CDISC Library

CDISC / Microsoft Workshop

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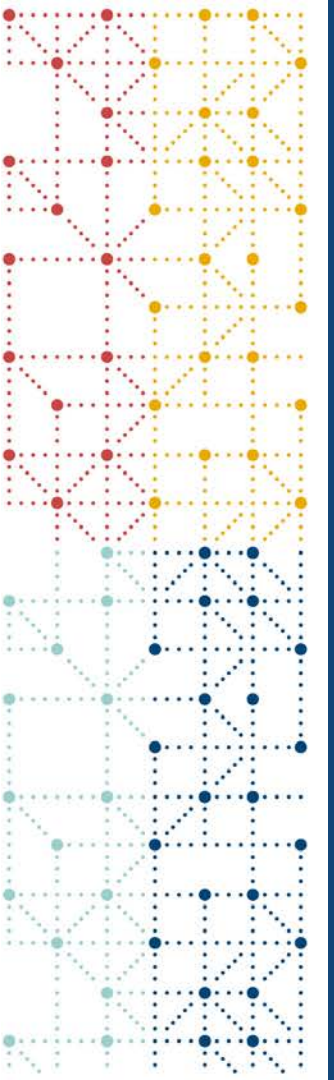
CDISC Library

1. CDISC Library on Azure
2. CDISC 360 Implementation
3. Access and Membership Levels
4. New Environments
5. Private CDISC Library Instances
6. Development Approach

Basic Premise: Solutions Over Specifications

- Standards implementers are interested in solutions to their data processing needs
  - Reduce reliance on experts that have mastered very long and detailed specifications
  - This includes standards development and management
- Embedding knowledge of standards in software tools is the best way to make CDISC standards implementations easier and more consistent
  - Maximize the value members get from their investment in standards
  - Maximize the benefits to members from our investment in CDISC Library
- CDISC 360 and CDISC Library seek to lower barriers to software tool development
  - Make it simpler to build software that automates standards-based processes

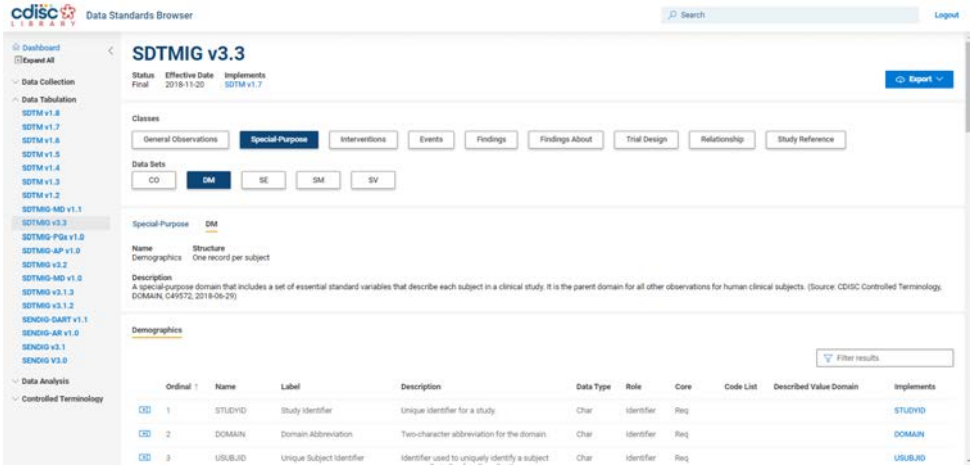


1. CDISC Library on Azure

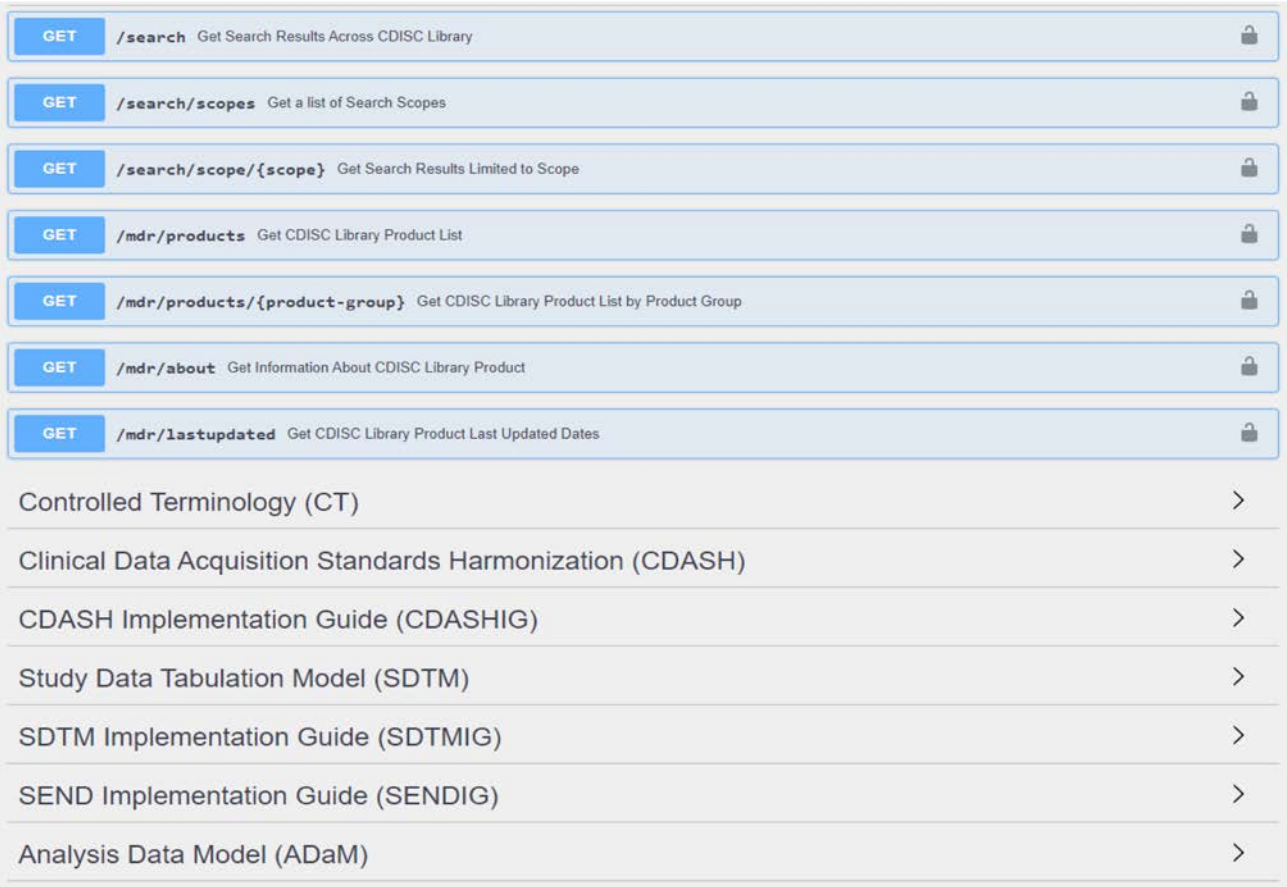
CDISC Library is moving to Azure

CDISC Library on Azure

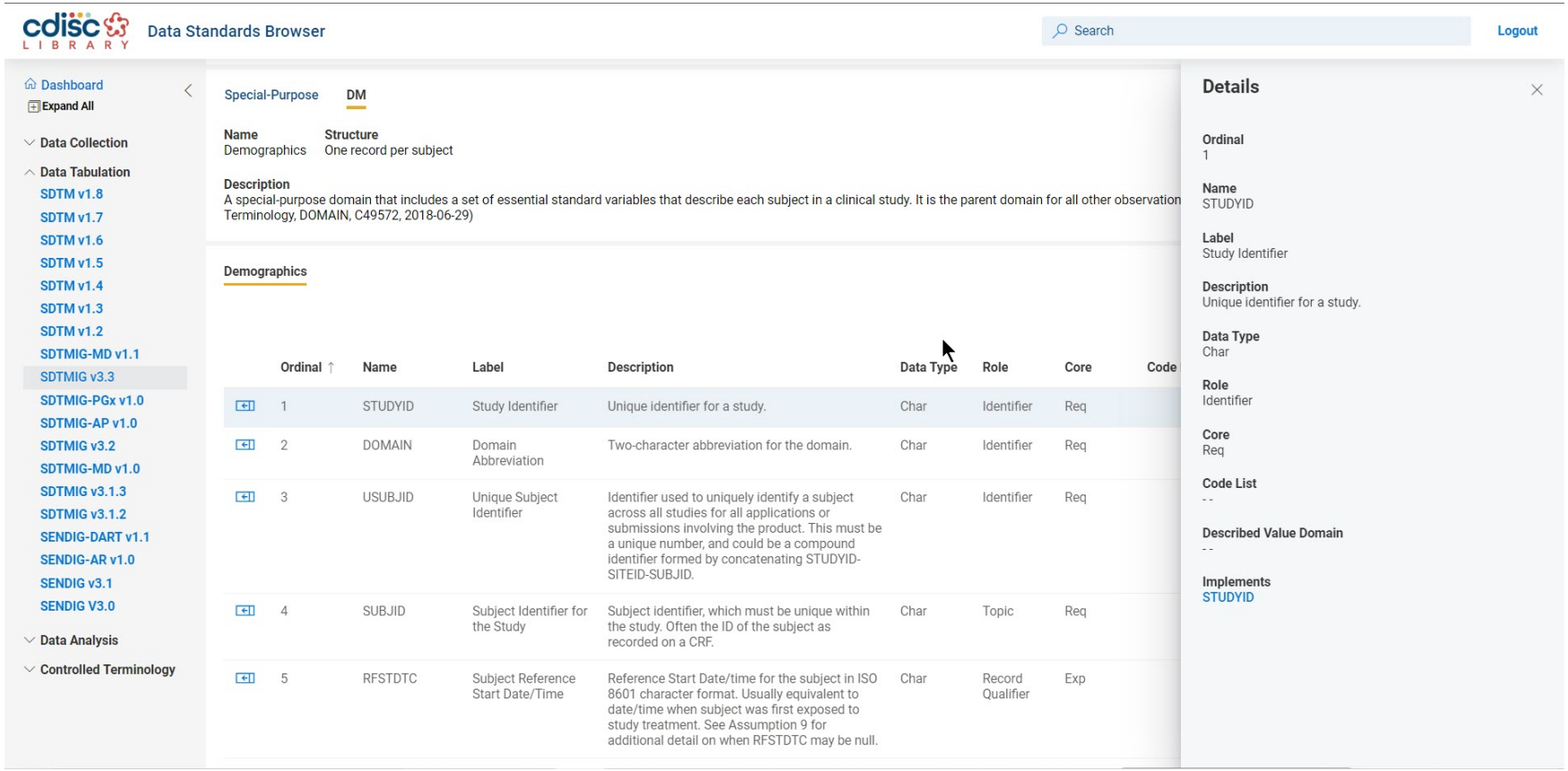
- Moving to a new version of CDISC Library hosted on Azure
  - Developed in partnership with Microsoft
  - Maintains the same CDISC Library API and an improved Data Standards Browser
- CDISC has the flexibility to update the code, models, and environment
  - Removes technical and business constraints on how, what, and when we update the system
- Basis for a new platform
  - Authoring standards
  - CDISC 360 support
  - Collaborative curation



