



# **Towards Semantic Interoperability of CDISC Foundational Standards**

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**CSHALS, 2014**

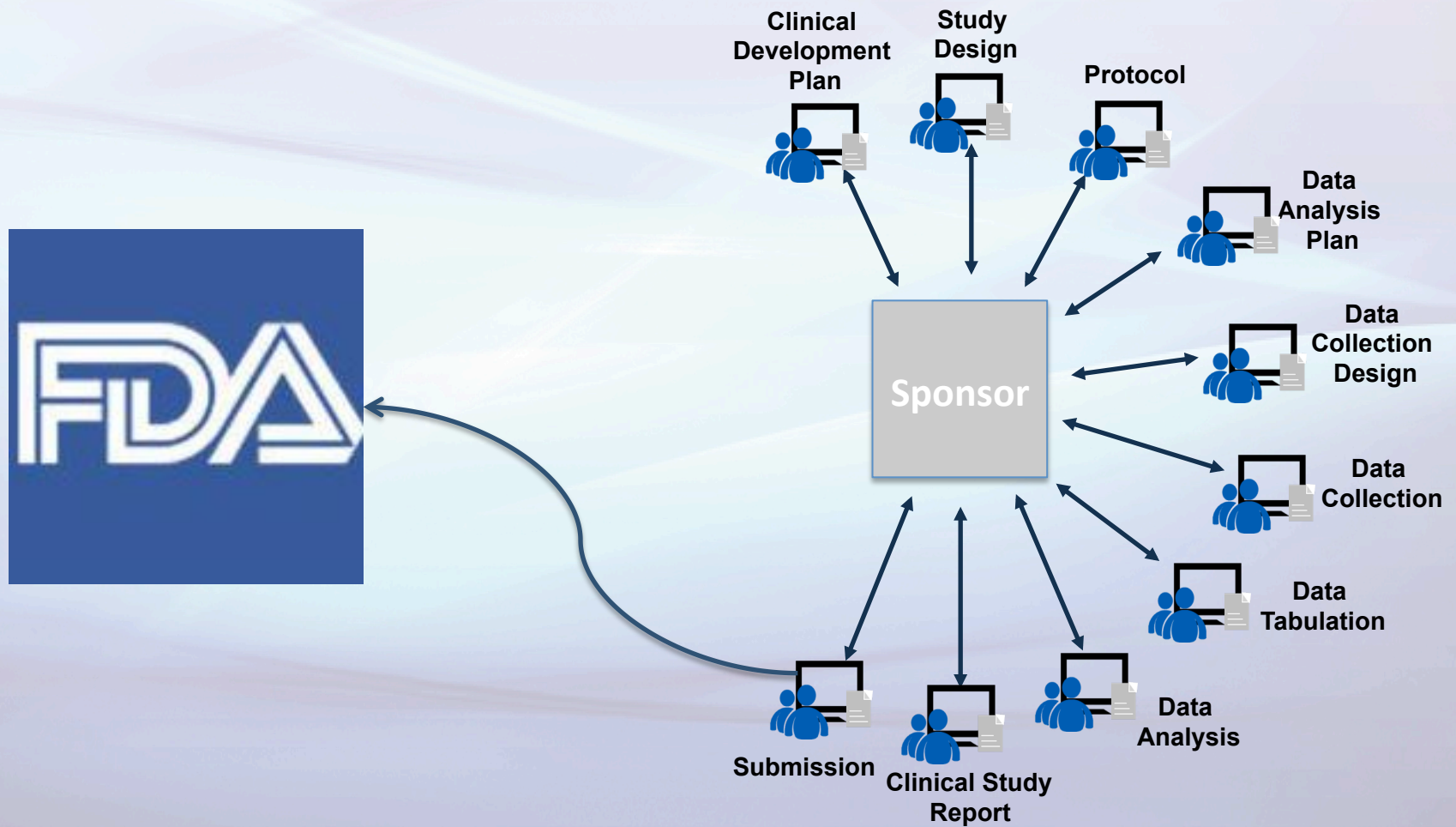


# Agenda

- Clinical Trial Life-Cycle
- CDISC Foundational Standards
- PhUSE Computational Science Symposium Working Groups
- CDISC Foundational Standards in RDF
- Case Study: Benefits of Machine-Processable Standards, Hoffmann-La Roche RDF-based Metadata Repository



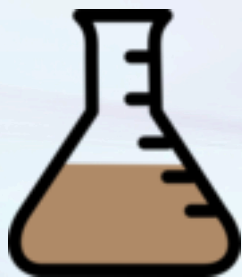
# Clinical Trial Life-Cycle







# Regulatory Submissions, Current State



DM:

- USUBJID: 101
- SEX: F
- BRTHDTC: 1975-02-22

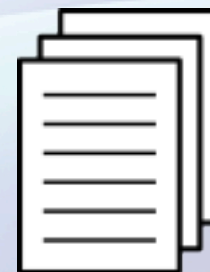
Pharma Co.

Demog:

- SUBJ: 101
- GENDER: FEMALE
- DOB: 02/22/1975



BioTech Inc.





