

SHARE: The Road Ahead

Metadata Repositories: Promises and Realities

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Strength *through Collaboration*

SHARE: The Road Ahead Agenda

1. SHARE Benefits available today
2. The SHARE Ecosystem
3. The SHARE API
4. New Exports: RDF and SHARE-XML
5. SHARE Model
6. End-to-End Standards
7. TA Standards and Specification Generation
8. What's next
9. MDR Pains in the C43362

1. SHARE Benefits Available Today

- Machine-readable standards as they're published
 - EU Interchange SHARE Showcase examples
- One metadata repository, many possible outputs
 - Reports on the metadata across versions
 - SDTM Core values across standards and versions
- End-to-End standards support
 - Helps with quality, uniformity, and completeness of the standards
- Standards examples repository

1. SHARE Benefits Available Today

ROOT_VARIABLE All Classes.--GRPID

Max of CoreN VARIABLE	PUBLICATION SDTMIG 3.1.2	SDTMIG 3.1.3	SDTMIG 3.2	SDTMIG 3.3	SDTMIG TAUG-QT 1.0
AEGRPID	Perm	Perm	Perm		
AGGRPID				Perm	
CCGRPID				Perm	
CEGRPID	Perm	Perm	Perm		
CMGRPID	Perm	Perm	Perm		
CVGRPID				Perm	
DAGRPID	Perm	Perm	Perm		
DSGRPID	Perm	Perm	Perm		
ECGRPID			Perm		
EGGRPID	Perm	Perm	Perm		Exp
EXGRPID	Perm	Perm	Perm		
FAGRPID	Perm	Perm	Perm		
FTGRPID				Perm	
HOGRPID			Perm		
ISGRPID			Perm		
LBGRPID	Perm	Perm	Perm		
MBGRPID	Exp	Exp	Exp		
MHGRPID	Perm	Perm	Perm		
MIGRPID			Perm		
MOGRPID			Perm		
MSGRPID	Req	Req	Req		

1. SHARE Benefits Available Today

 Tuberculosis Therapeutic Area Data Standard User Guide / TAUG-TB v2.0draft
TAUG-TB Examples

Created by Darcy Wold, last modified on Oct 15, 2015

This is the repository for all examples included in the TAUG-TB v2.0draft.

Browse examples by...

▼ Biomedical concept:

A-F	G-L	M-R	S	T-Z
adjudication antibody-tests associated-persons biospecimens conmeds contact-case-investigation culture-contamination disposition endpoints environmental-risk-factors	genetics hematology histology identification igra imaging infection-detection injection-site-reactions labs	meal-data medical-devices medical-history microbiology nervous-system nextgen-sequencing non-host-genetics pgx respiratory risk-factors	sex-gender skin-test source-case-investigation spoligotypes study-meds subject-characteristics supper suppmh symptoms	treatment-regimens trial-arms tumors-lesions urinalysis vaccines vital-signs

▼ Domain or dataset:

Class	Name	Examples	
Special-Purpose	Device Identifiers (DI) ¹	 Imaging 1  Labs 1  Labs 2  Labs 3  SPIDST 1  SPIDST 2	[*] Draft domain (not yet formally published) ¹ SDTMIG-MD domain or dataset ² SDTMIG-PGx domain or dataset ³ Includes Associated Persons rendition of the domain
Interventions	Procedure Agents (AG) [*]	 Skin Test 1	
Interventions	Prior & Concomitant Medications (CM)	 ConMeds 1  ConMeds 2  ConMeds 3  ConMeds 4	

