

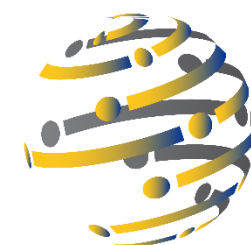
SCDM EMEA 2020 VIRTUAL CONFERENCE

SEPTEMBER 14 -16



SCDM
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SEPTEMBER 14-16

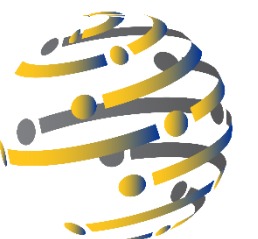


Designing Direct Data Capture CRFs using CDISC CDASH

ClinBuild
Éanna Kiely
2020-09-15

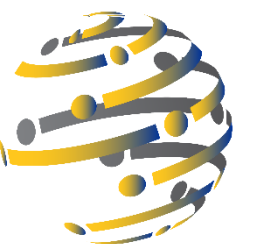
Agenda

- Direct Data Capture (DDC)
 - A Component of eSource
- Considerations for DDC eCRFs Design
 - Comments
 - eCRF Completion Instructions
 - Help Text
 - Edit Checks
- Demographics
 - Personally Identifying Information
- Benefits of CDASH
 - Conformance: Fields (Question Text and Prompts)
 - CDASHIG 2.x Variable Naming Conventions (VNC)
- Integrating Multiple DDC eCRFs
 - Standard CRFs Version, ODM/APIs
- More Information
 - TransCelerate, SCDM, IMI...



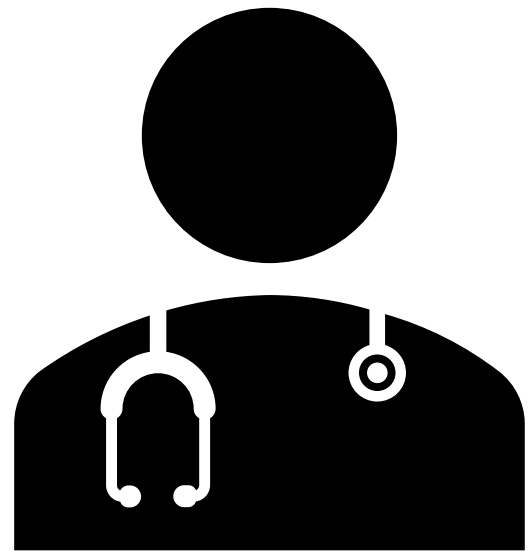
eSource: Direct Data Capture (DDC)

- The FDA Guidance for Industry: [Electronic Source Data in Clinical Investigations](#) released in 2013-09 describes electronic source data and the process of using it to populate the eCRF.
 - *This guidance addresses source data in clinical investigations used to fill the predefined fields in an electronic case report form (eCRF), according to the protocol.*
- What is Source data?
 - **Source Data:** *All information in original records and certified copies of original records of clinical findings, observations, or other activities (in a clinical investigation) used for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).*

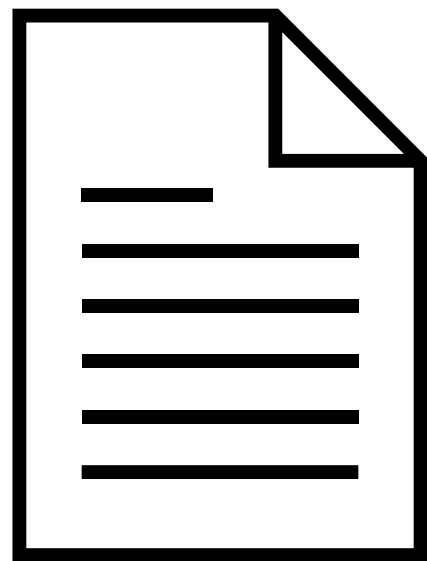


In Data Management

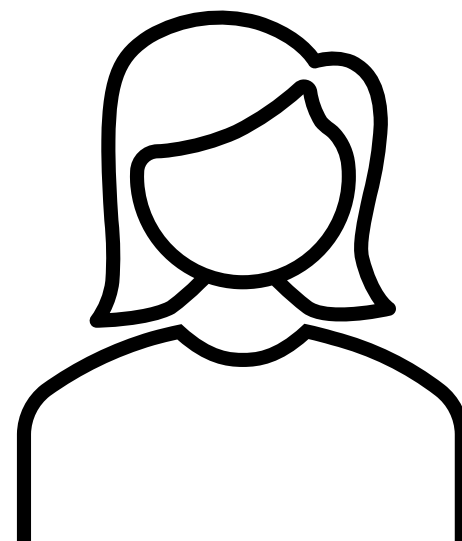
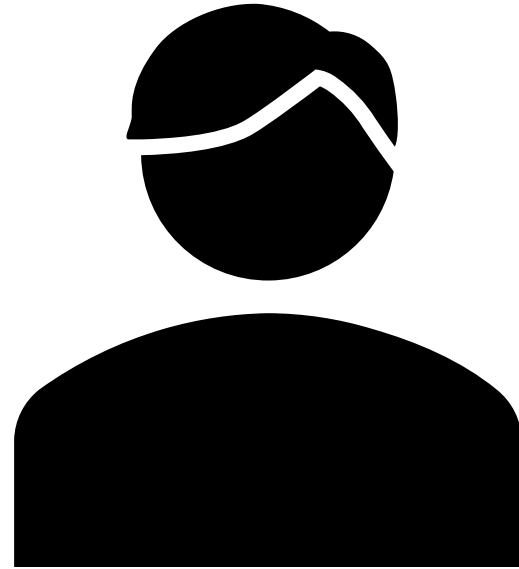
Investigator



Site Workbook



Site Staff

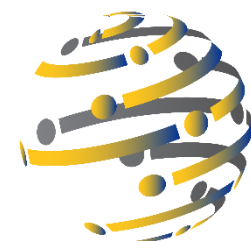
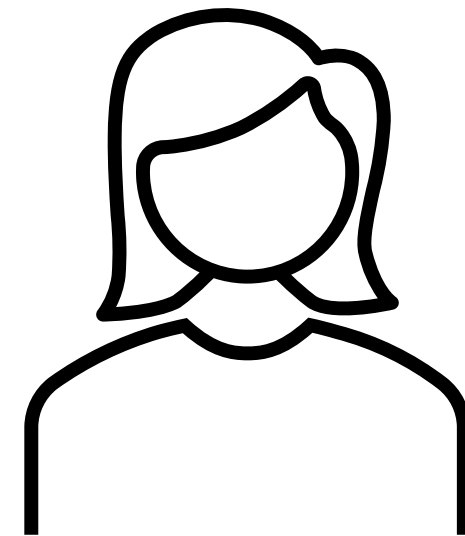


