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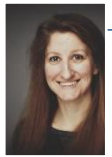

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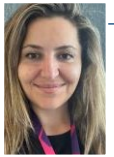

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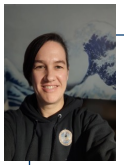

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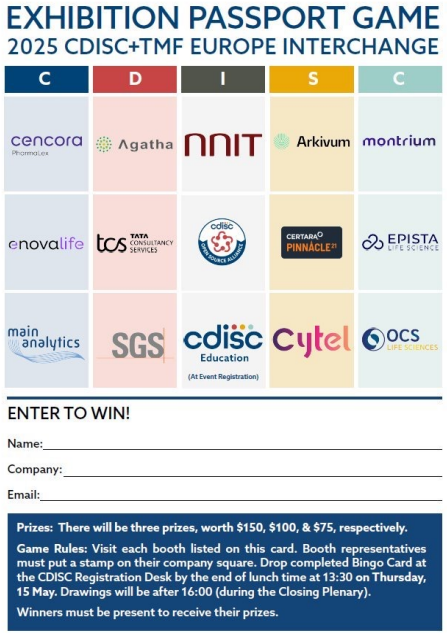

EXHIBITION PASSPORT GAME

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ENTER TO WIN!

Name: _____

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Prizes: There will be three prizes, worth $150, $100, & $75, respectively.

Game Rules: Visit each booth listed on this card. Booth representatives must put a stamp on their company square. Drop completed Bingo Card at the CDISC Registration Desk by the end of lunch time at 13:30 on Thursday, 15 May. Drawings will be after 16:00 (during the Closing Plenary).

Winners must be present to receive their prizes.

Best Poster

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Karine Provost

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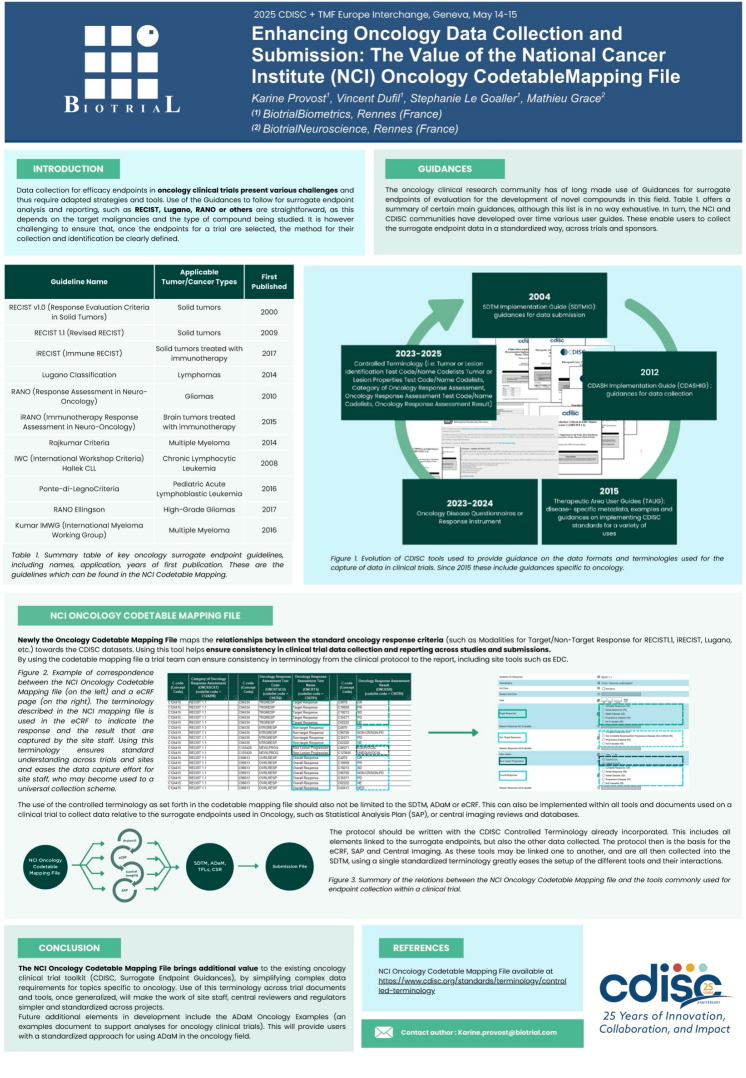