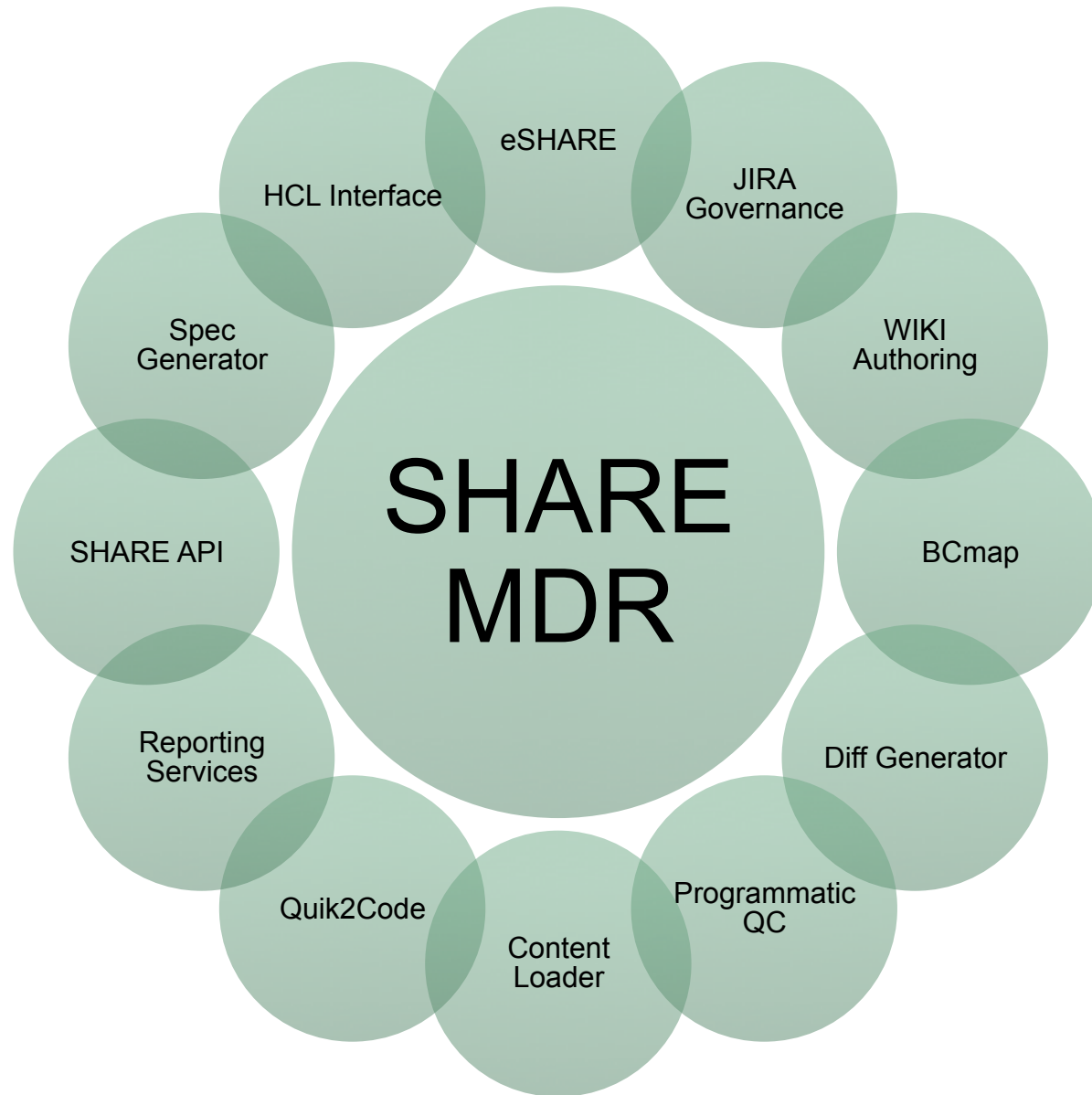
Index by BC,
Domains

Index by
Variables

FATEST	• TAUG-CHCV v1.0 Section 2.4.2.1 Example 1 • TAUG-Dyslipidemia v1 Section 2.3.1 Example 2 • TAUG-Schizophrenia v1 Section 4.1.2 Example 2 • TAUG-Schizophrenia v1 Section 4.1.2 Example 3 • TAUG-Schizophrenia v1 Section 4.3.1 Example 1 • TAUG-Schizophrenia v1 Section 5.2.1 Example 1
FATESTCD	• TAUG-CHCV v1.0 Section 2.4.2.1 Example 1 • TAUG-Dyslipidemia v1 Section 2.3.1 Example 2 • TAUG-Schizophrenia v1 Section 4.1.2 Example 2 • TAUG-Schizophrenia v1 Section 4.1.2 Example 3 • TAUG-Schizophrenia v1 Section 4.3.1 Example 1 • TAUG-Schizophrenia v1 Section 5.2.1 Example 1
HOCAT	• TAUG-TBI v1draft Section 4.2 Example 1
HOENDTC	• TAUG-Schizophrenia v1 Section 4.3.1 Example 1 • TAUG-Schizophrenia v1 Section 5.2.1 Example 1 • TAUG-Schizophrenia v1 Section 5.5.1 Example 3 • TAUG-TBI v1draft Section 4.2 Example 1

