CDISC UPDATE
20 February 2020

2019 In Review and Looking Forward to 2020

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Strategic Plan Goals

I. Transform
II. Expand
III. Support
IV. Include
V. Engage

I. Transform

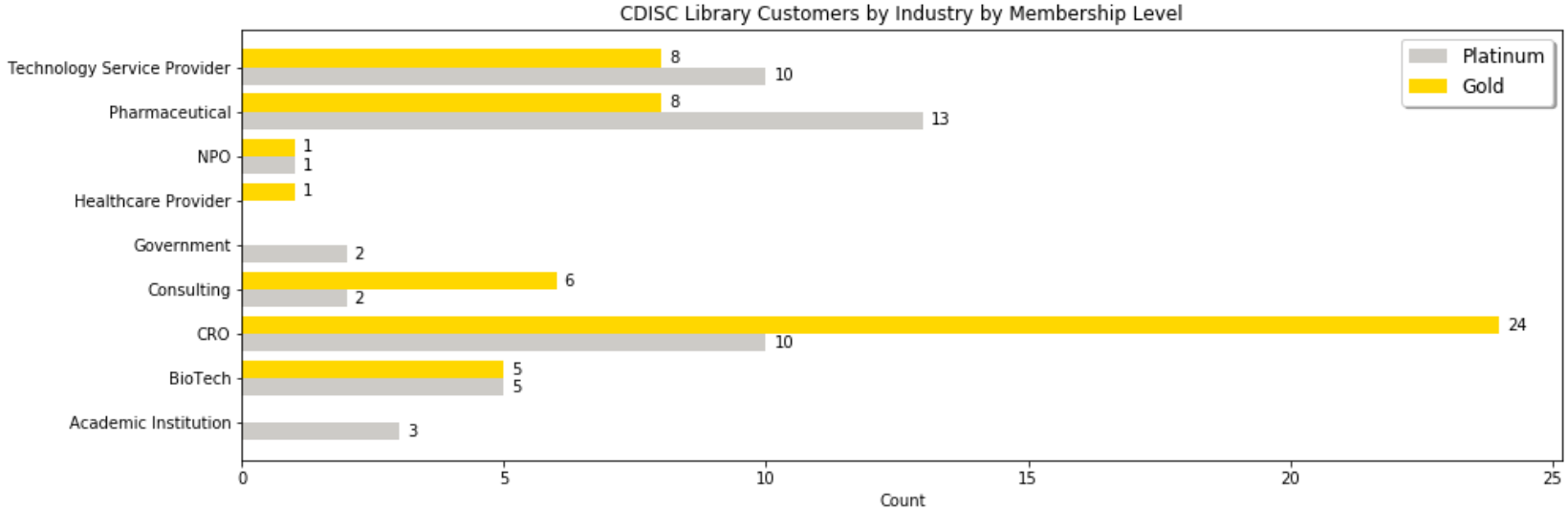
- Complete CDISC 360 pilot.
- Evolve the expression of foundational conformance rules to an electronic format to increase consistency. Instantiate multidimensional model artifacts in CDISC Library.
- Support use of CDISC Library API by open source, open access developers including hackathons, webinars, and other exposure of tools to the community.
- Implement cloud-based tools for all teams (including a centralized calendar) and promulgate through training.
- Commit to develop only end-to-end TAUGs from now on.

