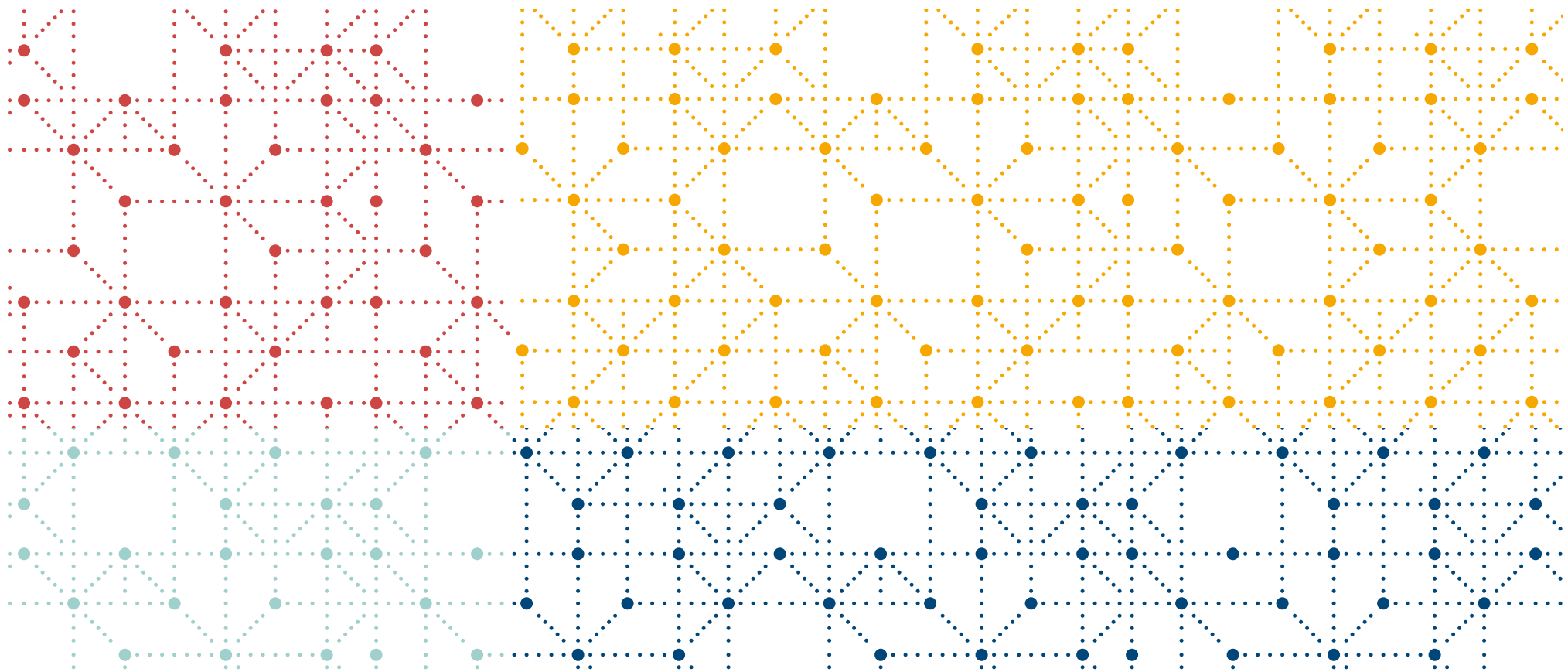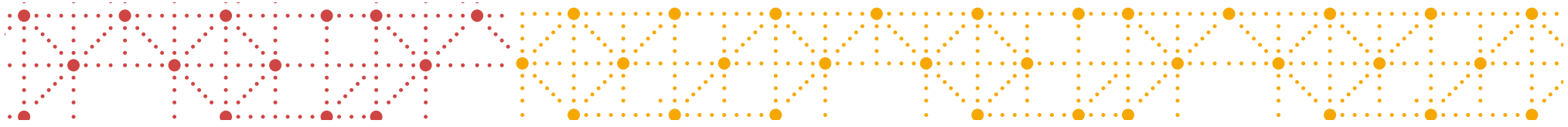# cdisc

2019–2022 Strategic Plan

Context

CDISC is on a journey of change. New sources of data and new technology platforms require CDISC standards to evolve even as the clinical, non-clinical, and observational science continues to evolve. Change and innovation are not easy, and no particular outcome is guaranteed. Yet the CDISC community and CDISC, as a nonprofit entity led by an all-volunteer Board of Directors, are committed to engaging with this change in a transparent and mutually supportive culture.

