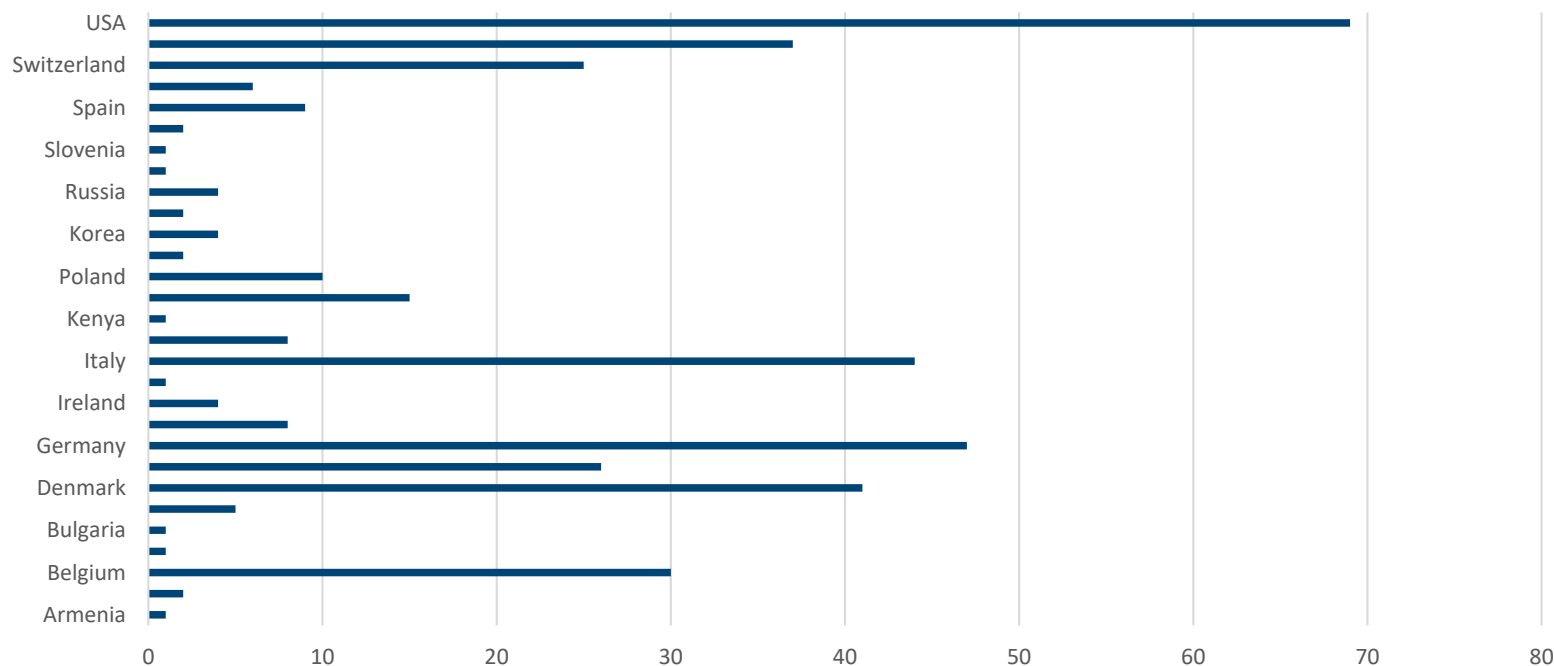
Thank You
Exhibitors!





2026 Attendance

Attendance by Country



*Record Breaking
Year for EU
Attendance with
425 Registrants!*

*Representation
from 29 Countries
across 5
Continents! (6 more
countries than 2025)*



Survey!

Please complete the **European Interchange Feedback Survey** sent to you by email next week.

In return, we will send you presentation slides!



#cdisc2026europe



Powering Standards-Based Technology Across Clinical Research

2026 CDISC TechniCon



Virtual | 9 September 2026 | 9:00am ET - 1:00pm ET

TechniCon provides a focused, virtual platform for companies to showcase solutions built on CDISC Standards and related technologies.

Event will bring together a global audience of sponsors, CROs, technology leaders, and implementation experts who are actively seeking practical, standards-based tools to improve interoperability, streamline workflows, and support more efficient clinical research.

Save the Date! More details soon!