CRA



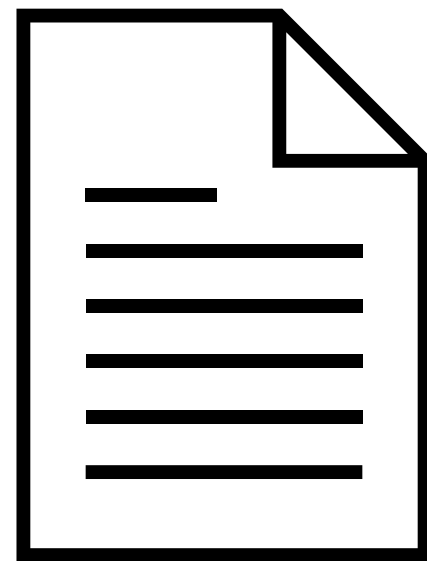
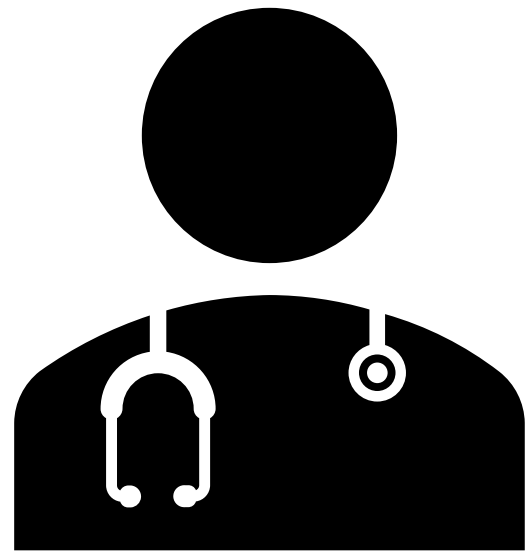
EDC