CDISC has established five high-level goals to help guide this organization, and the global community it supports, as follows:

I.   **Transform.** Transition to a multidimensional representation of CDISC standards and support automation.

II. **Expand.** Identify and prioritize adjacent research areas that can benefit from data standardization.

III. **Support.** Ensure that a vibrant global community is heard and well-served.

IV. **Include.** Reduce the barriers to entry and use for those who utilize CDISC standards.

V.   **Engage.** Raise awareness of the benefits of data standardization among key stakeholders.

This global community will attempt, learn, and iterate while maintaining the core strengths of the CDISC standards so that together we build a future where data standardization facilitates good science to help reduce human suffering.

I. TRANSFORM

Transition to a multidimensional representation of CDISC standards and support automation.

I. TRANSFORM	Transition to a multidimensional representation of CDISC standards and support automation.

ℹ	CURRENT STATE	*CDISC foundational standards are built in a two-dimensional model. There is no significant CDISC support for automation of foundational standards in the research enterprise.*

I.A. Develop multidimensional standards in an open, transparent manner that allows community members to transition with as little disruption to their research as possible while unlocking greater benefits of standardization. Engage in concrete steps to achieve end-to-end standardization.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
I.A.1	Complete CDISC 360 pilot.	Based on learnings in CDISC 360, iterate and refine the model. Create and load CDISC 360 artifacts into CDISC Library. Pilot a second CDISC 360 project in oncology, safety domains, or another high-impact area. Continue placing CDISC 360 artifacts into CDISC Library.	Extend the CDISC 360 data model to encompass external controlled terminologies and dictionaries such as LOINC, UCUM, MedDRA, etc.
I.A.2	Evolve the expression of foundational conformance rules to an electronic format to increase consistency. Instantiate multidimensional model artifacts in CDISC Library.	Initiate process to build the model for machines first, people second.	Establish a data standards collaboration framework where groups can generate extensions to the CDISC model.
I.A.3	Support use of CDISC Library API by open source, open access developers including hackathons, webinars, and other exposure of tools to the community.	Fully launch ODM 2.0 and an API.	
I.A.4	Implement cloud-based tools for all teams (including a centralized calendar) and promulgate through training.	Train CDISC volunteers and staff to utilize CDISC Library ecosystem tools to build new versions of standards for CDISC Library.	Develop a global, collaborative framework where the standards community can participate in the continuous creation and curation of data standards.
I.A.5	Commit to develop only end-to-end TAUGs from now on.	Obtain funding to retrospectively complete 9 legacy TAUGs so all are end-to-end.	Obtain funding to retrospectively complete remaining legacy TAUGs so all are end-to-end.

Primary Owners	*COO and CSO*
Secondary Owners	*Heads of Standards; VP, Data Science*

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<table>
<tr><td colspan="2" style="text-align:center">I. TRANSFORM</td><td colspan="2">Transition to a multidimensional representation
of CDISC standards and support automation.</td></tr>
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I.B. Transition to a model where volunteers develop standards first for CDISC Library. Build a new paradigm where community members can generate metadata that can become de facto a part of the CDISC standards or where that metadata can be designated as fit for a specific use case.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
I.B.1	Build an initial suite of tools to enable developing standards in the CDISC Library.	Determine the unmet needs of teams to develop standards in CDISC Library.	Build a more comprehensive suite of tools to enable developing standards in the CDISC Library.
I.B.2	Develop tools to facilitate moving content in to and out of the CDISC Library. Develop tools to facilitate community members utilizing CDISC Library content.	Conduct a community needs assessment to determine additional tools from CDISC Library that are beneficial to the community.	Publish standards models and IGs directly from CDISC Library.
I.B.3	Develop at least 4 new tools built on CDISC Library API to facilitate efficient standards development.	Train CDISC volunteers and staff to utilize CDISC Library ecosystem tools to build new versions of standards for CDISC Library.	
I.B.4	Articulate and align guiding principles for Foundational Standards development.	Build a collaborative pilot program where members can draft new content and subsequently CDISC ensures proper scope, model-compliance, and quality.	Define a mechanism whereby user generated content can be shared with the broader community whereby the content is vetted for quality and can be differentiated, for example as user-opinion, peer-reviewed, or CDISC GGG vetted.
I.B.5		Build a collaborative pilot program where member organizations can build new standards such that CDISC ensures proper scope, model-compliance, and quality.	Instantiate multidimensional model artifacts in CDISC Library. Build the model for machines first, people second.

