Managing Controlled Terminologies Across Clinical Lifecycle Stages

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Overview

- **Evolving Information Governance Framework**
  - Review of the IG Network, Processes, and Data Standards

- **Controlled Terminology**
  - Current State
  - Maintenance Use Cases
  - Evolving Toward the Future State

- **Q & A**

Information Governance Evolution
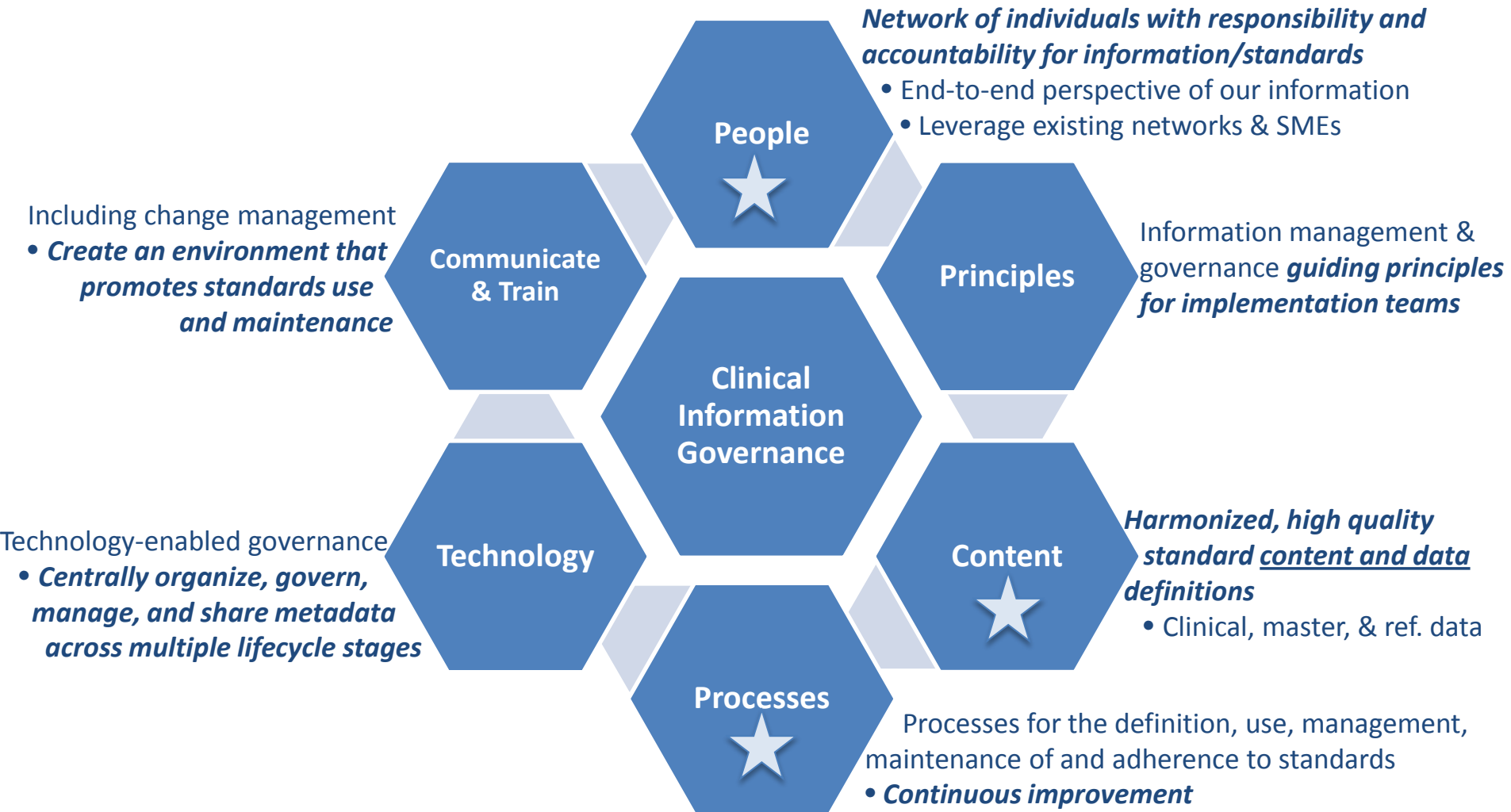

We're establishing:

➢ *A culture and organizational structure to empower information governance*

➢ *Global processes to manage information across the clinical lifecycle*

➢ *A common set of industry-based global clinical information standards*

➢ *Centrally controlled, consistent, governed, & accessible standards metadata*

　　➢ *Facilitate the use, reuse, maintenance, exchange & sharing of metadata*

*For the purpose of this presentation only; Sanofi is comprised of additional entities not listed on this slide
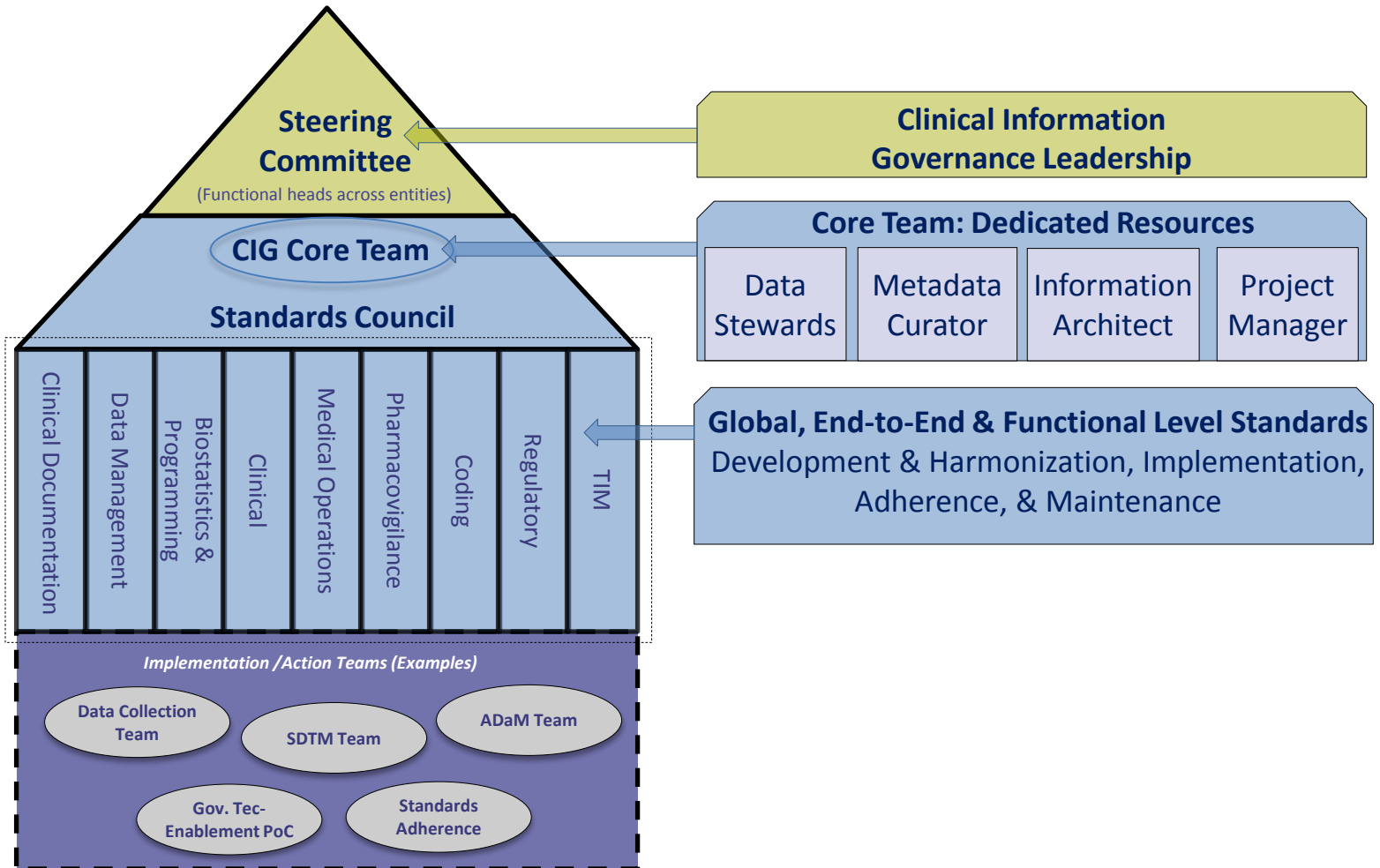
Governance Framework

Information Governance Provides A Framework

Network of individuals with responsibility and accountability for information/standards
- End-to-end perspective of our information
- Leverage existing networks & SMEs

People

Including change management
- *Create an environment that promotes standards use and maintenance*

Communicate & Train

Information management & governance *guiding principles for implementation teams*

Principles

Clinical Information Governance

Technology-enabled governance
- *Centrally organize, govern, manage, and share metadata across multiple lifecycle stages*

Technology

Harmonized, high quality standard <u>content and data</u> definitions
- Clinical, master, & ref. data

