

# **Access to CDISC SHARE Metadata:**

## **A la carte, prix fixe, or table d'hôte?**

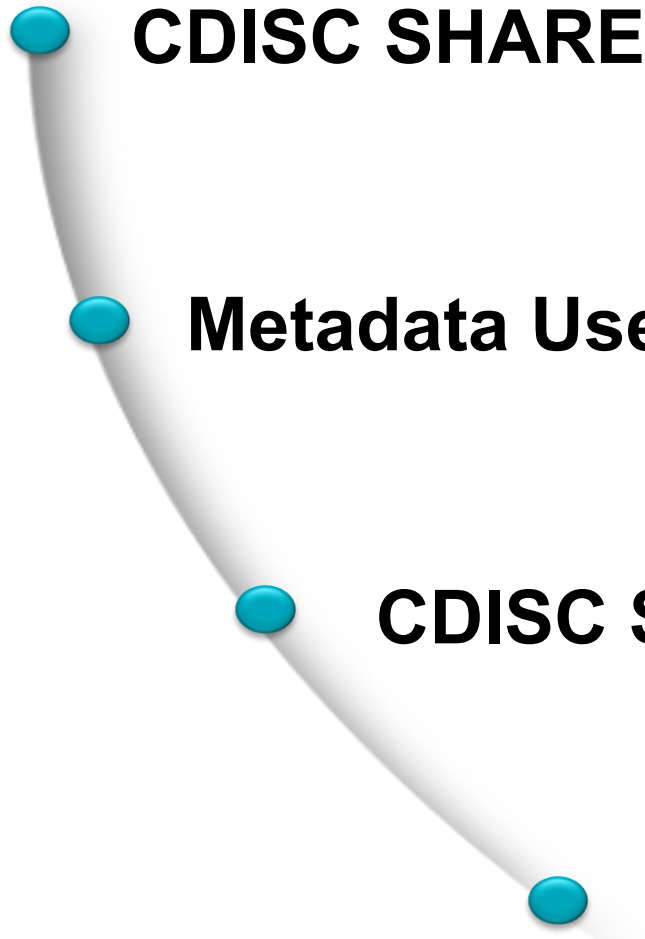
High performance. Delivered.

