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## **Non-Standard Variables in Standards Development – The Ultimate Oxymoron**

Presented by Rebecca Baker, MS, Standards Developer, CDISC  
Erin Muhlbradt, PhD, Biomedical/Clinical Information Specialist, NCI-EVS

# Meet the Speakers

Erin Muhlbradt, PhD

**Title:** Clinical/Biomedical Information Specialist; CDISC Terminology Lead

**Organization:** US NCI-EVS [c] & MSC, a Guidehouse company  
CDISC Controlled Terminology program lead for CDISC and NCI-EVS.



Rebecca Baker, MS, MHA, BSN, RN

**Title:** Standards Developer

**Organization:** CDISC

Rebecca Baker is the lead of the NSV Registry Sub-team. She has over 20 years of experience in healthcare, clinical research, and data standards. Rebecca has a Master of Science, Health Informatics and Bioinformatics, Master of Healthcare Administration, and a Bachelor of Nursing.





# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*



**Isn't a Non-standard variable (NSV) an oxymoron for standards development?**



## Agenda

1. What is a non-standard variable (NSV)
2. Where you may have seen NSVs before
3. The genesis of the NSV registry and where it is located on the CDISC website
4. How to use the NSVs and guidance for using fragments to build an NSV if there isn't one that covers the needed concept

# What is a non-standard variable (NSV)?

NSV vs SUPPQUAL







## What is an NSV?

- Data requiring the use of variables outside the standard set of variables published in the SDTM can be captured using **Non-Standard Variables**
- They may be authored and published in a CDISC standards document
- They may be authored and in use by your own organization
- They are not part of the SDTM data model

# What is an NSV?

## Use of NSV in a clinical SDTM Dataset:

is.xpt

**Rows 1, 2, 3, 4:** Show screen and quantification tests for IgA and IgG binding autoantibodies for the subject previously diagnosed with celiac disease.

**Rows 5-6:** Show screening and quantification tests for the subject with a history of Crohn's disease.

is.xpt

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISGRPID	ISLNKID	ISTESTCD	ISTEST	ISCAT	ISSCAT	ISORRES	ISORRESU	ISTSTRES	ISSTRESN	ISSTRESU	ISNAM	ISSPEC	ISMETHOD	VISITNUM	VISIT	ISDTC	ISBDAGNT	ISTSTOPO
1	ABC123	IS	0001	1	1	2	ATIGAAB	Binding IgA Autoantibody	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	Present					ABX	SERUM	ELISA	1	SCREENING	2017-09-01	Tissue Transglutaminase	SCREEN
2	ABC123	IS	0001	2	1	2	ATIGAAB	Binding IgA Autoantibody	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	1.9	U/mL	1.9	1.9	U/mL	ABX	SERUM	ELISA	1	SCREENING	2017-09-01	Tissue Transglutaminase	QUANTIFY
3	ABC123	IS	0001	3	1	2	ATIGGAB	Binding IgG Autoantibody	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	Present					ABX	SERUM	ELISA	1	SCREENING	2017-09-01	Tissue Transglutaminase	SCREEN
4	ABC123	IS	0001	4	1	2	ATIGGAB	Binding IgG Autoantibody	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	7.0	U/mL	7.0	7.0	U/mL	ABX	SERUM	ELISA	1	SCREENING	2017-09-01	Tissue Transglutaminase	QUANTIFY
5	ABC123	IS	0001	5	2	3	ANCPNCAB	Neutrophil Cytoplasmic Ab, Perinuclear	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	Present					ABX	SERUM	ELISA	1	SCREENING	2017-09-01		SCREEN
6	ABC123	IS	0001	6	2	3	ANCPNCAB	Neutrophil Cytoplasmic Ab, Perinuclear	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	1:64	Dilution	64	64	Titer	ABX	SERUM	ELISA	1	SCREENING	2017-09-01		QUANTIFY

### IS NSV Metadata

Variable	Label	Type	Role	Codelist	Origin
ISBDAGNT	Binding Agent	text	Non-standard Record Qualifier		CRF
ISTSTOPO	Test Operational Objective	text	Non-standard Variable Qualifier of --TESTCD and --TEST (TSTOPOBJ)		CRF

<https://w.iki.cdisc.org/display/DIAB1/History+of+Autoimmune+Disease>

\*NSV Metadata is described in the Define-XML documentation



# Supplemental Qualifiers (SUPPQUAL)

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ	SRRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU	SRLOC	VISITNUM	VISIT
1	SPI-001	SR	SPI-001-11035	1	FLRMDIAM	Flare Mean Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm	BACK	1	VISIT 1
2	SPI-001	SR	SPI-001-11035	2	FLRMDIAM	Flare Mean Diameter	Histamine Control 10 mg/mL	4	mm	4	4	mm	BACK	1	VISIT 1
3	SPI-001	SR	SPI-001-11035	3	FLRMDIAM	Flare Mean Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm	BACK	1	VISIT 1
4	SPI-001	SR	SPI-001-11035	4	FLRMDIAM	Flare Mean Diameter	Histamine Control 10 mg/mL	5	mm	5	5	mm	BACK	1	VISIT 1

suppsr.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	SPI-001	SR	SPI-001-11035	SRSEQ	1	SRSUBLOC	Anatomical Sub-Location	QUADRANT1	CRF
2	SPI-001	SR	SPI-001-11035	SRSEQ	2	SRSUBLOC	Anatomical Sub-Location	QUADRANT2	CRF
3	SPI-001	SR	SPI-001-11035	SRSEQ	3	SRSUBLOC	Anatomical Sub-Location	QUADRANT3	CRF
4	SPI-001	SR	SPI-001-11035	SRSEQ	4	SRSUBLOC	Anatomical Sub-Location	QUADRANT4	CRF

Is an NSV different from a SUPPQUAL?