Content

Processes for the definition, use, management, maintenance of and adherence to standards
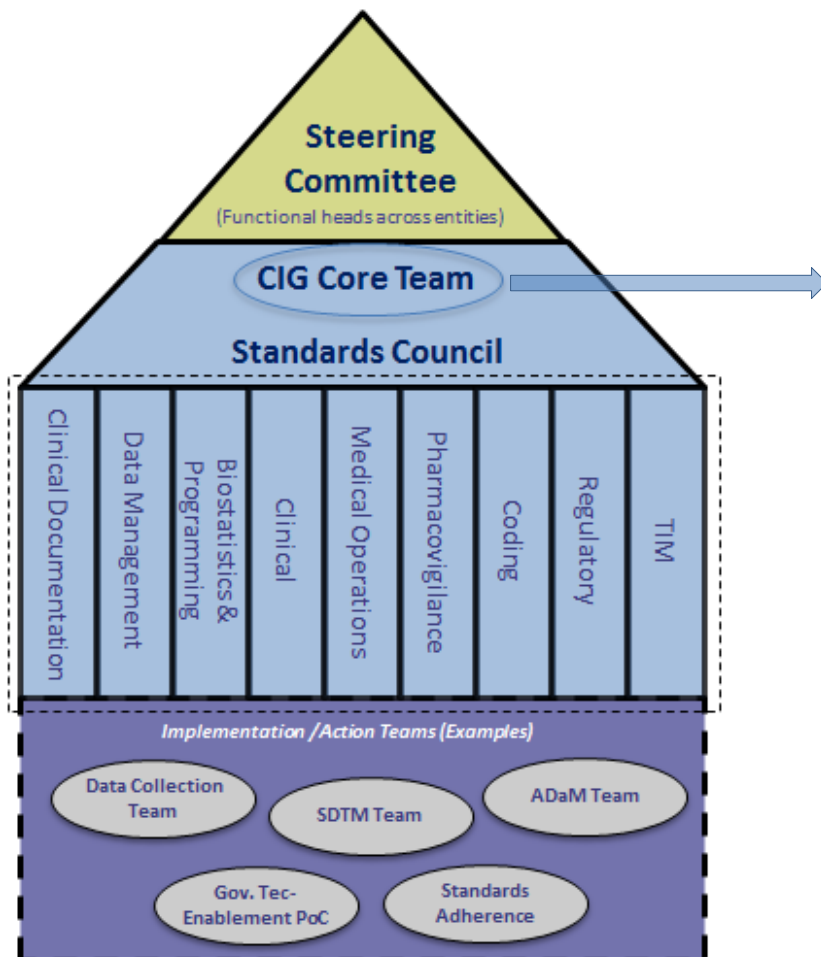- *Continuous improvement*

Processes

People, processes, and tools within the framework ensure information is well defined, of high quality, applied consistency, and properly managed across lifecycle stages

Clinical Information Governance Network

Steering Committee
(Functional heads across entities)

CIG Core Team

Standards Council

- Clinical Documentation
- Data Management
- Biostatistics & Programming
- Clinical
- Medical Operations
- Pharmacovigilance
- Coding
- Regulatory
- TIM

Clinical Information Governance Leadership

Core Team: Dedicated Resources

| Data Stewards | Metadata Curator | Information Architect | Project Manager |

Global, End-to-End & Functional Level Standards
Development & Harmonization, Implementation, Adherence, & Maintenance

Implementation /Action Teams (Examples)

- Data Collection Team
- SDTM Team
- ADaM Team
- Gov. Tec-Enablement PoC
- Standards Adherence

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Information Governance Processes

EXAMPLES

Develop Standards Metadata
(Global, incl. TA-Specific)

Standards Metadata Change Control
(Global Standards Metadata)

Standards Release Management
(Global Standards Metadata)

Standards Waiver &
Metadata Development
**(Study-Level)**

Develop Study-Level SDTM

Develop Study-Level ADaM

Perform Standards Maintenance
(Global Standards Metadata)

Define and Maintain Reference Data
(Global Standards Metadata)

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Sanofi Clinical Data Standards*

- **CDISC Foundational Standards**
  - **Data Collection**
    - CDASH
    - (Central) Lab
  - **Study Data Tabulation Datasets**
    - SDTM: Interventions, Events, Findings
  - **Analysis Datasets**
    - ADaM Datasets & Results Generation
  - **Controlled Terminology**
    - End-to-end across the clinical lifecycle

- **CFAST Therapeutic Area Standards**
  - Common data of interest for a therapeutic area that may be captured in addition to the foundational standards