2025 CDISC + TMF Europe Interchange, Geneva, May 14-15

Enhancing Oncology Data Collection and Submission: The Value of the National Cancer Institute (NCI) Oncology CodetableMapping File

Karine Provost[1], Vincent Dufil[1], Stephanie Le Goaller[2], Mathieu Grace[2]

(1) BiotrialBiometrics, Rennes (France)

(2) BiotrialNeuroscience, Rennes (France)

INTRODUCTION

Data collection for efficacy endpoints in **oncology clinical trials present various challenges** and thus require adapted strategies and tools. Use of the Guidances to follow for surrogate endpoint analysis and reporting, such as **RECIST, Lugano, RANO or others** are straightforward, as this depends on the target malignancies and the type of compound being studied. It is however challenging to ensure that, once the endpoints for a trial are selected, the method for their collection and identification be clearly defined.

GUIDANCES

The oncology clinical research community has of long made use of Guidances for surrogate endpoints of evaluation for the development of novel compounds in this field. Table 1. offers a summary of certain main guidances, although this list is in no way exhaustive. In turn, the NCI and CDISC communities have developed over time various user guides. These enable users to collect the surrogate endpoint data in a standardized way, across trials and sponsors.

Guideline Name	Applicable Tumor/Cancer Types	First Published
RECIST v1.0 (Response Evaluation Criteria in Solid Tumors)	Solid tumors	2000
RECIST 1.1 (Revised RECIST)	Solid tumors	2009
iRECIST (Immune RECIST)	Solid tumors treated with immunotherapy	2017
Lugano Classification	Lymphomas	2014
RANO (Response Assessment in Neuro-Oncology)	Gliomas	2010
iRANO (Immunotherapy Response Assessment in Neuro-Oncology)	Brain tumors treated with immunotherapy	2015
Rajkumar Criteria	Multiple Myeloma	2014
IWC (International Workshop Criteria) Hallek CLL	Chronic Lymphocytic Leukemia	2008
Ponte-di-LegnoCriteria	Pediatric Acute Lymphoblastic Leukemia	2016
RANO Ellingson	High-Grade Gliomas	2017
Kumar IMWG (International Myeloma Working Group)	Multiple Myeloma	2016

Table 1. Summary table of key oncology surrogate endpoint guidelines, including names, application, years of first publication. These are the guidelines which can be found in the NCI Codetable Mapping.

Figure 1. Evolution of CDISC tools used to provide guidance on the data formats and terminologies used for the capture of data in clinical trials. Since 2015 these include guidances specific to oncology.

NCI ONCOLOGY CODETABLE MAPPING FILE

Newly the Oncology Codetable Mapping File maps the **relationships between the standard oncology response criteria** (such as Modalities for Target/Non-Target Response for RECISTL1, iRECIST, Lugano, etc.) towards the CDISC datasets. Using this tool helps **ensure consistency in clinical trial data collection and reporting across studies and submissions.**
By using the codetable mapping file a trial team can ensure consistency in terminology from the clinical protocol to the report, including site tools such as EDC.

Figure 2. Example of correspondence between the NCI Oncology Codetable Mapping file (on the left) and a eCRF page (on the right). The terminology described in the NCI mapping file is used in the eCRF to indicate the response and the result that are captured by the site staff. Using this terminology ensures standard understanding across trials and sites and eases the data capture effort for site staff, who may become used to a universal collection scheme.

The use of the controlled terminology as set forth in the codetable mapping file should also not be limited to the SDTM, ADaM or eCRF. This can also be implemented within all tools and documents used on a clinical trial to collect data relative to the surrogate endpoints used in Oncology, such as Statistical Analysis Plan (SAP), or central imaging reviews and databases.