Data Manager

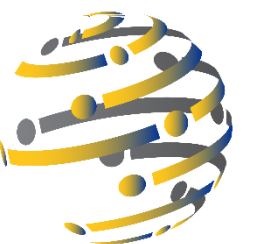


Investigator Enters Source Data

Investigator

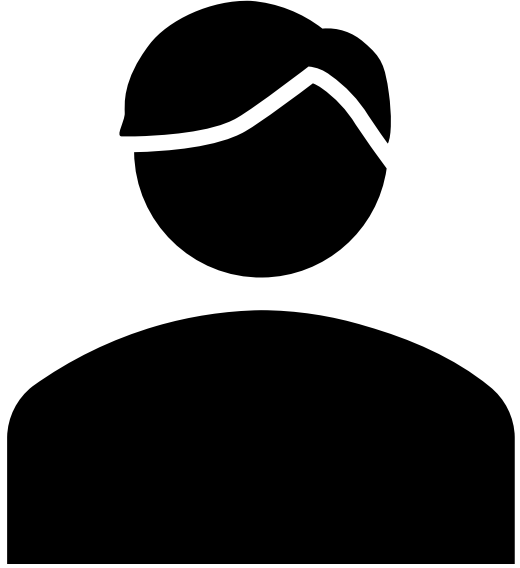


Site Workbook



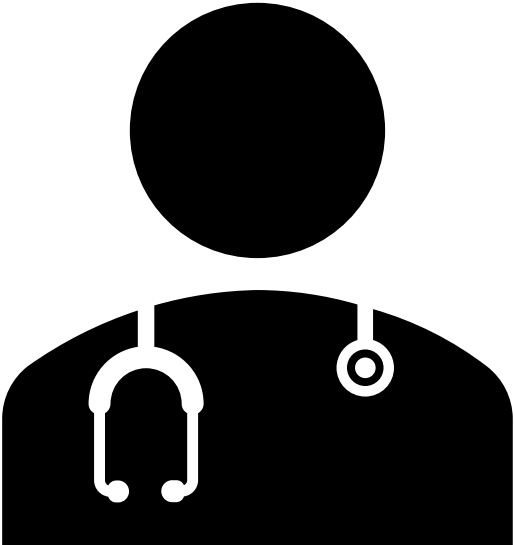
Site Staff Enters EDC

Site Staff



EDC

Investigator



Site Workbook

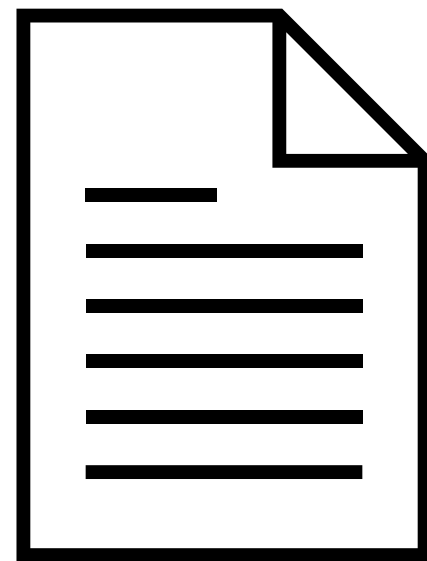


Data Manager Reviews EDC

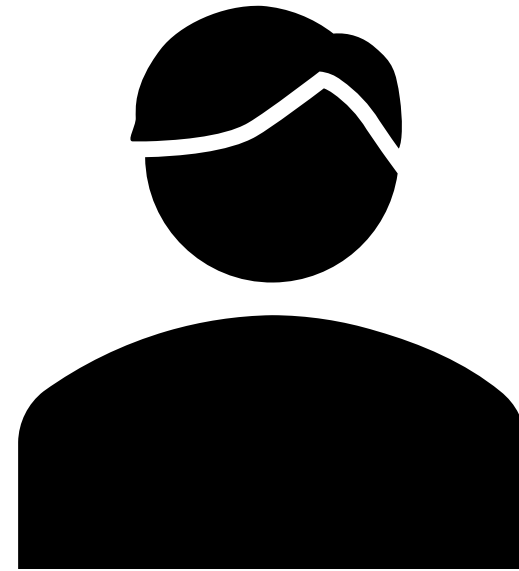
Investigator



Site Workbook

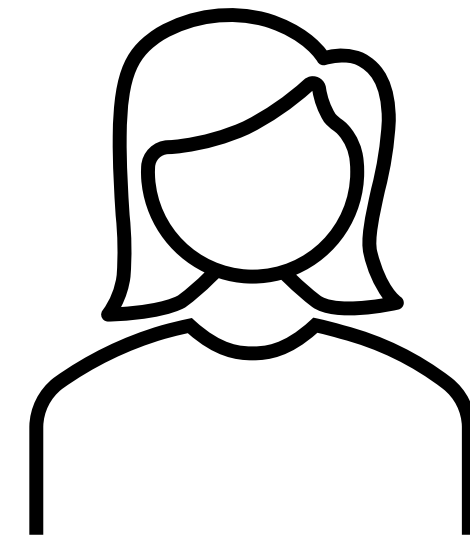


Site Staff



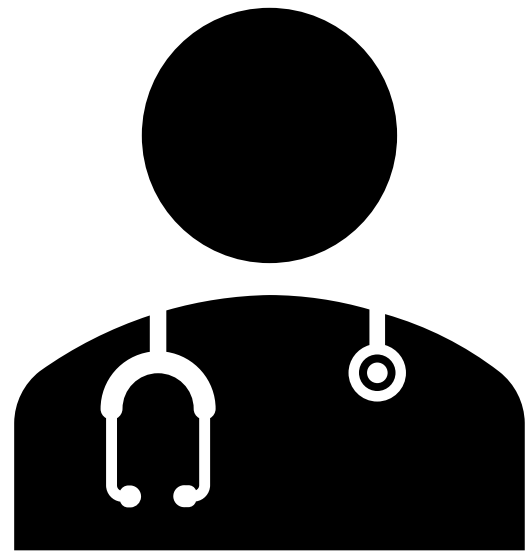
EDC

Data Manager

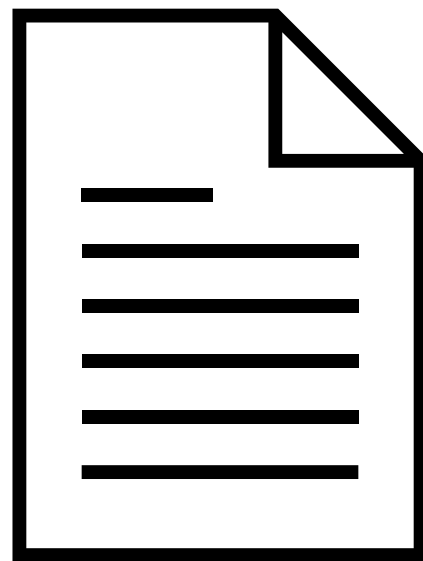


CRA Verifies Source Data

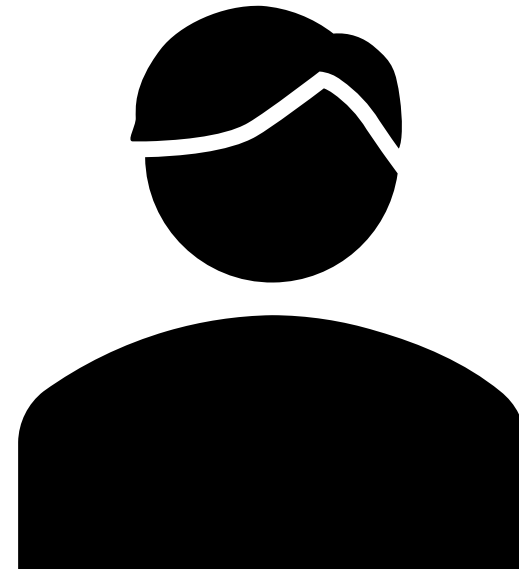
Investigator



Site Workbook

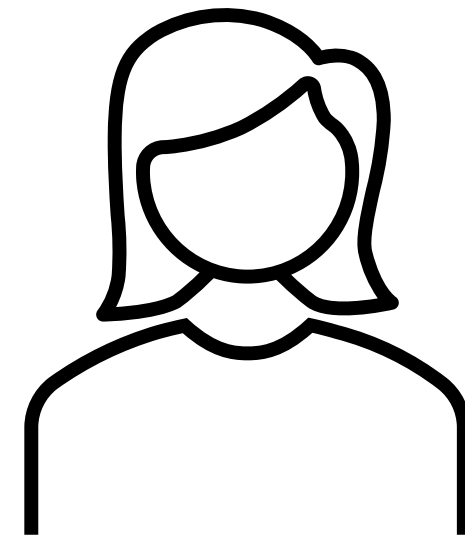


Site Staff

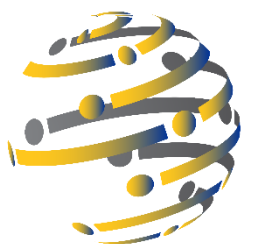
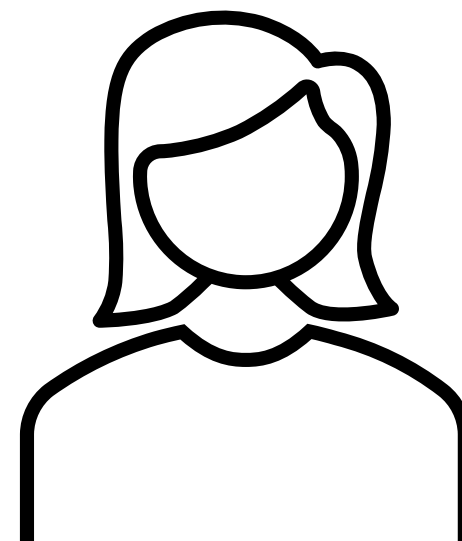


EDC

Data Manager



CRA



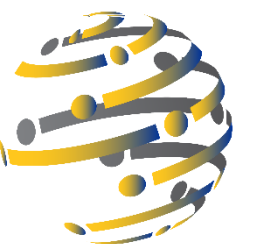
Source (Direct) Data Capture

FDA eSource

A. Data Capture

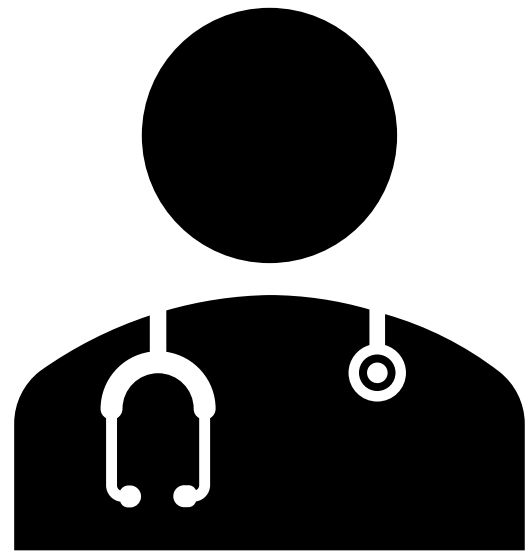
2. Source Data Capture

- *Data can be entered into the eCRF either manually or electronically as described below.*
 - a. Direct Entry of Data Into the eCRF*
- *Many data elements ... in a clinical investigation can be obtained at a study visit and can be entered directly into the eCRF by an authorized data originator. This direct entry of data can eliminate errors by not using a paper transcription step before entry into the eCRF. For these data elements, the eCRF is the source.*

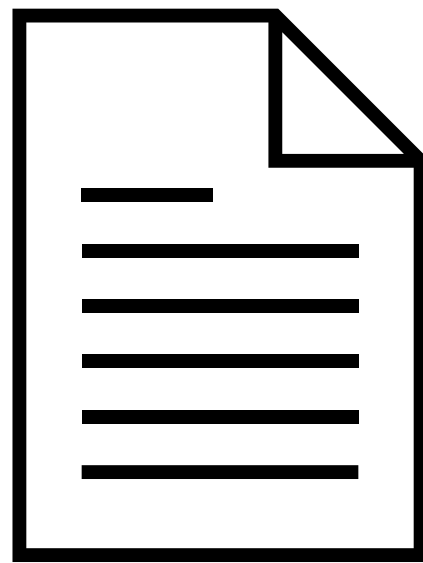


Source Documents Removed

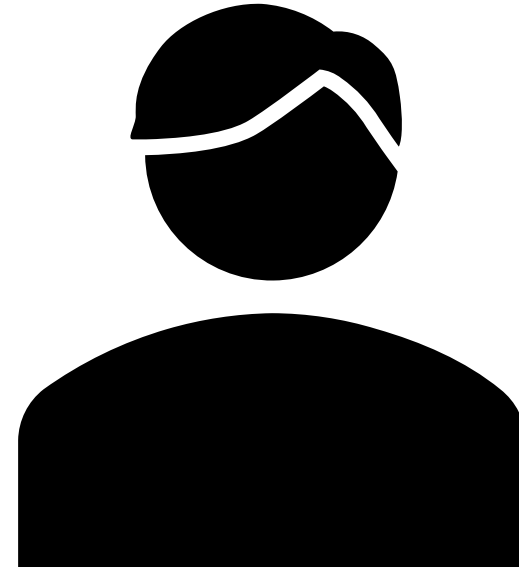
Investigator



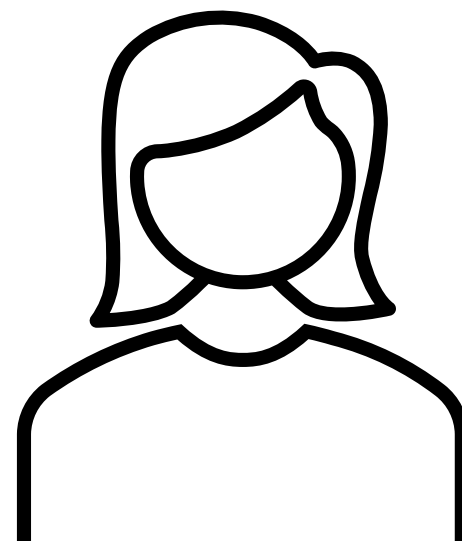
Site Workbook



Site Staff

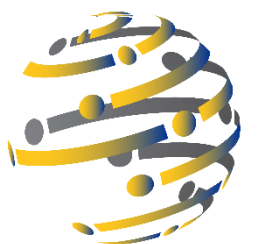
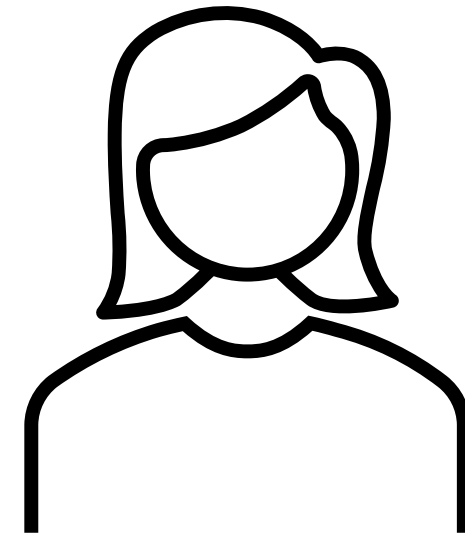