- **Sanofi Data Standards**
  - In addition to industry standards

Sanofi Data Standards

Current scope; future scope will be expanded (e.g., protocol)
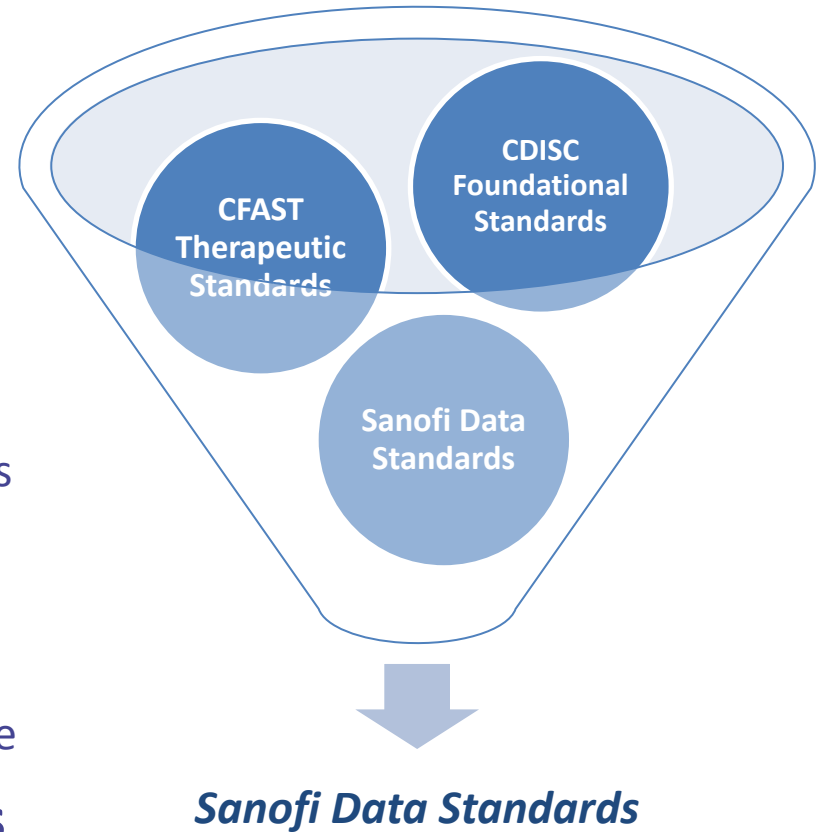
Controlled Terminology: Current State

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Sanofi Controlled Terminology (CT) Harmonization
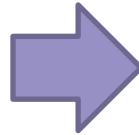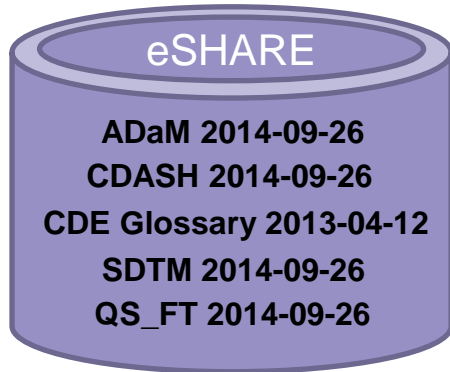
CDISC CT Release 2014-06-27

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term

ADaM 2011-01-07

CDASH 2014-03-28

CDE Glossary 2013-04-12

SDTM 2014-06-27

QS_FT 2014-06-27

Sanofi Harmonized Global CT Listing

Column Name	Versioning Impact
CODELIST_LONG_NAME	NO
CODELIST_SHORT_NAME	YES
CODELIST_EXTENSIBLE	YES
SASFMTNM	NO
DATA_TYPE	NO
ENDORSEMENT_LEVEL	NO
ENDORSEMENT_VALUE	NO
CODELIST_DEFINITION	NO
CODELIST_CODE	YES
CODE	YES
CODE_DEFINITION	NO
SUBMISSION_VALUE	YES
CDISC_SYNONYM	NO
NCI_PREFERRED_TERM	YES
CRF_DISPLAY_VALUE	YES
HAS_TRAN	NO
RANK	YES
DISPLAY_ORDER	NO
DECODE	YES
CODE_LIFECYCLE_STAGE	YES
SOURCE	NO
CDISC_RELEASE_140627	**N/A**

SANOFI_CT_Metadata (SDTM)

SANOFI_CT_Metadata (ADaM)

Codelists for Data Collection

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	(CDISC) Submission Value	CDISC Synonym(s)	CDISC/Sanofi Definition	NCI Preferred Term	CRF Display Value

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Sanofi Harmonized CT Maintenance

CDISC CT Release 2014-09-26

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term

eSHARE

ADaM 2014-09-26
CDASH 2014-09-26
CDE Glossary 2013-04-12
SDTM 2014-09-26
QS_FT 2014-09-26

Sanofi Harmonized Global CT Listing

Column Name	Versioning Impact
CODELIST_LONG_NAME	NO
CODELIST_SHORT_NAME	YES
CODELIST_EXTENSIBLE	YES
SASFMTNM	NO
DATA_TYPE	NO
ENDORSEMENT_LEVEL	NO
ENDORSEMENT_VALUE	NO
CODELIST_DEFINITION	NO
CODELIST_CODE	YES
CODE	YES
CODE_DEFINITION	NO
SUBMISSION_VALUE	YES
CDISC_SYNONYM	NO
NCI_PREFERRED_TERM	YES
CRF_DISPLAY_VALUE	YES
HAS_TRAN	NO
RANK	YES
DISPLAY_ORDER	NO
DECODE	YES
CODE_LIFECYCLE_STAGE	YES
SOURCE	NO
CDISC_RELEASE_140627	N/A
CDISC_RELEASE_140926	N/A