Upcoming 2026 Events



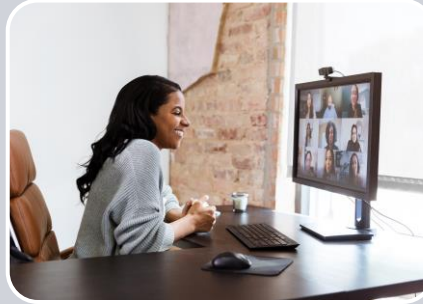
China CDISC Day

14 August
Shanghai



India CDISC Day

22 August
Chennai



TechniCon

9 September
Virtual



CDISC-SCDM Japan Event

4-5 November
Tokyo



Korea CDISC Day

Q4 2026
Seoul



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and Private Training options.

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Japanese Language Trainings.

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AI Innovation Challenge 2026

- Kickoff Webinar available on CDISC website
- Intent to Participate deadline: 29 May
- Final submission deadline: 31 July
- Participation requires active CDISC Membership





Volunteer

- Engage with CDISC 360i working groups
 - Test, pilot, and provide feedback on new models
- Support the adoption of open digital standards



**Join Us In
Building The
Future**

*Together, we are
breaking down
silos to deliver
faster, smarter,
more connected
clinical research*





Join Our Global
Community



**Join CDISC
as a Member**

Expanded Benefits in 2026!

Exciting New Initiatives:
AI Innovation Challenge 2026
2026 TechniCon
Members Only Webinars

New members who attend Interchange receive a
15% discount on membership fees.





Thank You E3C

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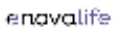
Montrium



Bingo!



2026 CDISC EUROPE INTERCHANGE CONNECT + COLLECT BINGO GAME

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Collect all stamps for a chance to win!

Visit each booth listed on this card. Booth representatives will put a stamp on their company square. Drop completed card at the CDISC Registration Desk by 21 May 2026, 16:00. Drawing will be held during the Closing Plenary. Winners must be present to receive their prizes.

Best Poster (CDISC)

Novo Nordisk A/S

- Henrik Bech Kjeldal
- Anne-Marie Wegeberg

Is Your Study Boat Secretly Taking on Water? Catching Standards Drift Before It Sinks Your Timeline

Henrik Bech Kjeldal¹; Anne-Marie Wegeberg¹

Accumulating incremental CRF deviations
leads to significant impact on build,
mapping and submission across studies –
like unnoticed leaks undermining a boat



Aim

- Establish continuous monitoring of Standard CRF compliance through a semi-automated dashboard that makes Standards drift visible during study setup.
- Use early drift detection to correct issues proactively, reducing downstream rework and the risk of costly amendments.

Methods

- Extraction - Python (python-docx) + AI assistance (Claude Sonnet 4.5)
- Deviation detection - sequence alignment + heuristic rule-based scoring
- Visualisation - Shiny for Python dashboard compliance overview and trend tracking

Key results

- Leak-O-Meter**: a user-friendly platform with simple steps to identify and monitor deviations from CRF Standards in a **time-resolved manner**.
- Improved method for early detection of deviations** that would otherwise remain unnoticed until downstream issues arise.
- Longitudinal drift assessment** enabled by dashboards displaying changes over time.

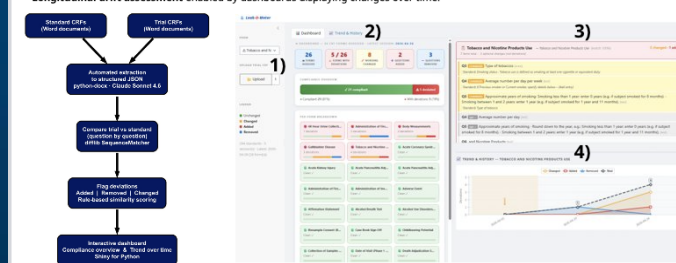


Figure 1: Automated CRF compliance pipeline. Standard and study CRFs are parsed to structured JSON, aligned question-by-question, and deviations flagged by rule-based scoring. Results are displayed in a dashboard with compliance overviews and trend tracking.

Figure 2: Leak-O-Meter dashboard. 1) The user uploads the current trial CRF, which is then automatically compared with Global Standard Library. 2) The dashboard is color-coded to highlight forms with text changes and added or removed items. 3) Detailed view of an individual form, with specific items where deviations have occurred highlighted. 4) Longitudinal view showing drift in deviations over time.

Conclusion

- Leak-O-Meter reveals drift between Standard and study-specific CRFs is common but often goes unnoticed at early stages.
- By automating extraction, comparison, and longitudinal tracking, it detects "silent leaks" before they impact build, mapping, and submission - turning CRF review into a proactive, evidence-based quality step.