# Regulatory Submissions, Future State

- 06-Feb-2014, FDA issues (draft) Guidance for Industry: Providing Regulatory Submissions in Electronic Format
- 06-Feb-2014, FDA issues (draft) Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Standardized Study Data
  - Standards requirements per FDA Data Standards Catalog
  - CDISC tabulation, analysis, and terminology standards are the current supported standards for study data
- Required 24 months after final guidance (~2016/2017)

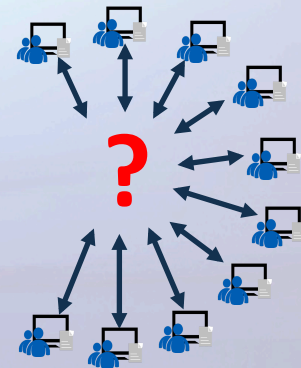


# CDISC Foundational Standards

## Clinical Data Interchange Standards Consortium (CDISC) Mission:

*“...to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research...”*

- Foundational Standards support clinical research lifecycle
  - PRM/SDM: Protocol Representation
  - CDASH: Data Collection
  - SDTM/SEND: Data Tabulation
  - ADaM: Data Analysis
  - Controlled Terminology: Vocabulary
  - ODM: Data Exchange







CDISC SDTM (Version 1.4)

CDISC

Study Data Tabulation Model  
Implementation Guide:  
Human Clinical Trials  
Version 3.2

|   | A              | B                     | C      | D                                   | E             | F                           | G    | H                             | I                           | J   | K       | L          |
|---|----------------|-----------------------|--------|-------------------------------------|---------------|-----------------------------|------|-------------------------------|-----------------------------|---|---------|------------|
|   | Seq. For Order | Observation Class     | Domain | Variable Name (minus domain prefix) | Variable Name | Variable Label              | Type | Controlled To Codelist or For | Role                        | CDISC Notes (for domains) Description (for General Classes)   | Control | References |
| 1 | 1              | Interventions-General |        | TRT                                 | --TRT         | Name of Treatment           | Char |                               | Topic                       | The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.  |         |            |
| 2 | 2              | Interventions-General |        | MODIFY                              | --MODIFY      | Modified Treatment Name     | Char |                               | Synonym Qualifier of --TRT  | If the value for --TRT is modified for coding purposes, then the modified text is placed here.  |         |            |
| 3 | 3              | Interventions-General |        | DECOD                               | --DECOD       | Standardized Treatment Name | Char |                               | Synonym Qualifier of --TRT  | Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries. |         |            |
| 4 | 4              | Interventions-General |        | CAT                                 | --CAT         | Category                    | Char |                               | Grouping Qualifier          | Used to define a category of topic-variable values.   |         |            |
| 5 | 5              | Interventions-General |        | SCAT                                | --SCAT        | Subcategory                 | Char |                               | Grouping Qualifier          | Used to define a further categorization of --CAT values.  |         |            |
| 6 | 6              | Interventions-General |        | PRES                                | --PRES        | Pre-specified               | Char |                               | Variable Qualifier of --TRT | Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.  |         |            |
| 7 | 7              | Interventions-General |        | OCCUR                               | --OCCUR       | Occurrence                  | Char |                               | Record Qualifier            | Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.   |         |            |
| 8 | 8              | Interventions-General |        | STAT                                | --STAT        | Completion Status           | Char |                               | Record Qualifier            | Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.   |         |            |
| 9 | 9              | Interventions-General |        | REASND                              | --REASND      | Reason Not Done             | Char |                               | Record Qualifier            | Reason not done. Used in conjunction with --STAT when value is NOT DONE.  |         |            |



# PhUSE CSS Working Groups

## **PhUSE Computational Science Symposium Mission:**

*“...bring together academia, industry, technology providers and the FDA to collaborate on projects to address unmet computational science needs.”*

## **Emerging Technologies, Semantic Technology Project:**

- Investigate the application of W3C semantic standards to support the clinical and non-clinical data life-cycle from protocol development to submission to regulatory agencies
- Activities
  - Representation of CDISC Foundational Standards in RDF
  - Representation of CDISC PRM/SDM in RDF
  - Representation of Analysis Results Metadata to Support Clinical and Non-Clinical Applications
  - Representation of Regulations and Guidance in RDF





# Representation of CDISC Foundational Standards in RDF

## **Project Overview:**

- Representing existing CDISC standards in RDF provides a foundation for interoperable end-to-end data standards in clinical and non-clinical research
- Separate sub-teams represented individual standards and leveraged CDISC community SMEs as needed
- Separate models were consolidated and vetted within the sub-team co-leadership, and a draft posted to GitHub
- Collaborating with CDISC to have the RDF representations adopted as CDISC standards