The protocol should be written with the CDISC Controlled Terminology already incorporated. This includes all elements linked to the surrogate endpoints, but also the other data collected. The protocol then is the basis for the eCRF, SAP and Central Imaging. As these tools may be linked one to another, and are all then collected into the SDTM, using a single standardized terminology greatly eases the setup of the different tools and their interactions.

Figure 3. Summary of the relations between the NCI Oncology Codetable Mapping file and the tools commonly used for endpoint collection within a clinical trial.

CONCLUSION

The NCI Oncology Codetable Mapping File brings additional value to the existing oncology clinical trial toolkit (CDISC, Surrogate Endpoint Guidances), by simplifying complex data requirements for topics specific to oncology. Use of this terminology across trial documents and tools, once generalized, will make the work of site staff, central reviewers and regulators simpler and standardized across projects.
Future additional elements in development include the ADaM Oncology Examples (an examples document to support analyses for oncology clinical trials). This will provide users with a standardized approach for using ADaM in the oncology field.

REFERENCES

NCI Oncology Codetable Mapping File available at https://www.cdisc.org/standards/terminology/controlled-terminology

Contact author : Karine.provost@biotrial.com

cdisc 25 Years of Innovation, Collaboration, and Impact

Best Poster

TMF

Christina Lannaccone

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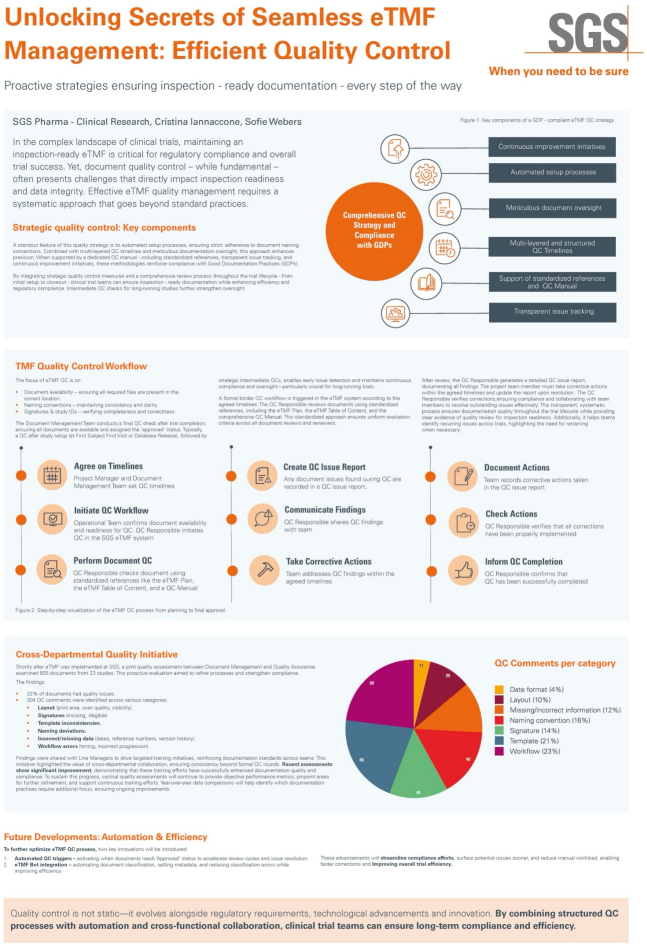

Unlocking Secrets of Seamless eTMF Management: Efficient Quality Control

SGS When you need to be sure

Proactive strategies ensuring inspection - ready documentation - every step of the way

SGS Pharma - Clinical Research, Cristina Iannaccone, Sofie Webers

In the complex landscape of clinical trials, maintaining an inspection-ready eTMF is critical for regulatory compliance and overall trial success. Yet, document quality control – while fundamental – often presents challenges that directly impact inspection readiness and data integrity. Effective eTMF quality management requires a systematic approach that goes beyond standard practices.