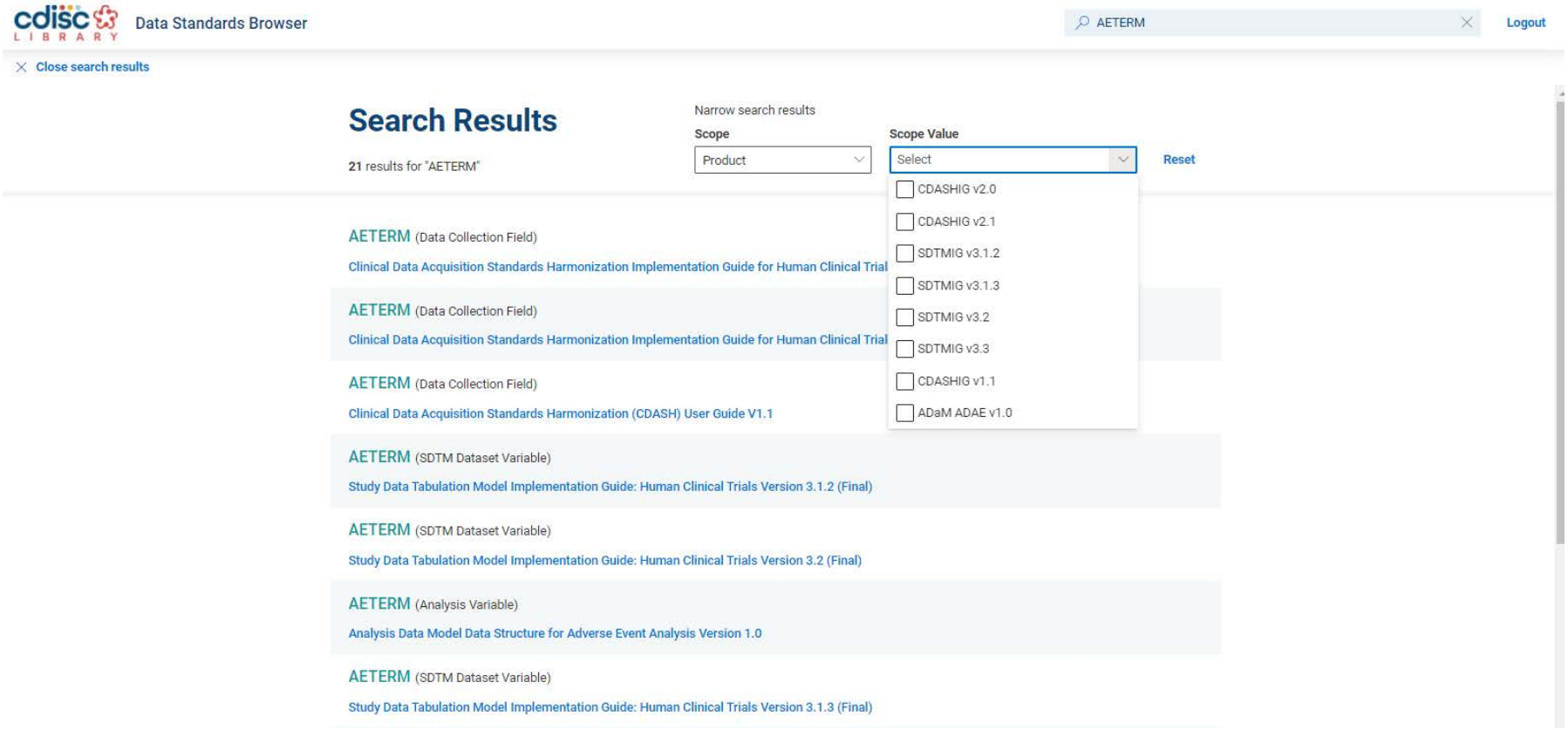
CDISC Library on Azure: API Remains Unchanged



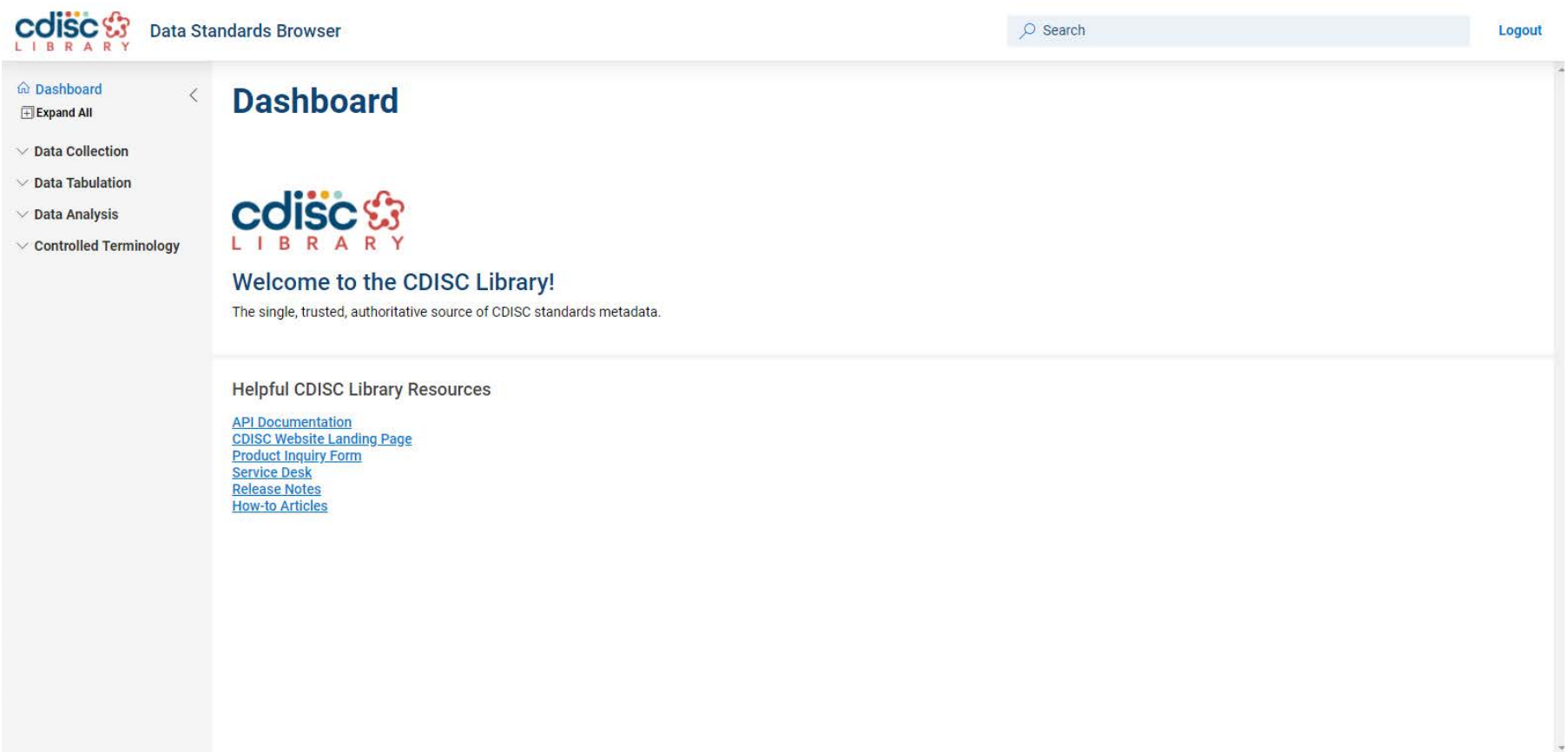
CDISC Library on Azure: Improved Data Standards Browser

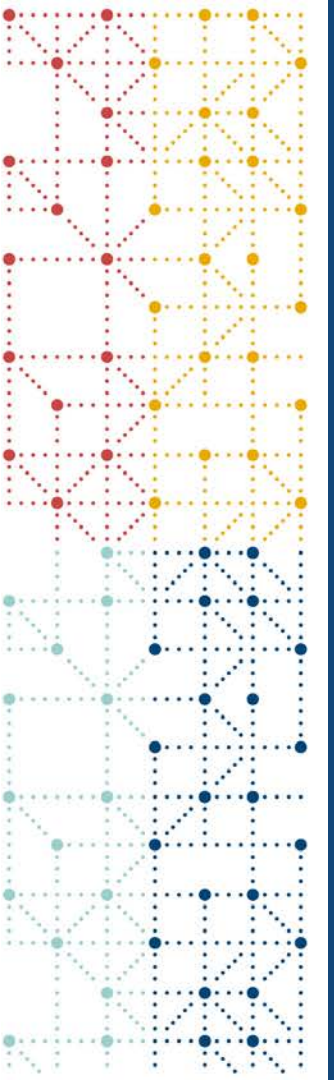


Data Standards Browser: Cognitive Search



Data Standards Browser: Room to Grow





2. CDISC 360 Implementation

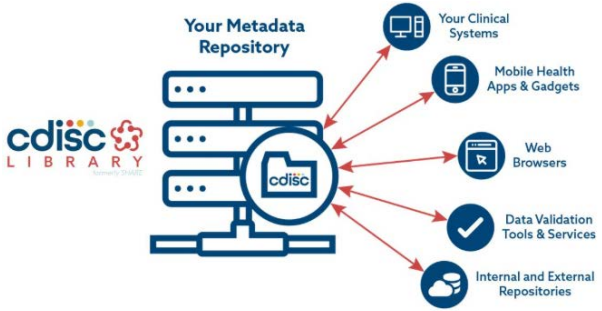
CDISC 360 and the CDISC Library

Goals:

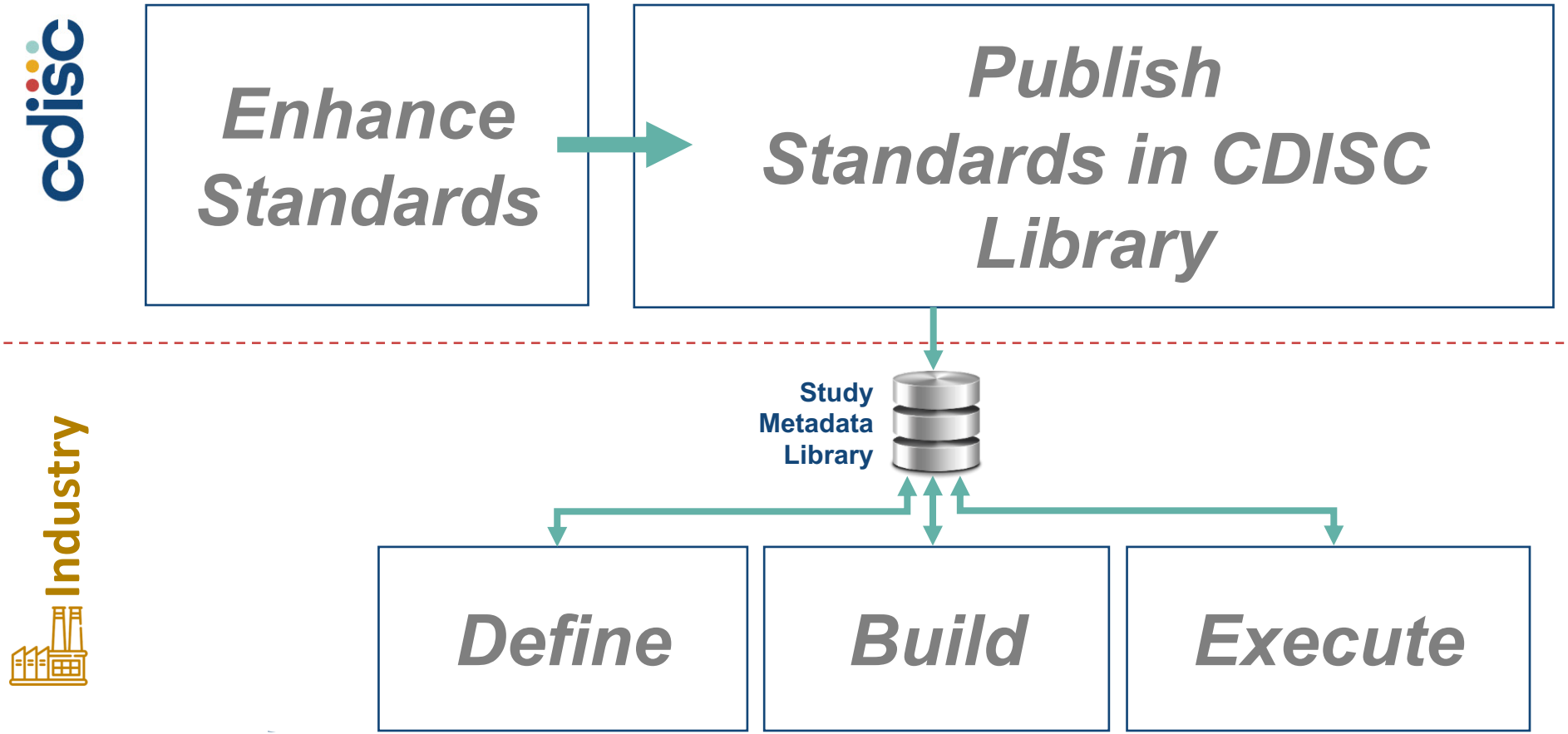
- Increase study implementation automation
- Reduce study implementation variability

Building Tools using the CDISC Library

Use CDISC Library to create additional concept-based metadata to support software tools that will provide additional study implementation automation while reducing the variability across CDISC standards implementations

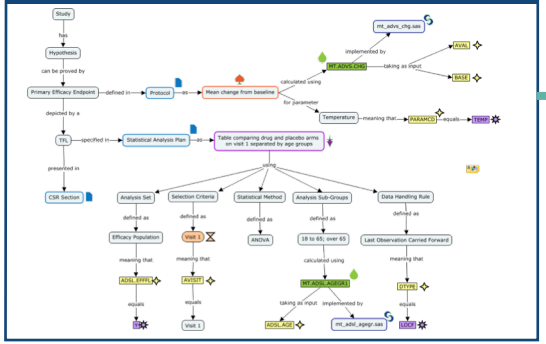


CDISC Library: Publishing CDISC 360 Pilot Metadata



CDISC 360: Applications

Workstream 1 - *ENHANCE STANDARDS*



Biomedical, Analysis Concepts, & Templates

Workstream 2 - *PUBLISH STANDARDS*

Load into library

Biomedical Concepts
Analysis Concepts
Foundational Standards

cdisc LIBRARY
formerly SHARE

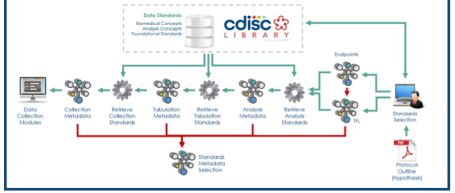
API

Extend API's

Transform concepts in machine readable form

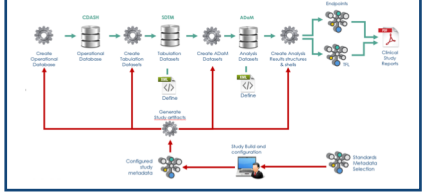
Study Metadata Library

Workstream 4 - *DEFINE*



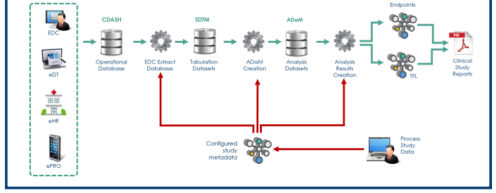
Identify and select standards specification (Use Case 1)

Workstream 5 - *BUILD*



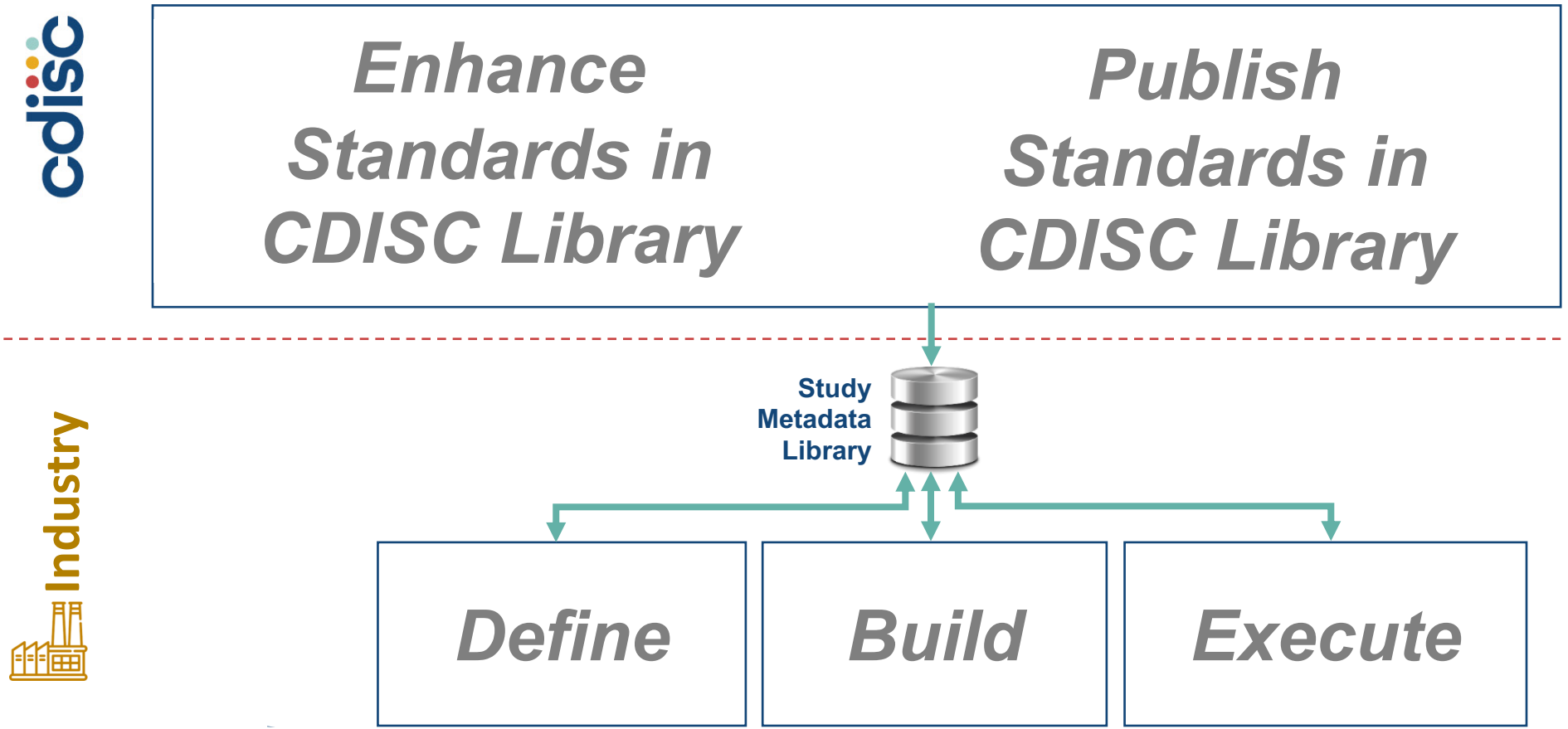
Configure study specification and create artifacts (Use Case 2)