# Representation of CDISC Foundational Standards in RDF

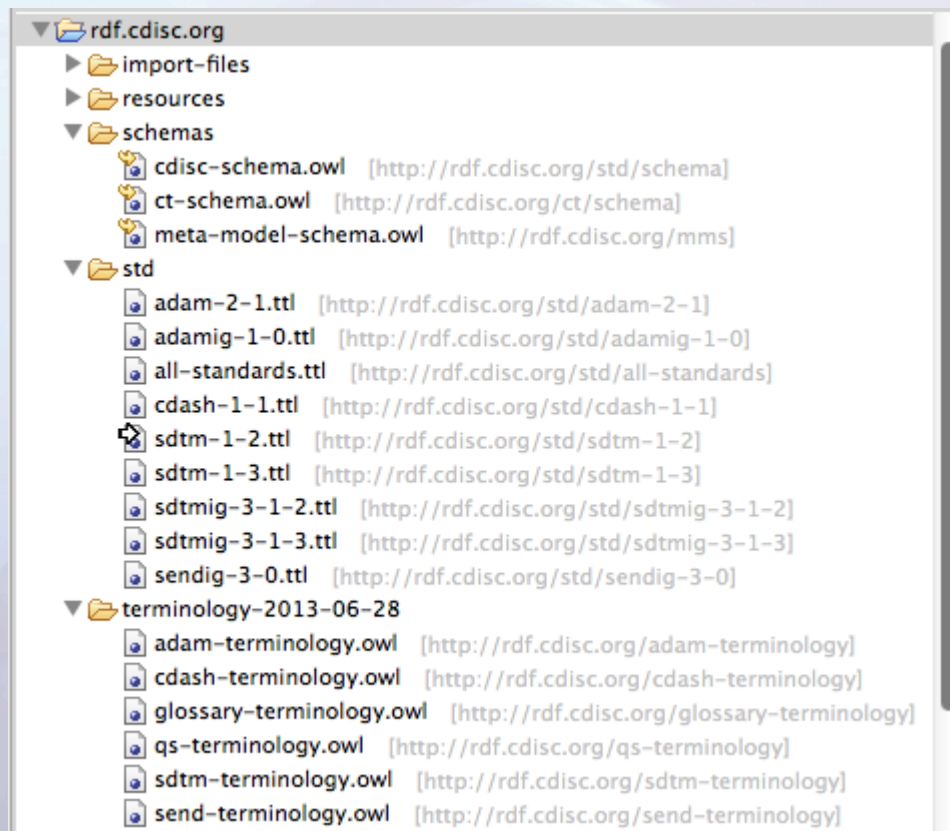
## **CDISC Standards Represented\*:**

- CDASH v1.1 including domain-level and variable-level recommendations
- SDTM v1.2, v1.3
- SDTM IG v3.1.2, v3.1.3 including domain-level assumptions
- SEND IG v3.0 including domain-level assumptions
- ADaM v2.1
- ADaM IG v1.0
- CDISC Controlled Terminology

\*: Additional standards (e.g. TA standards, SDTM v3.2, etc.) will be represented in the future



# CDISC Foundational Standards: RDF Walkthrough



- Based on ISO-11179 standard for metadata registries
- Schemas define classes and predicates for ontology to represent CDISC standards
- RDF datasets in Turtle (ttl) for each CDISC data standard and terminology standard





# CDISC Foundational Standards: RDF SDTM IG v3.1.2 Walkthrough

### Resource Form

Name: sdtmig-3-1-2:Model.SDTMIG-3-1-2 OK

Annotations

Other Properties

mms:contextDescription  
S The Study Data Tabulation Model Implementation Guide is a CDISC defined guide for the implementation of SDTM providing a detailed specification of the SDTM domains.

mms:contextLabel  
S Study Data Tabulation Model Implementation Guide (SDTMIG) Version 3.1.2

mms:contextName  
S sdtmig-3-1-2

rdf:type  
mms:Model

Incoming References

mms:context

- ◆ sdtmig-3-1-2:EventsObservationClass
- ◆ sdtmig-3-1-2:FindingsAbout
- ◆ sdtmig-3-1-2:FindingsObservationClass
- ◆ sdtmig-3-1-2:InterventionsObservationClass
- ◆ sdtmig-3-1-2:RelationshipDataset
- ◆ sdtmig-3-1-2:SpecialPurposeDomain
- ◆ sdtmig-3-1-2:TrialDesignModel

### Resource Form

Name: sdtmig-3-1-2:EventsObservationClass OK

Annotations

Other Properties

mms:context  
◆ sdtmig-3-1-2:Model.SDTMIG-3-1-2

mms:contextDescription  
S The Events class captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).

mms:contextLabel  
S Events Observation Class

mms:contextName  
S Events

mms:ordinal  
3

rdf:type  
mms:DatasetContext

Incoming References

mms:context

- ◆ sdtmig-3-1-2:Dataset.AE
- ◆ sdtmig-3-1-2:Dataset.CE
- ◆ sdtmig-3-1-2:Dataset.DS
- ◆ sdtmig-3-1-2:Dataset.DV
- ◆ sdtmig-3-1-2:Dataset.MH



# CDISC Foundational Standards: RDF SDTM IG v3.1.2 Walkthrough

**Resource Form**

Name: sdtmig-3-1-2:EventsObservationClass OK

Annotations

Other Properties

mms:context

mms:contextDescription

mms:contextLabel

mms:contextName

mms:ordinal

rdf:type

Incoming References

mms:context

sdtmig-3-1-2:Dataset.CE

sdtmig-3-1-2:Dataset.DS

sdtmig-3-1-2:Dataset.DV

sdtmig-3-1-2:Dataset.MH

**Resource Form**

Name: sdtmig-3-1-2:Dataset.AE OK

Annotations

Other Properties

mms:context

mms:contextLabel

mms:contextName

mms:ordinal

cdiscs:datasetCode

cdiscs:datasetStructure

rdf:type

Incoming References

mms:context

sdtmig-3-1-2:Column.AE.AEACNOTH

sdtmig-3-1-2:Column.AE.AEBODSYS

sdtmig-3-1-2:Column.AE.AECAT

sdtmig-3-1-2:Column.AE.AECONTRT

sdtmig-3-1-2:Column.AE.AEDECOD



# CDISC Foundational Standards: RDF SDTM IG v3.1.2 Walkthrough

**Resource Form**

Name: sdtmig-3-1-2:Dataset.AE

Annotations

Other Properties

mms:context

sdsmig-3-1-2:EventsObservationClass

mms:contextLabel

Adverse Events

mms:contextName

AE

mms:ordinal

8

cdiscs:datasetCode

AE

cdiscs:datasetStructure

One record per adverse event per subject

rdftype

mms:Dataset

Incoming References

mms:context

sdsmig-3-1-2:Column.AE.AEACN

sdsmig-3-1-2:Column.AE.AEACNOTH

sdsmig-3-1-2:Column.AE.AEBODSYS

sdsmig-3-1-2:Column.AE.AECAT

sdsmig-3-1-2:Column.AE.AECONTRT

sdsmig-3-1-2:Column.AE.AEDECOD

**Resource Form**

Name: sdtmig-3-1-2:Column.AE.AEACN

Annotations

Other Properties

mms:context

sdsmig-3-1-2:Dataset.AE

mms:dataElement

sdsm-1-2:DataElement.Event.--ACN

mms:dataElementDescription

Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.