Ken Stoltzfus

12 October, 2015

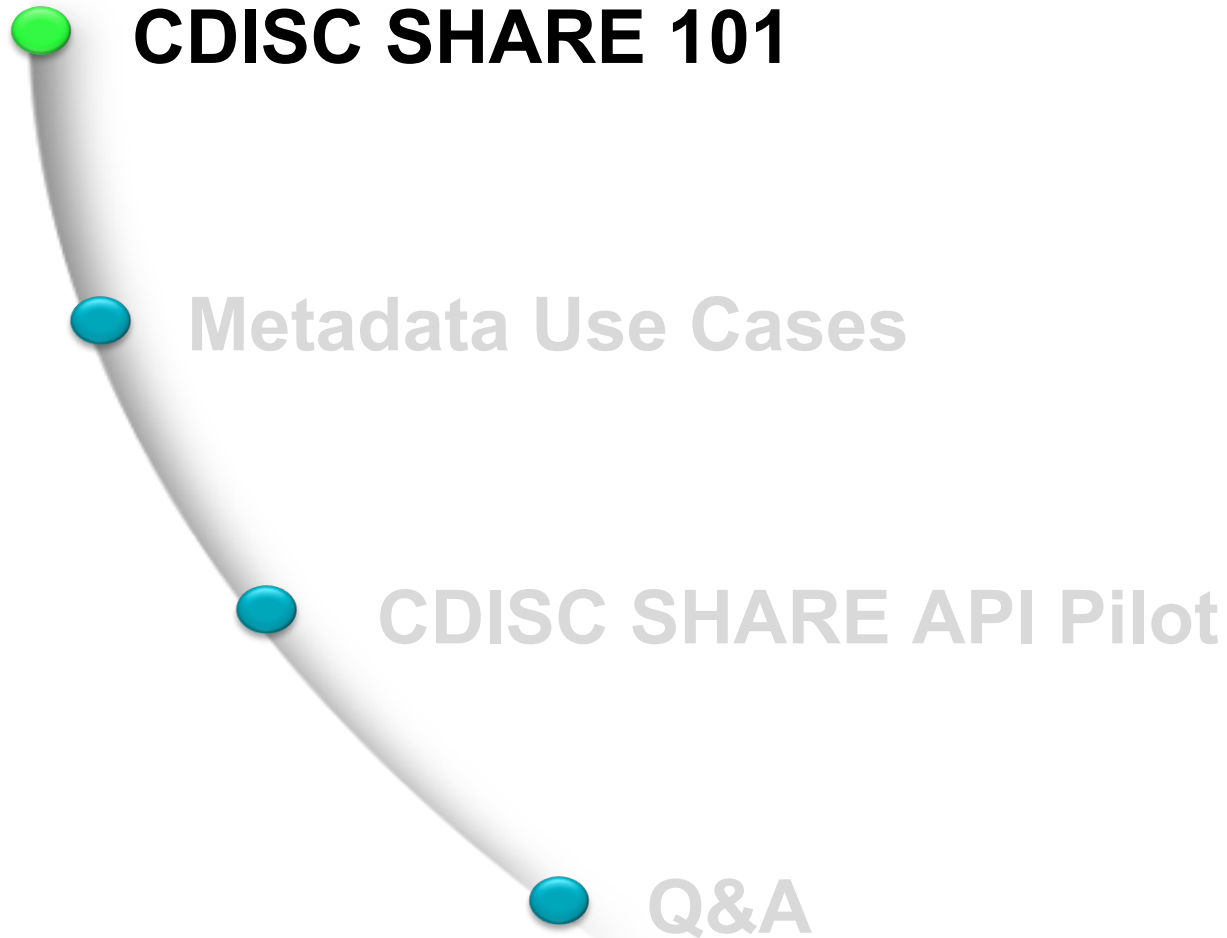
# Agenda

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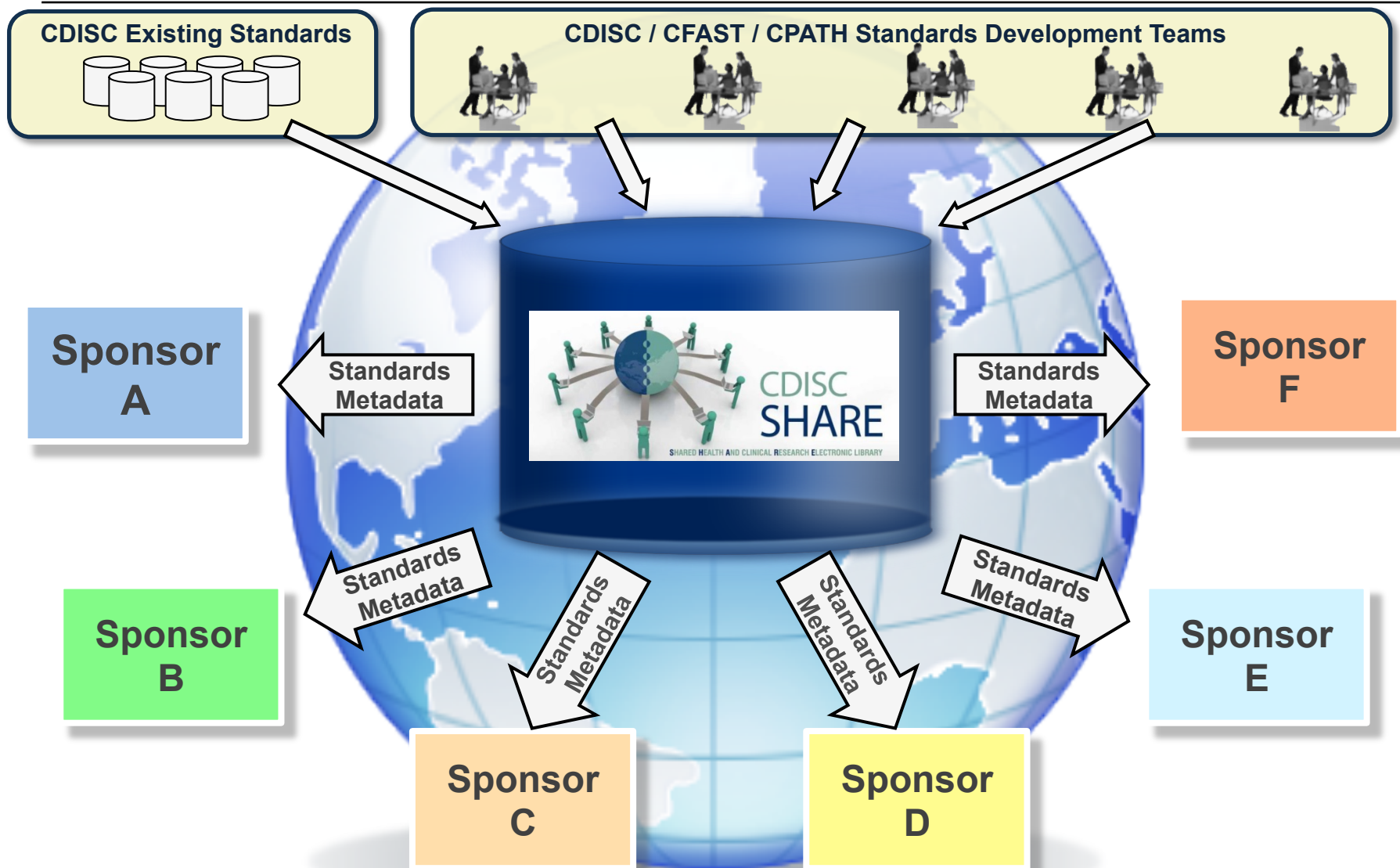
- 
- CDISC SHARE 101**
  - Metadata Use Cases**
  - CDISC SHARE API Pilot**
  - Q&A**

# Agenda

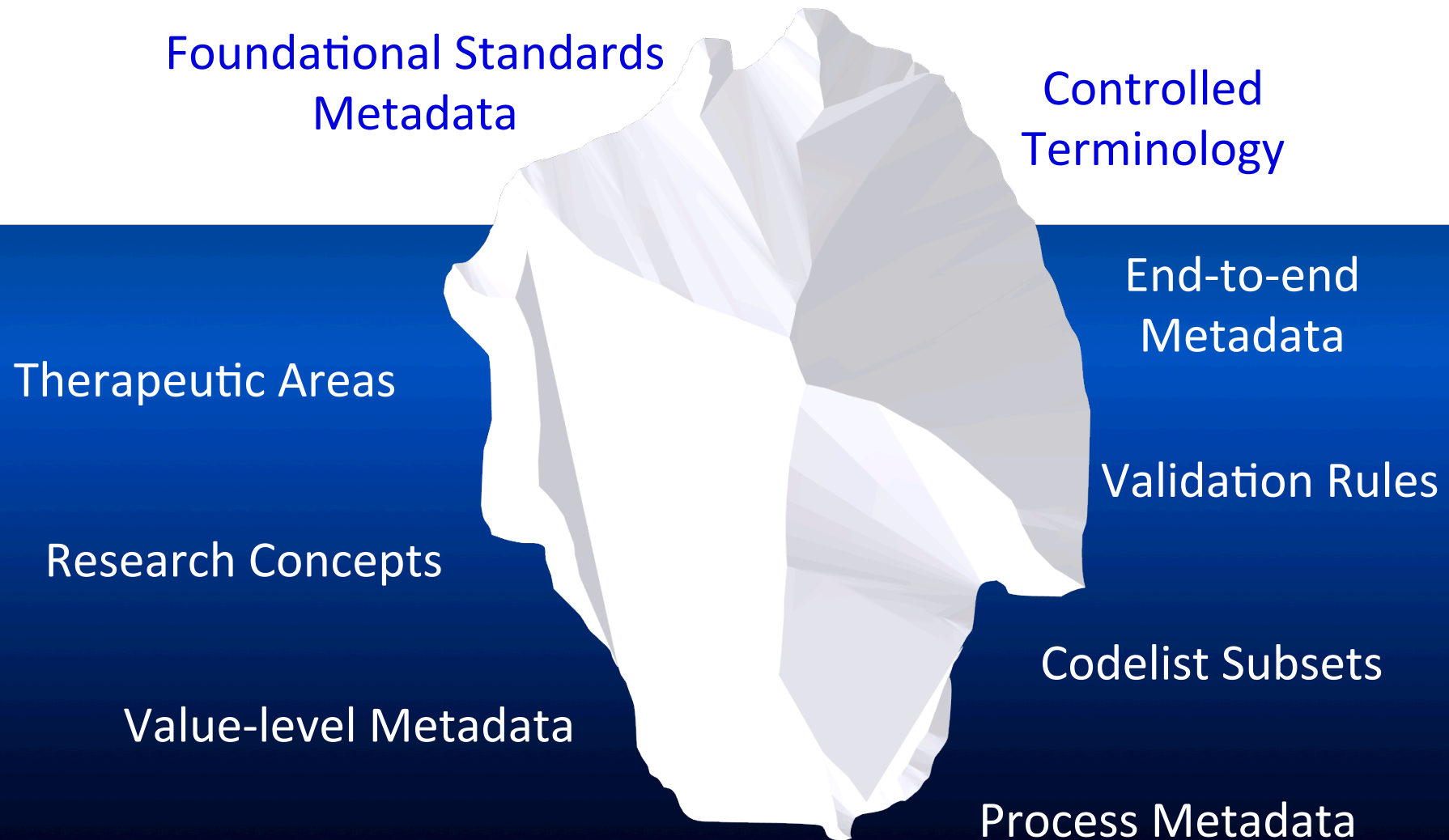
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# CDISC SHARE in the Industry