Figure 1: Key components of a GDP - compliant eTMF QC strategy.

Comprehensive QC Strategy and Compliance with GDPs

- Continuous improvement initiatives
- Automated setup processes
- Meticulous document oversight
- Multi-layered and structured QC Timelines
- Support of standardized references and QC Manual
- Transparent issue tracking

Strategic quality control: Key components

A standout feature of this quality strategy is its automated setup processes, ensuring strict adherence to document naming conventions. Combined with multi-layered QC timelines and meticulous documentation oversight, this approach enhances precision. When supported by a dedicated QC manual - including standardized references, transparent issue tracking, and continuous improvement initiatives, these methodologies reinforce compliance with Good Documentation Practices (GDPs).

By integrating strategic quality control measures and a comprehensive review process throughout the trial lifecycle - from initial setup to closeout - clinical trial teams can ensure inspection - ready documentation while enhancing efficiency and regulatory compliance. Intermediate QC checks for long-running studies further strengthen oversight.

TMF Quality Control Workflow

The focus of eTMF QC is on:

- Document availability – ensuring all required files are present in the correct location.
- Naming conventions – maintaining consistency and clarity.
- Signatures & study IDs – verifying completeness and correctness.

The Document Management Team conducts a final QC check after trial completion, ensuring all documents are available and assigned the 'approved' status. Typically, a QC after study setup (at First Subject First Visit or Database Release), followed by strategic intermediate QCs, enables early issue detection and maintains continuous compliance and oversight—particularly crucial for long-running trials.

A formal binder QC workflow is triggered in the eTMF system according to the agreed timelines. The QC Responsible reviews documents using standardized references, including the eTMF Plan, the eTMF Table of Content, and the comprehensive QC Manual. This standardized approach ensures uniform evaluation criteria across all document reviews and reviewers.

After review, the QC Responsible generates a detailed QC issue report, documenting all findings. The project team member must take corrective actions within the agreed timelines and update the report upon resolution. The QC Responsible verifies corrections, ensuring compliance and collaborating with team members to resolve outstanding issues effectively. This transparent, systematic process ensures documentation quality throughout the trial lifecycle while providing clear evidence of quality review for inspection readiness. Additionally, it helps teams identify recurring issues across trials, highlighting the need for retraining when necessary.

Agree on Timelines
Project Manager and Document Management Team set QC timelines

Initiate QC Workflow
Operational Team confirms document availability and readiness for QC. QC Responsible initiates QC in the SGS eTMF system

Perform Document QC
QC Responsible checks document using standardized references like the eTMF Plan, the eTMF Table of Content, and a QC Manual

Create QC Issue Report
Any document issues found during QC are recorded in a QC issue report.

Communicate Findings
QC Responsible shares QC findings with team

Take Corrective Actions
Team addresses QC findings within the agreed timelines

Document Actions
Team records corrective actions taken in the QC issue report

Check Actions
QC Responsible verifies that all corrections have been properly implemented

Inform QC Completion
QC Responsible confirms that QC has been successfully completed

Figure 2: Step-by-step visualization of the eTMF QC process from planning to final approval.

Cross-Departmental Quality Initiative

Shortly after eTMF was implemented at SGS, a joint quality assessment between Document Management and Quality Assurance examined 805 documents from 23 studies. This proactive evaluation aimed to refine processes and strengthen compliance.

The findings:

- 33% of documents had quality issues
- 304 QC comments were identified across various categories:
  - **Layout** (print area, scan quality, visibility).
  - **Signatures** (missing, illegible).
  - **Template inconsistencies.**
  - **Naming deviations.**
  - **Incorrect/missing data** (dates, reference numbers, version history).
  - **Workflow errors** (timing, incorrect progression).

Findings were shared with Line Managers to drive targeted training initiatives, reinforcing documentation standards across teams. This initiative highlighted the value of cross-departmental collaboration, ensuring consistency beyond formal QC rounds. **Recent assessments show significant improvement**, demonstrating that these training efforts have successfully enhanced documentation quality and compliance. To sustain this progress, cyclical quality assessments will continue to provide objective performance metrics, pinpoint areas for further refinement, and support continuous training efforts. Year-over-year data comparisons will help identify which documentation practices require additional focus, ensuring ongoing improvements.