mms:dataElementLabel

Action Taken with Study Treatment

mms:dataElementName

AEACN

mms:dataElementType

xsd:string

mms:dataElementValueDomain

sdsmct:C66767

mms:ordinal

18

cdiscs:controlledTermsOrFormat

(ACN)

cdiscs:dataElementCompliance

sdsm-1-2:Classifier.ExpectedVariable

cdiscs:dataElementRole

sdsm-1-2:Classifier.RecordQualifier

cdiscs:dataElementType

cdiscs:Classifier.Character





# CDISC Foundational Standards: RDF SDTM IG v3.1.2 Walkthrough

**Resource Form**

Name: sdtmig-3-1-2:Column.AE.AEACN

Annotations

Other Properties

mms:context  
sdtmig-3-1-2:Dataset.AE

mms:dataElement  
sdtm-1-2:DataElement.Event.--ACN

mms:dataElementDescription  
Describes changes to the study treatment as a result of the event. AEACN is specifically for the relationship to study treatment. AEACNOTH is for actions unrelated to dose adjustments of study treatment. Examples of AEACN values include ICH E2B values: DRUG WITHDRAWN, DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.

mms:dataElementLabel  
Action Taken with Study Treatment

mms:dataElementName  
AEACN

mms:dataElementType  
xsd:string

mms:dataElementValueDomain  
sdtmct:C66767

mms:ordinal  
18

cdiscs:controlledTermsOrFormat  
(ACN)

cdiscs:dataElementCompliance  
sdtm-1-2:Classifier.ExpectedVariable

cdiscs:dataElementRole  
sdtm-1-2:Classifier.RecordQualifier

cdiscs:dataElementType  
cdiscs:Classifier.Character

**Resource Form**

Name: sdtmct:C66767

Annotations

Other Properties

cts:cdiscDefinition  
Terminology specifying changes to the study treatment as a result of an adverse event.

cts:cdiscSubmissionValue  
ACN

cts:cdiscSynonyms  
Action Taken with Study Treatment

cts:codeListName  
Action Taken with Study Treatment

cts:isExtensibleCodeList  
false

cts:nciCode  
C66767

cts:nciPreferredTerm  
CDISC SDTM Action Taken with Study Treatment Terminology

rdftype  
mms:EnumeratedValueDomain

Incoming References

mms:dataElementValueDomain  
sdtmig-3-1-2:Column.AE.AEACN

mms:inValueDomain  
sdtmct:C66767.C17998  
sdtmct:C66767.C48660  
sdtmct:C66767.C49501  
sdtmct:C66767.C49502  
sdtmct:C66767.C49503  
sdtmct:C66767.C49504  
sdtmct:C66767.C49505

**Resource Form**

Name: sdtmct:C66767.C49502

Annotations

Other Properties

cts:cdiscDefinition  
An indication that a medication schedule was modified through termination of a prescribed regimen of medication. (NCI)

cts:cdiscSubmissionValue  
DRUG WITHDRAWN

cts:nciCode  
C49502

cts:nciPreferredTerm  
Drug Withdrawn

mms:inValueDomain  
sdtmct:C66767

rdftype  
mms:PermissibleValue



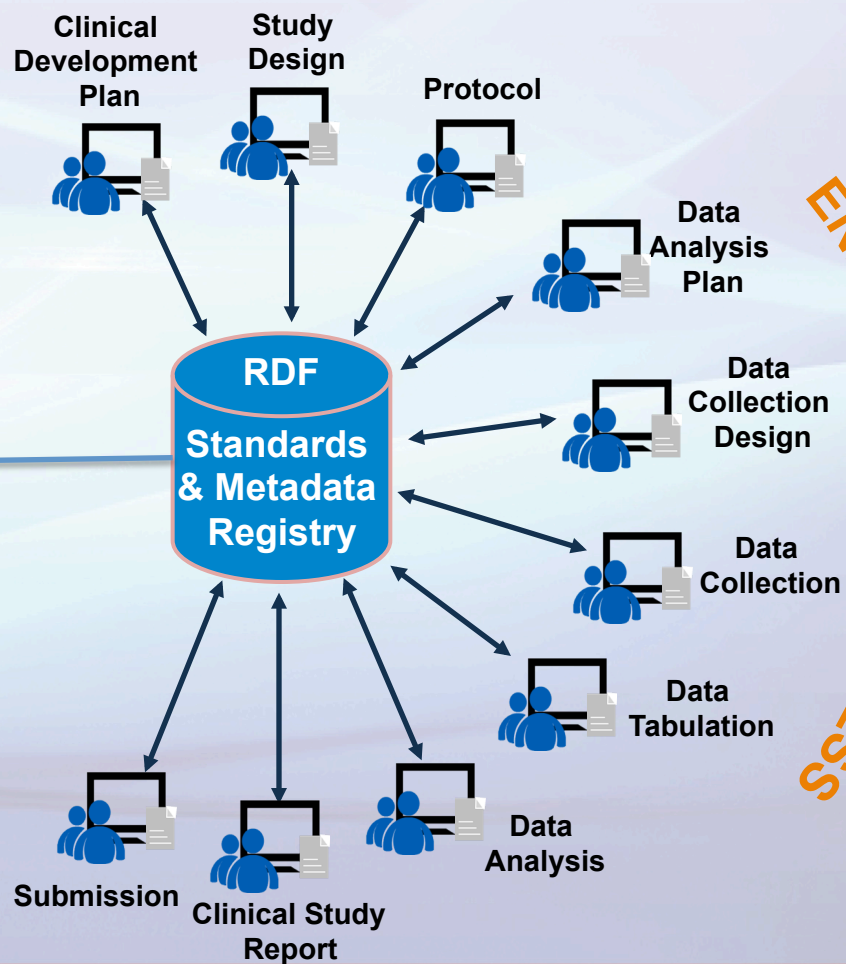
# Case Study: Benefits of Machine-Processable Standards