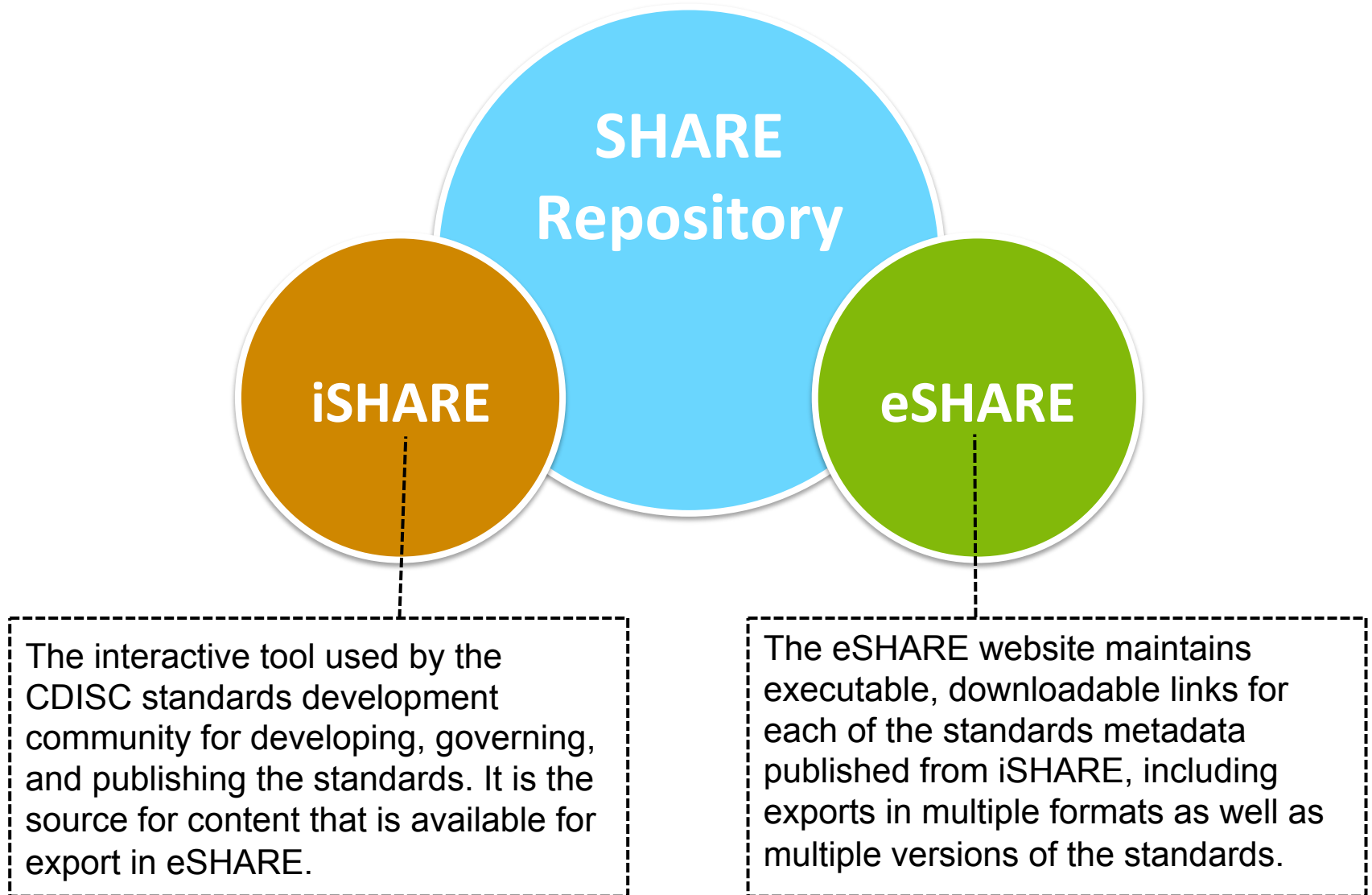
# New Opportunities for Standardized Metadata to Improve Interoperability



Slide Courtesy of: Sam Hume, CDISC, VP SHARE Technology & Services

# iSHARE and eSHARE

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# eSHARE Access

- ▶ CDISC eSHARE website
- ▶ Pre-defined logical sets of standards metadata
  - SDTM IG 3.2, 3.1.3, etc.
  - TA UG Virology, Devices, etc.
- ▶ Export files:
  - XML
  - Excel
  - RDF
- ▶ Manual processing of SHARE export files

| SDTM                       |              |                | eSHARE Standards Catalog |                                                                                           |
|----------------------------|--------------|----------------|--------------------------|-------------------------------------------------------------------------------------------|
| Date Posted                | Content      | Version        | Type                     | Download Files                                                                            |
| SDTMUG Virology            |              |                |                          |                                                                                           |
| 2015-04-28                 | SDTM UG      | 1.0            | For Review               | <a href="#">Excel</a>                                                                     |
| SDTMIG Medical Devices 1.0 |              |                |                          |                                                                                           |
| 2014-11-20                 | SDTM IG      | 1.0            | Metadata                 | <a href="#">Define-XML v2.0</a>   <a href="#">Define-XML v1.0</a>   <a href="#">Excel</a> |
| 2014-11-20                 | SDTM IG      | 1.0            | Document                 | <a href="#">PDF</a>                                                                       |
| SDTM 1.4 (IG 3.2)          |              |                |                          |                                                                                           |
| 2015-02-02                 | SDTM IG Diff | 3.2 - 3.1.3    | For Review               | <a href="#">Excel</a>                                                                     |
| 2014-08-21                 | SDTM (IG)    | 1.4 (3.2)      | Metadata                 | <a href="#">Define-XML v2.0</a>   <a href="#">Define-XML v1.0</a>   <a href="#">Excel</a> |
| 2014-08-21                 | SDTM + CT    | 1.4+2013-12-20 | Bundle                   | <a href="#">Define-XML v2.0</a>   <a href="#">Excel</a>                                   |
| 2014-08-21                 | SDTM (IG)    | 1.3 (3.1.3)    | Document Bundle          | <a href="#">PDF</a>                                                                       |
| SDTM 1.3 (IG 3.1.3)        |              |                |                          |                                                                                           |
| 2014-08-21                 | SDTM (IG)    | 1.3 (3.1.3)    | Metadata                 | <a href="#">Define-XML v2.0</a>   <a href="#">Define-XML v1.0</a>   <a href="#">Excel</a> |
| 2014-08-21                 | SDTM + CT    | 1.3+2013-12-20 | Bundle                   | <a href="#">Define-XML v2.0</a>   <a href="#">Excel</a>                                   |
| 2014-08-21                 | SDTM (IG)    | 1.3 (3.1.3)    | Document Bundle          | <a href="#">PDF</a>                                                                       |



# SHARE: Patterns of Metadata Use

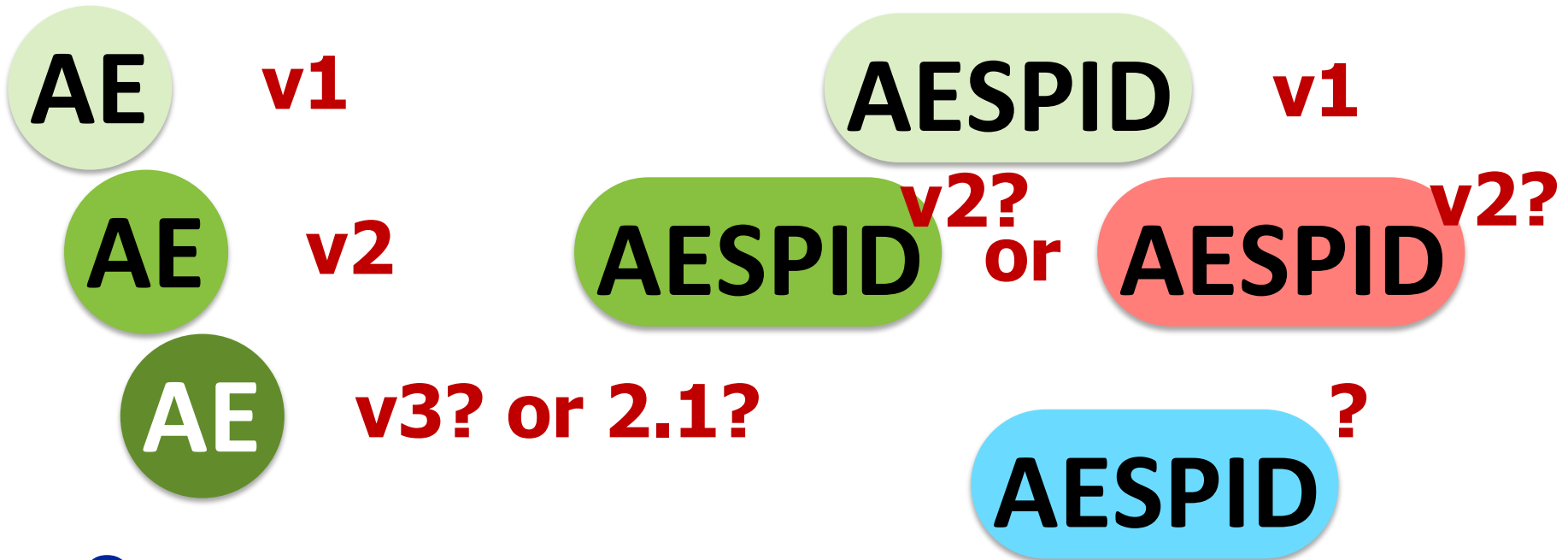
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New metadata products to support new patterns of use

- ▶ Diff files – process the updates
- ▶ Bundles – process related content together
- ▶ Metadata + Examples + Test Data
- ▶ Normative + Non-normative
- ▶ New formats – XML & RDF

# Version Control

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? Hard decisions!