Future Developments: Automation & Efficiency

To further optimize eTMF QC process, two key innovations will be introduced:

1. **Automated QC triggers** – activating when documents reach 'Approved' status to accelerate review cycles and issue resolution.
2. **eTMF Bot integration** – automating document classification, setting metadata, and reducing classification errors while improving efficiency.

These advancements will **streamline compliance efforts**, surface potential issues sooner, and reduce manual workload, enabling faster corrections and **improving overall trial efficiency.**

Quality control is not static—it evolves alongside regulatory requirements, technological advancements and innovation. **By combining structured QC processes with automation and cross-functional collaboration, clinical trial teams can ensure long-term compliance and efficiency.**

Best Presentation

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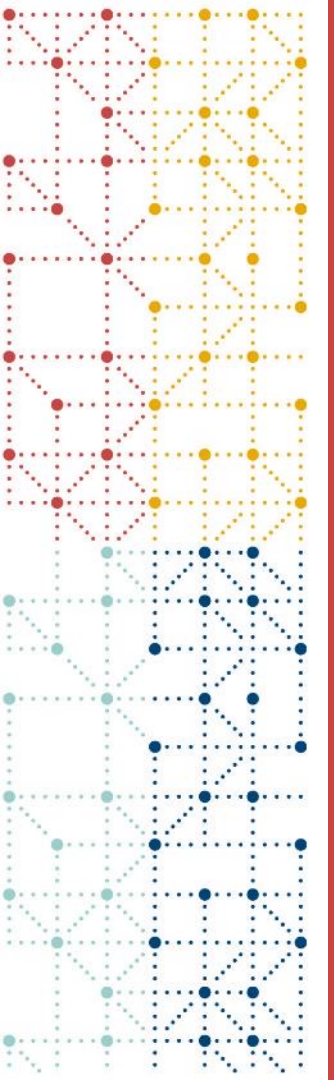
AI-Powered Discovery of Biomedical Concepts
Amiel Kollek, Lindus Health

- TMF

How to Quiet the TMF Noise Using AI
Traci Wendler, Genmab



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Nicole Harmon, PhD
COO
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Most Attendees Found Out About Event Via **eBlast** (35%) and
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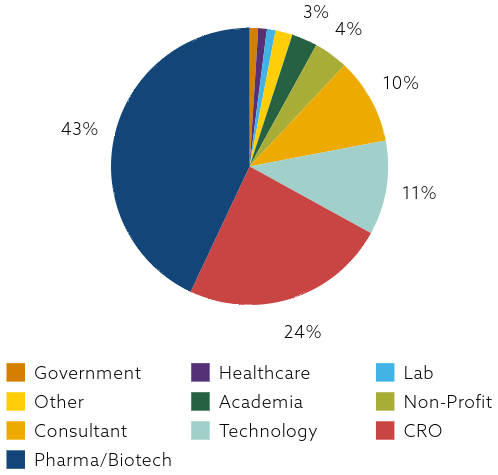

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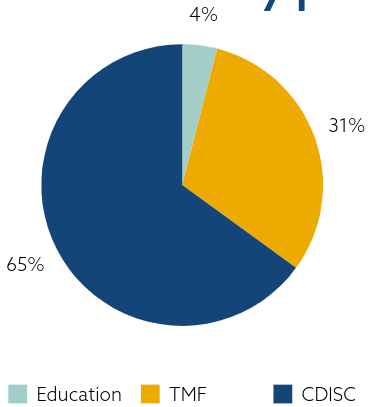

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Cheese, Cheers, CDISC!