## **Hoffmann-La Roche Case Study Overview:**

- Machine-processable standards enable consistent management of standards including development, usage, and governance
- Implementation of standards enables workflow and business process automation
- Workflow and business process automation enables expedited submission of clinical trial results to regulatory agencies



# End to End Data Standards



DRIVEN VIA AUTOMATION  
END TO END PROCESS





# Roche Information Model

Production

Partial / Future

Sponsor Extensions

PRM

CDASH

SDTM

ADaM

define

Biomedical Concept Model [partial]

ISO 11179 MDR Schema [subset]

BRIDG and ISO 21090

NCI Thesaurus

RDF

OWL

SKOS

CDISC  
Standards

Metadata  
Management

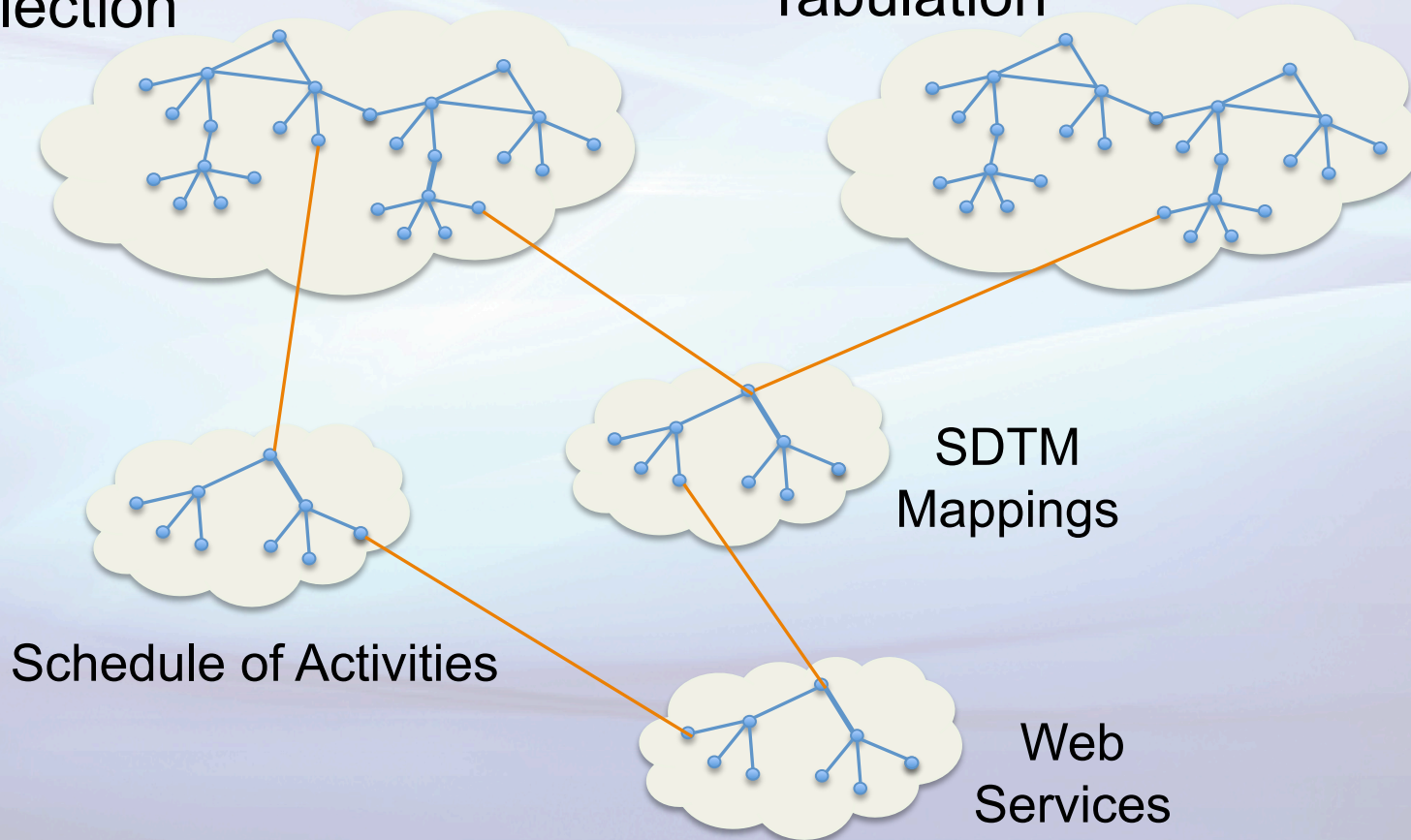
Knowledge  
Management



# Roche Linked Data Standards

Data  
Collection

Data  
Tabulation





# Use Case: Schedule of Activities

## 5. SCHEDULE OF ASSESSMENTS AND PROCEDURES

Table 2 Schedule of Assessments and Procedures—Group A (PEG-IFN) and Group C (Advanced Fibrotic PEG-IFN)