- Regardless of the exact nature of the standards metadata

✓ CDISC SHARE metadata can help

# Version Control with SHARE metadata

[illegible]

<Study OID="Study SDTM.MDES\_3.2">

- ~~<GlobalVariables>~~

<StudyName> Stud

# Metadata Element Set

```
<ItemGroupDef OID="IG.MDES.AE.[SDTM]_MDES_3" Name="AE" def:Struc
def:Class="EVENTS" Repeating="yes" Pur
```

- <Description>

## Metadata Element Set

```
'ItemOID="IT.MDE.STUDYID.[SDTM_AE]_MDE_1"/>
```

```
' ItemOID="IT.MDE.DOMAIN.[SDTM_AE]_MDE_1"/>
```

```
'ItemOID="IT.MDE.USUBJID.[SDTM AE] MDE 1"/>
```

'ItemOID="IT.MDE.AESEFO.[SDTM AE] MDE 1"/>

ItemOID="IT.MDE(AEGRPID.[SDTM AE] MDE 1)/>

ItemOID="IT.MDE.AEREFID.[SDTM AE] MDE 2"/>

ItemOID="IT.MDE.AESPID.[SDTM AE]

```
mOID="IT.MDE.AETERM.[SDTM AE] M
```

## Metadata Element

```
prv="No" ItemOID="IT.MDE.AEMODIFY.[SDTM AE] MDE 1"/>
```

```
<?xml version='1.0' encoding='UTF-8'>  
  <ItemOID>IT.MDE.AE.LT.[SDTM AE] MDE 1</ItemOID>  
  <?xml version='1.0' encoding='UTF-8'>
```

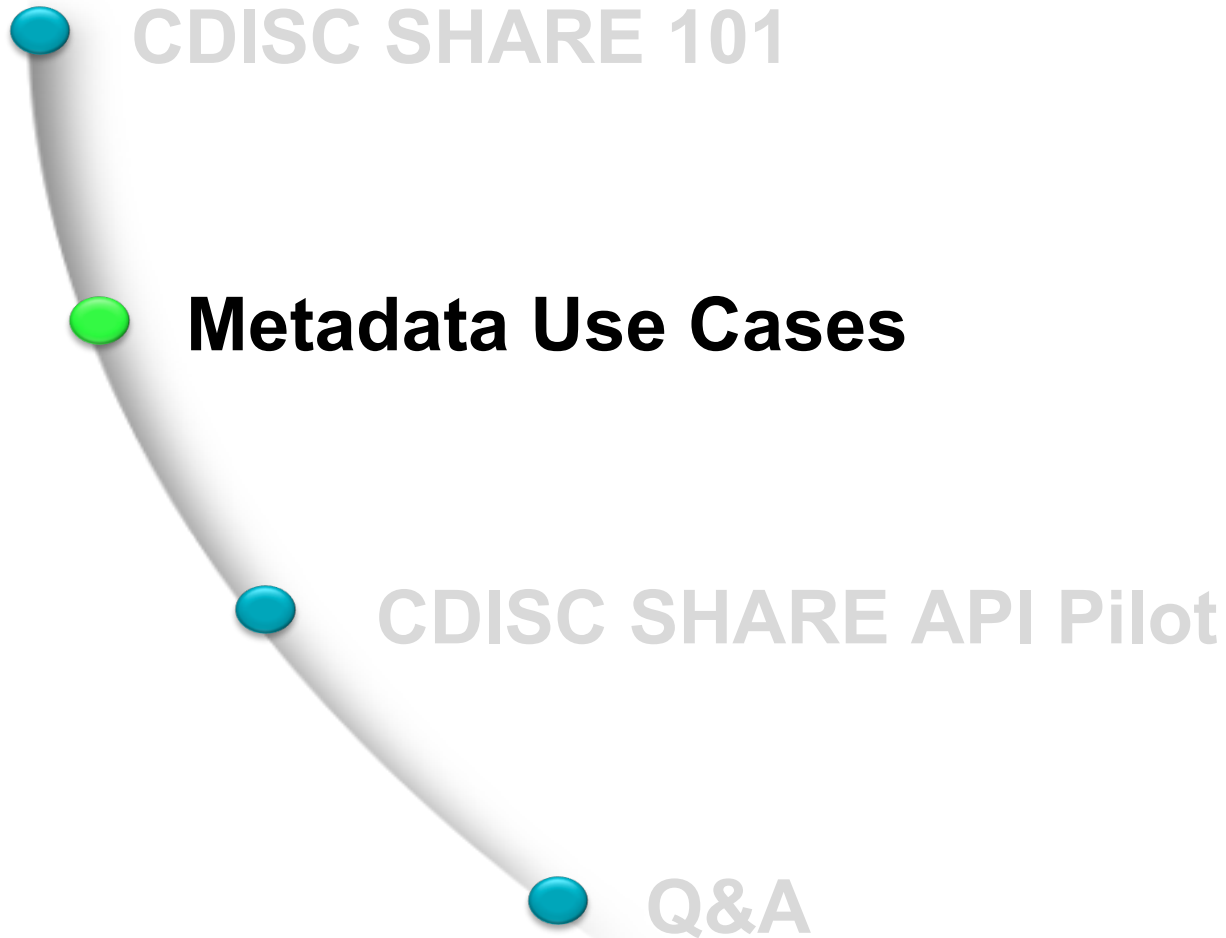
ory="No" ItemOID="IT MDE AE11 TCD [SDTM AE] MDE 1"/>