CRA



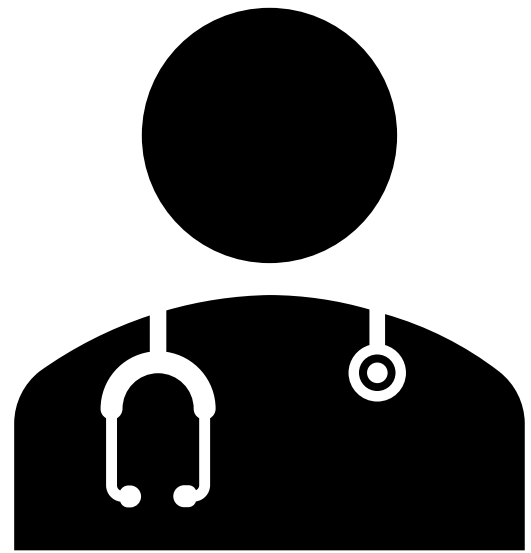
EDC

Data Manager



Site Staff and CRAs Reassigned

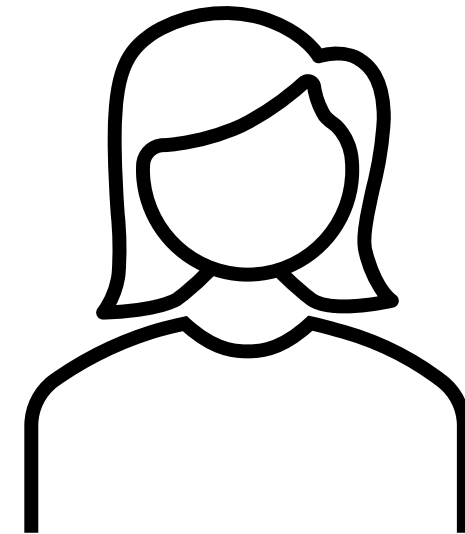
Investigator



Data Manager



EDC

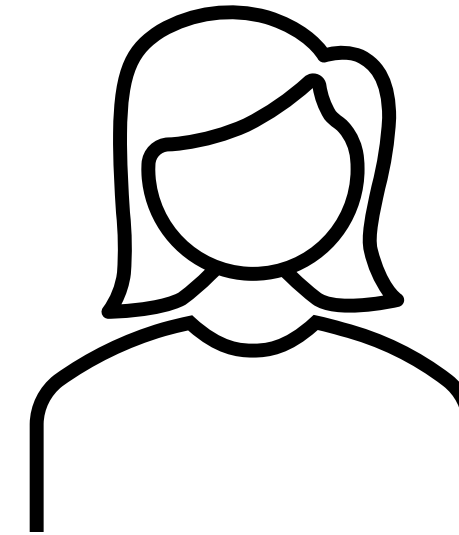


Real Time, Direct Data Capture

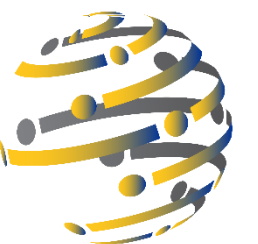
Investigator



Data Manager

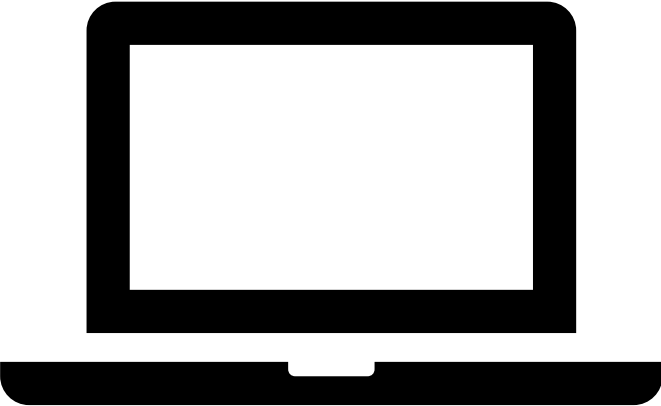
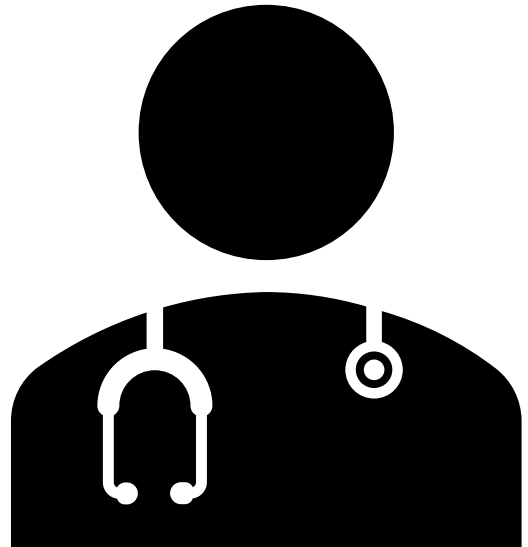