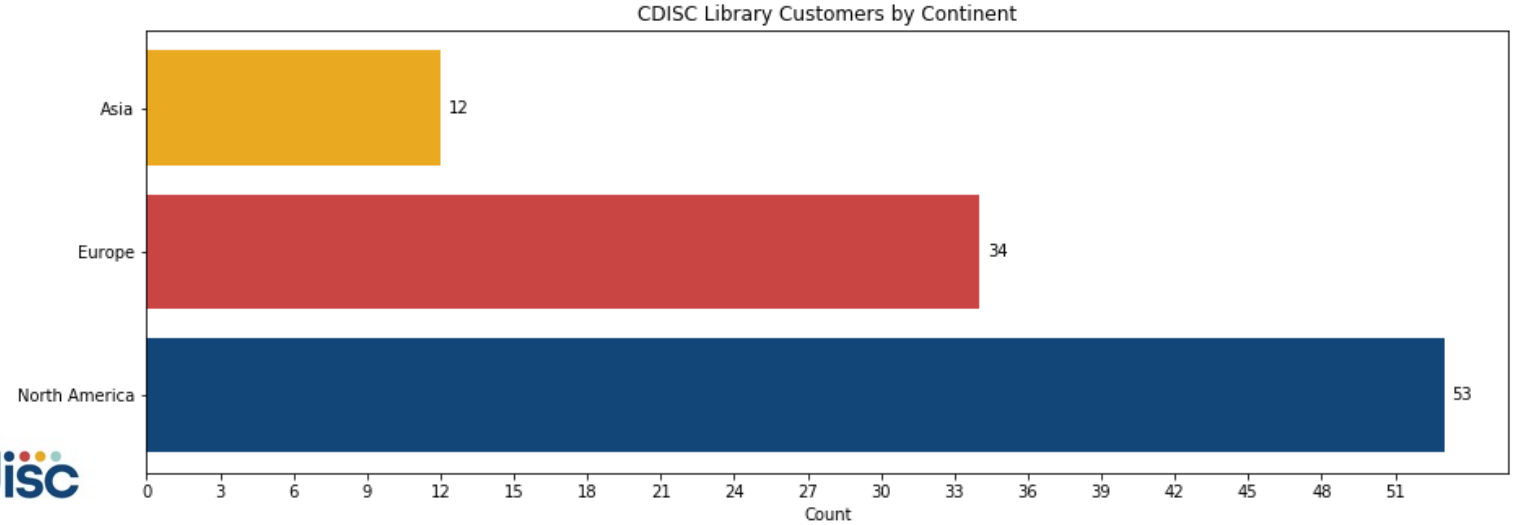
I. Transform

- Build an initial suite of tools to enable developing standards in the CDISC Library.
- Develop tools to facilitate moving content in to and out of the CDISC Library. Develop tools to facilitate community members utilizing CDISC Library content.
- Develop at least 4 new tools built on CDISC Library API to facilitate efficient standards development.
- Articulate and align guiding principles for Foundational Standards development.

2019 Transform Highlights

- We have launched CDISC 360 with a significant number of participating companies and the 18-month project is on track.
- More than 100 member companies have signed on to use the CDISC Library API. We have engaged several member companies that will build tools on top of the API as well as one member company that will offer it's tool to build the examples library (which we will call "examples collection" to minimize confusion.
- Our teams are effectively articulating guiding principles.
- All five new TAUG agreements are BTE.


CDISC Library Customers by Industry by Membership Level
Platinum
Gold
Technology Service Provider
Pharmaceutical
NPO
Healthcare Provider
Government
Consulting
CRO
BioTech
Academic Institution
8
10
8
13
1
1
1
2
6
2
24
10
5
5
3
0
5
10
15
20
25
Count


CDISC Library Customers by Continent
Asia
Europe
North America
12
34
53
0
3
6
9
12
15
18
21
24
27
30
33
36
39
42
45
48
51
Count

II. Expand

- 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.
- 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.
- Expand educational offerings to a specific set of offerings for academic users of CDISC standards.
- 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.
- Perform a BRIDG alignment / update need analysis

Expand Highlights

- Peter Van Reusel represented CDISC on a Margolis Center panel sponsored by FDA on standardizing analysis concepts. FDA use case in CDISC 360 identified.
- Members of the executive team have had four conversations with leading HL7 FHIR volunteers on interoperability with more to come.
- We have engaged a well-qualified contractor for the CDISC RWD Connect project to better understand and meet the needs of academic researchers. So far more than a dozen key individuals have agreed to participate including staff from FDA, PMDA, and EMA.
- Working with BRIDG leadership we are exploring public exposure of the BRIDG model in an open source format.

IIII. Support

- 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.
- Formalize team lead selection, leadership rotation, and succession planning.
- **Support Mature Markets.** Ensure strong Interchanges in core markets: currently US, Europe, Japan.
- **Support Growth markets.** Launch engagement in South Korea. Continue to grow engagement in China and support China Interchange.
- **Ensure accessibility of CDISC content in users own languages, where practical.** Plan for promulgating major content in English, Japanese and Chinese.

Support Highlights

- Staff and volunteer leadership completed the volunteer needs assessment and implemented a standardized orientation. Working with volunteers, Marine, Peter, Amy, Bess and the team have implemented the team leadership succession planning.
- Our Interchanges in Europe and Japan experienced slightly declined and significantly declined attendance, respectively. US Interchange achieved record turnout.
- China Interchange grew significantly.
- Japanese translations are ahead of schedule. China translations are on track to be complete by year end. New webinar translations into Japanese are on track.

Korea Summit

- November 7, Daegu, South Korea
- 200+ attendees
- Free event, 100% underwritten by Government of South Korea, City of Daegu, Daegu Digital Industry Promotion Agency (economic development agency), MediCity (local coalition of medical schools and private sector)
- Meeting and lunch with Dr. Syong-ryu Lee of Ministry of Food and Drug Safety (MFDS)
- Interest in repeating a small scale, paid version in 2020.