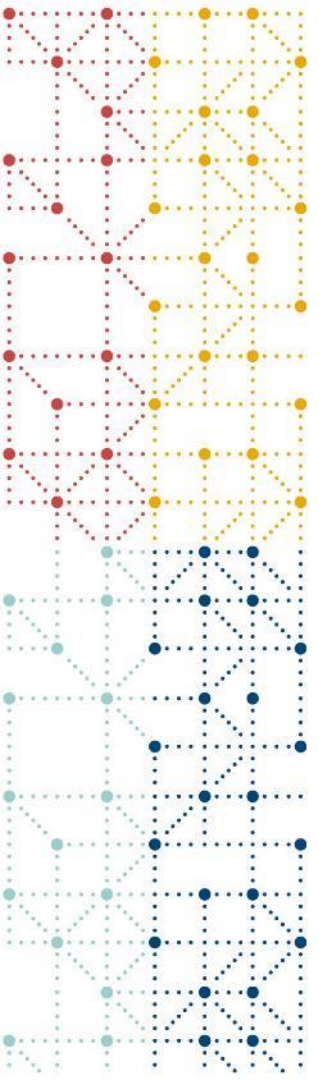




***NSVs are simply a different representation of the same content in a supplemental qualifier....***

***QNAM/QLABEL = NSV Name/NSV Label***

***It is just the structure that is changing***



## Where you may have seen NSVs before

*IGs, TAUGs, CT Relationships, etc.*

cdisc

New to CDISC Standards Educ

Home / Standards / Foundational / QRS

Description QRS Supplements New QRS Supplements FAQ QRS Resou

How can I access the published supplements?

QRS Supplements  
Displaying 1 - 287 of 287

SDTM Domain/ADaM Dataset Permission QRS Name Starts

SDTM Domain/ADaM T Permission

--CAT Contains

Apply

QRS Name	Short Name (--CAT)
<a href="#">10-Meter Walk/Run</a>	10-METER WALK/RUN
<a href="#">10-Meter Walk/Run</a>	10-METER WALK/RUN
<a href="#">12-Item Multiple Sclerosis Walking Scale</a>	MSWS-12
<a href="#">6 Minute Walk Test</a>	SIX MINUTE WALK

cdisc.org/standards/terminology/controlled-terminology

NIH NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services

CDISC, in collaboration with the [National Cancer Institute's Enterprise Vocabulary Services \(EVS\)](#), supports the Controlled Terminology needs of CDISC Foundational and Therapeutic Area Standards.

Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you WHAT to collect; it tells you IF you collected a particular data item, how you should submit it in your electronic dataset.

New requests or changes to existing Terminology can be accessed through the CDISC [New Term Request Page](#).

Controlled Terminology Release

As of 29 September 2023, the DDF, Protocol Entities, SDTM, and SEND Controlled Terminology files have been updated on the NCI-EVS Ftp site. The version dates of the new files are 2023-09-29. These terminology files replace all older DDF, Protocol Entities, SDTM, and SEND terminology files and include terms from Review Package 55. There are approximately 266 new QRS terms and 387 new terms across DDF, Protocol Entities, SDTM, and SEND terminology files. Additionally there are:

- Update to 7 published Codetable Mapping files: DS, EG, IS, RE, RP, SC, and TS
- Update to 4 Terminology Development Rules documents: IS, LB, MB and MS, and QRS
- Update to Unit-UCUM Codetable Mapping file
- Update to Controlled Terminology Requests Denied file
- Update to CDISC Terminology Publication Schedule
- Update to the SDTM and SEND paired view files

[Controlled Terminology Release 29 September 2023](#)

Supplemental Files

NCI FTP Links **Resources** Rules Codetable Mapping Files Unit-UCUM Mapping File LOINC to LB Mapping Files Paired Codelists

SEND Tumor Combinations

[New Term Request Page](#)

[Multiple Term Request](#)

[CT Requests Denied](#)

[Publication Schedule](#)

[Controlled Terminology Relationships v1.0 for SDTM v1.4 and SDTMIG v3.2](#)

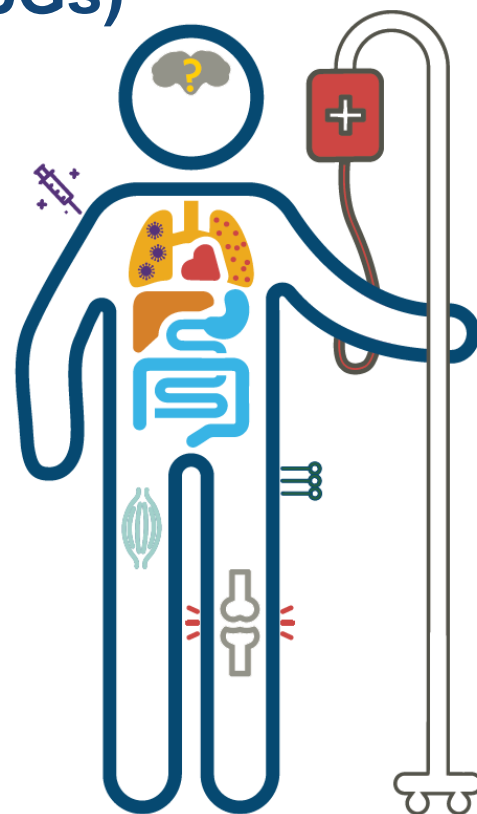
Non-standard variables can be found in IGs, QRS Supps, CT relationships

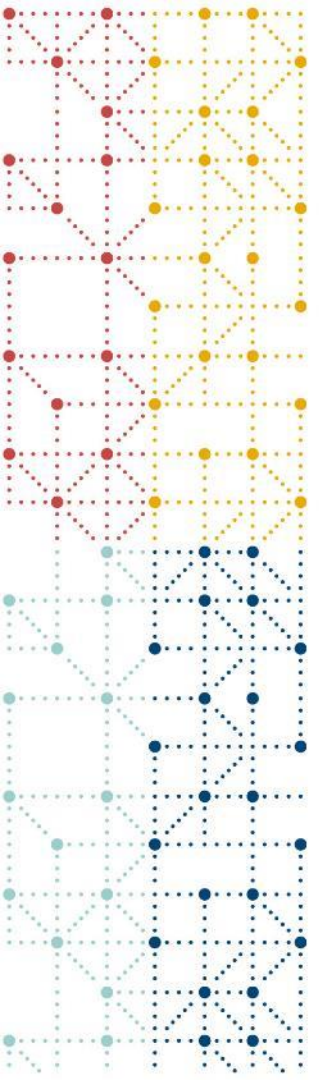
# Therapeutic Area User Guides (TAUGs)

CDISC has published 50 TAUGs in the following categories:

- Autoimmune
- Cardiovascular
- Endocrine
- Gastrointestinal
- Infectious
- Mental Health
- Neurology
- Oncology
- Rare Diseases
- Respiratory
- Treatments
- Other

Almost all of the TAUGs contain non-standard variables!