DDC

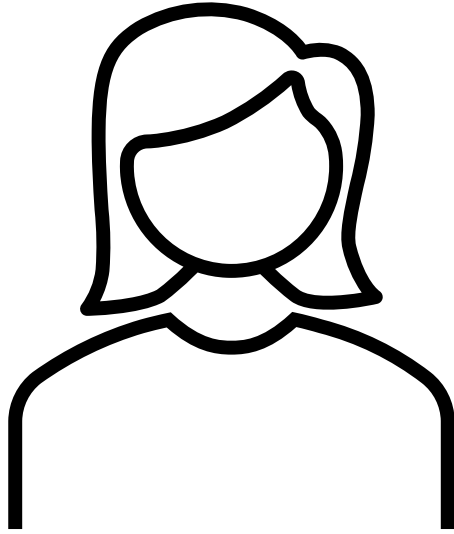


More Time for Clinical Research

Investigator

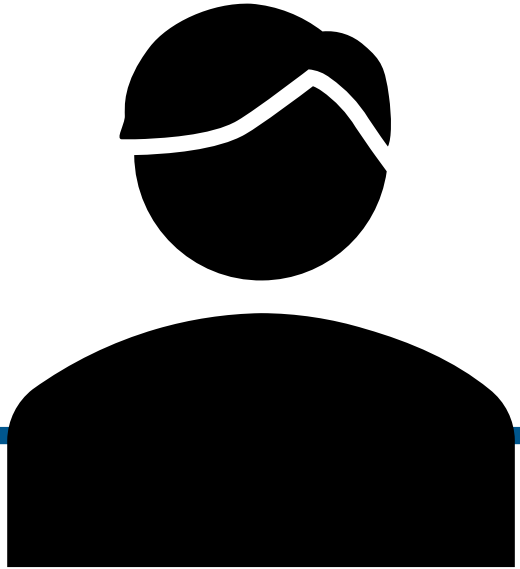


Data Manager

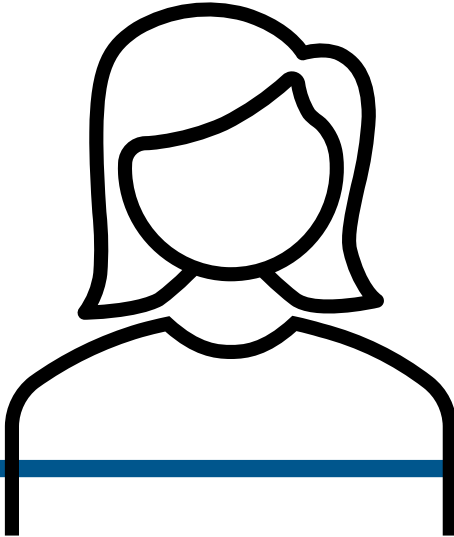


DDC

More patient focused



Site Staff



More site focused

CRA



Smoking History EDC eCRF

Asthma Trial

- **Exclusion Criteria**
- Current smokers of more than 10 pack years.
- Former smokers of more than 10 pack years in the last 6 months.

Smoking History (Cigarettes) [SU-01-001-CIG]	
SCDM-01	Site 01 Subject 001
Substance Use Category	Smoking Tobacco History
Usage	<input type="radio"/> Never <input type="radio"/> Current <input type="radio"/> Former
End Date	<input type="text" value="dd / MMMM / yyyy"/>
Cigarettes Amount	<input type="text" value="-----"/>
Unit	Pack Year
<input type="button" value="Submit"/> <input type="button" value="Clear"/>	

Smoking History DDC eCRF

Solicited Comment: Pack Years

- A pack year is a quantification of the exposure an individual has had to tobacco. It takes a pack of 20 cigarettes per day per year as a type of unit.
 - 20 cigarettes a day for 2 year = 2 pack year
 - 40 cigarettes a day for 1 year = 2 pack year
- The investigator may have to ask multiple questions to ascertain this information.

Unsolicited/General Comments

- Are general free-text comments not linked to a specific field.

Smoking History (Cigarettes) DDC [DDC-SU-01-001-CIG]	
SCDM-01	Site 01 Subject 001
Substance Use Category	Smoking Tobacco History
Usage	<input type="radio"/> Never <input type="radio"/> Current <input type="radio"/> Former
End Date	dd / MMMM / yyyy
Smoking History Description	
Cigarettes Amount	-----
Unit	Pack Year
Smoking History Comments	
<input type="button" value="Submit"/> <input type="button" value="Clear"/>	

Comments from a CDASH/GCDMP Perspective

CDASHIG 2.1 Assumptions for the CDASHIG CO - Comments Domain

Unsolicited/General comments

- CDASH advises against the collection of (unsolicited) general comments

Solicited Comments

- Should be used as needed but supported with **Value List Fields** to reduce data entry.

SCDM Good Clinical Data Management Practices (GCDMP)

- Recommends the collection of free-text comments and acknowledges the challenges of processing comments data.

Safety Data Management and Reporting (2007-05)

- Other Data
 - *In considerations of data capture, free-text commentary boxes are generally discouraged.*

FDA eSource Guidance: Edit Checks (and CRF Completion Instructions)

FDA eSource Guidance

5. Use of Electronic Prompts, Flags, and Data Quality Checks in the eCRF

- *We encourage the use of electronic prompts, flags, and data quality checks in the eCRF to minimize errors and omissions during data entry.*
- The investigator receives real time feedback on trial.
- A screening failure subject was excluded in DDC but potentially enrolled in EDC because the query fires after fact...

Smoking History (Cigarettes) DDC [DDC-SU-01-001-CIG]	
SCDM-01	Site 01 Subject 001
Substance Use Category	Smoking Tobacco History
Usage	<input type="radio"/> Never <input checked="" type="radio"/> Current <input type="radio"/> Former
End Date	dd / MMMM / yyyy
Smoking History Description	cigarettes and cigars
Cigarettes Amount	11
Unit	Pack Year
The subject has smoked over 10 pack years and is ineligible to join the trial. Please update the value if incorrect or exclude the subject.	
Smoking History Comments	Plans to give up
<input type="button" value="Submit"/> <input type="button" value="Clear"/>	

CDASHIG 2.1 Demographics Example CRF 1

- The Demographics Example CRF 1 from CDASHIG 2.1 collects the minimum amount of fields for an EDC eCRF.
- The data maps to the SDTM DM (Demographics) Domain

Demographics [C2-1 DM01]		
SCDM-01	Site 01	Subject 001
Birth Date	<input type="text" value="dd / MMMM / yyyy"/>	
Sex	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown <input type="radio"/> Undifferentiated	
Ethnicity	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported	
Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White	
<input type="button" value="Submit"/> <input type="button" value="Clear"/>		

SCDM-01 Site 01 Subject 001

Collection Date	<input type="text" value="dd / MMMM / yyyy"/>
First Name	<input type="text"/>
Last Name	<input type="text"/>
Birth Date	<input type="text"/>
Age	<input type="text" value="----"/>
Age Unit	Years
Sex	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown <input type="radio"/> Undifferentiated
What is the subject's address?	<input type="text"/>
Town	<input type="text"/>
State (Abbreviation)	<input type="text"/>
ZIP Code	<input type="text"/>
Phone No.	<input type="text" value="----"/>
Email Address	<input type="text"/>
Ethnicity	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported
Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other
Specify Other Race	<input type="text"/>

DDC Demographics - US

- The clinical site's require more personally identifying information (PII) about the subjects than the fields in the Demographics domain allow.
- In most clinical trials this PII would not be used in analysis and would not be populated in the eCRF
- This data also has data privacy concerns (e.g. GDPR).



SCDM-01 Site 01 Subject 001

Collection Date	<input type="text" value="dd / MMMM / yyyy"/>
First Name	<input type="text"/>
Last Name	<input type="text"/>
Birth Date	<input type="text"/>
Age	<input type="text" value="-----"/>
Age Unit	Years
Sex	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown <input type="radio"/> Intersex
What is the subject's address?	<input type="text"/>
Suburb	<input type="text"/>
City	<input type="text"/>
Postcode	<input type="text"/>
Phone No.	<input type="text" value="-----"/>
Email Address	<input type="text"/>
Ethnicity	<input type="checkbox"/> New Zealand European <input type="checkbox"/> Maori <input type="checkbox"/> Samoan <input type="checkbox"/> Cook Island Maori <input type="checkbox"/> Tongan <input type="checkbox"/> Niuean <input type="checkbox"/> Chinese <input type="checkbox"/> Indian <input type="checkbox"/> Other
Other (Dutch, Japanese, Tokelauan)	<input type="text"/>
Demographics Comments	<input type="text"/>

DDC Demographics - NZ

- In other countries and geographical regions address are collected differently.
- There are different codelists used for race and ethnicity.
- In some countries:
 - Ethnicity is used in the place of Race
 - Intersex is used in place of Undifferentiated
- These examples are still conformant to CDASH



CDASH Variables & Domains

- Demographics data is mapped into the DM domain.
- The PII is mapped into the Subject Characteristics (SC) domain.
- The SC domain belongs the Findings General Observation Classes (GOC) the variable requires a SCTEST/CD
- In CDASHIG 2.x Variable Naming Conventions the SCTESTCD (Topic Value) is prepended to the front of the variable with an underscore.
- **xxTESTCD_xxORRES** -> **FRSTNAME_SCORRES**
- **<TopicValue>_<xx><RootVariable>**