Workstream 6 - *EXECUTE*

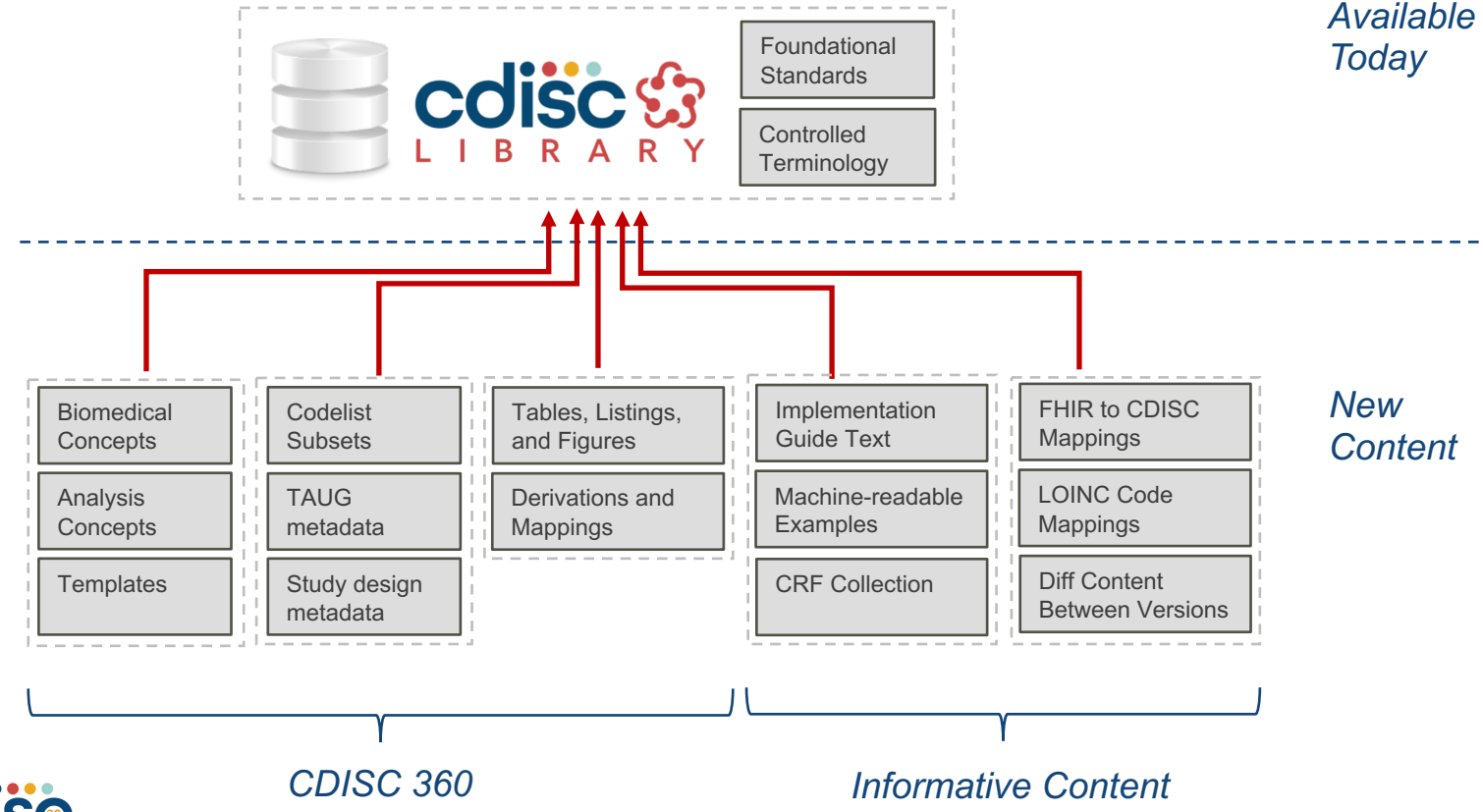


Automatically process and transform data (Use Case 3)

CDISC Library: Author, Publish, and Manage Standards

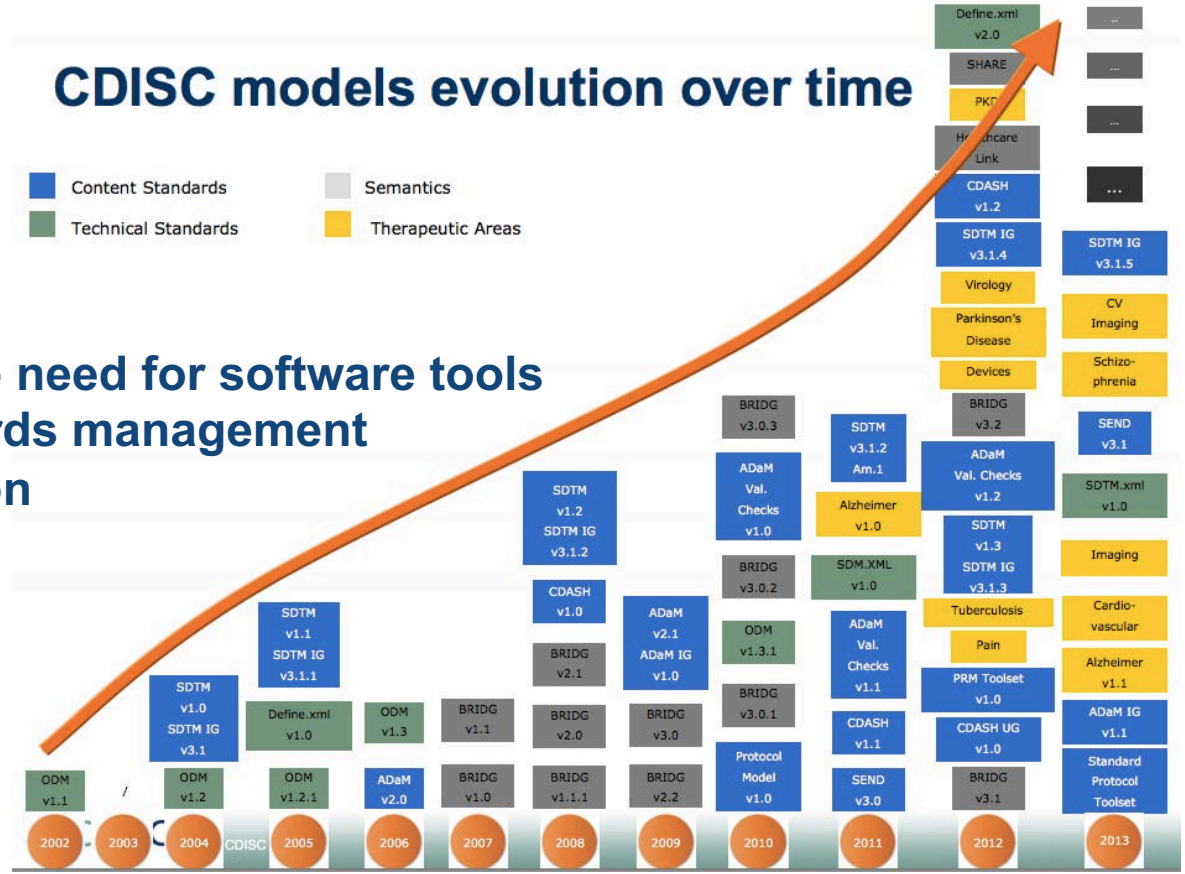


CDISC Library on Azure: New Content & Tools



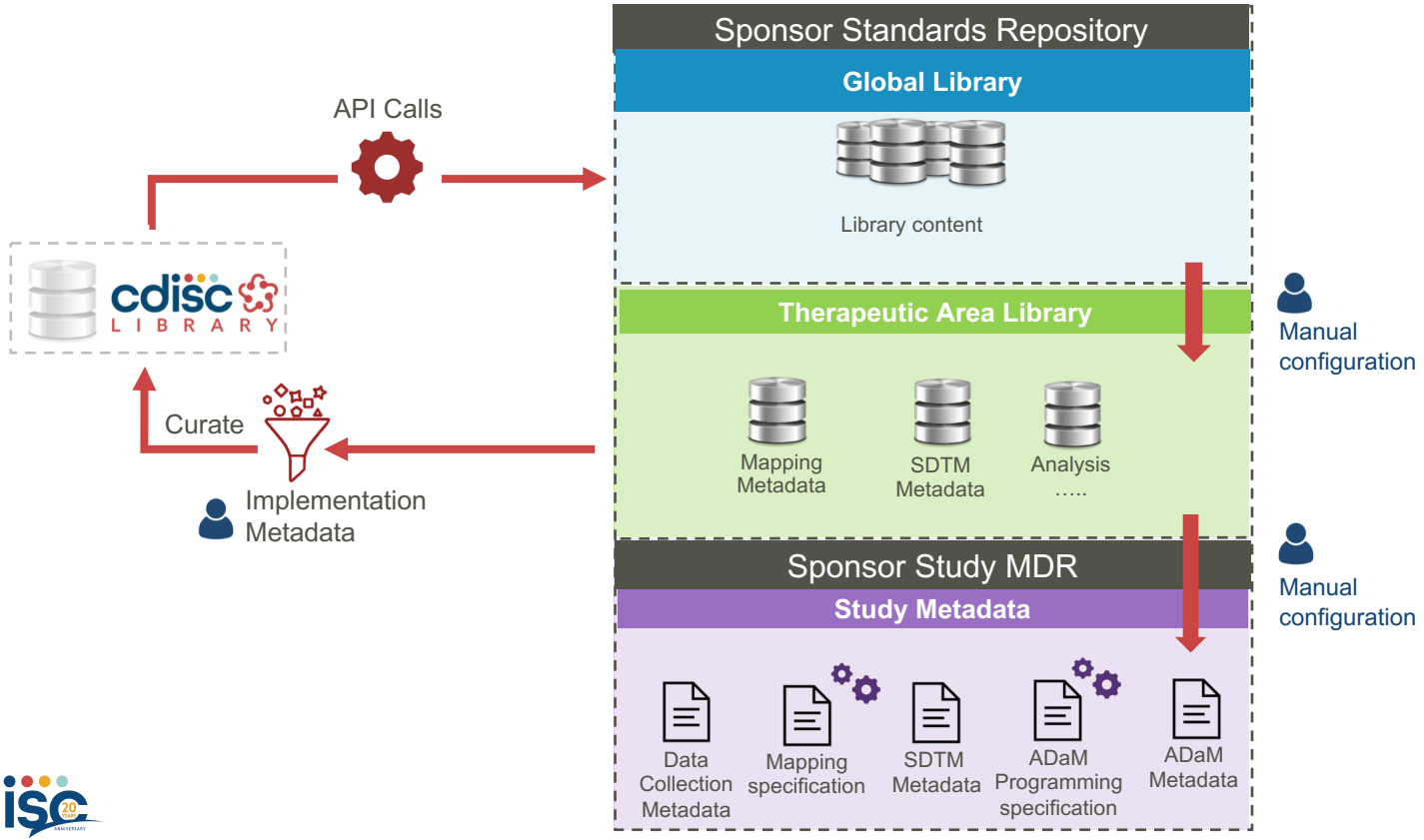
Standards Growth Projections Steepen…

…emphasizing the need for software tools to support standards management and implementation



Slide courtesy of Lauren Shinaberry, Business & Decision Life Sciences

Collaborative Curation: Collaborative Standards Authoring and Governance



3. Access and Membership Levels

Developer access

Titanium – New Membership Level

- **Federated Model**
- **Create a Library Advisory Board: Investors have a vote**
  - Functionality priority
  - User Requirements
- **Opens back-end access**
  - Authoring, governance, integrated metadata

No account limitation (all@company.com)

- Ability to 'deploy' on own environment
- Community curation of content

No bandwidth limit (fair use policy)

Members – Via CDISC membership

- **Additional functionality**
  - Full Standards download
  - Diff tables

Named accounts

Per plan

Bundles

Bundle Option	Bundle Cost*	Bandwidth Allocation % (per bundle)**
10 accounts	$2,500/year	4 GB/month
20 accounts	$3,500/year	8 GB/month
50 accounts	$5,000/year	20 GB/month

Gold

License	Maximum Bandwidth	Maximum # of Accounts
Member	1.5 GB/month	2
Commercial	2.5 GB/month	3