story="Yes" ItemOID="IT MDE AEDECOD [SDTM AE] MDE 2"/>

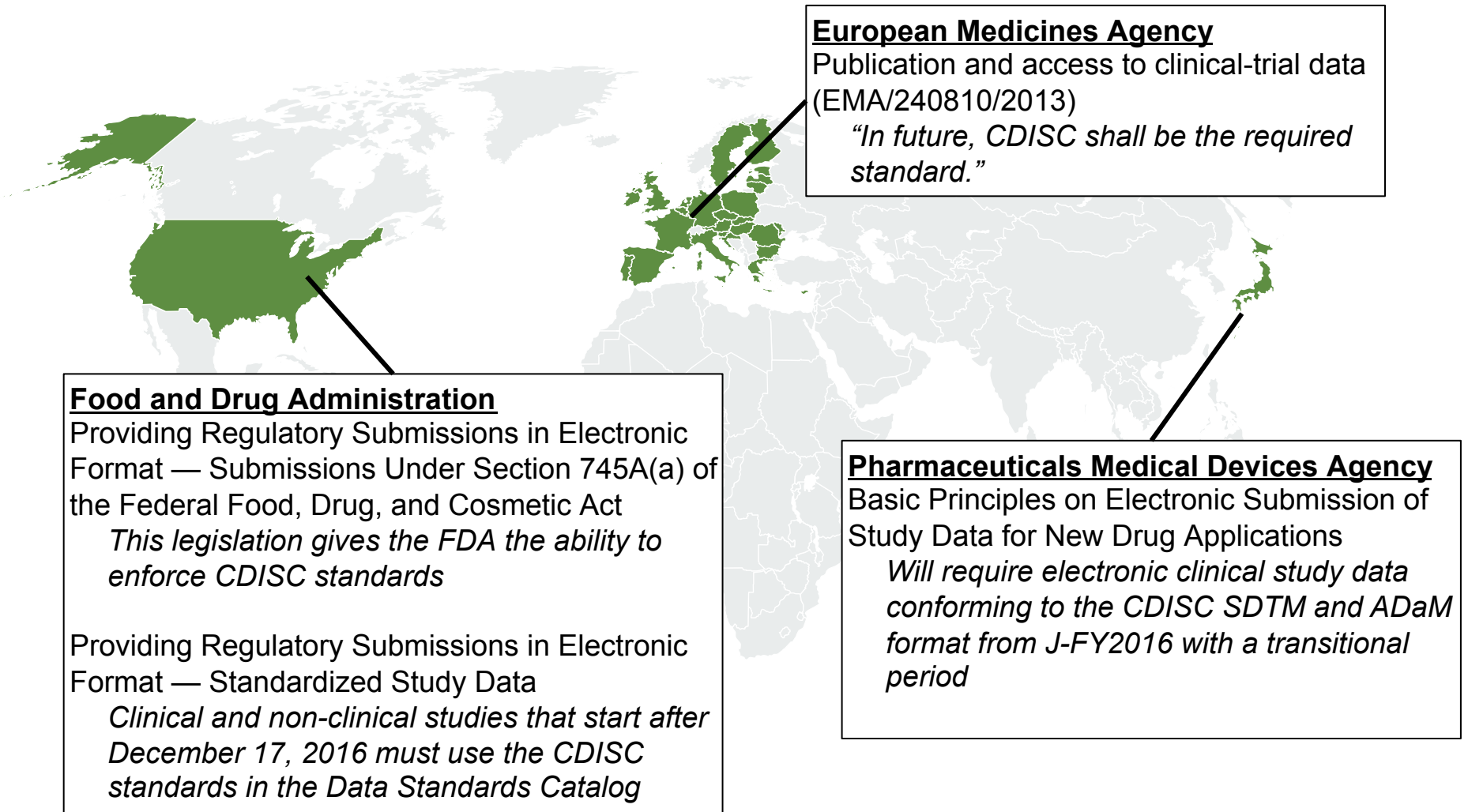
copy="No" ItemOID="IT MDE AERTCD [SDTM AE] MDE 1"/>

# Agenda

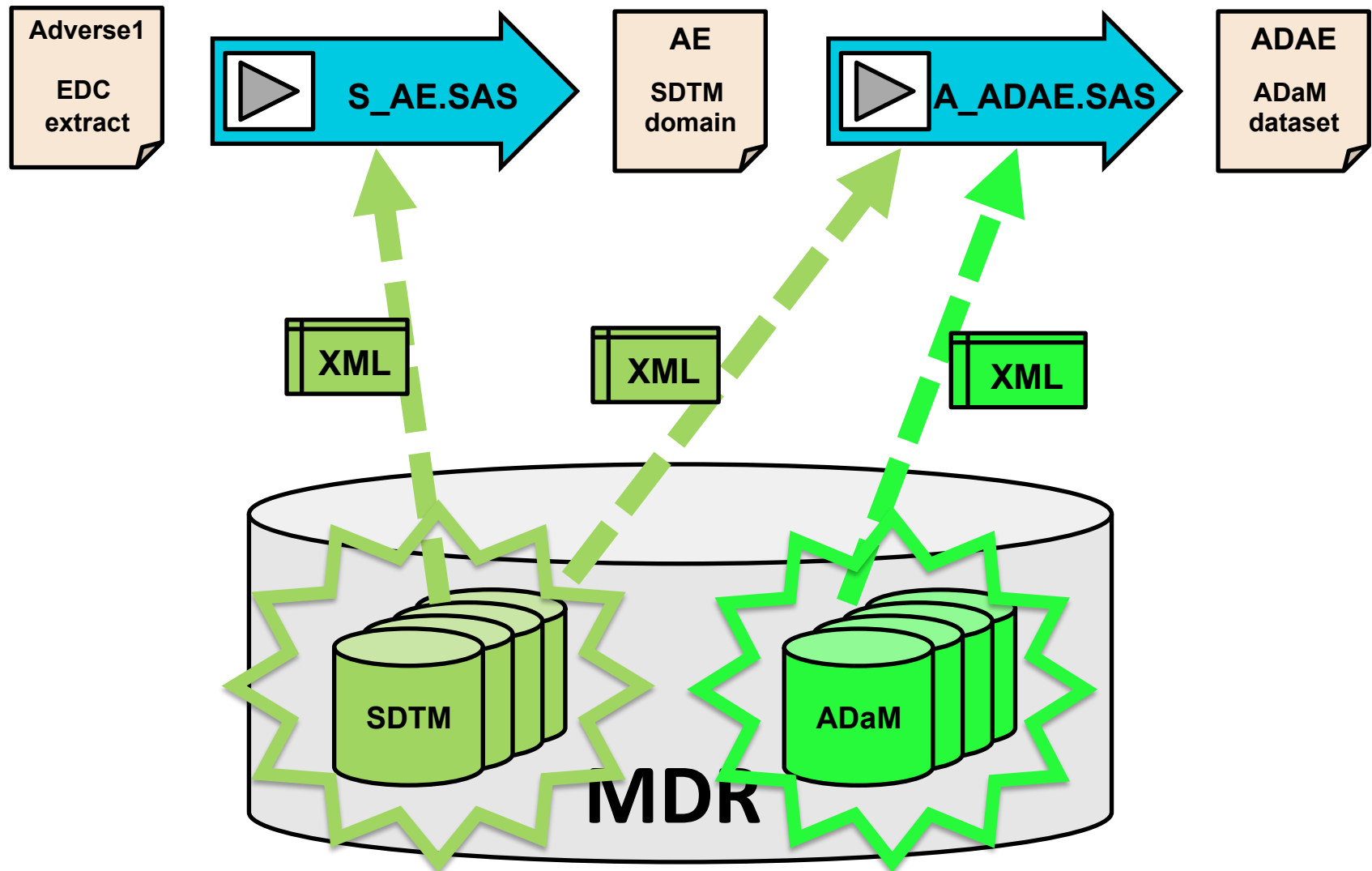
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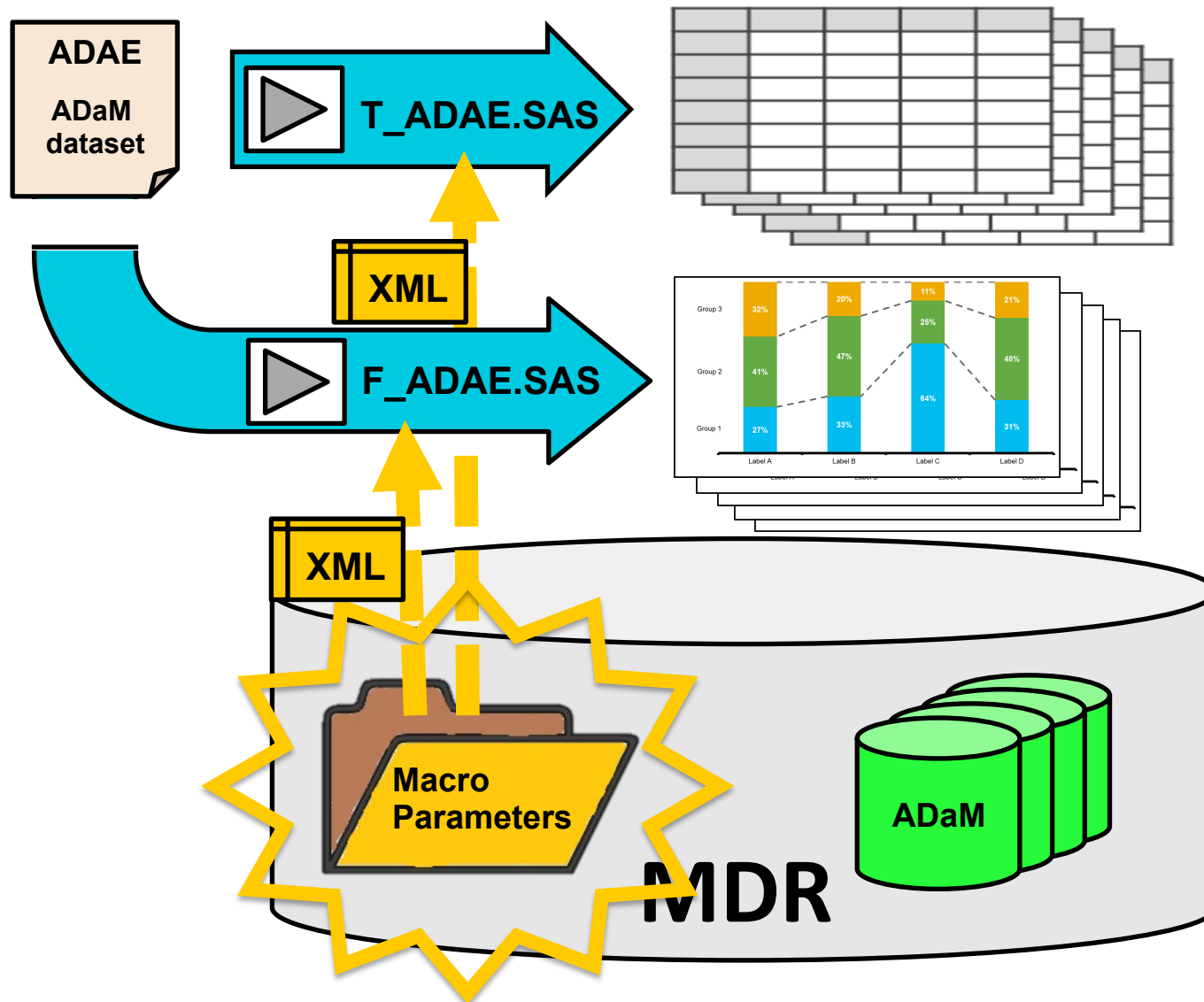
# Emerging Regulatory Requirements