The screenshot shows a CDASH form with several fields. A green box highlights the address-related fields: 'What is the subject's address?' (ADDRESS_SCORRES), 'Town' (TOWN_SCORRES), 'State (Abbreviation)' (STATEABR_SCORRES), 'ZIP Code' (ZIPCODE_SCORRES), 'Phone No.' (PHONENO_SCORRES), and 'Email Address' (EMAIL_SCORRES). A purple box highlights the demographic fields: 'Collection Date' (DMDAT), 'Birth Date' (BRTHDAT), 'Age' (AGE), 'Age Unit' (AGEU), and 'Sex' (SEX). Another purple box highlights the ethnicity and race fields: 'Ethnicity' (ETHNIC) with radio buttons for 'Hispanic or Latino', 'Not Hispanic or Latino', and 'Not Reported'; 'Race' (RACE) with checkboxes for 'American Indian or Alaska Native', 'Asian', 'Black or African American', 'Native Hawaiian or Other Pacific Islander', 'White', and 'Other'; and 'Specify Other Race' (RACEOTH). The form also includes 'First Name' (FRSTNAME_SCORRES) and 'Last Name' (LASTNAME_SCORRES) fields. The top left shows 'Demographics US' and 'SCDM-01 Sit'. At the bottom are 'Submit' and 'Clear' buttons.

Variable Order & Clinical Flow

- Why not split the CRF into DM and SC?

CDASHIG 2.1

4.2 CRF Design Best Practices

2. *Fields should be placed on the form in the order that they are expected to be collected during the clinical assessment. It is acceptable to include fields from different domains on the same form if consistent with the clinical flow.*

Demographics NZ DC	
SCDM-01	Site 0
Collection Date	What is the subject's address?
DMDAT	ADDRESS_SCORRES
First Name	Suburb
FRSTNAME_SCORRES	SUBURB_SCORRES
Last Name	City
LASTNAME_SCORRES	CITY_SCORRES
Birth Date	Postcode
BRTHDAT	POSTCODE_SCORRES
Age	Phone No.
AGE	PHONENO_SCORRES
Age Unit	Email Address
AGEU	EMAIL_SCORRES
Sex	Ethnicity
SEX	RACE
	<input type="checkbox"/> New Zealand European
	<input type="checkbox"/> Maori
	<input type="checkbox"/> Samoan
	<input type="checkbox"/> Cook Island Maori
	<input type="checkbox"/> Tongan
	<input type="checkbox"/> Niuean
	<input type="checkbox"/> Chinese
	<input type="checkbox"/> Indian
	<input type="checkbox"/> Other
	Other (Dutch, Japanese, Tokelauan)
	RACEOTH
	Demographics Comments
	COVAL
<input type="Submit"/> <input type="Clear"/>	

CDASH Conformance: Controlled Terminology

Sex
SEX

Male
 Female
 Unknown
 Undifferentiated

Sex
SEX

Male
 Female
 Unknown
 Intersex

- The DM variable SEX seems to have a different value.
- Conformance Rules 5.1.4.a
 - ...the relevant CDISC Controlled Terminology should be used in the Question Text or Prompt as much as possible. It is acceptable to use **synonym text** that will directly map to a **CDISC Submission Value** (including an **NCI Preferred Term**)
- These will map to the same submission value in SDTM

CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
SEX	Sex
F	Female	...	Female
M	Male	...	Male
U	U; UNK; Unknown	...	Unknown
UNDIFFERENTIATED		A person (one of unisexual specimens) who is born with genitalia and/or secondary sexual characteristics of indeterminate sex, or which combine features of both sexes. (NCI)	Intersex

CDASH Conformance: CRACE/CETHNIC

CDASHIG 2.1 section 3.4.3.3.1.3

- If the mapping to SDTM is similar, but not direct, "C" can be included before the root variable name to indicate a "collected" version of the variable to which that data will map.*

Controlled Terminology: Racec-Ethnic Codetable

Ethnicity Hispanic or Latino
 Not Hispanic or Latino
 Not Reported

ETHNIC

Race American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White
 Other

RACE

Specify Other Race

RACEOTH

Ethnicity New Zealand European
 Maori
 Samoan
 Cook Island Maori
 Tongan
 Niuean
 Chinese
 Indian
 Other

CRACE

Other (Dutch, Japanese, Tokelauan)

RACEOTH

Value	C-code	RACEC		RACE
New Zealand European	C43851	EUROPEAN	C41261	WHITE
Maori	C158274	MAORI	C41219	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
Chinese	C43391	CHINESE	C41260	ASIAN
Indian	C41262	ASIAN INDIAN	C41260	ASIAN

Rules

Codetable Mapping Files

Unit-UCUM Mapping File

ables,

5,

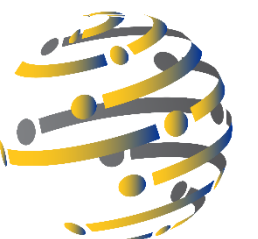
ed to

SDTMIG3.2 Variable_Codelist

DD Codetable

Oncology Codetable

Racec-Ethnic Codetable



CDASH Conformance: Fields (Question Text & Prompt) and Variables

- Field a question on the CRF
 1. Question Text
 - provides a full sentence for the collection of data.
 - *What was the adverse event end date?*
 - can contain detailed information
 - *What was the position of the subject during the ECG measurement?*
 2. Prompt
 - reduce the amount of information on a CRF
 - End Date
 - not as detailed
 - Position

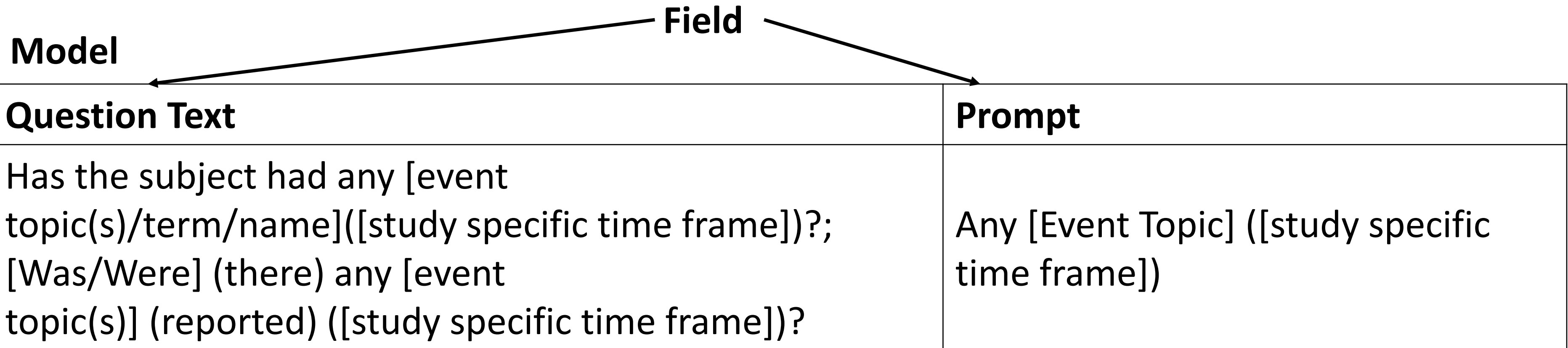
CDASH	REDCap	ODM	RAVE	InForm
Field	Field Label	ItemDef Name	Field Label	Item Default Question

- Variable
 - A (unique) code to refer to the data from the CRF field in the EDC database.