# The genesis of the NSV Registry



- **Non-standard variables (NSVs) exist across many standards documents.**
  - Hard to find for re-use purposes
- **NSVs may have inconsistent names and labels.**
  - NSVs may be duplicated conceptually
- **NSVs may be incorrect conceptually.**



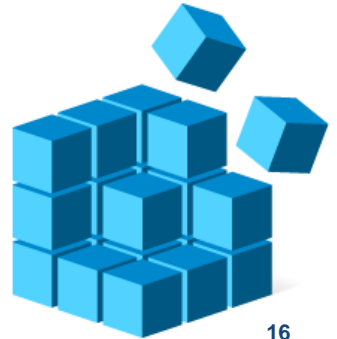
# Solution



We need a place that contains all published NSVs (to promote re-use) and an oversight process for the development of new NSVs...

A Team was Formed:

- Identified the issues
- Performed an analysis
- Proposed the NSV Registry



# Vision:

1

Ensure the development teams use the NSVs consistently.

2

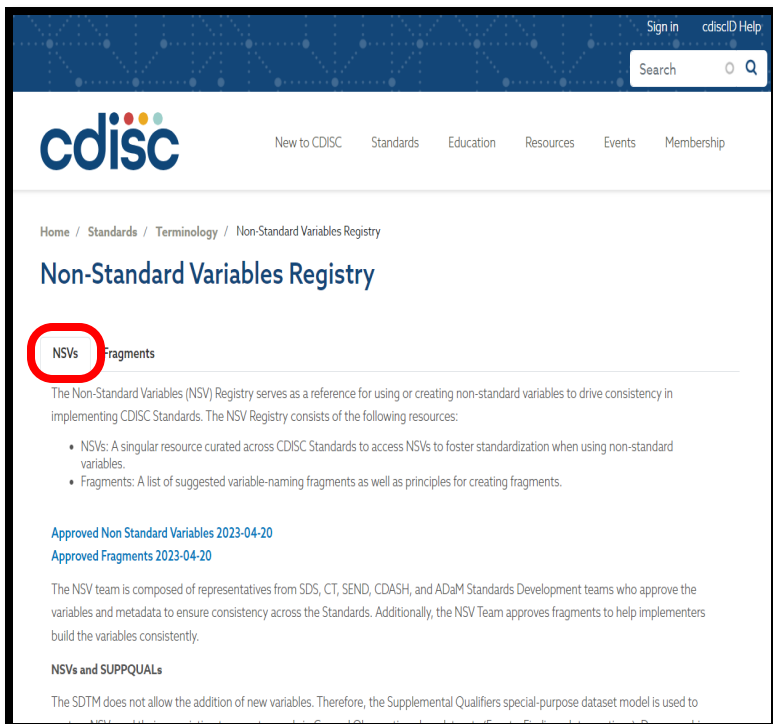
Help identify NSVs for promotion to the model/IG.

3

Allow CDISC users to access the NSV information so they can use them within their organizations

# NSV Registry - Two Ways to Search

## From the CDISC Website



Sign in cdiscID Help

Search

cdisc

New to CDISC Standards Education Resources Events Membership

Home / Standards / Terminology / Non-Standard Variables Registry

### Non-Standard Variables Registry

**NSVs** Fragments

The Non-Standard Variables (NSV) Registry serves as a reference for using or creating non-standard variables to drive consistency in implementing CDISC Standards. The NSV Registry consists of the following resources:

- NSVs: A singular resource curated across CDISC Standards to access NSVs to foster standardization when using non-standard variables.
- Fragments: A list of suggested variable-naming fragments as well as principles for creating fragments.

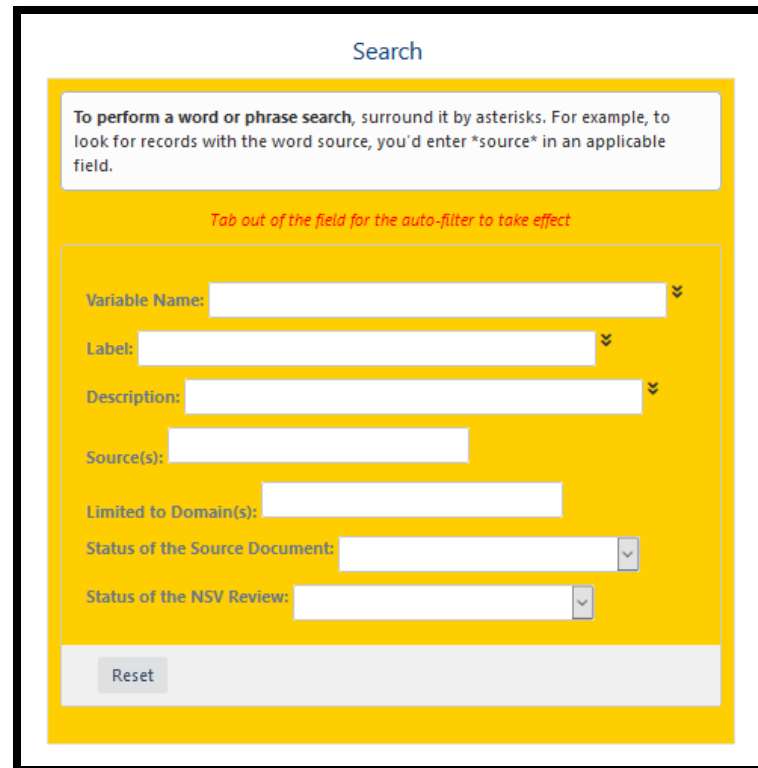
[Approved Non Standard Variables 2023-04-20](#)  
[Approved Fragments 2023-04-20](#)

The NSV team is composed of representatives from SDS, CT, SEND, CDASH, and ADaM Standards Development teams who approve the variables and metadata to ensure consistency across the Standards. Additionally, the NSV Team approves fragments to help implementers build the variables consistently.