Primary Owners	*CSO and VP, Data Science*
Secondary Owners	*CEO; Heads of Standards; Head of Data Science; VP, Development Opportunities*

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II. EXPAND

Identify adjacent research areas that can benefit from data standardization.
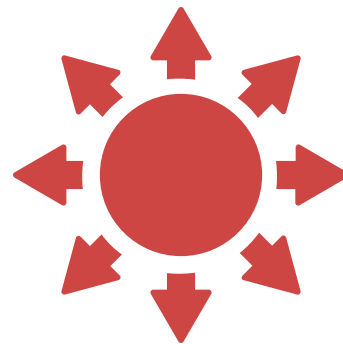
II. EXPAND	Identify adjacent research areas that can benefit from data standardization.

	CURRENT STATE	*Many stakeholders in adjacent research areas recognize the benefits of standardizing data including support for collaboration; data sharing; and rendering data findable and interoperable. CDISC has limited capacity to incentivize these stakeholders to standardize their data at this time. What CDISC can do is reduce the barriers to utilizing CDISC standards as one way to support promulgation of standardization in these adjacent research areas.*

II.A. Evaluate the following opportunities and determine whether it is ready for significant investment. Monitor, prioritize, choose, and seek external funding as appropriate. As a consequence of the evolution of the model, selectively extend CDISC standards to support new data types and / or new technologies.

- In-house expertise in RWD/RWE
- Consumer wearables
- Medical devices (in addition to consumer wearables)
- Augment/replace patient-reported outcomes data from consumer wearables and/or medical devices
- Device registry, likely via collaboration, that uniquely identifies devices and enables automated mappings to CDISC standards.
- CDISC-compliant registry toolkit that is built on the CDISC Library API.
- 'Mapping registry', which standardizes the conversion of proprietary device data to CDISC standards.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
II.A.1	Regularly engage with activities of regulators, as well as other thought leaders (e.g. Duke Margolis Center) and standards development organizations including ICH, ISO HL7 and ICHOM to align and increase global understanding.		
II.A.2	Establish formal partnerships with appropriate SDOs—for example ICHOM, HIMSS, Comet, HL7 FHIR, and OMOP—to ensure aligned development of CDISC standards and these RWD sources.		

Primary Owners	*CSO and VP, Development Opportunities*
Secondary Owners	*VP, Data Science; COO; CEO; Heads of Standards*

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II. EXPAND	Identify adjacent research areas that can benefit from data standardization.

II.B. Pilot extension of the CDISC standards to better support academic investigators. Provide those researchers the knowledge and tools they need to support good science.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
II.B.1	Expand educational offerings to a specific set of offerings for academic users of CDISC standards.	Establish a strategic roadmap for CDISC engaging academic investigators incorporating milestones. Seek input from academic researchers who already utilize CDISC standards regularly.	
II.B.2	Understand the gaps in terms of academic researchers using CDISC. Establish guidelines for a "fit for use" designation to address the needs of academic researchers, not for the sponsor-regulator submission use case.	Establish at least two active collaborations with academic consortia to generate new extensions of the standards for observational studies e.g., a registries toolkit.	Promulgate at least five new open-source, open-access tools for academic researchers built from the CDISC Library API.
II.B.3	Perform a BRIDG alignment / update need analysis	Depending on need analysis outcome, obtain buy-in from the BRIDG Steering Committee and obtain funding to build a full machine-readable instantiation of BRIDG in CDISC Library.	Link BRIDG alignment metadata to the CDISC standards metadata in the CDISC Library and include this content in API responses.