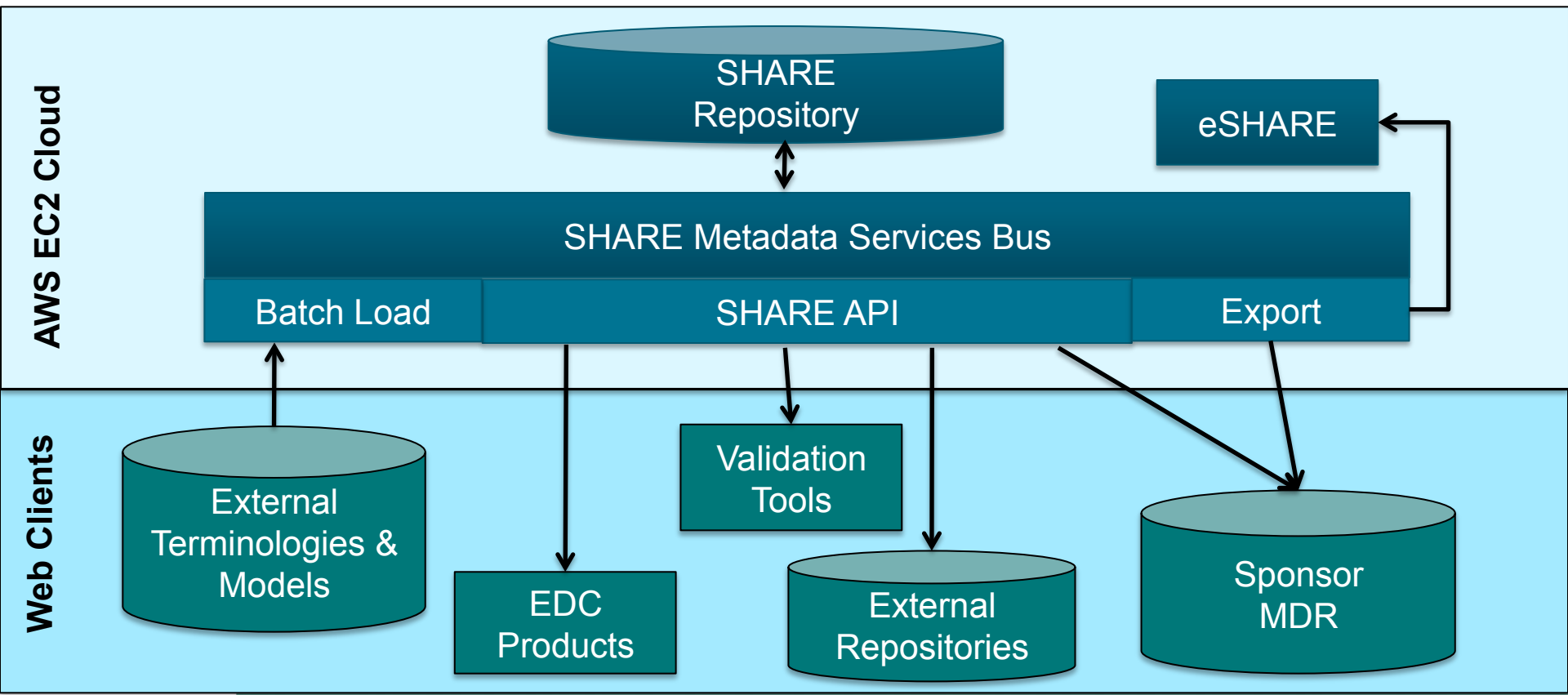
Example Registry – Sample Outputs

2. SHARE Ecosystem



3. The SHARE API

The SHARE API provides programmatic access to machine-readable SHARE content for Metadata Repositories (MDR) and other software tools.



3. A quick look at the API

- RESTful API: uses HTTP requests to Get standards metadata
 - `http://{system-endpoint}/{context-root}/rest/semantics/{library-name}/{rest-api-name}/{rest-api-parameter}?{query-parameters}`
- Standards metadata returned in the following formats:
 - SHARE-XML
 - Extended ODM v1.3.2 XML
 - Extended Define-XML v2.0
 - RDF (only available for top-level standards)
 - rdf-xml
 - turtle
 - n-triples
 - JSON (experimental)

3. A quick look at the API

- Get Standards API - Example

- https://smpoc3.akana.com/sm/rest/semantics/CDISCAPI/standards?user-id=bus_user&encoding=identity&lifecycle-status=Approved%20Final