Platinum

License	Maximum Bandwidth	Maximum # of Accounts
Member	2 GB/month	3
Commercial	3 GB/month	4

Non Members - World – Free of charge

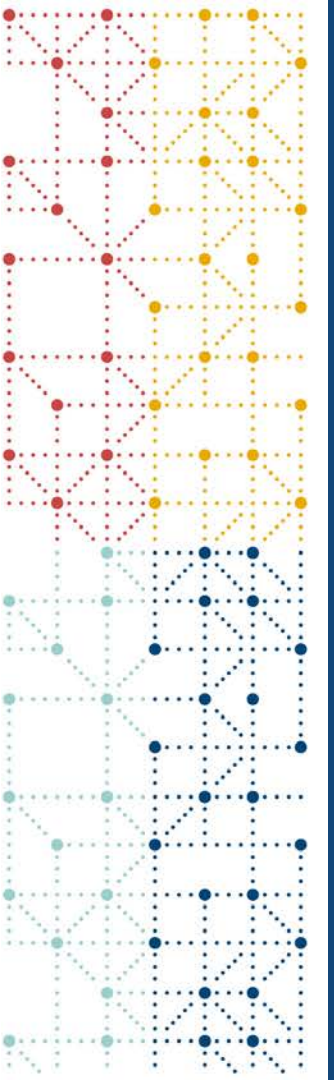
- **"Adoption of standards"**

Self sign-up

- Small downloads (XLS – CSV)

Limited bandwidth (browsing only)

API

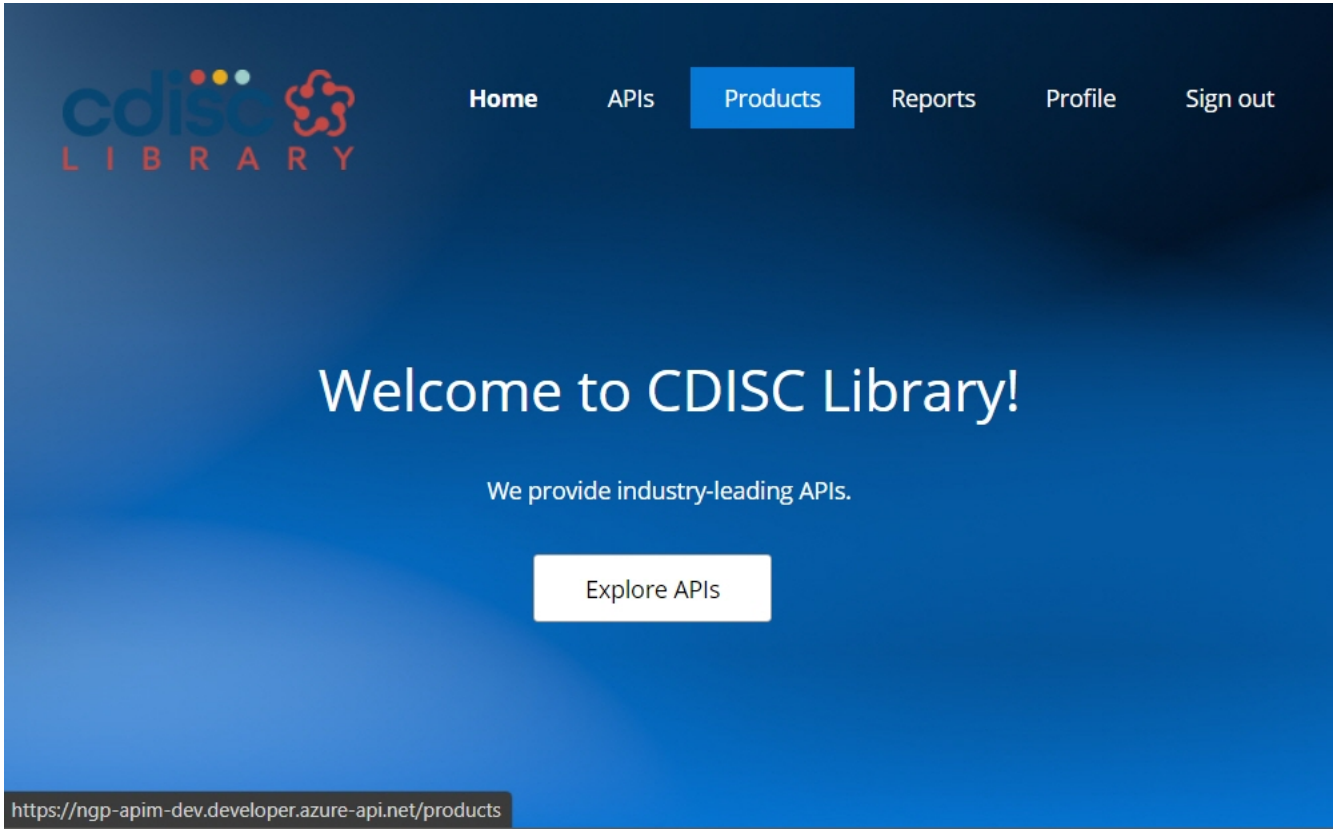


4. New Environments

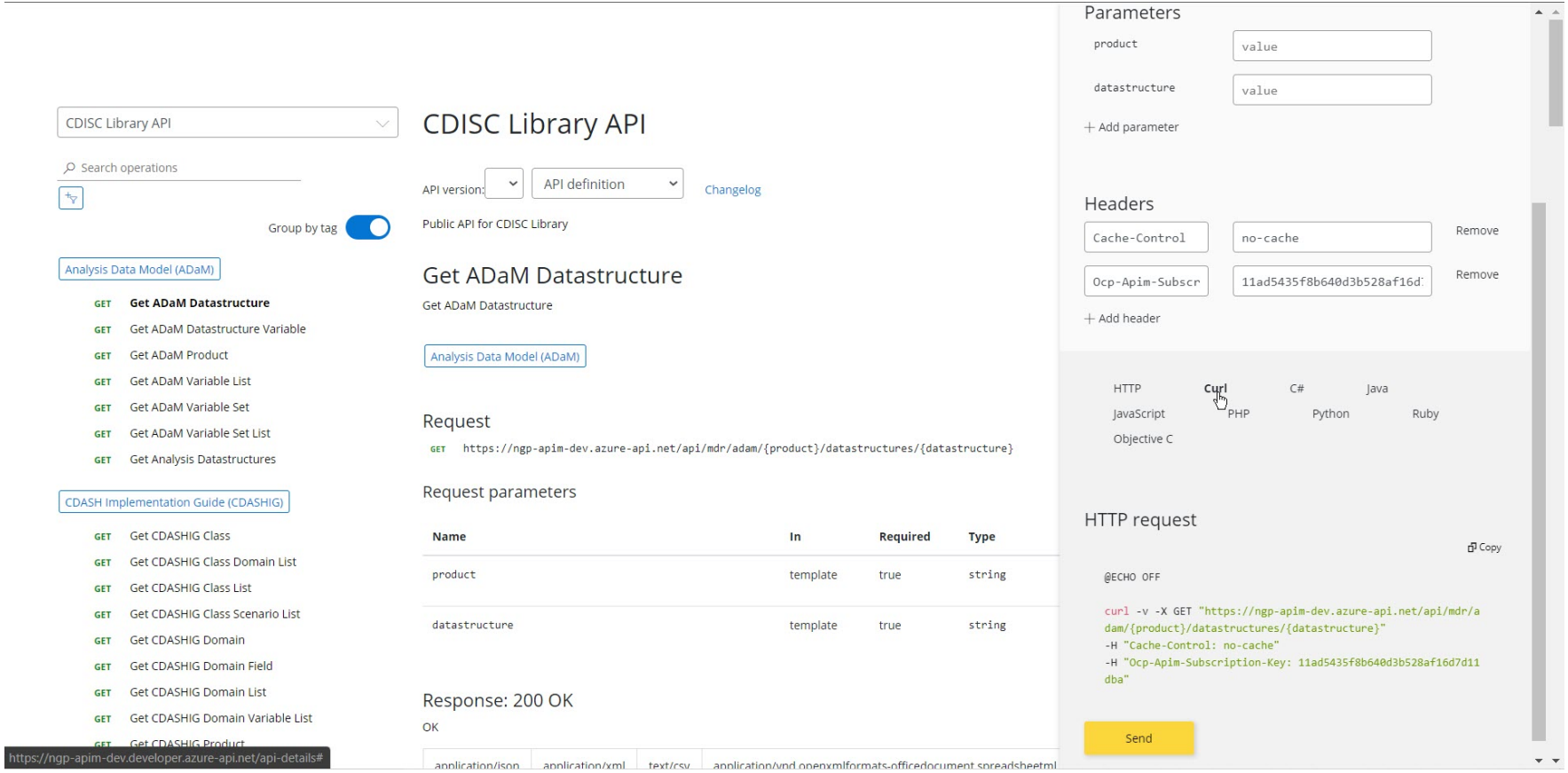
New CDISC Library Environments

- CDISC Development environments
  - Sandbox
  - Dev
  - Test
- Standards Implementer environments
  - Preview
  - Production
- Dynamic Environments
  - Temporary environments created as needed

API Developer Portal

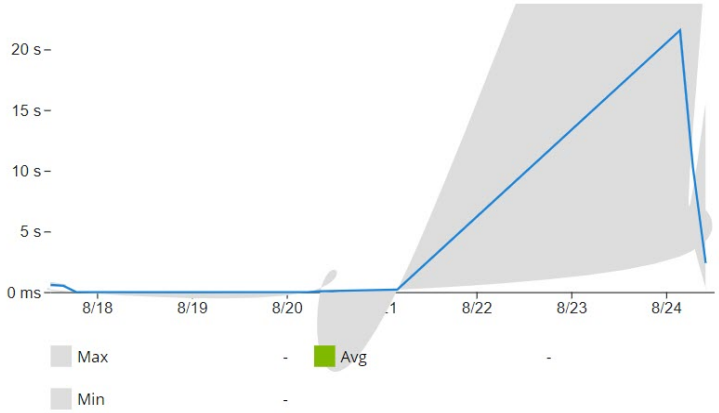


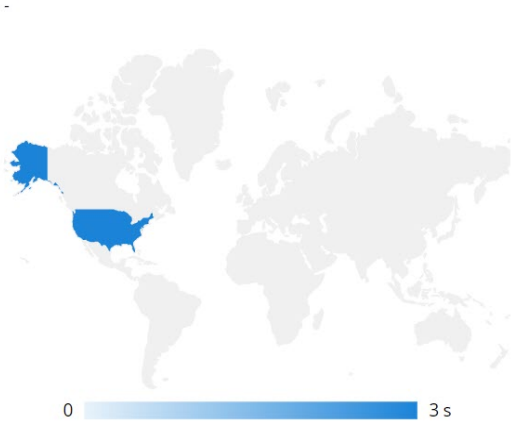
API Developer Portal: Documentation and Code Generation