Laughter + Leadership








cdisc 25 YEARS ANNIVERSARY

Support CDISC Across The World

See You Soon In Japan, Korea, India, China, and Nashville, Tennessee, USA

2025 CDISC
Japan Interchange
26 June 2025

2025 CDISC + TMF
US Interchange
13 -14 October 2025

KOREA CDISC DAY
All the Insights, All the Impact, All in One Day!

24 June 2025

INDIA CDISC DAY
All the Insights, All the Impact, All in One Day!

19 July 2025

CHINA CDISC DAY
All the Insights, All the Impact, All in One Day!

29 August 2025

Join Us As An Exhibitor/Sponsor!

Education Virtual, On-Demand, In-Person

Learn from Standards Experts and Developers.

Enroll in English, Mandarin, or Japanese Language Trainings.

Use Member Credits and Discounts.

Learn More *training@cdisc.org*

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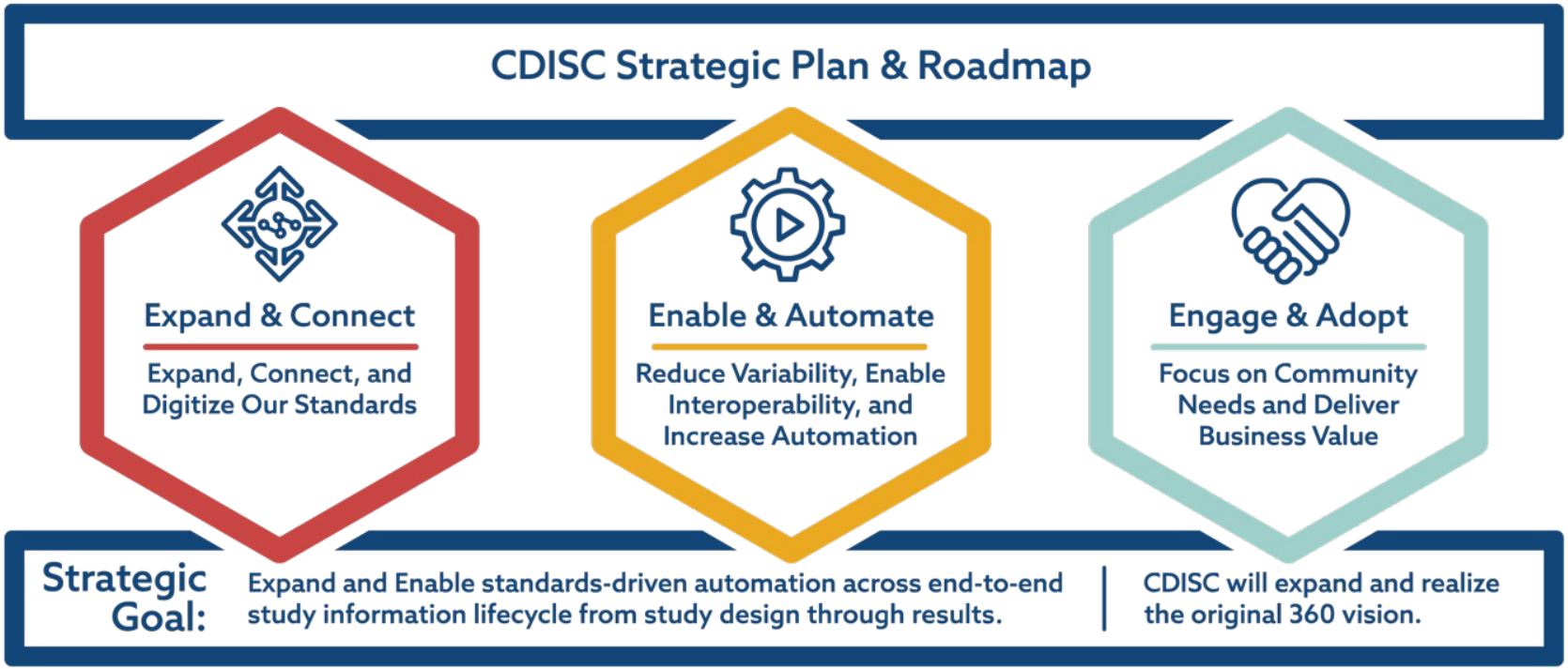
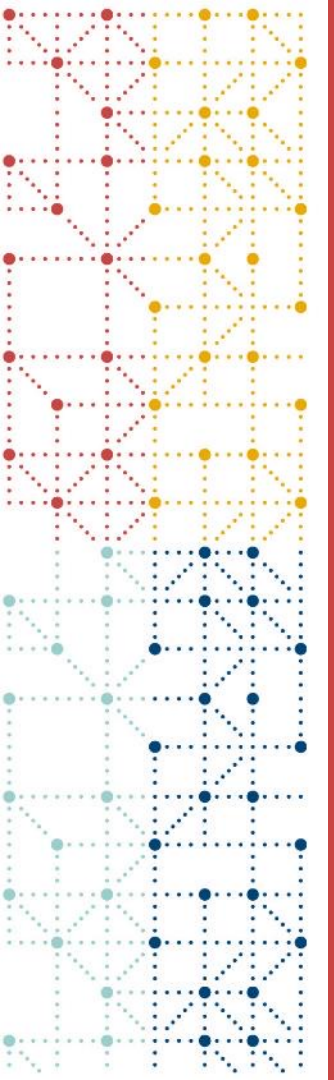
cdisc® Education