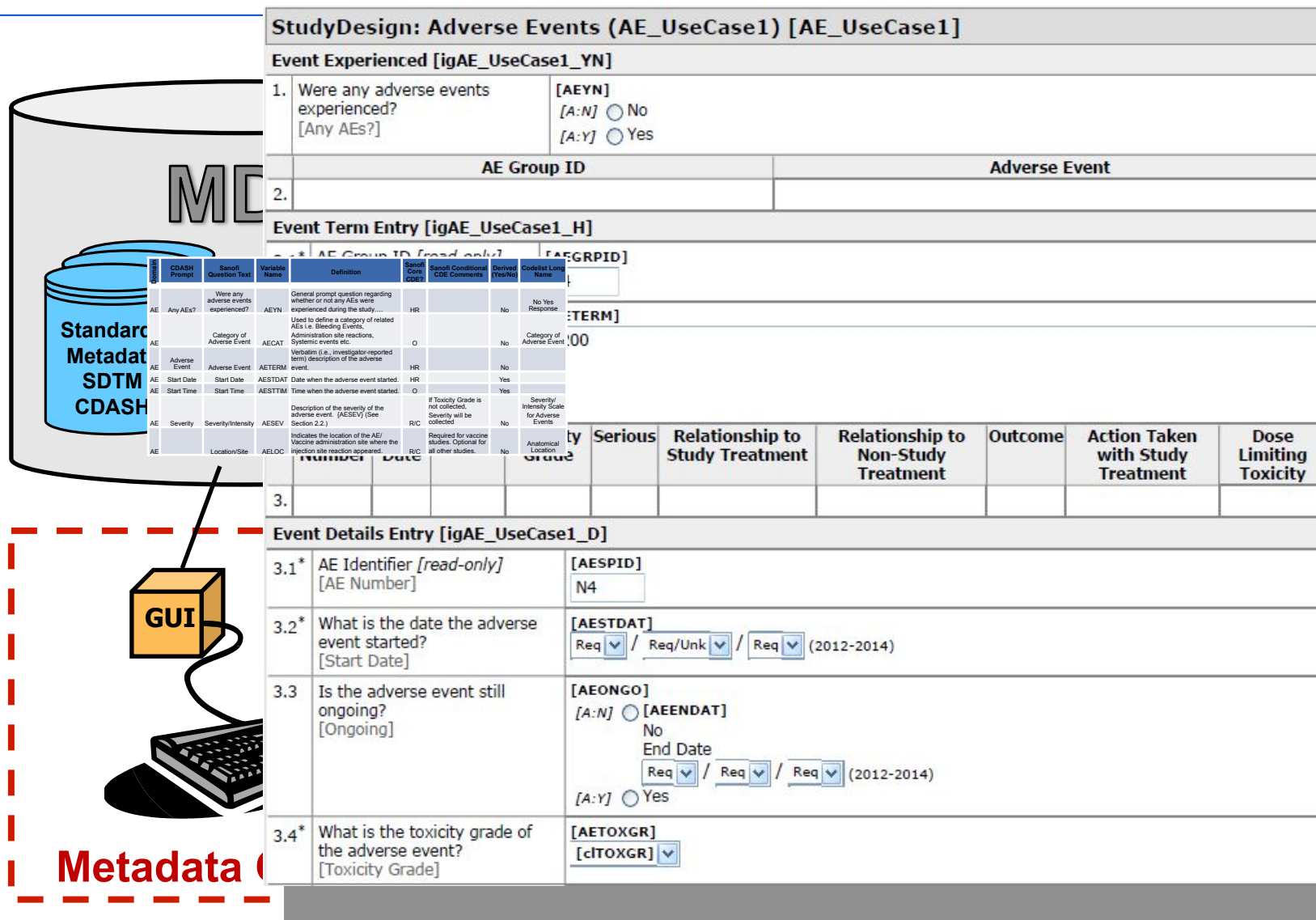
# Metadata Use Case #1



# Metadata Use Case #2



# Metadata Use Case #3



**StudyDesign: Adverse Events (AE\_UseCase1) [AE\_UseCase1]**

**Event Experienced [igAE\_UseCase1\_YN]**

1. Were any adverse events experienced? [AEYN]  
 [A:N] ☐ No  
 [A:Y] ☐ Yes

**AE Group ID** **Adverse Event**

2. **Event Term Entry [igAE\_UseCase1\_H]**

\* AE Group ID [read-only] [A:EGRPID]