| Assessment/Procedure   | Screen<br>(days) | BL<br>(days)   | Treatment Period<br>(weeks) |   |   |   |    |    |    |    |    |    |    |                |                 |                 |                |                  | Initial 24 Weeks of<br>Follow-Up<br>(Weeks Post-End<br>of Treatment) |                |                | Extended Long-Term<br>Follow-Up Period<br>(Years Post-End of<br>Treatment Period) |   |  |  |  |
|--|------------------|----------------|-----------------------------|---|---|---|----|----|----|----|----|----|----|----------------|-----------------|-----------------|----------------|------------------|--|----------------|----------------|---|---|--|--|--|
|  | -35 to -1        | 1              | 1                           | 2 | 4 | 8 | 12 | 16 | 24 | 30 | 36 | 42 | 48 | 4 <sup>a</sup> | 12 <sup>a</sup> | 24 <sup>a</sup> | 1 <sup>a</sup> | 1.5 <sup>a</sup> | 2 <sup>a</sup>   | 3 <sup>a</sup> | 4 <sup>a</sup> | 5 <sup>a</sup>  |   |  |  |  |
| Informed Consent/Assent <sup>1</sup>                         | x                |                |                             |   |   |   |    |    |    |    |    |    |    |                |                 |                 |                |                  |  |                |                |   |   |  |  |  |
| Complete medical history, including<br>family history of HBV | x                |                |                             |   |   |   |    |    |    |    |    |    |    |                |                 |                 |                |                  |  |                |                |   |   |  |  |  |
| Physical examination   | x                |                |                             |   |   |   |    |    |    |    |    |    |    |                |                 |                 | x              |                  |  |                |                |   |   |  |  |  |
| Symptom-directed physical examination                        |                  | x              | x                           | x | x | x | x  | x  | x  | x  | x  | x  | x  | x              | x               | x               |                |                  |  |                |                |   |   |  |  |  |
| Vital signs  | x                | x              | x                           | x | x | x | x  | x  | x  | x  | x  | x  | x  | x              | x               | x               |                |                  |  |                |                |   |   |  |  |  |
| Weight <sup>2</sup>  | x                | x <sup>1</sup> | x                           | x | x | x | x  | x  | x  | x  | x  | x  | x  | x              | x               | x               |                |                  |  |                | x              | x   | x |  |  |  |
| Height <sup>3,4</sup>  | x                | x <sup>1</sup> | x                           | x | x | x | x  | x  | x  | x  | x  | x  | x  | x              | x               | x               |                |                  |  |                | x              | x   | x |  |  |  |
| Parental height <sup>2</sup>                                 |                  | x              |                             |   |   |   |    |    |    |    |    |    |    |                |                 |                 |                |                  |  |                | x              | x   | x |  |  |  |
| Ultrasound <sup>5</sup>                                      | x                |                |                             |   |   |   |    |    |    |    |    |    |    |                |                 |                 |                |                  |  |                |                |   |   |  |  |  |
| Ophthalmology exam <sup>1</sup>                              | x                |                |                             |   |   |   |    |    |    | x  |    |    |    |                |                 |                 | x              |                  |  |                |                |   |   |  |  |  |

<sup>a</sup> Or upon and following study treatment withdrawal.

</

Web Service

- owl:Thing (0 + 509)
  - sdm:StudyDesignElement (0 + 509)
    - sdm:Activity (0 + 455)
      - sdm:DefinedActivity
      - sdm:PlannedActivity (415)
      - sdm:StudyActivity (40)
      - sdm:Arm (2)
      - sdm:Cell (7)
      - sdm:CellReference (10)
      - sdm:Epoch (5)
      - sdm:Protocol
      - sdm:ProtocolVersion
      - sdm:Schedule (1)
      - sdm:Segment (7)
      - sdm:Study
      - sdm:StudyEvent (22)
      - sdm:TimingConstraint
      - sdm:Transition
      - sdm:Trigger
    - skos:Collection
    - skos:Concept
    - skos:ConceptScheme

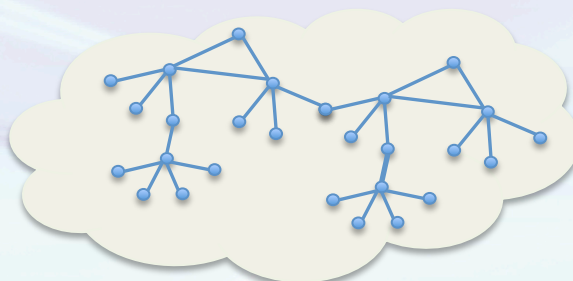
Schedule of Activities





# Use Case: Annotated Case Report Form

## Data Collection



## Web Service

**GDSR** Operational CRF  
Modified Hachinski Ischemia Scale

**Modified Hachinski Ischemia Scale (MHIS)**

Form OID: MBHS  
Form Source: Global Data Standards  
Domain: Alzheimer  
Form Layout: Single Form  
Study Build Policy: Study Build Optional Form  
SDTM Annotations: ZA = Clinical Findings  
ZA.ZACAT = MODIFIED HACHINSKI ISCHEMIA SCALE

|   | Field Label  | Field OID | Format      | Dictionary                 | SDTM Annotation                           |
|---|--|-----------|-------------|----------------------------|---|
| R | Was the Modified Hachinski Ischemia Scale performed?       | MBHFF     | \$3         | YES_NO_V1                  | ZA.ZASTAT, if assessment performed = 'No' |
| R | 1. Date of assessment                                      | MBHD      | dd-MMM-yyyy |                            | Date part of ZA.ZADTC                     |
| R | Rate initials  | RAINT     | \$3         |                            | ZA.EVALID in SUPPEA                       |
| R | 1. Abrupt onset<br>○ Absent = 0<br>○ Present = 2           | MBHAM1    | \$11        | PRESSENT, ABSENT_V1_REVIEW | ZA.ZAORRES<br>ZA.ZATESTCD = 'MBHS01'      |
| R | 2. Stepwise deterioration<br>○ Absent = 0<br>○ Present = 2 | MBHAM2    | \$11        | PRESSENT, ABSENT_V1_REVIEW | ZA.ZAORRES<br>ZA.ZATESTCD = 'MBHS02'      |

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**GDSR** Submission CRF  
Neurological Exam

**Neurological Exam**  
[ZA = Clinical Findings]  
[ZA.ZACAT = 'NEUROLOGICAL EXAMINATION']

At the Screening visit, enter any findings/conditions on the General Medical History and Baseline Conditions form. After the screening visit, enter any new or worsened findings/conditions on the Adverse Event form.