Realizing the CDISC Mission





Pillar 3: Engage & Adopt

To inform our efforts to support the CDISC Global Community and deliver increased value.

To accept feedback on how our organization can most effectively adapt and align with current data standards and interoperability priorities.

Community Engagement Survey: 7a. How would you sum up what CDISC provides the community that you feel is most useful for you and/or your organization in ~10 words?

"Standardization, Compliance, Training, Collaboration"

"Standards the whole industry adheres to"

"Guidance on submission requirements"

TMF Reference Model and the support that CDISC provides to us

"Making standards available even during DRAFT stage which helps us to incorporate early in our standards"

"Community based standards"

"Standards that realize end-to-end data flow from protocol through submission"

"A single Source of Standards Truth"

"A core set of clinical data standards mandated or accepted by health authorities around the world."

"Transparent data standards"

"Standardization is crucial when working with multiple vendors"

"The standards themselves. The connection between CDISC, Industry, and FDA is crucial to useful standards development, and CDISC provides that link."

"Consistency, rules and structure in an evolving landscape."

An authoritative voice in implementing and maintaining standards across the industry

"Easy to understand advanced data standards that make data collaboration better."

"A central place to discuss, develop, and implement new data standards"

"Connections and network building"

"A standard that can be used across the industry, accepted by regulators."

Next Up: Focus Groups by Stakeholder (We Want To Hear From You)

CRO

- Clinical Standards
- Product Manager
- Solution Engineer
- Statistical Programming
- Clinical Operations
- Clinical Data Management
- Trial Planning
- Consultant
- Project Manager

Biopharma

- Business Development
- Developer
- Program Lead
- Clinical Strategy
- Clinical Records Management
- Researcher
- Informatics
- Medical Safety & Regulatory
- Quality and Compliance