| CDASH Prompt                 | Sanofi Question Text                 | Variable Name | Definition                                                                                                         | Sanofi Core CDE? | Sanofi Conditional CDE Comments                                | Derived (Yes/No) | CodeList Long Name                          |
|------------------------------|--------------------------------------|---------------|--------------------------------------------------------------------------------------------------------------------|------------------|----------------------------------------------------------------|------------------|---------------------------------------------|
| AE Any AEs?                  | Were any adverse events experienced? | AEYN          | General prompt question regarding whether or not any AEs were experienced during the study.                        | HR               |                                                                | No               | No Yes Response                             |
| AE Category of Adverse Event | Category of Adverse Event            | AECAT         | Used to define a category of related AEs i.e. Bleeding Events, Administration site reactions, Systemic events etc. | O                |                                                                | No               | Category of Adverse Event                   |
| AE Adverse Event             | Adverse Event                        | AETERM        | Verbatim (i.e. investigator-reported term) description of the adverse event.                                       | HR               |                                                                | No               |                                             |
| AE Start Date                | Start Date                           | AESTDAT       | Date when the adverse event started.                                                                               | HR               |                                                                | Yes              |                                             |
| AE Start Time                | Start Time                           | AESTTM        | Time when the adverse event started.                                                                               | O                |                                                                | Yes              |                                             |
| AE Severity                  | Severity/Intensity                   | AESV          | Description of the severity of the adverse event. (AESV) (See Section 2.2.)                                        | R/C              | If Toxicity Grade is not collected, Severity will be collected | No               | Severity/Intensity Scale for Adverse Events |
| AE Location                  | Location/Injection Site              | AELC          | Indicates the location of the AE/ Vaccine administration site where the injection site reaction appeared.          | R/C              | Required for vaccine studies. Optional for all other studies.  | No               | Anatomical Location                         |

**Event Details Entry [igAE\_UseCase1\_D]**

3.1\* AE Identifier [read-only] [AE Number] [AESPID]  
N4

3.2\* What is the date the adverse event started? [Start Date] [AESTDAT]  
 Req  / Req/Unk  / Req  (2012-2014)

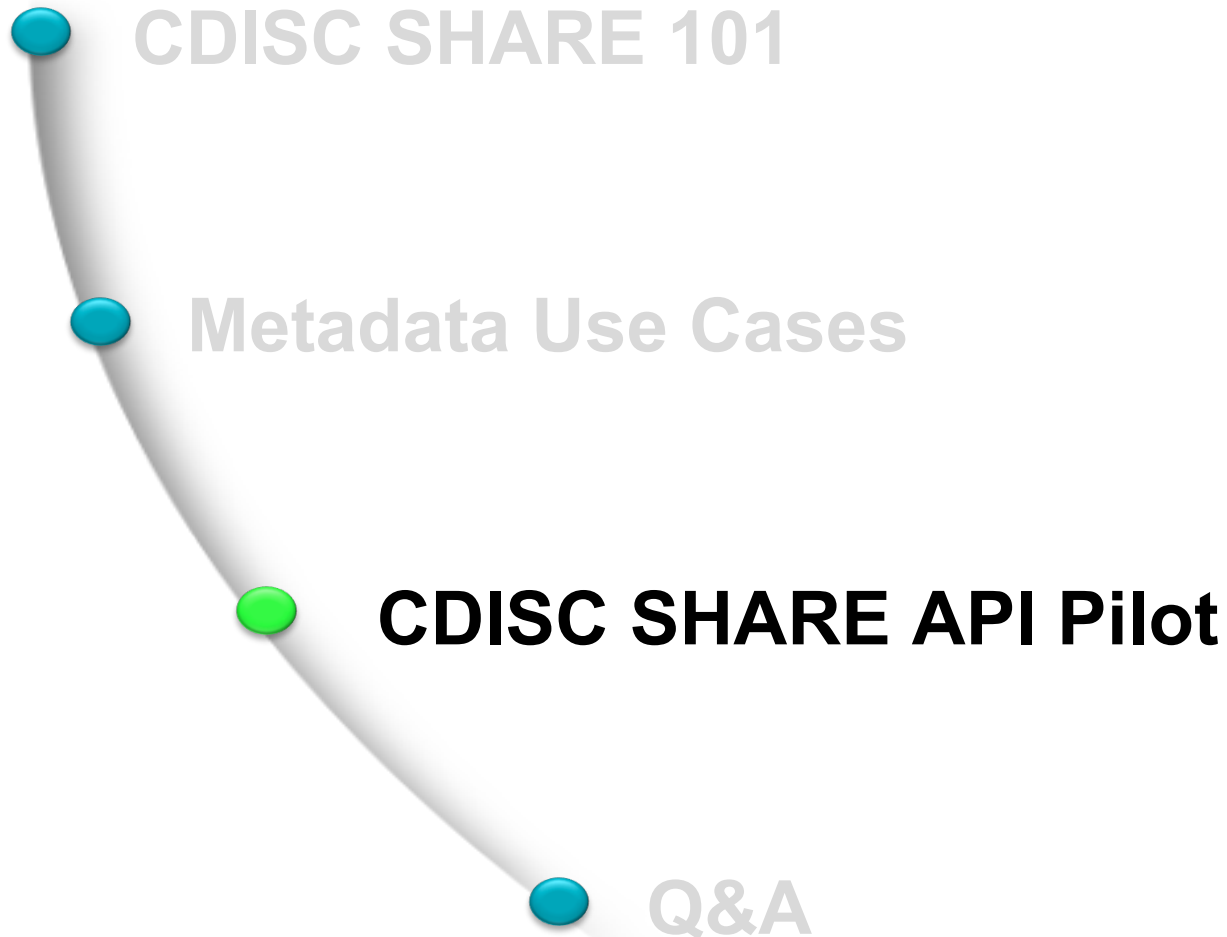
3.3 Is the adverse event still ongoing? [Ongoing] [AEONGO]  
 [A:N] ☐ [AEENDAT]  
 No  
 End Date  
 Req  / Req  / Req  (2012-2014)  
 [A:Y] ☐ Yes

3.4\* What is the toxicity grade of the adverse event? [Toxicity Grade] [AETOXGR]  
 [cTOXGR]