**NSVs and SUPQUALs**

The SDTM does not allow the addition of new variables. Therefore, the Supplemental Qualifiers special-purpose dataset model is used to

## From the CDISC Wiki



### Search

To perform a word or phrase search, surround it by asterisks. For example, to look for records with the word source, you'd enter \*source\* in an applicable field.

*Tab out of the field for the auto-filter to take effect*

Variable Name:

Label:

Description:

Source(s):

Limited to Domain(s):

Status of the Source Document:

Status of the NSV Review:

Reset



1	2	3	4	5	6	7	8	9	10	11	Qualify
Variable Name	Label	Description	Notes	Status of the NSV Review	Source(s)	Status of the Source Document	Publication Date of the Source Document	Requester Remarks	Curator Remarks	Role	Qualify
ACIGD	Active Ingredients	The name(s) of the active ingredients used in the medication taken or administered.	This may be collected in addition to the medication/therapy name. Collecting this provides more detailed information	Approved	CDASHIG vXY				If going to SDTM may need to have one active ingredient record per variable. This will allow space	Non-Standard Variable Qualifier	
ADMDEV	Administration Device	Response value of device used for data collection, either in the protocol, or study documents	Used in QRS domains	Approved	QRS: ADCS-ADL MCI v1.0	Internal Review				Non-Standard Record Qualifier	
ADMODP	Administration Mode of Presentation	Response value for how the instrument was presented to the subject as defined in a protocol, or study	Used in QRS domains	Approved	QRS: ADCS-ADL MCI v1.0	Internal Review				Non-Standard Record Qualifier	
AFFPER	Affected Performance	For a complete trial, record any circumstances that affected the patient's performance:	QRS:NHPT, PASAT, T25FW	Approved	QRS: NHPT v1.0 QRS: PASAT v1.0 QRS: T25FW v1.0				NSV updated to remove the domain name, now it meets the character requirements. Moved	Non-Standard Result Qualifier	
ANTPLN	Anatomical Plane	The position and orientation of the image slice relative to the patient-based coordinate system.		Approved	QRS: RECIST V1.1 v1.0	Public Review				Non-Standard Record Qualifier	
ANVLHI	Anchor Numeric Value High	The numeric value of the highest anchor value along a continuum of values.		Approved	TAUG-COVID-19 v2.0	In-Development				Non-Standard	

# Non-standard Variable Registry Home

Created by John Owen, last modified on Feb 23, 2021

For more information on the CDISC NSV Registry please contact Rebecca Baker (rbaker@cdisc.org) or John Owen (jowen.external@cdisc.org)

💡 Have an idea or improvement we can make for the NSV Registry - Use this [link](#) to enter a JIRA issue and we will take a look 😊



## NSV Registry

- [NSV Registry Overview](#)
- [Search/Request NSVs](#)
- [Register New Source Document](#)
- [Request a Change to an NSV](#)



## Fragment Database

- [Fragment Database Overview](#)
- [Search/Request Fragments](#)
- [Request a Change to a Fragment](#)



## NSV Team

- [SDTM NSV Sub-Team Meeting Notes](#)
- [SDTM NSV Ongoing Projects with NSVs](#)
- [SDTM NSV Curation Process](#)
- [SDTM NSV Suggestions](#)



# NSV Search on Wiki

Enter  
\*keyword\* in  
Description field

### Search

To perform a word or phrase search, surround it by asterisks. For example, to look for records with the word source, you'd enter \*source\* in an applicable field.

Tab out of the field for the auto-filter to take effect

Variable Name:

Label:

Description:

Source(s):

Limited to Domain(s):

Status of the Source Document:

Status of the NSV Review:

Reset

### NSV Registry Results

	Status of the Source Document	Status of the NSV Review	Variable Name	Label	Simple Datatype	XML Datatype	Define-XML Datatype	Codelist	External Dictionary	Notes	Description	Role	Qualifying Variable(s)	Status of the Source Document	Limited to Domain(s)
<a href="#">Edit</a> <a href="#">Delete</a>		Requested	--INFADJ	Infusion Duration Adjusted Reason	Char	string	text				Infusion Duration Adjusted Reason	Non-Standard Record Qualifier			
<a href="#">Edit</a> <a href="#">Delete</a>		Requested	--FRQADJ	Treatment Frequency Adjustment Reason	Char	string	text				Treatment Frequency Adjustment Reason	Non-Standard Record Qualifier			
<a href="#">Edit</a> <a href="#">Delete</a>	Public Review	Approved	RINCAS	Reason Investigator Changed Assessment	Char	string	text				The reason the investigator recorded an assessment that was different from the subject's assessment.	Non-Standard Record Qualifier		Public Review	
<a href="#">Edit</a> <a href="#">Delete</a>	Review for Publication	Approved	RSNRVF	Reason for Record Validity Flag Value	Char	string	text			May be provided for records flagged as invalid. May be assigned by the device that produces the data.	The reason for the value of --RECVFL.	Non-Standard Record Qualifier		Review for Publication	Find
<a href="#">Edit</a> <a href="#">Delete</a>	Review for Publication	Approved	REAS	Reason for the Intervention	Char	string	text				The reason for performing the intervention.	Non-Standard Record Qualifier		Review for Publication	

[Export](#) Records: 17 Size: 22.9 KB



Home / Standards / Terms

## Non-Standard

NSVs

**Fragments**

If a desired NSV can't be identified in the fragment database was created, this page provides guidance for the creation of a new fragment.

When using the fragment search tool, fragments that have meaning dependent on other fragments in these locations are highlighted.

### Variable Label/Variable Fragment

#### Summary

- The Variable Label is the text that provides meaning/concept into the fragment.
  - What is the primary meaning?
  - What is being measured?