- AEENDAT
- EGPOS

CDASH	REDCap	ODM	RAVE	InForm
Variable	Variable Name	ItemDef OID	Field OID	Item RefName

CDASH Conformance: Question Text & Prompts Flexibility

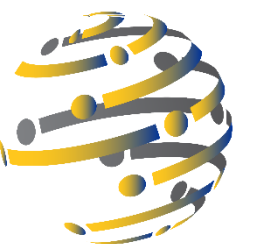


CDASH Conformance: Question Text & Prompts: **Optional Text**

Model

Question Text	Prompt
Has the subject had any [event topic(s)/term/name] ([study specific time frame])?; [Was/Were] (there) any [event topic(s)] (reported) ([study specific time frame])?	Any [Event Topic] ([study specific time frame])

Text	Description
brackets []	Required text
parentheses ()	Optional text
forward slash /	Chose an item of text
Semicolon ;	Choice of sentence



CDASH Conformance: Question Text & Prompts: **Optional Text**

Model

Question Text	Prompt
<p>Has the subject had any [event topic(s)/term/name]([study specific time frame])?; [Was/Were] (there)-any [adverse events] (reported) ([study specific time frame])?</p>	<p>Any [Adverse Events]-([study specific time frame])</p>

CDASH Conformance: Question Text & Prompts

Model

Question Text	Prompt
Were any adverse events reported?	Any Adverse Events

CDASH Conformance: Question Text & Prompts:

Model

Question Text	Prompt
Were any adverse events reported?	Any Adverse Events

Implementation Guide

Question Text	Prompt
Were any adverse events experienced?	Any Adverse Events

CDASH Conformance: Question Text & Prompts

Model

Question Text	Prompt
Were any adverse events reported?	Any Adverse Events

Implementation Guide

Question Text	Prompt
Were any adverse events experienced?	Any Adverse Events

DDC

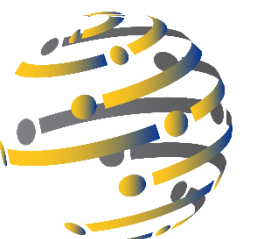
Question Text
Are there any adverse events?

5.1 Conformance Rules 4.d: *CDASH Model Question Text may contain options for the tense, but if the option is not provided, the tense of the Question Text may be modified to reflect the needs of the study.*

CDASH Conformance: Question Text & Prompt

CDASHIG 2.1 section 5.1 Conformance Rules

4. *The wording of CRF questions should be standardized; CDASH Question Text or Prompt must be used to ask the question.*
 - c. *In some cases, CDASH Questions Text and Prompt allow for flexibility while still being considered conformant. See Section 2.3, CRF Development Overview, for further details on the usage of Question Text and Prompt.*
 - d. *...the tense of the Question Text may be modified to reflect the needs of the study.*
- CDASH conformance validation checks can be run on DDC metadata to ensure that the fields and variables are in line with CDASH and have the same meaning.



CDASHIG 2.1 CRF Metadata Provided to the Site

CDASH Variable	Order	Question Text	Prompt	CRF Completion Instructions	Type	SDTMIG Target Variable	SDTMIG Target Mapping	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value	Query Display	List Style	Hidden
SUCAT	1	What is the category of the substance used?	Substance Use Category		Text	SUCAT				Smoking Tobacco History	Prompt		Yes
TOBACCO_SUNCF	2	Has the subject ever used tobacco?	Usage	Check the appropriate box to indicate if the subject currently or formerly consumed alcohol.	Text	SUOCCUR	SUOCCUR = "N" WHERE SUNCF = "NEVER". SUOCCUR = "Y" WHERE SUNCF = "CURRENT". SUOCCUR = "Y" WHERE SUNCF = "FORMER".	(NCF)	Never; Current; Former			radio	
TOBACCO_SUENDAT	3	What was the end date of tobacco use?	End Date	Record the end date of the tobacco consumption using this format (DD-MON-YYYY).	Date	SUENDTC					Prompt		
CIGARETTES_SUDSTXT	4	What was the amount of cigarettes consumed?	Cigarettes Amount	Indicate the amount of pack years the subject consumes tobacco on.	Num	SUDOSE; SUDOSTXT	SUDOSE/SUDOSTXT WHERE SUTRT = "CIGARETTES"						
CIGARETTES_SUDOSU	5	What was the unit for the amount of cigarettes consumption?	Unit	A quantification of lifetime tobacco exposure defined as (number of cigarettes smoked per day x number of years smoked)/20. One pack-year is smoking 20 cigarettes a day for one year.	Text	SUDOSU	SUDOSU WHERE SUTRT = "CIGARETTES"	(UNIT)		Pack Year			Yes

Site Creates CDASH Conformant DDC eCRF

CDASH Variable	Order	Question Text	Prompt
SUCAT	1	What is the category of the substance used?	Substance Use Category
TOBACCO_SUNCF	2	Has the subject ever used tobacco?	Usage
TOBACCO_SUENDAT	3	What was the end date of tobacco use?	End Date
CIGARETTES_SUDSTXT	4	What was the amount of cigarettes consumed?	Cigarettes Amount
CIGARETTES_SUDOSU	5	What was the unit for the amount of cigarettes consumption?	Unit

Smoking History (Cigarettes) DDC [DDC-SU-01-001-CIG]