API Developer Portal: Self Service Reports

API response times





Products

Product	Successful calls	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
CDISC Library	73	0	5	0	78	3 s	5 Mb

Subscriptions

Subscription	Successful calls	Blocked calls	Failed calls	Other calls	Total calls	Average response time	Bandwidth
Product CDISC Library subscription	70	0	2	0	72	3 s	4 Mb

5. Private CDISC Library Instances

New Features for Titanium members using a private instance of the CDISC Library to manage standards

CDISC Library: Private Instance of CDISC Library

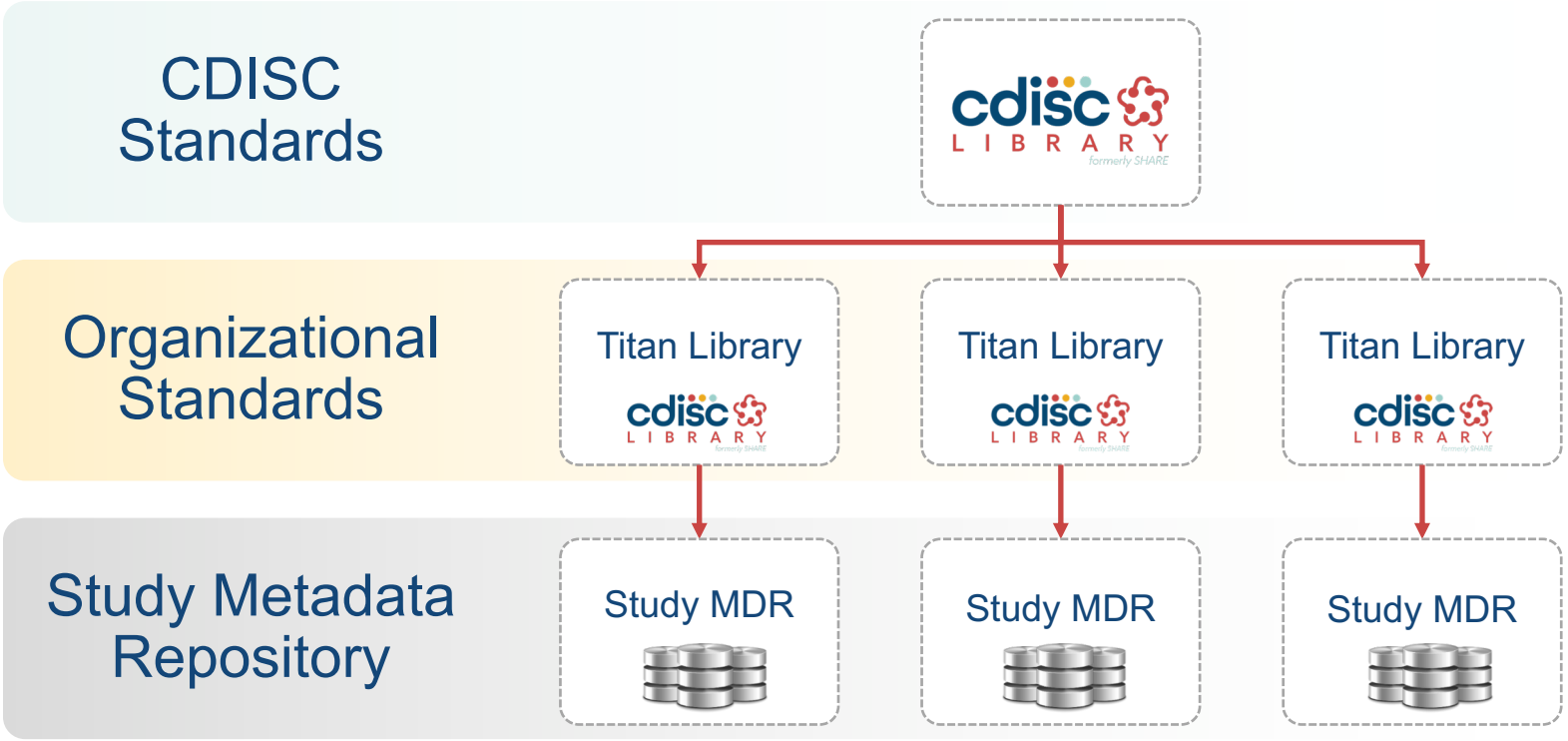
- Every private instance starts with the same content as the CDISC Library
  - Primary / replica architecture
  - Create sponsor, therapeutic area, and project level standards based on the CDISC standards
- Every private instance of CDISC Library starts with the same code base
  - CDISC Library API
  - Provides standards management tools such as authoring and governance
  - Create sponsor-specific additions and extensions
- Provides tools to help up-version organizational standards for new versions of CDISC standards

Common API Across all CDISC Library Instances

- Every CDISC Library instance has a common API making it easy for vendors to build applications that target all instances

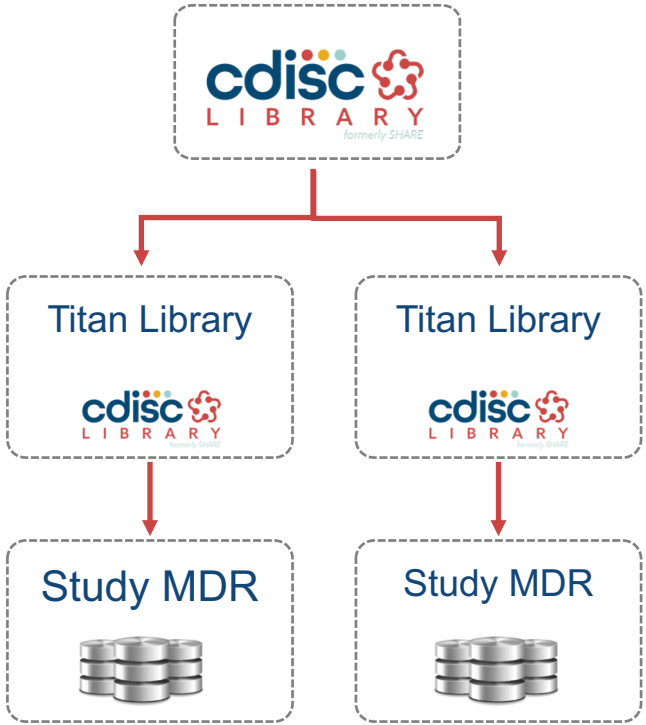
- Vendor applications that target the API have a ready-made market
  - Enables a ecosystem of vendor applications that use the CDISC Library API