	1	2	3	4	5	6	7
	Fragment Keyword	6 Character Fragment	5 Character Fragment	4 Character Fragment	3 Character Fragment	2 Character Fragment	1 Character Fragment
2	ACTION	ACTION	ACTON	ACTN	ACN	AC	A
3	ADJUSTMENT	ADJUST	ADJST	ADJT	ADJ	AJ	A
4	ADMINISTER	ADMNST	ADMNS	ADMN	ADM	AD	A
5	ANCHOR	ANCHOR	ANCHR	ANCR	ANR	AN	A
6	ASSAY	-----	ASSAY	ASAY	ASY	AS	A
7	BASELINE	BASLNE	BASLN	BSLN	BLN	BL	B
8	BIRTH	-----	BIRTH	BRTH	BTH	BT	B
9	BODY	-----	-----	BODY	BOD	BD	B
10	CANCER	CANCER	CANCR	CANC	CAN	CA	C
11	CATEGORY	CATGRY	CATGY	CATG	CAT	CT	C
12	CAUSED	CAUSED	CAUSD	CASD	CSD	CD	C
13	CHANGE	CHANGE	CHNGE	CHNG	CHG	CH	C
14	CHARACTER	CHARCT	CHARC	CHAR	CHR	CR	C
15	CLASS	-----	CLASS	CLAS	CLS	CS	C
16	CLINICAL	CLINCL	CLINC	CLIN	CLN	CL	C
17	CODE	-----	-----	CODE	COD	CD	C
18	COLLECT	COLLCT	COLCT	COLT	COL	CL	C
19	COMMENT	COMMNT	COMNT	COMT	COM	CO	C
20	COMPLETE	COMPLT	CMPLT	CMPT	CMP	CP	C
21	CONCOMITANT	CNCMNT	CNCMT	CCMT	CON	CM	C
22	CONDITION	CONDTN	CNDTN	COND	CND	CN	C
23	CONGENITAL	CNGNTL	CGNTL	CONG	CNG	CG	C
24	CONTACT	CONTCT	CNTCT	CNTT	CNT	CT	C
25	CONTROL	CONTRL	CNTRL	CTRL	CRL	CL	C
26	COUNTRY	CONTRY	CNTRY	CTRY	CNR	CR	C

READ ME

Approved Fragments



# NSV Fragment Search on Wiki

## Non-standard Variable Registry Home

Created by John Owen, last modified by Rebecca Baker on Mar 12, 2021

### User - NSV Fragments

Created by John Owen, last modified by Rebecca Baker on Mar 12, 2021



For more information

Have an idea

[Request a new fragment](#) | [Request a Change to a Fragment](#)

When using the fragment database to create NSVs, it is important to remember that there are conventions used in CDASH and ADaM that have meaning dependent on where the fragment sits in the variable (whether prefix, suffix or in the middle). It is best to avoid using fragments in these locations for NSVs to avoid conflicts in traceability across the foundational models.

- Generally, for ADaM non-standard variable, the naming convention is the one some times could associated with what expected variable type, expected value they are usually considered as overall.
- For example, if any variable ending with \*FL, then its value can only be null, Y or N, and no others, otherwise, it will trigger ADaM compliance.
- Another example, any variable ending with \*DT, DTM, the expected variable type is integer and can't be character.
- For SDTM NSV, when these variables carry to ADaM datasets, how their name choose could be impact the ADaM compliance if not following the ADaM name convention associated with expected type and/or value. It seems for SDTM NSV the naming convention currently focus more on the name.

For more information, see [Variable Label/Variable Fragment Names Rules](#).

### NSV Registry

- NSV Registry Overview
- Search/Request New Fragment
- Register New Source
- Request a Change

### Search

FRAGMENT KEYWORD

6 Character Fragment:

5 Character Fragment:

4 Character Fragment:


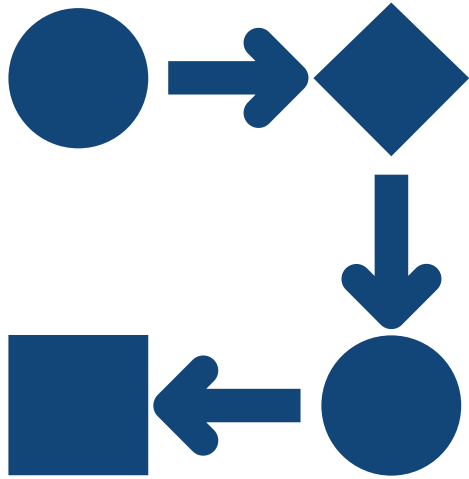
3 Character Fragment:

2 Character Fragment:

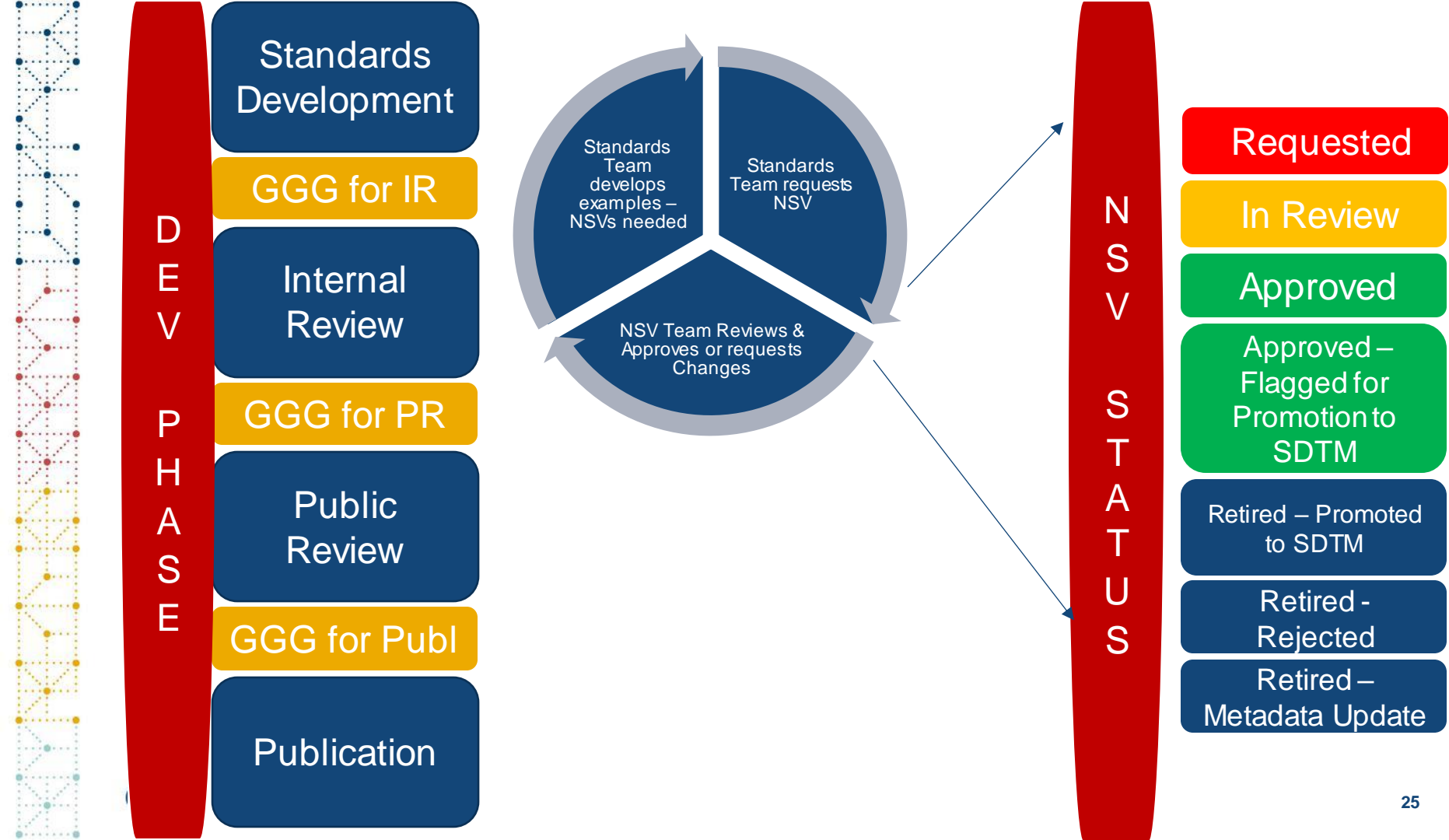
1 Character Fragment:

### Fragment Database Results

Status	Fragment Keyword	6 Character Fragment	5 Character Fragment	4 Character Fragment	3 Character Fragment	2 Character Fragment	1 Character Fragment
APPROVED	ACTION	ACTION	ACTON	ACTN	ACN	AC	A
APPROVED	ADJUSTMENT	ADJUST	ADJST	ADJT	ADJ	AJ	A
APPROVED	ANCHOR	ANCHOR	ANCHR	ANCR	ANR	AN	A
APPROVED	ASSAY	ASSAY	ASSAY	ASAY	ASY	AS	A
APPROVED	BASELINE	BASLINE	BASLN	BSLN	BLN	BL	B
IN-REVIEW	BIRTH		BIRTH	BRTH	BTH	BT	B
IN-REVIEW	BODY			BODY	BOD	BD	B
APPROVED	CANCER	CANCER	CANCR	CANC	CAN	CA	C
APPROVED	CATEGORY	CATGRY	CATGY	CATG	CAT	CT	C
APPROVED	CHARACTER	CHARCT	CHARC	CHAR	CHR	CR	C
IN-REVIEW	CLASS		CLASS	CLAS	CLS	CS	C
APPROVED	CLINICAL	CLINCL	CLINC	CLIN	CLN	CL	C
APPROVED	CODE			CODE	COD	CD	C
APPROVED	COMMENT	COMMNT	COMNT	COMT	COM	CO	C
IN-REVIEW	CONCOMITANT				CON	CM	C
APPROVED	CONDITION	CONDTN	CNDTN	COND	CND	CN	C
IN-REVIEW	CONGENITAL				CONG		
APPROVED	COUNTRY	CONTRY	CNTRY	CTRY	CNR	CR	C
APPROVED	CRITERIA	CRITRA	CRITR	CRIT	CRT	CR	C
IN-REVIEW	DAY				DAY	DY	
IN-REVIEW	DEATH				DTH		
IN-REVIEW	DECODE		DECOD				



# Curation Process



# NSV requested

Directly populated in the registry on the CDISC wiki.

Dashboard / Non-standard Variable Registry Home / User Area

## User - NSV Registry

Created by John Owen, last modified by Rebecca

Request a new NSV for your document (a) (b)

Request a change to an NSV

Search

To perform a word or phrase search, enter a word or phrase in the search field to look for records with the word or phrase in the applicable field.

Tab out of the field for the search.

Variable Name:

Label:

Description:

Source(s):

Limited to Domain(s):

Status of the Source Document:

Status of the NSV Review:

Reset

### NSV Registry

Please check the [Source Documents](#) page to ensure that your document is registered - If your document is not present, please register your source document before entering any NSVs