Primary Owners	*VP, Development Opportunities and CSO*
Secondary Owners	*VP, Data Science; CEO; COO*

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III. SUPPORT

Ensure that a vibrant global community is heard and well-served.

III. SUPPORT	Ensure that a vibrant global community is heard and well-served.

	CURRENT STATE	*A vibrant global community composed of those who make and utilize standards exists and requires CDISC to continue to support their aspirations and to understand their needs even as changes including new sources of data and new technologies continue at a significant pace.*

III.A. Ensure a positive culture and utilize technology tools so volunteers can be recruited, onboarded, and retained so the global CDISC community can benefit from their expertise and skills.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
III.A.1	Engage in a user experience process to determine how to ease onboarding of new volunteers from initially seeking information through to orientation. Formalize orientation of all new volunteers.	Generate an annual volunteer recruitment strategy (based on the needs of teams and on strategic plan goals) and process (connecting with partners such as PharmaSUG and PhUSE and with SMEs from past TAUGs and other projects).	In light of CDISC 360 results, consider the structure of all teams to facilitate collaborative creation of metadata and of tools.
III.A.2	Formalize team lead selection, leadership rotation, and succession planning.	In addition to long-term commitments and where practicable, parse projects into short-term sprints and match with volunteers who can make short-term time commitments.	

Primary Owners	*Heads of Standards and Head of Data Science*
Secondary Owners	*CSO; VP, Data Science*

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III.B. Operate globally, building greater local visibility and impact in growing markets while maintaining in established markets.

		Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
III.B.1		**Support Mature Markets** Ensure strong Interchanges in core markets: currently US, Europe, Japan.	Launch a North America 3C to support the mature North American market.	
III.B.2		**Support Growth markets** Launch engagement in South Korea. Continue to grow engagement in China and support China Interchange.	Establish at least one additional regular conference that generates net revenue. Hold CDISC Days in India.	Based on local support, consider launching a regular Interchange in South Korea and / or India. Hold CDISC Days in Australia, New Zealand, Singapore, or another potential growth new market.
III.B.3		**Ensure accessibility of CDISC content in users own languages, where practical** Plan for promulgating major content in English, Japanese and Chinese.	Facilitate an open-source web-based depository for translations of CDISC materials into other languages where the content cannot be curated by CDISC.	Define a mechanism whereby user-generated content is vetted for quality and can be differentiated, for example, as user-opinion, peer-reviewed, or CDISC GGG approved and can be shared with the broader community.

Primary Owners	*VP, Membership and Events and CSO*
Secondary Owners	*COO; CEO; CSO; Heads of Standards*

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IV. INCLUDE

Reduce the barriers to entry and barriers to use for those who utilize CDISC standards.
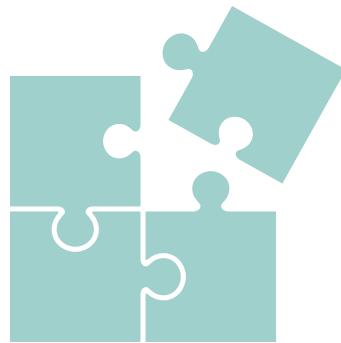
IV. INCLUDE	Reduce the barriers to entry and barriers to use for those who utilize CDISC standards.

	CURRENT STATE	There are high barriers to entry and use including (1.) CDISC standards and documentation are largely only available in English; (2.) it is expensive for most entities initially to standardize comprehensively with CDISC standards (although most entities later experience cost savings related to standardization); and (3.) standards implementers must become standards experts in order to attain significant benefits of standardization.

IV.A. Facilitate the development of quality tools to help unlock the benefits of standardization to a variety of community members/stakeholders.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
IV.A.1	Articulate and harmonize conformance rules for all foundational standards.	Build a collaborative pilot program where member organizations can build new standards such that CDISC ensures proper scope, model-compliance, and quality.	Instantiate multidimensional model artifacts in CDISC Library. Build the model for machines first, people second.
IV.A.2	Create an online examples library.	Train CDISC volunteers and staff to utilize CDISC Library ecosystem tools to build new versions of standards for CDISC Library.	
IV.A.3	Articulate and align guiding principles for foundational standards development.		
IV.A.4	Empower implementers through tooling, education and training. Support the efforts of partner organizations including PhUSE, SCDM, and PharmaSUG.		