CDISC Library: Syndicated Standards

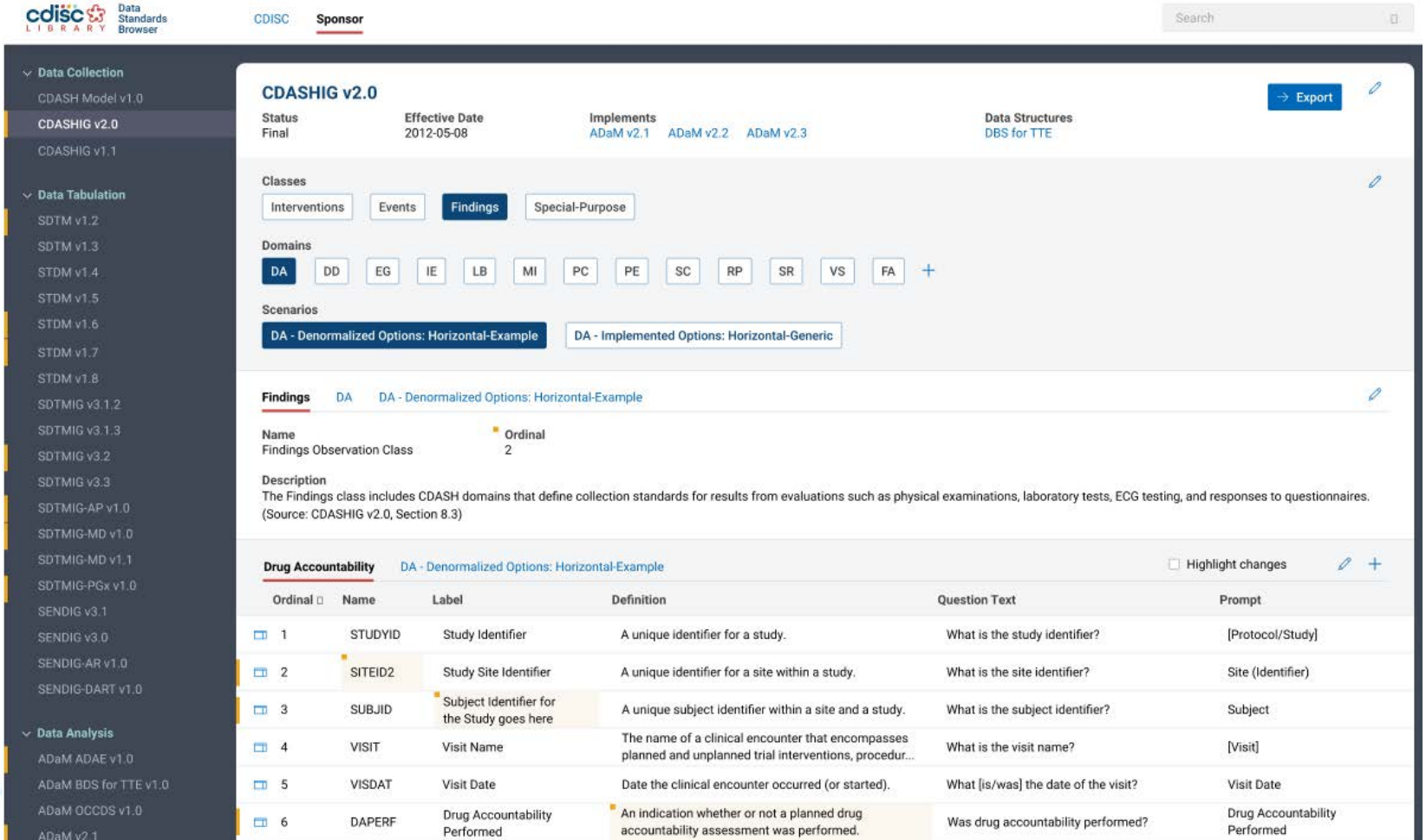


CDISC Library: Syndicated Standards

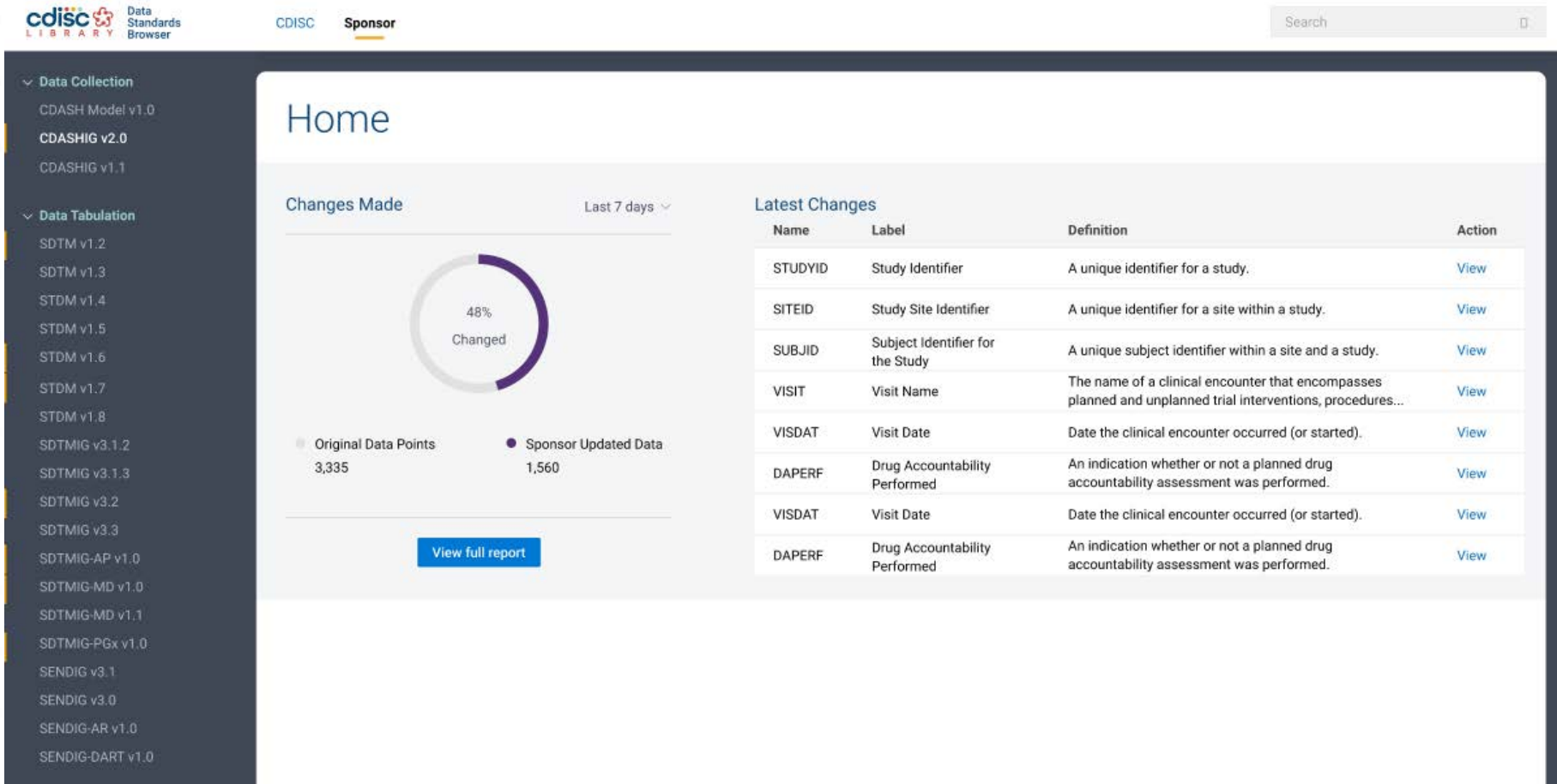
- Industry standards published to member Libraries
  - Primary / replica architecture
- Members add organization, TA, project, and study level standards
  - Members configure standards for their needs
  - Automation support or up-versioning
- Detailed study metadata is maintained in a local MDR
  - Studies configure organizational standards
- The Study MDR integrates with operational systems



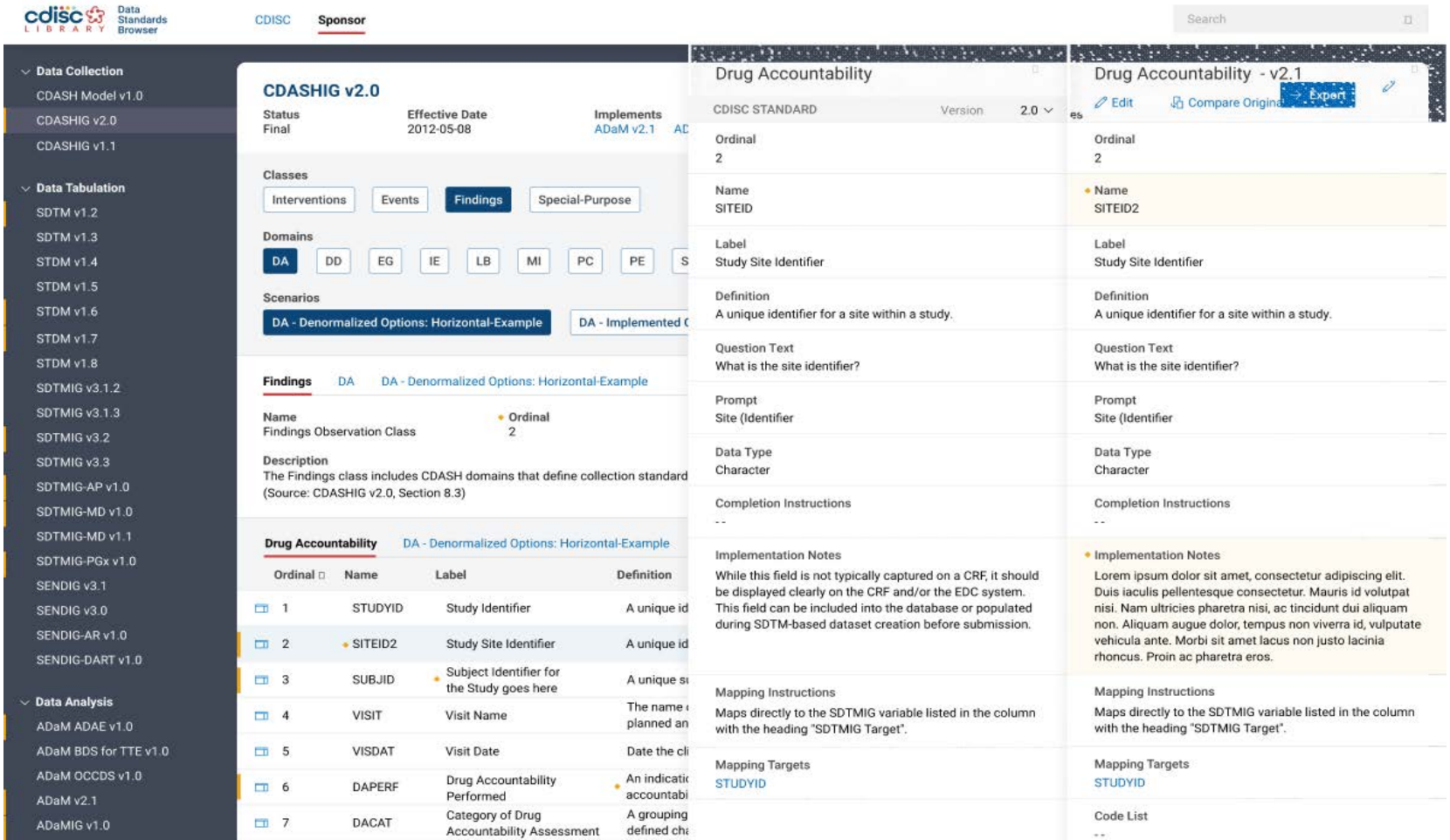
CDISC Library Titanium: Authoring Sponsor Standards



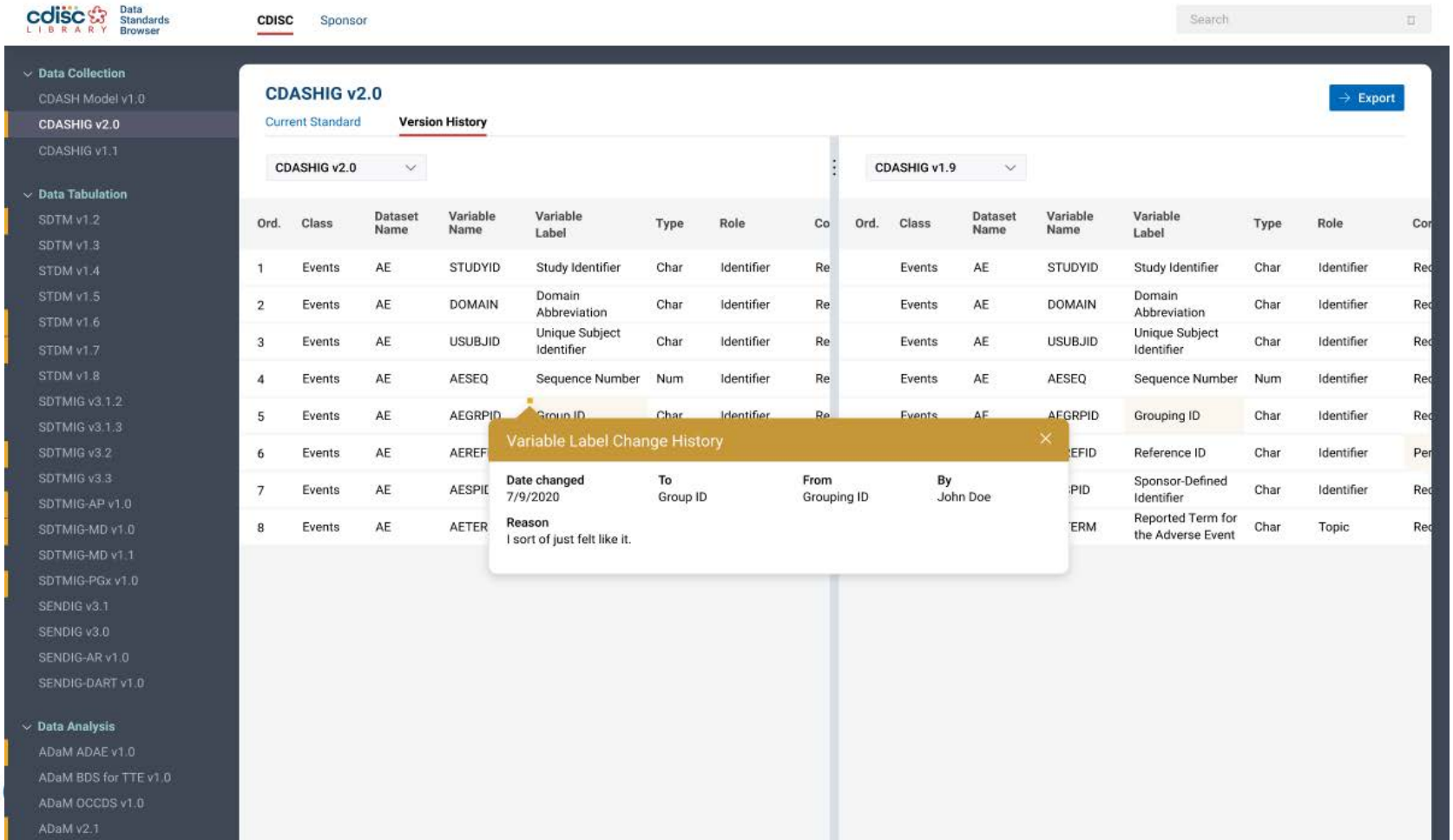
CDISC Library Titanium: Managing Sponsor Standards