Status of the NSV Review: \*

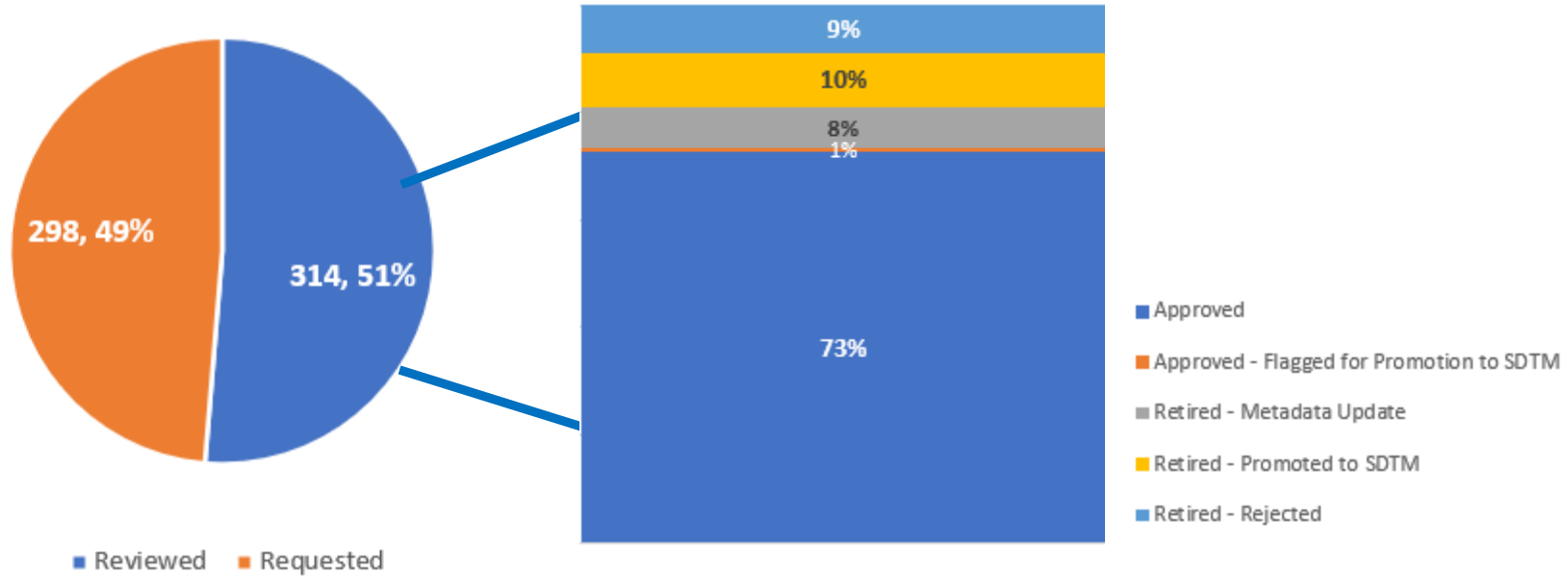
NSV General Information		* Required
<b>Variable Name: *</b> <input type="text"/> <small>Provide variable name in root form, without a domain or "--" prefix.</small>	<b>Label: *</b> <input type="text"/>	Provide variable name in root form, without a domain or "--" prefix.
Descriptive Information		
<b>Description *</b> <input type="text"/>	<input type="text"/>	These two parts typically come together as "CDISC Notes" in a specification table. "Description" describes what the NSV is/does, and "Notes" covers how to use it, including examples of values.
<b>Notes</b> <small>Usage notes and/or examples for the NSV</small> <input type="text"/>	<input type="text"/>	
Class and Domain Restriction		
<b>Limited to Class(es)</b> <small>Leave blank if the NSV is not class-specific.</small> <input type="text"/>	<input type="text"/>	
<b>Limited to Domain(s)</b> <small>Leave blank if the NSV is not domain-specific.</small> <input type="text"/>	<input type="text"/>	To list the domain(s) in which the NSV has been used, see "Used in Domain(s)".
Role Information *		

Save Close

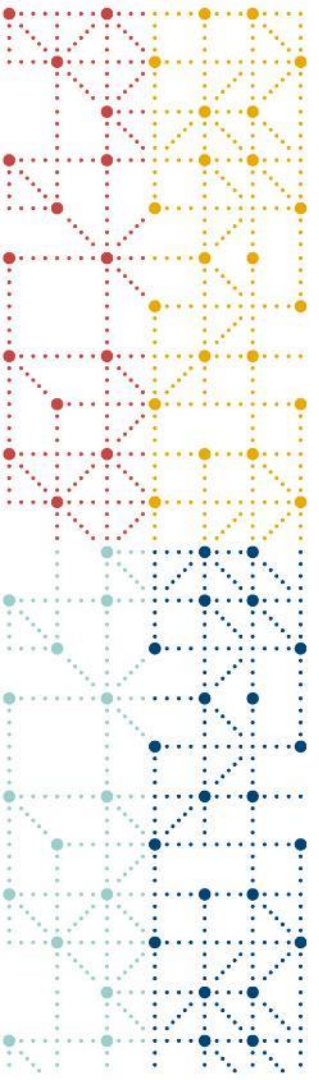
Edit Delete

#	Review Item by Team	SEND	CDASH	CT	SDS	ADaM	Admin
1	Variable name less than 6 characters (defaulted programmatically)						X
2	Make sure it is not more than 40 characters (defaulted programmatically)						X
3	Make sure there are no special characters used (with exception of a dash)						X
4	Make sure all the domains that are used are listed.						X
5	What is the NSV intended to do and is it doing it? Is this the right use of the variable?	X	X	X	X	X	
6	Is there another standard variable that could have been used?	X	X	X	X	X	
7	Look at the Variable Name and check that the correct fragments have been used and it makes sense?	X	X	X	X	X	
8	Look at the Variable Label and check that the correct name has been used and it makes sense?	X	X	X	X	X	
9	Check the Variable Definition that it is consistent and worded similarly to other similar variables. ( <a href="#">Variable Definitions Team Home</a> - slide resource)	X	X	X	X	X	
10	Make sure there are no examples in the description field, only in the notes	X	X	X	X	X	
11	Review the Role to make sure it is the same as others in that Role (resource- <a href="#">SDTM Variable Roles Team Charter</a> )	X	X	X	X	X	
12	Has the correct CodeList been used? If no CodeList, should their be one?			X			
13	Review of label from SDS perspective - what is the meaning of the variable, check NCIt for similar dictionary, do due diligence of what is being collecting. What does the data point that is being collected that cannot go back to the domain? Check the CRF (if available). Check the SDTMIG to ensure it reads consistently to other labels.			X	X		
14	The variable name is meaningful with respect to the variable label.			X	X		
15	If there is a CDASH example, is the NSV used on the form correctly and follow from CDASH to SDTM?		X				
16	Is the way the variable is collected and the way it is represented make sense? (DEFINE)		X				
17	Is the datatype correct?					X	
18	Does any of the metadata have an impact on ADaM?					X	
19	Does any of the metadata have an impact on SEND?	X					

# NSV Registry Count, Percentage (n=612)



Started registry review team in 2020, numbers cumulative



## How to use the NSVs

*and guidance for using fragments to build an NSV if there isn't one that covers the concept needed*



# Uses for the NSV Registry

## CDISC Standards Dev Team

- Easily search and find existing NSVs
- Request the development of new NSVs for new standards
- Identifies those NSVs eligible for promotion to SDTM variables

## CDISC User Community

- Easily search and find existing NSVs
- Identifies CDISC Controlled Terminology codelists that support existing NSVs

Enables consistent use of non-standard variable names and labels

# How to make a Non-Standard Variable Name & Label

#1

Identify the Concept where a variable is needed



#2

Determine the best Label for the identified concept

Ingredients
Active Ingredients
Effective Ingredients
Functional Ingredients
Active Components

#3

Use fragment database to determine options for the Variable Name.