IV. Include

- Articulate and harmonize conformance rules for all foundational standards.
- Create an online examples library.
- Articulate and align guiding principles for foundational standards development.
- Empower implementers through tooling, education and training. Support the efforts of partner organizations including PHUSE, SCDM, and PharmaSUG.
- Pilot a mechanism to expose knowledge inside CDISC to members via the website in order to improve heterogeneity of implementations.
- Build a Certification program that certifies individuals in implementing SDTM and ADaM at an advanced level.
- 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.

Include Highlights

- Teams are on track in terms of articulating conformance rules.
- Formedix is donating Formedix-On as an online tool for examples library (examples are from TAUG).
- PHUSE MOU will be signed for three-year term.
- “Knowledge Vault” a mechanism to expose CDISC-internal knowledge on implementation and standards to broader community is launched in beta-version.
- SDTM Certification task force meeting next week in Virginia.

V. Engage

- Engage with TransCelerate BioPharma on the Digital Data Flow Initiative
- Engage regulatory authorities around the globe with emphasis on US FDA, Japan PMDA, China NMPA, and EU EMA.
- 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.
- Deepen key current partnerships …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.

Good news to share.

The Chinese NMPA has issued a new eCTD guidance for public comment.

如果申请人以临床数据交换标准协会（CDISC）标准递交数据，则可将研究数据表格模型（SDTM）数据库视为原始数据库，分析数据模型（ADaM）数据库视为分析数据库。
If the applicant submits data in accordance with the Clinical Data Interchange Standards Consortium (CDISC) standard, the Study Data Tabulation Model (SDTM) database can be considered the original database, and the Analytical Data Model (ADaM) database is considered the analysis database.

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What does this mean?

- It is not technically a mandate. And we want to avoid using that term.
- Nevertheless CDISC is the only standard mentioned named by NMPA in this new technical guidance.
- Data submitted in SDTM and ADaM will be administratively accepted. Data submitted in other standards and non standardized data face a set of acceptance criteria.
- This is an even stronger statement by NMPA supporting use of CDISC in China than the past recommendation.
- More than two years of focus on China are bearing fruit for CDISC.
- CDISC is now, even more than ever, the global standard.

Next steps.

- We prepared a positive, affirming response for the public comment period in Chinese. CDISC recommends two changes:
  - Increase break point of data sets from 4MB to 5MB (to match what FDA and PMDA require)
  - Recommend Define.XML instead of general XML or PDF for data description file.
- NMPA has coordinated an in-person meeting in Beijing later this month.
- Response and changes, if any, from NMPA should go up on CDISC.org soon.
- Staff will work with NMPA and our China stakeholders to prepare an appropriate press release, member communications.

Looking Forward to 2020

I. Transform

- CDISC 360, and what comes after?
  - Plan for how we rebuild the backend model
  - Pilot community curation of meta-content
- Launch ODM 2.0 and API
- Train volunteers to build machine-readable standards in the Library
- 9 new BTE TAUGs
- Continue to add Library content and conduct community-wide needs assessment for Library-based tools
  - Secure commercial and open sources tools built on Library API

From a Standards Development Perspective, What Are the Next Steps to Advance to Standards as Metadata?

Assumptions:

- We're in the beginning phases of developing standards as metadata
- We're in the beginning phases of the pipeline standards development architecture
- We're using the pipeline architecture for the next few years
- We're committed to developing standards as metadata

II. Expand

- Continue to engage regulators
- Continue key alliances
- Complete RWD Connect and establish a strategic roadmap for CDISC engaging academic investigators: tools, goals, funding
- Explore an extension of the standards, e.g. registries toolkit
- Consider how to develop a useful machine-readable instantiation of BRIDG in Library

III. Support

- Volunteer recruitment including short-term commitment projects
- Recruit and launch NA3C
- New profitable conference
  - TechniCon
  - Korea Interchange
  - Something else?
- Plan for CDISC India Days (mid-2021)
- Continue to add updated Japanese and Chinese pages on website

IV. Include

- Pilot community curation of meta-content
- Train volunteers to build machine-readable standards in the Library
- Develop a matrix that identifies demand for courses in languages other than English and recruit additional non-English speaking authorized instructors
- Fully launch certification for SDTM and ADaM.

V. Engage

- One new significant mandate
- Align with DDF: CDISC 360 is the content.
- Monitor partnerships and ensure correct mix over time.
- Engage governmental funders, patient foundations, and private foundation funders of scientific research to educate them on the benefits of standardization.

MEMBERSHIP

If you are a CDISC Member

We Thank You!

It is our members' support which enables us to develop standards, keeping it free and accessible to all.

CDISC Members Drive Global Standards.

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