Perspectives

- Current detection is constrained by document-based formats such as mock CRFs.
- Using structured EDC output directly as the program's input and comparing it against the Veeva Standard Library would provide a far more robust and reliable approach.

¹Novo Nordisk, Aalborg, Denmark
Presented at the CDISC Europe Interchange conference, May 18th-22nd, Milan, Italy.

References:
Python Software Foundation, Python Language Reference, <https://www.python.org>

Best Poster (TMF)

- Lul Hassan, Phlexglobal

PHLEXGLOBAL

TMF Culture and Engagement

Bringing everyone under the same umbrella

Lu Hassan – Senior TMF Study Owner

Weathering the Storm of TMF Activities

Engagement starts in TMF Kick-off meeting, preparing for TMF kick-off activities and introductions to study team members.

Engagement should be a continuous process, not just a one-time event. TMF Kick-off meeting includes all key stakeholders, TMF set-up and

initialisation and review processes are defined and set.

Engage business and academic researchers through the communication and set up, so that they know we align on approach and next steps.

Engagement is a culture to deliver more responsibilities on customer and sponsor. TMF Plan, often aware to consider include frequency of study

team meetings, level of communication and understanding of key TMF metrics (KPIs) and activities.

Establish a culture of open communication and engagement early on makes it a great working relationship and environment during the study.

Providing training (e.g. an expert TMF KOL) and engagement resources to the study team is a key part of ensuring everyone remains current, particularly

those from the pharmaceutical industry.

And how taking on any part of the TMF process can be rewarded and reinforced to study team members as needed.

Following up study team is important as engagement sets the tone for any given TMF activities.

Checking the
Forecast

Being
Prepared

Weathering the
Storm

Checking the forecast: Check in with your study team regularly in addition to TMF Meetings, it is a good idea to check in with other study team members and your sponsor and keep up to date with any study details. Ask yourself what you need to be successful in the TMF.

Being prepared: when your sponsor indicates the start of upcoming activities, make sure you have team to ensure requirements are met, being prepared in TMF is a winning strategy. Participants/visitors to ensure documents are not missed or a costly, difficult process to resolve.

Weathering the storm: Check in with your study team regularly in addition to TMF Meetings, it is a good idea to check in with other study team members and your sponsor and keep up to date with any study details. Ask yourself what you need to be successful in the TMF.

TMF Meetings

- Establish TMF meetings where possible, e.g. monthly, once a month (keep frequent as required).
- Ensure key stakeholders are invited, especially those actively working in the TMF.
- Opening agenda with study team, to build after the meeting time and discuss any open points to ensure that they may be addressed collaboratively.
- Provide information of start of meeting the day of the documents and which version is currently being used.
- Ensure all participants are invited to the meeting agenda (TMF Notes, TMF Plan, Key KPIs).
- Leave time for and encourage questions.

Presenting Data/Metrics

- Ensure up to date metrics are provided to the study team consistently, e.g. monthly.
- Highlighting key study metrics, e.g. compliance, timeliness and safety.
- Monthly safety or prepared briefing notes to be review prior to calls.
- In further communication, present the data in a user-friendly manner, e.g. data sheets for print tables and highlights are great of convenient positive updates for health authorities.
- Use both charts and figures and use any findings, this avoids confusion and helps team communicate.

Communication

Communication is essential to ensure everyone is aligned. The sponsor, investigators, and other stakeholders are essential to ensure everyone is aligned. The sponsor, investigators, and other stakeholders are essential to ensure everyone is aligned.

Engagement

Good study team members are essential to ensure everyone is aligned. The sponsor, investigators, and other stakeholders are essential to ensure everyone is aligned.

Teamwork

Working collaboratively to ensure everyone is aligned. The sponsor, investigators, and other stakeholders are essential to ensure everyone is aligned.

Culture

Building the TMF culture and ensuring everyone is aligned. The sponsor, investigators, and other stakeholders are essential to ensure everyone is aligned.

Tailor Approach

- Review approach with study team to determine how they work and what they need to better understand the study.
- Use a team, other teams will better understand the study.

Plan Ahead

- Review timelines regularly and ensure alignment between all stakeholders.
- Ensure all stakeholders are aligned in advance and reviewing regularly updates the team, ensure alignment and plan preparation.

Be Flexible

- Be flexible to support sponsor changes during the study.
- Use a team, other teams will better understand the study.
- Use a team, other teams will better understand the study.