Technology

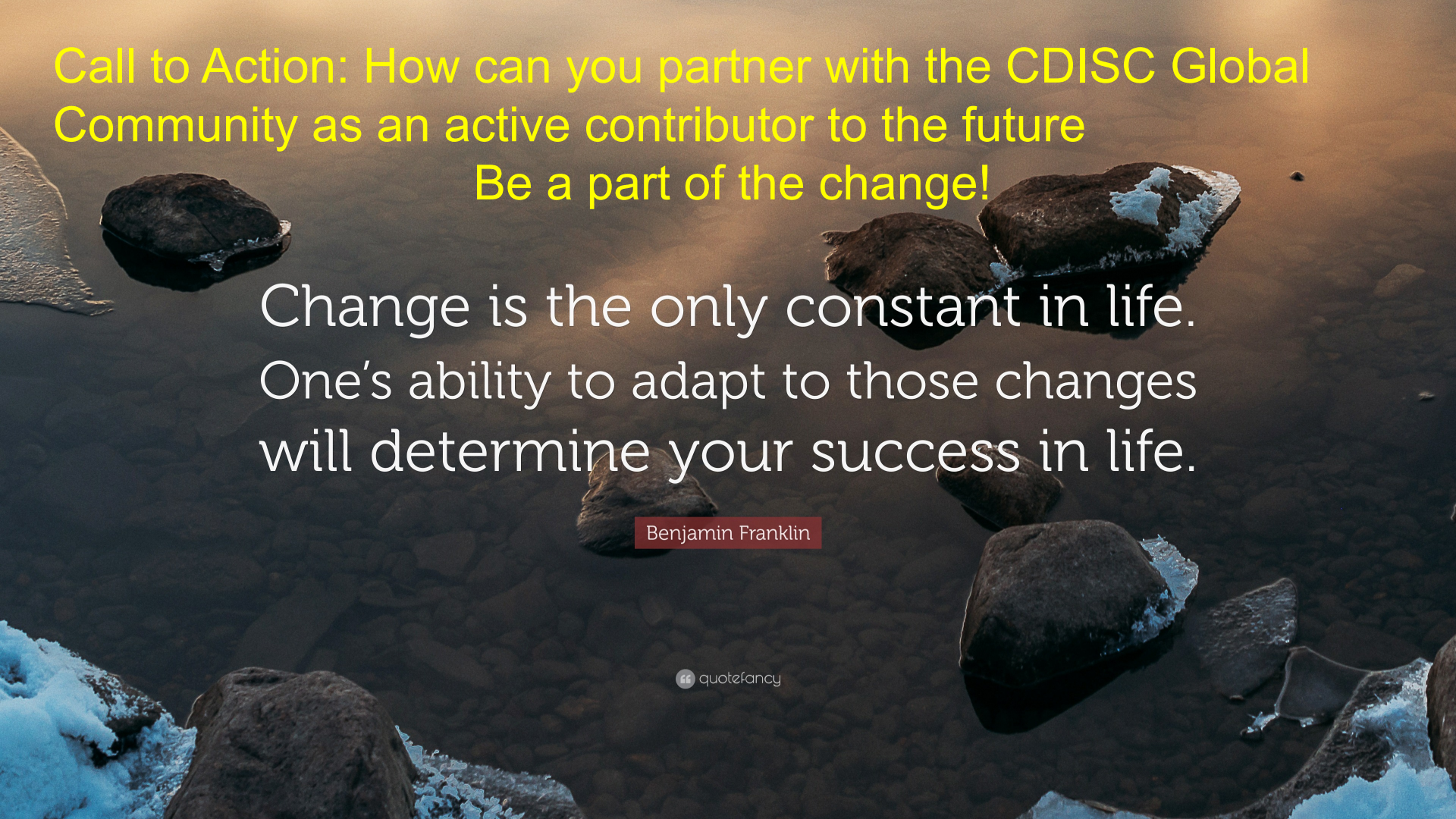
- TMF Records
- Document Manager
- System Analyst
- Data Engineer

Consulting

Government

Academic Research Institutes / Healthcare

Nonprofit Research Institutes


Call to Action: How can you partner with the CDISC Global Community as an active contributor to the future
Be a part of the change!
Change is the only constant in life.
One's ability to adapt to those changes
will determine your success in life.
Benjamin Franklin
quotefancy

Join us in Building the Future:

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

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

Join us tomorrow ~ Register @ cdisc.org

- **CDISC 360i Working Group**
  Friday, May 16, 2025
  8:30 AM-2:30 PMCET

- This working session, open to both current participants and those interested in joining the 360i transformative program, provides an exceptional opportunity to collaborate with CDISC leaders and other key stakeholders.

- The session is designed to foster meaningful discussion and hands-on contributions to shape the future of standards development and implementation.

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CDISC+TMF Europe Interchange

Milan 2026

18-22 May 2026 | Details Soon