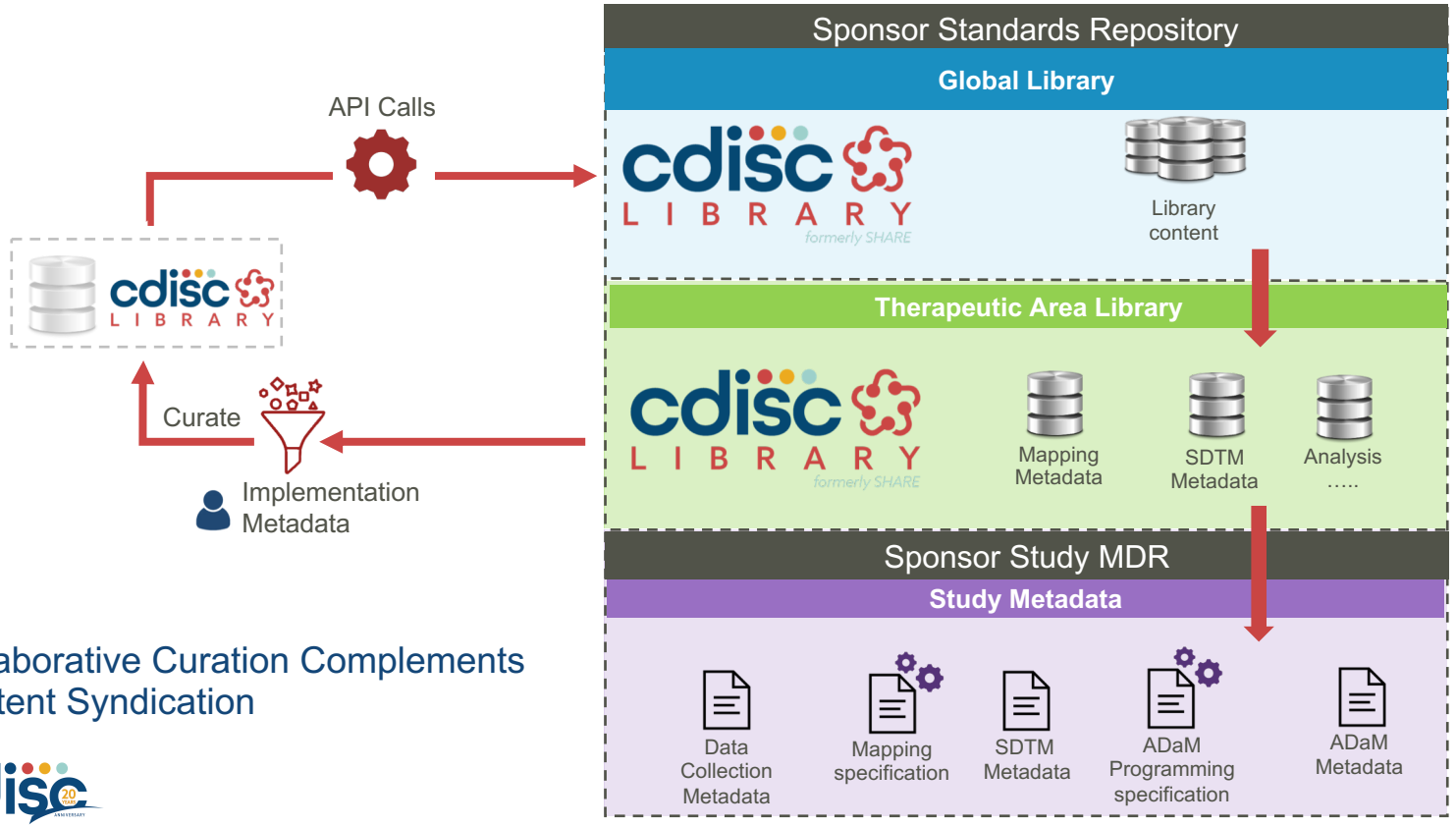
CDISC Library Titanium: Standards Change Management



CDISC Library Titanium: Standards Change Management

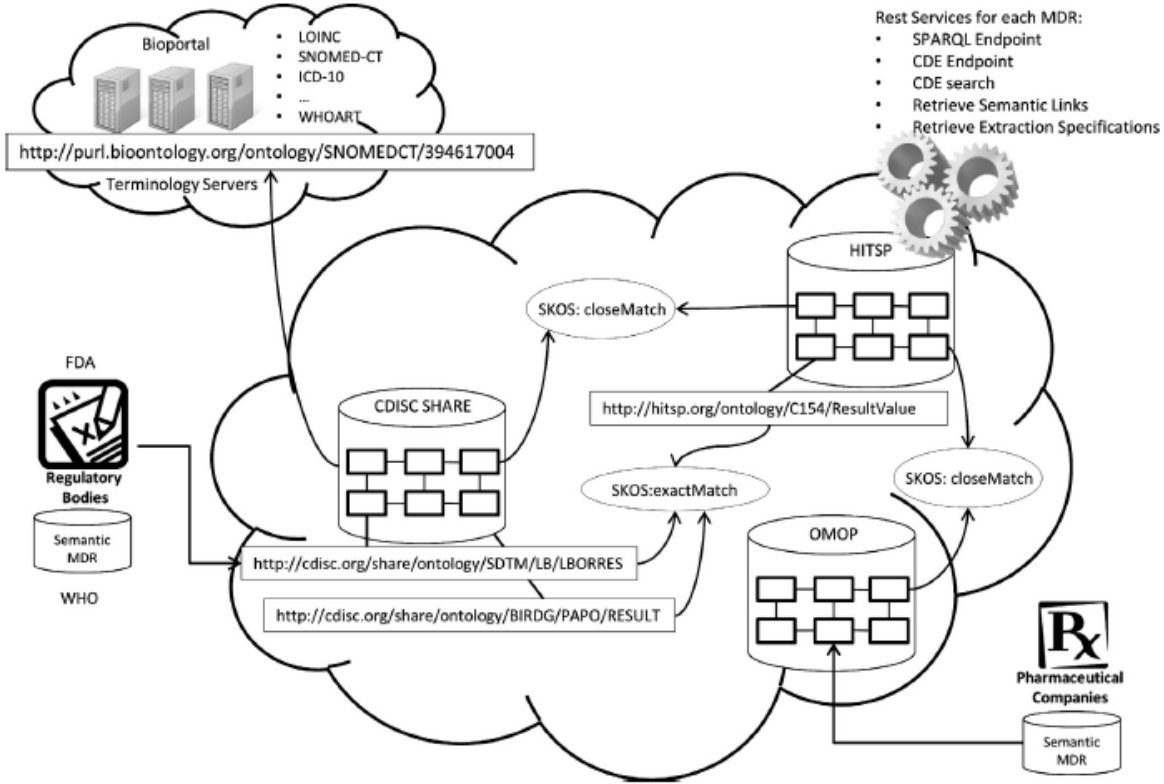


Common CDISC Library Authoring and Governance Tools Enable Collaborative Curation

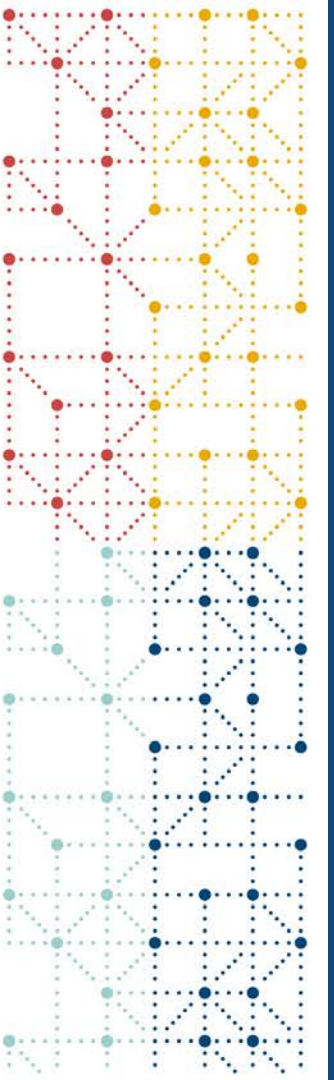


Collaborative Curation Complements Content Syndication

CDISC Library: Federated MDRs



SINACI, A. A.; LALECI ERTURKMEN, G. B. A federated semantic metadata registry framework for enabling interoperability across clinical research and care domains. Journal of Biomedical Informatics, v. 46, n. 5, p. 784-794, 2013.

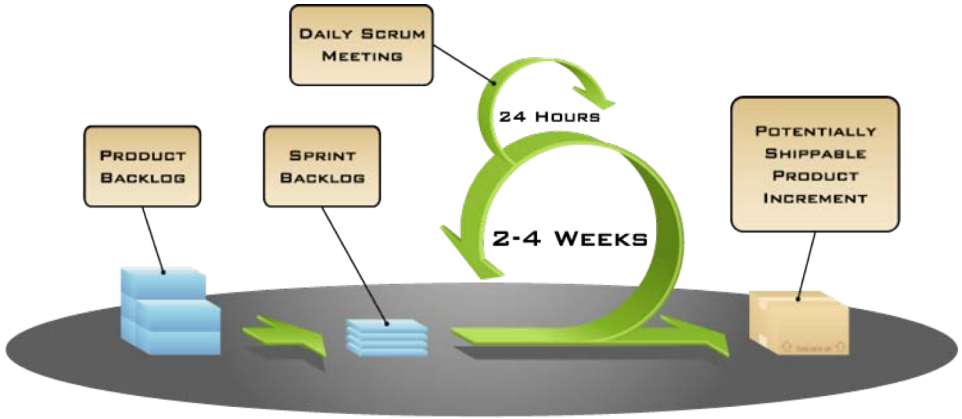


6. Development Approach

High-level thoughts on our approach to software development

Agile Development Process

- Scrum-based process
- 1 dedicated CDISC Library development team to create all the new features
- New features from numerous projects are fed into 1 product backlog and prioritized
- Commit to delivering potentially shippable increments after each sprint



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Thank You!