Primary Owners	*Heads of Standards; Head of Data Science*
Secondary Owners	*VP, Data Science; CSO*

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<tr><td colspan="2">**IV. INCLUDE**</td><td>Reduce the barriers to entry and barriers to use
for those who utilize CDISC standards.</td></tr>
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IV.B. Provide high-quality training and education so that the global community can benefit from CDISC standards.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
IV.B.1	Pilot a mechanism to expose knowledge inside CDISC to members via the website in order to improve heterogeneity of implementations.	Generate a full self-help desk where the exposed knowledge is searchable. The self help-desk will enable community contributions, which may be curated by CDISC.	
IV.B.2		Develop a matrix that identifies demand for courses in languages other than English and recruit non-English speaking authorized instructors as necessary.	
IV.B.3	Build a Certification program that certifies individuals in implementing SDTM and ADaM at an advanced level.	Build a Certification program that certifies individuals in implementing SEND and CDASH at an advanced level.	Build a Corporate Certification program where a CDISC-member organization with a critical mass of certified individuals signifies corporate certification.
IV.3.4	Expand the CDISC webinar series to reflect ongoing and new work of teams. Continue to provide webinars in global time zones and to place webinar recordings on the CDISC website.	Leverage 3Cs and User Groups to develop new tools and new meta-content for CDISC standards.	Share stories of research successes empowered by data standardization in media sources other than those specific to the pharmaceutical industry.

Primary Owners	*VP, Development Opportunities and VP, Data Science*
Secondary Owners	*COO; Head of Data Science; VP, Membership and Events*

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V. ENGAGE

Raise awareness of the benefits of data standardization among key stakeholders.

V. ENGAGE	Raise awareness of the benefits of data standardization among key stakeholders.

ℹ **CURRENT STATE**	*CDISC is a small organization and thus relies on many partners to complete aspects of our mission. At the same time, partners change over time as other organizations begin and end and as the many industries touched by CDISC evolve. CDISC must be vigilant to identify the current optimal mix of partners to best ensure our goals are achieved. In additional, not all stakeholders among the industries and stakeholders CDISC touches are aware of the benefits of standardization.*

V.A. Be an excellent partner.

	Near-term *1-18 months*	Medium-term *19-36 months*	Long-term *37 months or longer*
V.A.1	Engage with TransCelerate BioPharma on the Digital Data Flow Initiative	Align Digital Data Flow Initiative and CDISC 360. Staff-led gap analysis to determine how 360 results constrain a protocol content standard.	In collaboration with one or more key external initiatives, launch a protocol standard that can be legitimately described as a CDISC standard and that encompasses Statistical Analysis Plan and Clinical Trial Report standards.
V.A.2	Engage regulatory authorities around the globe with emphasis on US FDA, Japan PMDA, China NMPA, and EU EMA.	Ensure the sustainability of CDISC standards by ensuring their mandate and use in the rules governing clinical research data development and communication.	
V.A.3	Identify specific partners on critical activities (1.) development of a protocol model; (2.) quality implementation of CDISC standards; (3.) semantic interoperability of CDISC standards with other data standards and relevant code lists.	Be attentive and responsive to partners and note that partnerships may evolve and even change over time. Ensure that critical functions are maintained even if partners involved in those functions move on.	
V.A.4	Deepen key current partnerships including those with C-PATH; NCI EVS; PhUSE; PharmaSUG; SCDM; BRIDG Steering Committee; TransCelerate BioPharma; regulators; IMI; NIH divisions; AMED; and other entities that share CDISC's vision of developing quality data standards in service to humanity. Demonstrate these partnerships in tangible agreements. Regularly review and update partnerships to ensure they represent stakeholders.	Engage governmental funders, patient foundations, and private foundation funders of scientific research to educate them on the benefits of standardization. Obtain commitments from at least one new funder to request data in CDISC standards.	Attain at least two new significant recognitions of CDISC standards among government, funding, or regulatory entities. (Significant commitments include a mandate, writing CDISC standards into national law, or otherwise requiring data in CDISC standards.)

Primary Owners	*CEO; VP, Membership and Events; VP Development Opportunities*
Secondary Owners	*COO; CSO; VP Data Science*

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