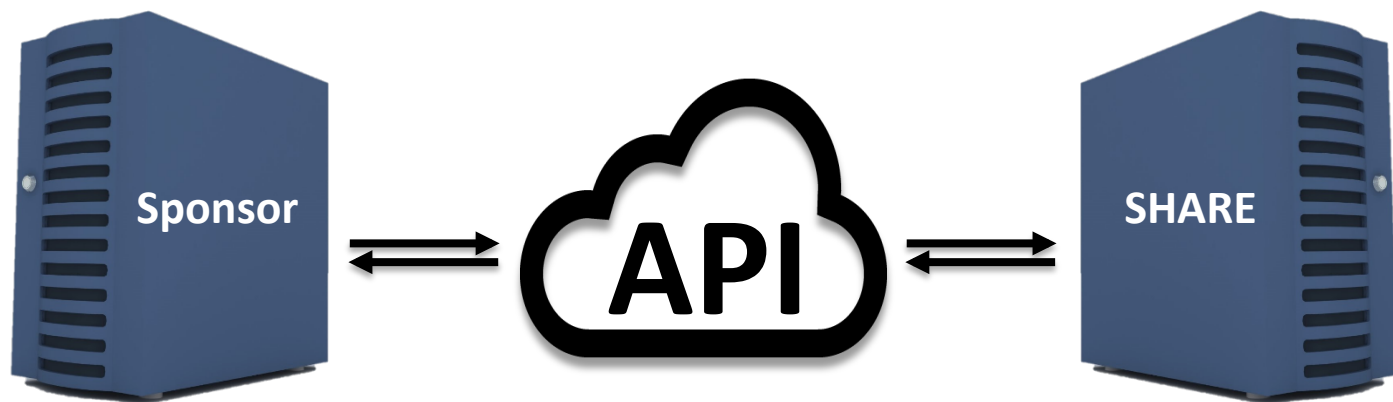
**Metadata**

# Agenda

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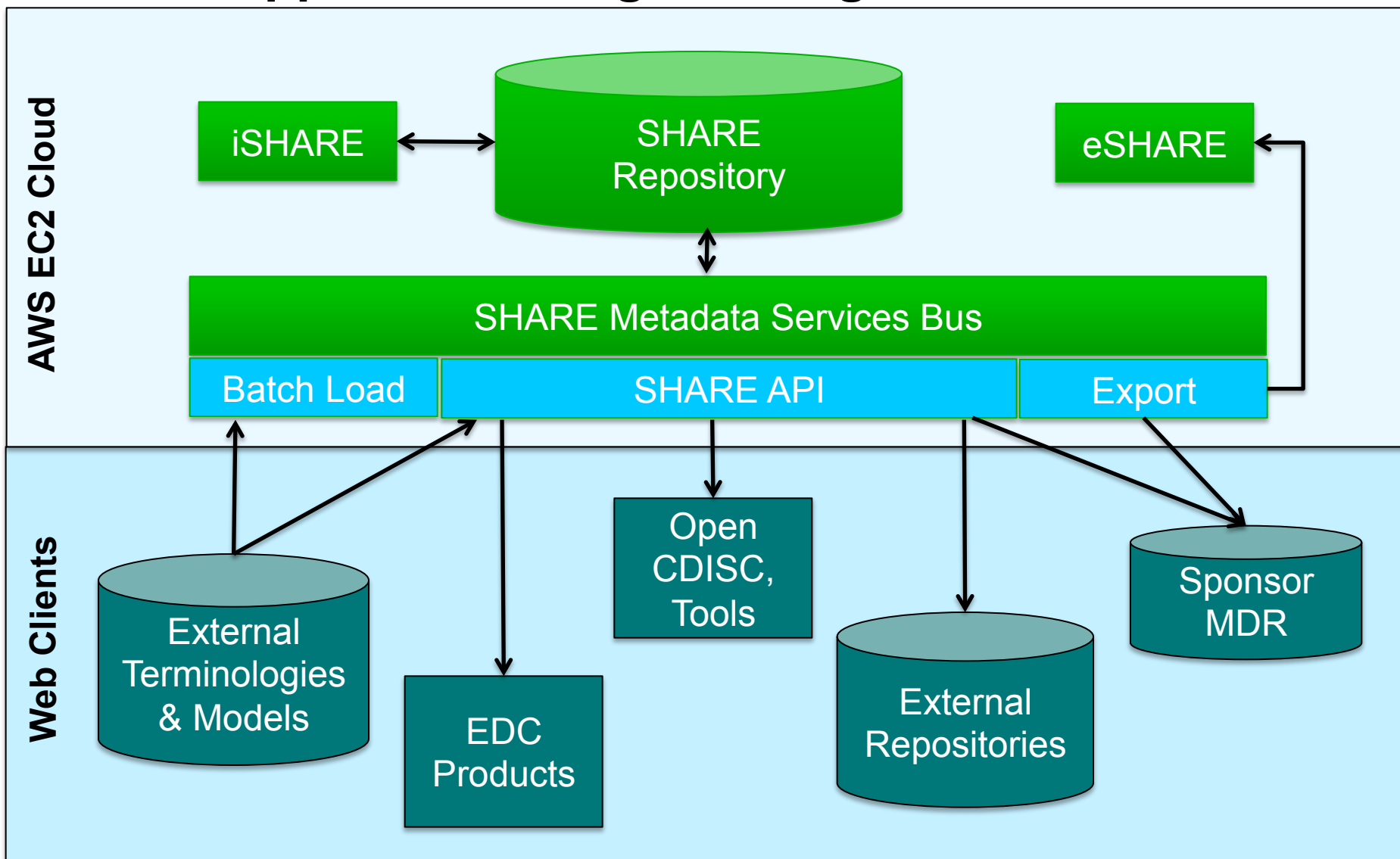


# MDR to MDR



- ▶ Application Programming Interface (API)
  - Direct automated interaction between CDISC Share Repository and Sponsor MDR

# SHARE: Application Programming Interface



Slide Courtesy of: Sam Hume, CDISC, VP SHARE Technology & Services

# CDISC SHARE API Pilot

## Details:

- ▶ RFI published - April 2015
- ▶ Started – August 2015
- ▶ Anticipated end - Q4 2015
- ▶ Participant organizations:
  - CDISC
  - Accenture
  - Business and Decisions
  - Cambridge Semantics
  - Entimo
  - eTriks
  - Fujitsu
- ▶ Committal of a dedicated resource (~ 0.25 FTE)

- ▶ Participation fee

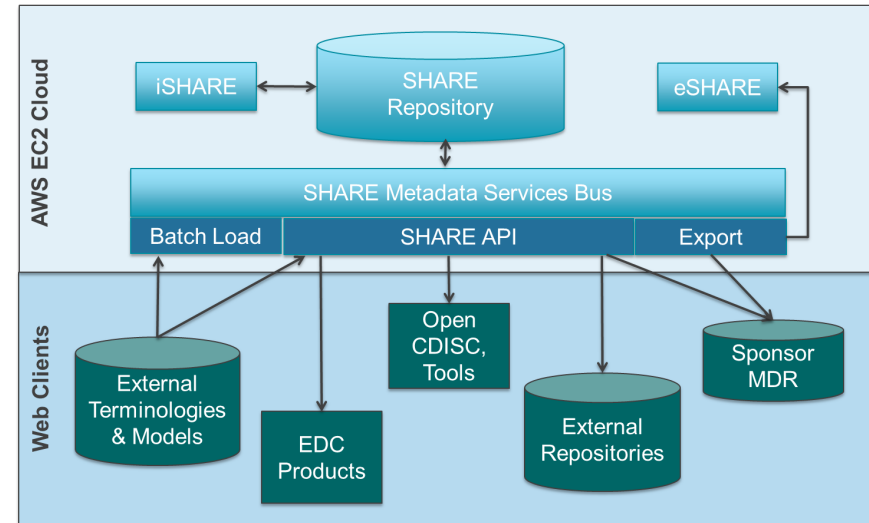


**CDISC SHARE**  
SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

# CDISC SHARE API Pilot

## ► Goals

- Enable automated programmatic access to SHARE content
- Develop use cases
- Enhance design aspects
- Review and test the Web API features



- ★ Final specification for the API will be delivered during the pilot
  - Draft specification currently exists

# SHARE Access - Future

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## API access yields opportunities:

- ▶ Sets of standard metadata or specified components
  - Domains
  - Variables
- ▶ Update packages (changes between versions)
- ▶ Lookup capabilities:
  - Test names associated with Test codes
  - Available supplemental qualifiers
  - Validation rules
- ▶ Mapping data for variables (e.g.: CDASH to SDTM)
- ▶ Research concepts
- ▶ Value--level metadata

# SHARE Interoperability Benefits

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- ▶ Increases process automation opportunities
- ▶ Increases metadata quality
- ▶ Improves data quality through standardization
- ▶ Improves data quality through semantics
- ▶ Encourages data re-use
- ▶ Facilitates data aggregation
- ▶ Improves data exchange across organizations
- ▶ Improves end-to-end data lifecycle efficiency

# Contact Information

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## Ken Stoltzfus

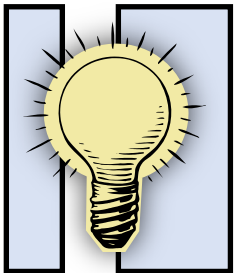
Clinical Data Strategies

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Berwyn, PA 19312

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*Feel free to visit the Accenture booth for  
more information on Accenture's solutions*

# Q&A

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