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Best Presentations

- CDISC:

Tom Smeets, OCS
Ine Wolfs, argenx



Tom Smeets, Clinical & Biomarker Programmer
Ine Wolfs, Clinical & Biomarker Data Standards Manager

Best Presentations

- TMF: Christina Mantzioros, Montrium

The banner for the cdisc 2026 Europe Interchange conference. On the left is a graphic of a globe with a network of lines and colored nodes (yellow, red, blue, teal). To the right of the globe is the cdisc logo and the text "2026 Europe Interchange". Below this, in smaller text, is the tagline "THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION". The background of the banner features a dark blue silhouette of a city skyline. At the bottom, the text "MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY" is displayed. Below the banner, the title of the presentation "Leveraging AI to Enhance TMF Risk Assessment: A Practical Framework" is shown, followed by the presenter's name and title: "Presented by Christina Mantzioros, Director, Product & Clinical Intelligence @ Montrium".

cdisc 2026 Europe Interchange
THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Leveraging AI to Enhance TMF Risk Assessment: A Practical Framework

Presented by Christina Mantzioros
Director, Product & Clinical Intelligence @ Montrium



**Thank You
Regulators, Keynote Speakers, All
Presenters and Attendees!
We had a great week hosting you!**

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Vittoria Sparacio
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2027 CDISC Europe Interchange

Barcelona, Spain | More Details Soon





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Clear Data. Clear Impact.

Standards Transform Clinical Research
Membership Join Our Global Community
Education Learn CDISC From CDISC