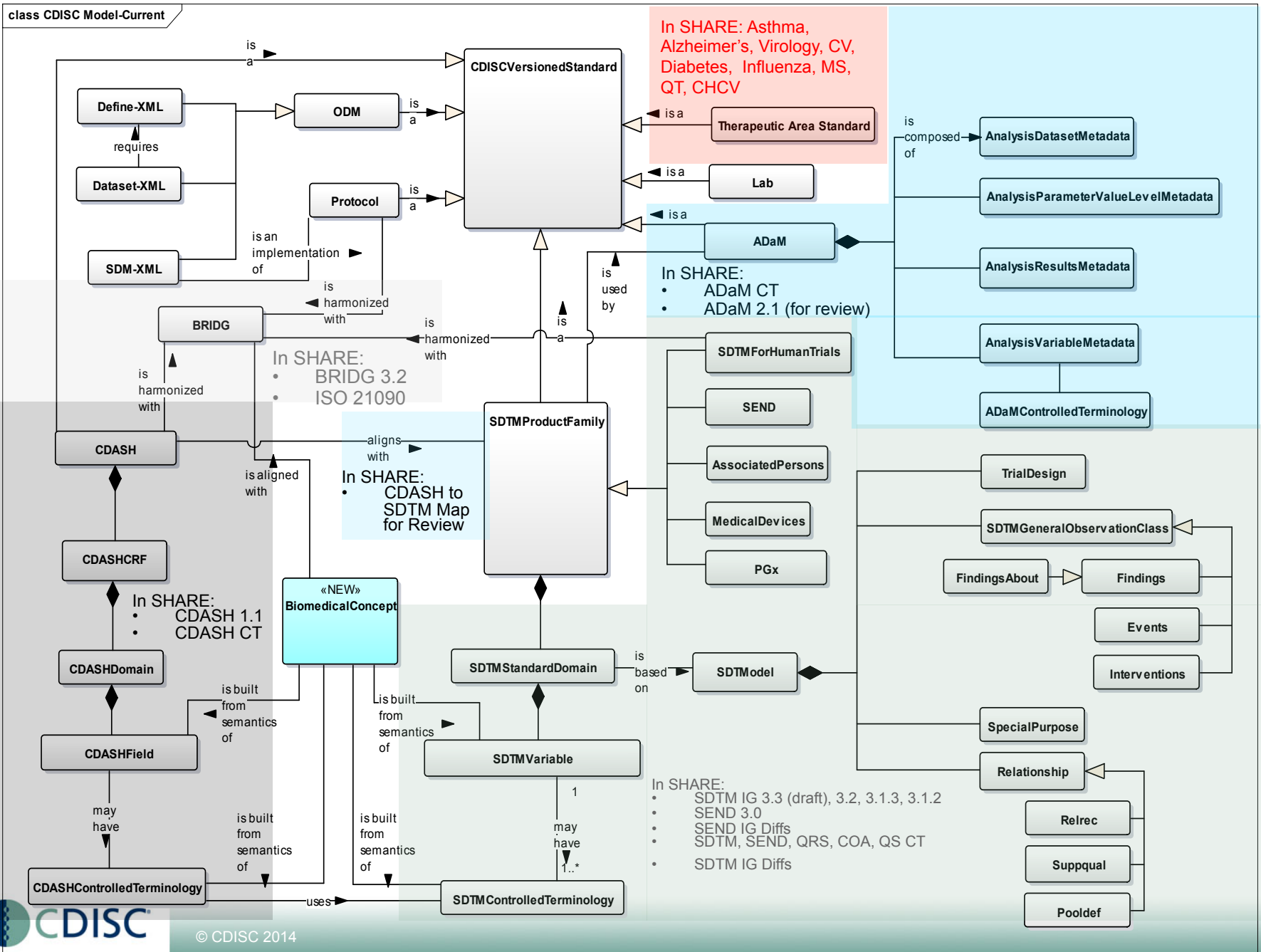
```
▼<MetaDataVersion Name="CDISCAPI" OID="MDV.28.1.getStandards" mdr:ShareXMLVersion="1.0.0">
▼<ItemGroupDef Name="CDASH (MDES 1.1)" OID="1.0_13910561168727094932" Purpose="Data Collection" Repeating="No" mdr:D
10" mdr:Status="Approved Final">
▼<Description>
▼<TranslatedText xml:lang="en">
Clinical Data Acquisition Standards Harmonization (CDASH) v1.1
</TranslatedText>
</Description>
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<Alias Context="Data Domains API" Name="/standards/{asset-id}/domains"/>
<Alias Context="Standard Metadata API" Name="/standards/{asset-id}/metadata"/>
</ItemGroupDef>
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mdr:DatePublished="2016-03-10" mdr:Status="Approved Final">
▼<Description>
▼<TranslatedText xml:lang="en">
Study Data Tabulation Model (SDTM) 1.3, SDTM IG 3.1.3
</TranslatedText>
```

4. RDF and SHARE-XML Exports

- SHARE API and Exports use the same code base
- RDF exports have recently completed testing
- SHARE-XML offers additional metadata available in SHARE as an extension to ODM or Define-XML
 - Can easily re-create the metadata spreadsheets from the XML
 - Includes additional information not available in the spreadsheets
- Coming to eSHARE soon