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Sanofi Harmonized CT Maintenance Use Cases

- Codelist/Code – additions/deletions

- Codelist/Code – changes in attributes with impact on versioning
  - **Codelist Short Name (i.e. CDISC Submission Value)**
  - **Codelist Code**
  - **Extensible Yes/No**
  - **Code**
  - **Code Submission Value**
  - **Code NCI Preferred Term**

- Codelist/Code – changes in attributes with no impact on versioning
  - **Codelist Long Name**
  - **Codelist Definition**
  - **Code Definition**
  - **Code Synonym**
  - **Code CRF Display Value**

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Sanofi Harmonized CT Maintenance – Use Case 1
Codelist/Code flag assignment to track CDISC quarterly releases

Codelist Additions

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
Graft Type	GRAFTTYP	Yes	C117737	C117816	A vessel graft comprised of an art	ARTERIAL GRA	Free Arterial Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117817	A vessel graft comprised of an art	ARTERIAL GRA	In Situ Arterial Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117818	A vessel graft comprised of a vein	AUTOLOGOUS	Autologous Vein Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117819	An arterial graft harvested from a c	CADAVERIC GR	Cadaveric Arterial Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117820	A venous graft harvested from a c	CADAVERIC GR	Cadaveric Venous Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117821	A vessel graft comprised of two or	COMPOSITE G	Composite Vessel Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117822	A vessel graft comprised of the sa	SAPHENOUS V	Saphenous Vein Graft					X
Graft Type	GRAFTTYP	Yes	C117737	C117823	A vessel graft comprised of non-b	SYNTHETIC GR	Synthetic Vessel Graft					X

Code Additions

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
SDTM Domain Abbreviation	DOMAIN	Yes	C66734	C117755	A domain for the agents administe	AG	Procedure Agents Domain					X
SDTM Domain Abbreviation	DOMAIN	Yes	C66734	C117756	A domain for named, stand-alone	FT	Functional Tests Domain					X
SDTM Domain Abbreviation	DOMAIN	Yes	C66734	C117757	A domain for inpatient and outpati	HO	Healthcare Encounters Domain					X

Code Deletions

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
ECG Test Code	EGTESTCD	Yes	C71153	C62121	The mean (average) direction (ran	PAXIS	Mean P Axis		X	X	X	
ECG Test Name	EGTEST	Yes	C71152	C62121	The mean (average) direction (ran	Summary (Mean) P Axis	Mean P Axis		X	X	X	

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Sanofi Harmonized CT Maintenance – Use Case 2
Changes in attributes with impact on versioning

Code Changes

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
Method	METHOD	Yes	C85492	C16290	An image of blood vessels.	ANGIOGRAM	Angiogram	Angiogram			X	X
Method	METHOD	Yes	C85492	C16805	An X-ray representation of blood vessels made after the injection of a radiopaque substance.	ANGIOGRAM	Lymphangiogram		X	X		

Submission Value Changes

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
PK Parameter Units of Measure	PKUNIT	Yes	C85494	C85657	Liters per gram per day.	L/g/day	Liter per Gram per Day		X	X	X	
PK Units of Measure	PKUNIT	Yes	C85494	C85657	Liters per day (flow), divided by grams (weight).	(L/day)/g	Liter per Gram per Day					X

NCI Preferred Term Changes

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
Anatomical Location	LOC	Yes	C74456	C12664	The portion of the body that lies between the thorax and the pelvis. (NCI)	ABDOMINAL CAVITY	Abdomen	Abdominal Cavity				X
Anatomical Location	LOC	Yes	C74456	C12664	The portion of the body that lies between the thorax and the pelvis. (NCI)	ABDOMINAL CAVITY	Abdominal Cavity	Abdominal Cavity	X	X	X	

Sanofi Harmonized CT Maintenance – Use Case 3
Changes in attributes with no impact on versioning (1)

Changes in Code Synonym(s)

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C64780	C71620		Unit	fL	Femtoliter	The unit of volume equal 10E-15 liter.	Femtoliter

ReadMe · SDTM Terminology 2014-06-27

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C64780	C71620		Unit	fL	Cubic Micrometer; Cubic Micron; Femtoliter; um3	The unit of volume equal 10E-15 liter.	Femtoliter

ReadMe · SDTM Terminology 2014-09-26

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	CDISC_SYNONYM	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
Unit	UNIT	Yes	C71620	C64780	The unit of volume equal 10E-15 liter.	fL	Cubic Micrometer; Cubic Micron; Femtoliter; um3	Femtoliter	fL	X	X	X	X