Timepoint [ ] [ZA.ZATPT]

Was a [Neurological] examination performed?

Yes ☐  
No ☐

If Yes, date of exam [ ] [Date part of ZA.ZADTC]  
Enter the complete date in dd MMM yyyy format.

Time of exam [ ] [Time part of ZA.ZADTC]

Type of [Neurological] examination performed [ ] [ZA.ZATESTCD (see Value Level Metadata, Clinical Findings)]  
[ZA.ZATEST (see Value Level Metadata, Clinical Findings)]

Exam performed?

Yes ☐  
No ☐

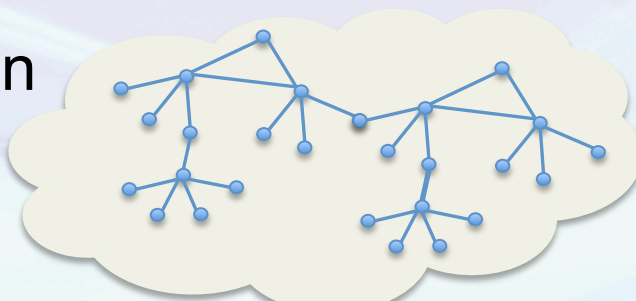
[ZA.ZASTAT, if test done = 'No']

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# Use Case: Data Management System Build

Data  
Collection



Web  
Service

|   | D       | E       | F                                      | G               |
|---|---------|---------|--|-----------------|
| 1 | OID     | Ordinal | DraftFormName                          | DraftFormActive |
| 2 | ALZH    | 1       | Alzheimer Disease History              |                 |
| 3 | MHIS    | 2       | Modified Hachinski Ischemia Scale      |                 |
| 4 | NE      | 3       | Neurological Exam                      |                 |
| 5 | SCHZH   | 4       | History of Schizophrenia               |                 |
| 6 | CGINFO1 | 5       | Caregiver Information (Screening)      |                 |
| 7 | CGINFO2 | 6       | Caregiver Information (Post Screening) |                 |

|    | C                       | D         | E       | F                                     | G       | H | I | J |
|----|-------------------------|-----------|---------|---------------------------------------|---------|---|---|---|
| 1  | DataDictionaryName      | CodedData | Ordinal | UserDataString                        | Specify |   |   |   |
| 2  | CAREGIVER_DATA_V1       |           | 1       | In person                             | FALSE   |   |   |   |
| 3  | CAREGIVER_DATA_V1       |           | 2       | By phone                              | FALSE   |   |   |   |
| 4  | CAREGIVER_DATA_V1       |           | 3       | Not at all                            | FALSE   |   |   |   |
| 5  | CAREGIVER_DATA_V2       |           | 1       | Family member living with subject     | FALSE   |   |   |   |
| 6  | CAREGIVER_DATA_V2       |           | 2       | Family member not living with subject | FALSE   |   |   |   |
| 7  | CAREGIVER_DATA_V2       |           | 3       | Professional caregiver                | FALSE   |   |   |   |
| 8  | CAREGIVER_DATA_V2       |           | 4       | Friend/Neighbor                       | FALSE   |   |   |   |
| 9  | CAREGIVER_DATA_V2       | OTHER     | 5       | Other                                 | FALSE   |   |   |   |
| 10 | DURATION_V1             |           | 1       | 6 months and < 1 years                | FALSE   |   |   |   |
| 11 | DURATION_V1             |           | 2       | 1 to <= 5 years                       | FALSE   |   |   |   |
| 12 | DURATION_V1             |           | 3       | > 5 years                             | FALSE   |   |   |   |
| 13 | NORMAL_ABNORMAL_V4      | NORMAL    | 1       | Normal                                | FALSE   |   |   |   |
| 14 | NORMAL_ABNORMAL_V4      | ABNORMAL  | 2       | Abnormal                              | FALSE   |   |   |   |
| 15 | NUMERIC_VALUE_V5        |           | 1       | 0                                     | FALSE   |   |   |   |
| 16 | NUMERIC_VALUE_V5        |           | 2       | 1                                     | FALSE   |   |   |   |
| 17 | NUMERIC_VALUE_V5        |           | 3       | 2                                     | FALSE   |   |   |   |
| 18 | NUMERIC_VALUE_V5        |           | 4       | 3                                     | FALSE   |   |   |   |
| 19 | NUMERIC_VALUE_V5        |           | 5       | 4                                     | FALSE   |   |   |   |
| 20 | PRESENT_ABSENT_V1_REVIE |           | 1       | Absent = 0                            | FALSE   |   |   |   |
| 21 | PRESENT_ABSENT_V1_REVIE |           |         |                                       |         |   |   |   |



# Data Management System Validation Rules

**Resource Form**

Name: Check.GEA\_V1\_FORMS

**Annotations**

**Incoming References**

- ← raves:checkActionOf
  - CheckAction.GEA\_V1\_FORMS.01
  - CheckAction.GEA\_V1\_FORMS.02
  - CheckAction.GEA\_V1\_FORMS.03
  - CheckAction.GEA\_V1\_FORMS.04
- ← raves:checkStepOf
  - CheckStep.GEA\_V1\_FORMS.01
  - CheckStep.GEA\_V1\_FORMS.02