5. SHARE Model

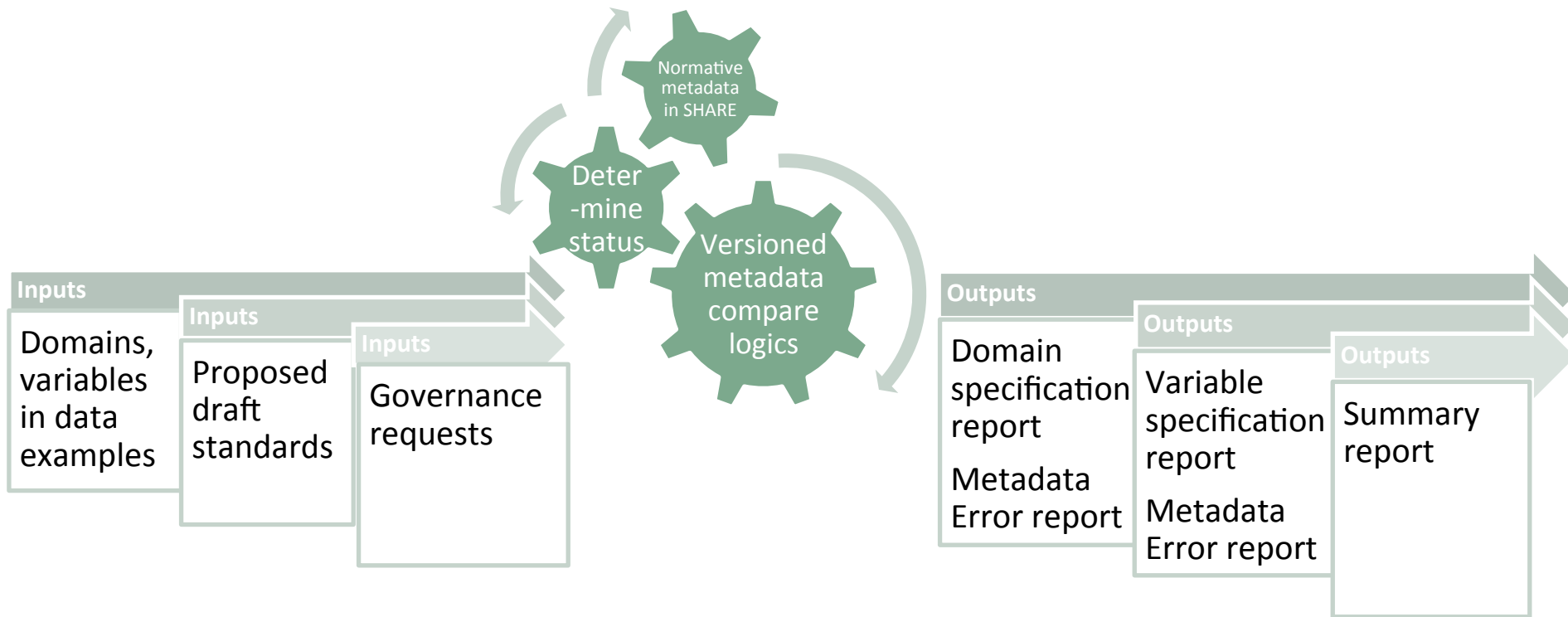
class CDISC Model-Current



6. End-to-End Standards

- Integrated protocol objectives and endpoints in SHARE
 - BC model integrated with protocol objectives and endpoints
 - Links going from TA to objectives to endpoints to BCs to CDASH
- Identify the key protocol concepts for TransCelerate CPT and CDISC CTR
 - Deliverable is a protocol vocabulary that can be loaded into SHARE as part of the concept model
- PoC for end-to-end standards that includes protocol
 - Objectives, endpoints, biomedical concepts, CDASH, SDTM, ADaM

7. TA Standards and Specification Generation



Process for TA Specification Generation* To Automate ~90% of Entire Document

* Normative section, excluding informative section such as comments

8. What's Next

- SHARE approach to standards development
 - Evolve foundational standards development
 - Continue to innovate and accelerate TA standards development
- Controlled Terminology improvements
 - Formal sub-setting in SHARE & updated new term request system
- Biomedical Concepts & VLM
 - Start loading TA BC content into SHARE
 - Address BCs more broadly
- Alignment with healthcare standards
 - Support for the use of EHRs in clinical research (HCL)
 - SHARE on FHIR

9. MDR Pains in the C43362

- MS Smart Quotes: bane of the machine world
 - `’`; `“`; `”`; `‑`
- Generating Define-XML datatypes from SDTM
 - Map Char & Num to...
 - Text, integer, float, datetime, time, partialDate, durationDateTime, etc.
- CDISC Notes and Definitions
 - Should be replaced by a formal, persistent definition
- Value list is used instead of Controlled Terminology codelist
- Standards in silos instead of an end-to-end model
 - Core (mandatory vs. core)

Thanks!

Q & A