Sanofi Harmonized CT Maintenance – Use Case 4
Changes in attributes with no impact on versioning (2)

Changes in Code Definition

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C32123	C74456		Anatomical Location	AORTIC ARCH	Aortic Arch	The curved section of the aorta between the ascending and the descending tracts. The brachiocephalic, left common carotid and left subclavian arteries branch from the aorta at this section. (NCI)	Aortic Arch

▶ ▶| **ReadMe** SDTM Terminology 2014-06-27

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C32123	C74456		Anatomical Location	AORTIC ARCH	Aortic Arch	The curved segment of the aorta between the ascending and the descending segments.	Aortic Arch

▶ ▶| **ReadMe** SDTM Terminology 2014-09-26

CODELIST_LONG_NAME	CODELIST_SHORT_NAME	CODELIST_EXTENSIBLE	CODELIST_CODE	CODE	CODE_DEFINITION	SUBMISSION_VALUE	CDISC_SYNONYM	NCI_PREFERRED_TERM	CRF_DISPLAY_VALUE	CDISC_RELEASE_131220	CDISC_RELEASE_140328	CDISC_RELEASE_140627	CDISC_RELEASE_140926
Anatomical Location	LOC	Yes	C74456	C32123	The curved segment of the aorta between the ascending and the descending segments.	AORTIC ARCH	Aortic Arch	Aortic Arch	Aortic Arch	X	X	X	X

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Controlled Terminology: Evolving Toward the Future State

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Introducing … Metadata Management Tool PoC

CDISC Release YYYY-MM-DD

CDE Glossary   **CDASH**   **SDTM**   **QS_FT**   **ADaM**

Sanofi Harmonized CT

Column Name
CODELIST_LONG_NAME
CODELIST_SHORT_NAME
CODELIST_EXTENSIBLE
SASFMTNM
DATA_TYPE
ENDORSEMENT_LEVEL
ENDORSEMENT_VALUE
CODELIST_DEFINITION
CODELIST_CODE
CODE
CODE_DEFINITION
SUBMISSION_VALUE
CDISC_SYNONYM
NCI_PREFERRED_TERM
CRF_DISPLAY_VALUE
HAS_TRAN
RANK
DISPLAY_ORDER
DECODE
CODE_LIFECYCLE_STAGE
SOURCE

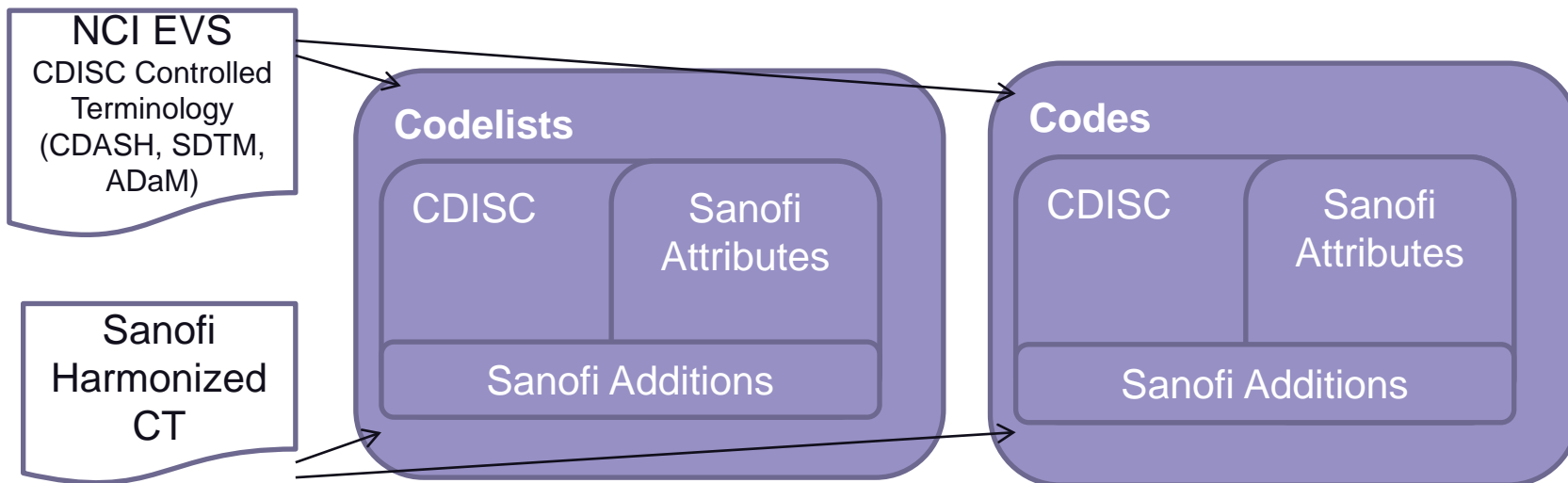**Metadata Management Tool**

Trial design metadata | eCRF design metadata | Collection DB metadata | Submission DB metadata | Analysis & Reporting metadata