**Other Properties**

- mdr:administrationRecord
  - mdr:AR.GDSII
- mdr:context
  - mms:Model.PD-Biometrics.Rave
- raves:checkActive
  - true
- raves:checkBypassDuringMigration
  - true
- raves:checkInfix
  - If VISD in Visit Date in Visit 1 with record position 0 IsNotEmpty then... add the "Hypoglycemic Events" form to the current folder, and add the "Home Glucometer Readings (for hypoglycemic events)" form to the current folder, and add the "Allergic Reaction Events" form to the current folder, and add the "Pancreatitis Events" form to the current folder
- raves:checkName
  - GEA\_V1\_FORMS
- raves:checkNeedsRetesting
  - false
- rdf:type
  - raves:Annotation.Check

**mdr:administrationRecord**

- mdr:AR.GDSII

**mdr:context**

- mms:Model.PD-Biometrics.Rave

**raves:checkStepFunction**

- CheckStepFunction.IsNotEmpty

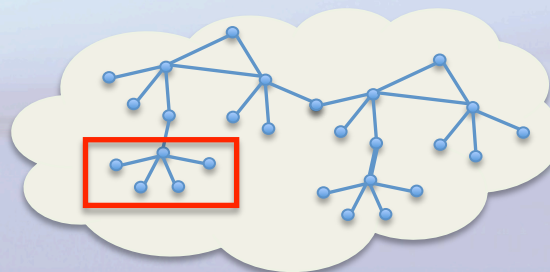
**raves:checkStepOf**

- Check.GEA\_V1\_FORMS

**raves:checkStepOrdinal**

- 2

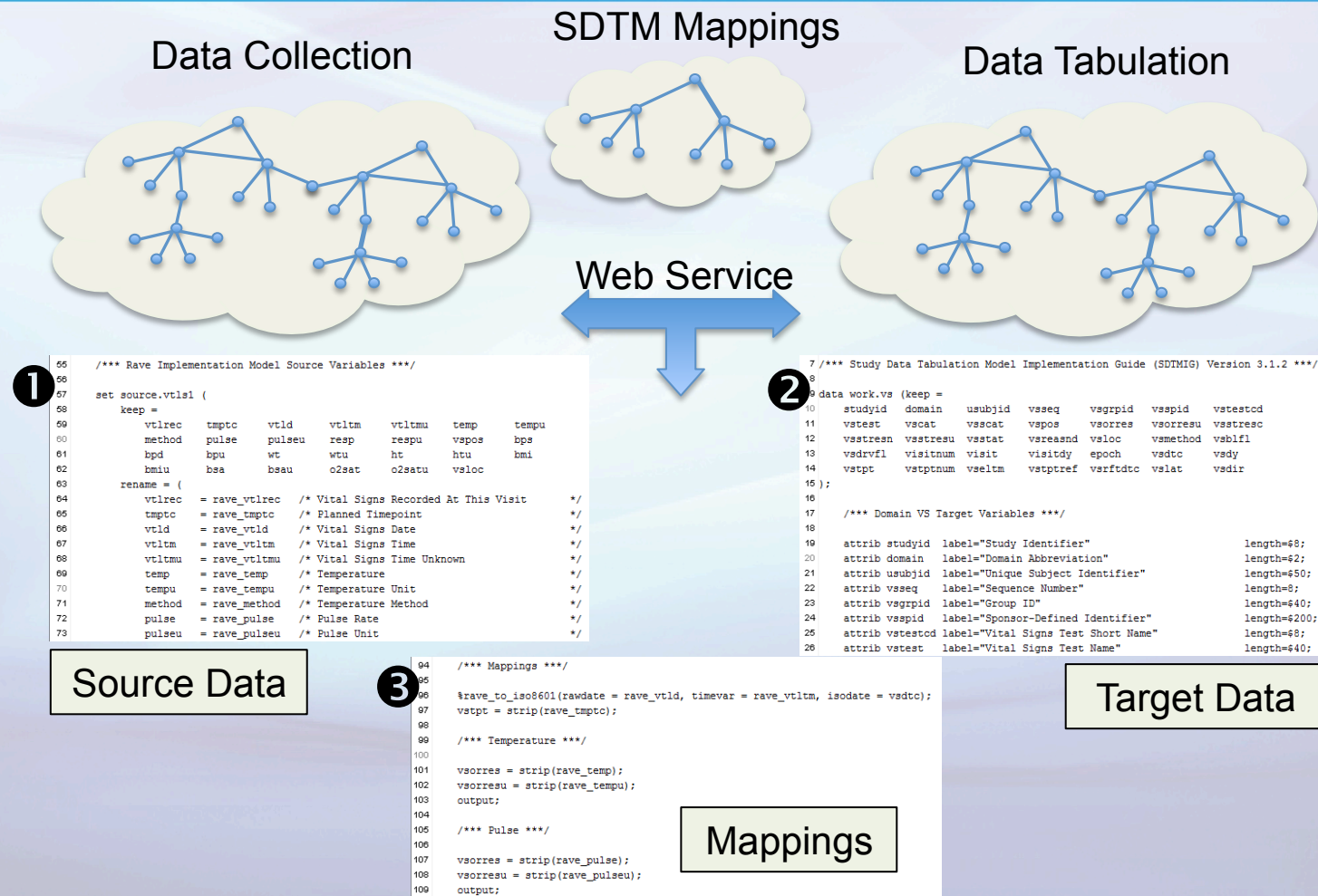
Data Collection







# Use Case: Transformation of Collected Data to SDTM Data





## Case Study: Future State

- Linked biomedical concept layer
- Representation of biomarker vocabulary
- Representation of standard data analysis concepts and displays
- Submission package automation
- Integration with Hoffmann-La Roche master data
- Integration of clinical trial metadata with clinical trial data
- Cross-trial clinical data integration



# Questions