Fragment	6 Char	5 Char	4 Char	3 Char	2 Char	1 Char
ACTIVE	ACTIVE	ACTVE	ACTV	ACT	AC	A
INGREDIENT	INGRED	INGRD	IGRD	IGD	IG	I

*Options:*

ACTIVEI  
 ACTIVIG  
 ACTIGD  
 ACIGRD  
 AINGRD

#4

Select the best Variable Name for the concept.

Variable Name	Variable Label
AINGRD	Active Ingredient

# Guidance for using fragments to build an NSV if there isn't one that covers the concept needed

- Use the fragment database to build the Variable Name
  - Made available on the CDISC website and CDISC wiki
- Variable Name should be six characters or less
  - Reserve two letters for the domain code
- Reserve the most letters for the main concept or idea in the Variable Label  
Remove vowels first, then consonants
  - Start with 'skinny' vowel "I" first
- Remove duplicate letters
  - Double-duty!
- Consider multiple options to assess the best readability
  - Uniqueness is still of primary importance but readability helps to remember what the variable is used for

# The team

NIH NATIONAL CANCER INSTITUTE

GILEAD  
Creating Possible

GSK

IQVIA

Biogen

EPHICACY

Johnson & Johnson

charles river

cdisc

propharma

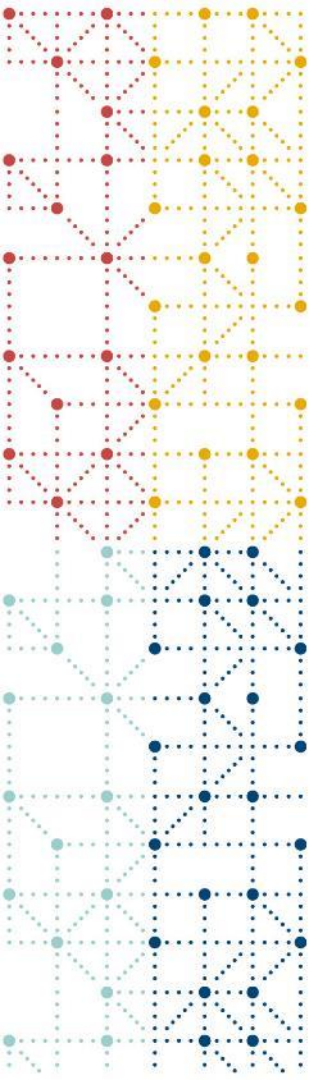
## NSV Sub Team Members

Team Member	Representing
@ Rebecca Baker	CDISC Standards Development
@ Dianna DiRusso	CDISC Project Management
@ Erin Muhlbradt	CT/Variable Definitions
@ Smitha Karra	CT
@ Linshan	ADaM
@ Gustav Bernard	ADaM
@ Amy Adyanthaya	SDS
@ Ramya.gangadi	SDS
@ Erin Tibbs-Slone	SEND
@ Emilea Norris	CDASH



# Additional Resources and Important Links

- CDISC Website: <https://www.cdisc.org/standards/terminology/non-standard-variables>
- CDISC Wiki: <https://wiki.cdisc.org/display/NSVREG/Non-standard+Variable+Registry+Home>
  - <https://wiki.cdisc.org/display/PUB/Alternative+Representation+of+Non-Standard+Variables>
- Knowledge Base:
  - <https://www.cdisc.org/kb/articles/cdisc-published/why-would-standards-development-organization-make-non-standard>
  - <https://www.cdisc.org/kb/articles/does-qnam-need-start-domain-code>
- SDTMIG v3.4:
  - <https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-4>



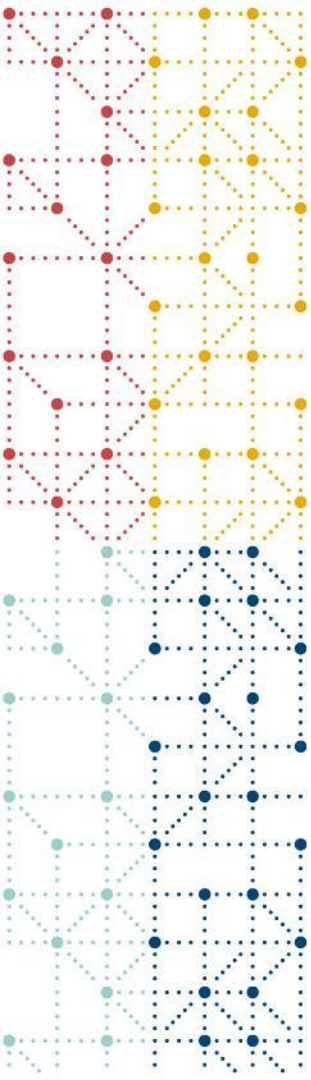
## Thank You and Questions!

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## Supplemental Materials





# What is coming?

....the SUPP NSV dataset

- A new structure for NSVs instead of SUPPQUALs
- [NS-- Assumptions](#)

SUPP-- to NS--  
the new structure proposed for SDTMIG v4.0

<https://wiki.cdisc.org/display/SDTMIG4DOT0/NS---+Assumptions>



## ***NSVs are simply a different representation of the same content in a supplemental qualifier....***

***QNAM/QLABEL = NSV Name/NSV Label***

- Permitting direct viewing of standard variables and NSVs within the same structure, eliminating the need for tools or the writing of programs to display the data together.
- Eliminating some current SUPP-- structural limitations by allowing:
  - Numeric NSVs to be represented in a numeric data type
  - Character NSVs to be defined with an appropriate length for each variable, rather than the typical default of #200 for QVAL
  - Allowing metadata for NSVs (including Controlled Terminology) to be applied at the variable level instead of the value-level

***Future Versions of Clinical IGs/UGs will transition to the exclusive use of NSVs structures***