Global

TA

Project

Study

Controlled Vocabulary

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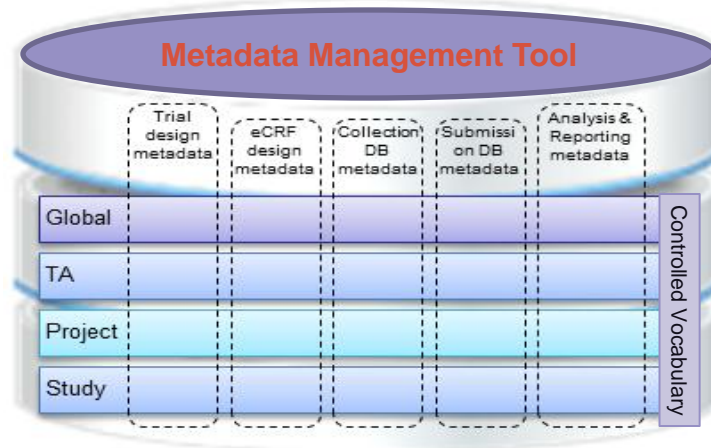
Why a Metadata Management Tool?

- ## Semantic Web Technology
  - **flexible modeling driven by semantic standards**
  - **powerful tools to load data from various sources (e.g., spreadsheets)**
  - **customizable dashboards for metadata search and curation**
  - **robust architecture capable of integrating with other systems**

- ## Semantic Information Modeling = Ontology
  - *"…moves beyond structural, logical data modeling in the sense that it models <u>semantics (meaning)</u> and <u>relationships</u> of data. It unifies vocabularies (terms and concepts) across multiple knowledge domains."*
  - *Ontology solves problems with:*
    - *Information Integration*
    - *Model Transformation*
    - *Text Understanding*
    - *Search and Navigation*
    - *Document Preparation*

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Metadata Management Tool – CT Ontology

NCI EVS
CDISC Controlled Terminology (CDASH, SDTM, ADaM)

Sanofi Harmonized CT

Codelists

CDISC	Sanofi Attributes
Sanofi Additions	

Codes

CDISC	Sanofi Attributes
Sanofi Additions	

Codelist Implementation Example:

Short Name	CDISC Code	Long Name	Definition	Extensible	NCI Preferred Term	Source	Original Endorse...	Endorsements	Originating Lifecy...	Applicable Lifecy...
ACN	C66767	Action Taken with Study Treatment	Terminology specifying changes to the study treatment as a result of an adverse event.	False	CDISC SDTM Action Taken with Study Treatment Terminology	CDISC	Global	Global	Data Tabulations	Data Collection, Data Tabulations, Statistical Analysis, Study Planning
ACN_01	C66767	Action Taken with Study Treatment Subset 01	Terminology specifying changes to the study treatment as a result of an adverse event.	False		Internal	Global	Global	Data Tabulations	Data Collection, Data Tabulations, Statistical Analysis, Study Planning
ACN_02	C66767	Action Taken with Study Treatment Subset 02	Terminology specifying changes to the study treatment as a result of an adverse event.	False		Internal	Global	Global	Data Collection, Data Tabulations	Data Collection, Data Tabulations, Statistical Analysis, Study Planning