Alliances Collective Strength



Regulatory Relationships

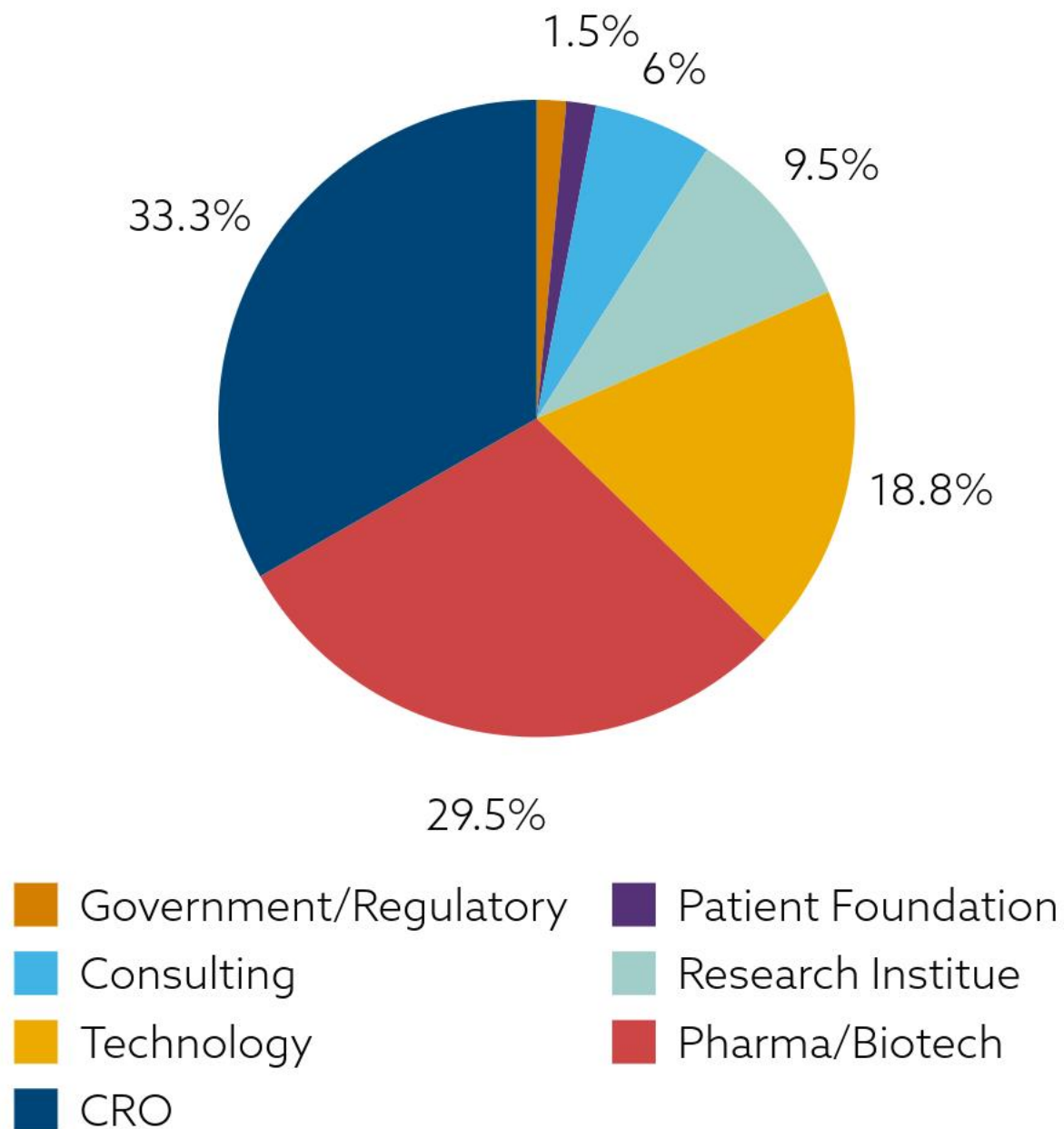




Collaboration Members From Across The Industry

By working together, we can reduce data quality issues and help expedite regulatory review.

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A **World** Of
Opportunity

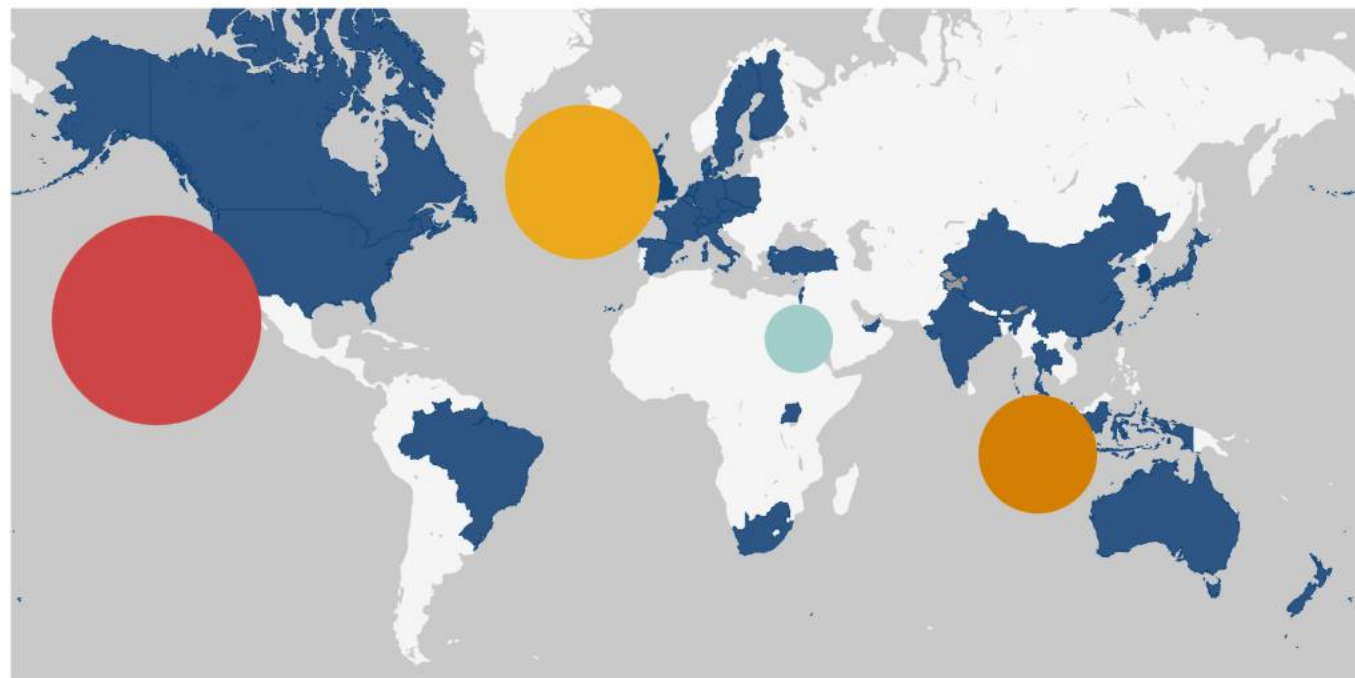
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Member Map



● Americas - 237

● Europe, UK, Ireland - 121

● Asia, Oceania - 90

● Africa, Middle East - 4