POC Metadata – Linking the Information

Excel Plug-in

DATA_TYF	ENDORSE	ENDORSE	CODELIST	CODELIST	CODELIST	CODE	CODE_DE	SUBMISSI	CDISC_SY	NCI_PREF	CRF_DISF	HAS_TRAI	INT_TRAN	RANK
text	Global	II	Study Plan	Terminolog	C66767			DOSE DELAYED		Dose Delayed				8
text	Global	II	Study Plan	Terminolog	C66767			DOSE DELAYED AND REDUCED	Dose Delayed and Reduced					9
text	Global	II	Study Plan	Terminolog	C66767	C49503	An indicatic	DOSE INCREASED	Dose Incre	Dose Increased				5
text	Global	II	Study Plan	Terminolog	C66767	C49504	An indicatic	DOSE NOT CHANGED	Dose Not C	Dose Not Changed				1
text	Global	II	Study Plan	Terminolog	C66767	C49505	An indicatic	DOSE REDUCED	Dose Redu	Dose Reduced				2
text	Global	II	Study Plan	Terminolog	C66767	C49501	An indicatic	DRUG INTERRUPTED	Drug Intern	Drug Interrupted				3
text	Global	II	Study Plan	Terminolog	C66767	C49502	An indicatic	DRUG WITHDRAWN	Drug Withd	Drug Withdrawn				4
text	Global	II	Study Plan	Terminolog	C66767	C48660	Determinat	NOT APPLI NA; Not Ap	Not Applica	Not Applicable				6
text	Global	II	Study Plan	Terminolog	C66767	C17998	Not known,	UNKNOWN U; Unknow	Unknown	Unknown				7
text	Global	II	Study Plan	Terminolog	C66767	C49503	An indicatic	DOSE INCREASED	Dose Incre	Dose Increased				
text	Global	II	Study Plan	Terminolog	C66767	C49504	An indicatic	DOSE NOT CHANGED	Dose Not C	Dose Not Changed				
text	Global	II	Study Plan	Terminolog	C66767	C49505	An indicatic	DOSE REDUCED	Dose Redu	Dose Reduced				
text	Global	II	Study Plan	Terminolog	C66767	C49501	An indicatic	DRUG INTERRUPTED	Drug Intern	Drug Interrupted				
text	Global	II	Study Plan	Terminolog	C66767	C49502	An indicatic	DRUG WITHDRAWN	Drug Withd	Drug Withdrawn				
text	Global	II	Study Plan	Terminolog	C66767	C48660	Determinat	NOT APPLI NA; Not Ap	Not Applica	Not Applicable				
text	Global	II	Study Plan	Terminolog	C66767			DOSE DELAYED		Dose Delayed				
text	Global	II	Study Plan	Terminolog	C66767			DOSE DELAYED AND REDUCED	Dose Delayed and Reduced					

Properties

Applicable Lifecycle Stages — *Lifecycle Stages*
These are the life cycle stages which use this codelist. Allowable values are "Study Pla...
↦ 🔽 8

T **Author** — *String*
- no comments -
↦ f_x sysadmin AnzoGetCurrentUserName()

T **CDISC Code** — *String*
Unique numeric code randomly generated by NCI Thesaurus (NCIt) and assigned t... ▾
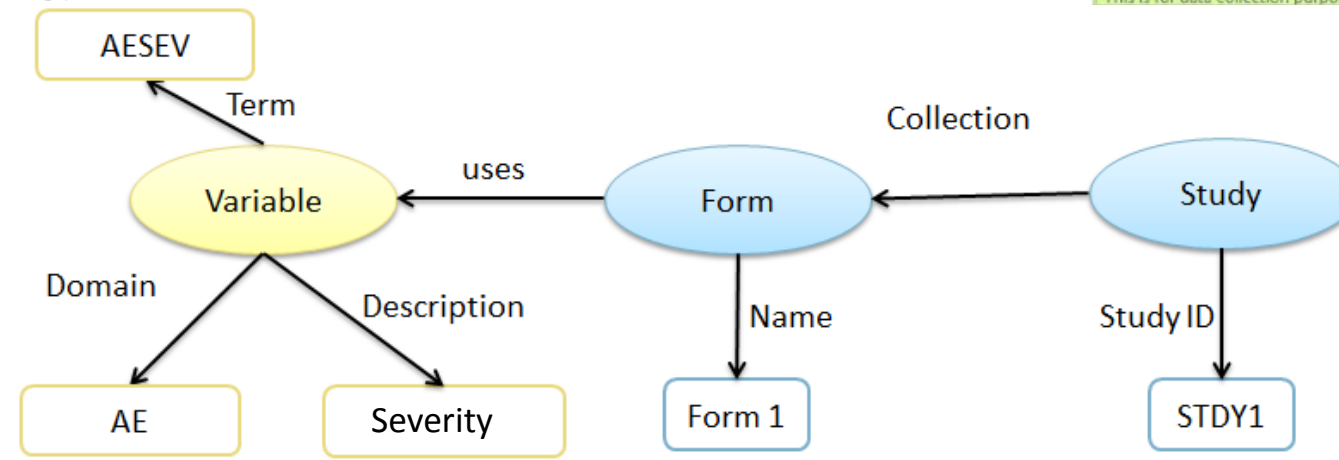↦ C66767

↹ 🔍 **Codelist** ↦ 🔍 — *Codelist*
Every Code exists within the context of exactly 1 Codelist, and if the same Code/Submi...

Short Name ↦ 🔍 ACN

☑ **Consider for Endorsement Promotion** — *Boolean*
- no comments -
↦ f_x False IF(F2="Global",False,True)

T **CRF Display Value** — *String*
This is for data collection purposes only. This is the text to appear on the CRF. As speci...

Ontology for Sanofi

Our Journey Continues…

- Implementing and maintaining controlled terminology is a challenge we're facing industry-wide

- We've shared our approach today and insight into our future direction

  - effectively managing controlled terminology requires people, processes, & technology to ensure the consistent use/reuse

- We would like to hear your feedback & insights as well!

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Managing CT across Clinical Lifecycle Stages

Thank you!

Questions?

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