SCDM-01 Site 01 Subject 001

Substance Use Category Smoking Tobacco History

SUCAT

Usage Never
 Current
 Former

TOBACCO_SUNCF

End Date

TOBACCO_SUENDAT

Smoking History Description

COVAL_CIGARETTES_SUDSTXT

Cigarettes Amount

CIGARETTES_SUDSTXT

Unit Pack Year

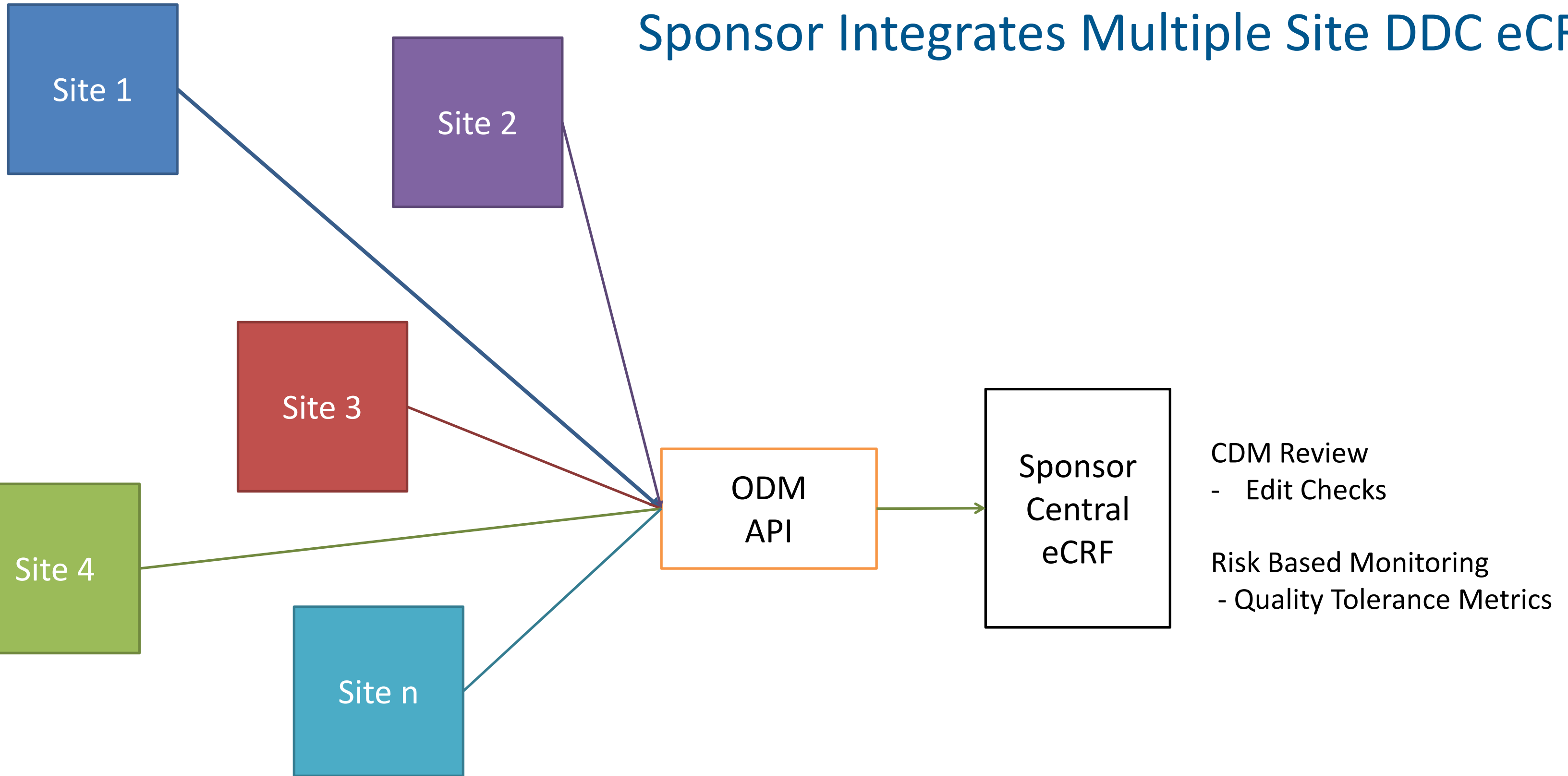
CIGARETTES_SUDOSU

Smoking History Comments

COVAL_CIGARETTES_SUTRT

Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value	Query Display	List Style	Hidden
		Smoking Tobacco History	Prompt		Yes
NCF)	Never; Current; Former			radio	
			Prompt		
UNIT)		Pack Year			Yes

Sponsor Integrates Multiple Site DDC eCRFs



Integrating Multiple DDC into a Sponsor EDC eCRF

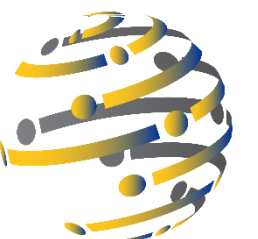
- For **Early Phase (EP)** studies in a single site (or small number of sites) the sponsor could manually review site DDC eCRF and manually map the data into a sponsor EDC eCRF system for review.
 - DDC eCRF review
 - Data Exchange (Export/Import) through ODM/APIs(/Data Transfers?)
- For **late phase**, multiple center trials the administrative burden to review and map multiple DDC eCRFs to sponsor EDC eCRF would be challenging

CDASH Conformant Site DDC eCRFs

- If the sites DDC eCRFs design process is conformant to CDASH the sponsor could send the expected **CDASHIG 2.x Variable Naming Conventions** conformant variables
 - **<TopicValue>_<xx><RootVariable>**
- The site would be free to create ~conformant fields

Sponsor CDASH Conformance Checks

- The sponsor could run CDASH conformance checks on the sites CDASH CRF Metadata for variables, fields and controlled terminology version. This could give a score metric e.g. 86% conformance which could show which DDC eCRFs require a manual review.



CDASH Conformance Score

CDASH Variable	Order	Question Text	Prompt	CRF Item Name	Type	SD ID	Target Text	Controlled Terminology Code List Name	Permissible Values	Pre- Populated Value	Query Display	List Style	Hidden
SUCAT	1	What is the category of the substance used?	Substance Use Category		Text	SUCAT				Smoking Tobacco History	Prompt		Yes
TOBACCO_SUNCF	2	Has the subject ever used tobacco?	Usage	Check the appropriate box to indicate if the subject currently or formerly consumed alcohol.	Text	SUOCCUR	SUOCCUR = "N" WHERE SUNCF = "NEVER". SUOCCUR = "Y" WHERE SUNCF = "CURRENT". SUOCCUR = "Y" WHERE SUNCF = "FORMER".	(NCF)	Never; Current; Former			radio	
TOBACCO_SUENDAT	3	What was the end date of tobacco use?	End Date	Record the end date of the tobacco consumption using this format (DD-MON-YYYY).	Date	SUENDTC					Prompt		
CIGARETTES_SUDSTXT	4	What was the amount of cigarettes consumed?	Cigarettes Amount	Indicate the amount of pack years the subject consumes tobacco on.	Num	SUDOSE; SUDOSTXT	SUDOSE/SUDOSTXT WHERE SUTRT = "CIGARETTES"						
CIGARETTES_SUDOSU	5	What was the unit for the amount of cigarettes consumption?	Unit	A quantification of lifetime tobacco exposure defined as (number of cigarettes smoked per day x number of years smoked)/20. One pack-year is smoking 20 cigarettes a day for one year.	Text	SUDOSU	SUDOSU WHERE SUTRT = "CIGARETTES"	(UNIT)		Pack Year			Yes

CDASH Variable	Order	Question Text	Prompt	Type	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value	Query Display	List Style	Hidden
SUCAT	1	What is the category of the substance used?	Substance Use Category	Text			Smoking Tobacco History	Prompt		Yes
TOBACCO_SUNCF	2	Has the subject ever used tobacco?	Usage	Text	(NCF)	Never; Current; Former			radio	
TOBACCO_SUENDAT	3	What was the end date of tobacco use?	End Date	Date				Prompt		
CIGARETTES_SUDSTXT	4	What was the amount of cigarettes consumed?	Cigarettes Amount	Num						
CIGARETTES_SUDOSU	5	What was the unit for the amount of cigarettes consumption?	Unit	Text	(UNIT)		Pack Year			Yes

CDASH Variable	Order	Question Text	Prompt
SUCAT	1	What is the category of the substance used?	Substance Use Category
CIGARETTES_SUNCF	2	Has the subject ever used tobacco?	Usage
CIGARETTES_SUENDAT	3	What was the end date of tobacco use?	Date Ended
COVAL_CIGARETTES_SUDSTXT	4	Describe the subjects smoking history?	Smoking History Description
CIGARETTES_SUDSTXT	5	What was the amount of cigarettes consumed?	Cigarettes Amount
CIGARETTES_SUDOSU	6	What was the unit for the amount of cigarettes consumption?	Unit
COVAL_CIGARETTES_SUTRT	7	Comments on the smoking history of the subject.	Smoking History Comments

CDASH Conformance Score			
	Base	Reviewed	Status
	80%		Review
Base	Variables	Fields	Terminology
	60%	80%	100%

DDC Variable	Src Variable	DDC Order	DDC Prompt	Src Prompt	IG Metadata Table	Model Metadata Table	Variable Sponsor Comment	Field Sponsor Comment
CIGARETTES_SUNCF	TOBACCO_SUNCF		Cigarette Usage	Usage	([Substance]) Usage	Usage	No action needed. Conformant. More specific, consider updating standard CRF.	No action needed. Conformant to domain metadata
CIGARETTES_SUENDAT	TOBACCO_SUENDAT		Date Ended	End Date	End Date	([Intended/Planned/Actual]) ([End/Discharge/Stop]) Date	No action needed. Conformant. More specific, consider updating standard CRF.	No action needed. Not conformant but semantically equivalent.
COVAL_CIGARETTES_SUDSTXT		3.1	Smoking History Description		[protocol-specified targeted question]	[Protocol-specified Targeted Question]		
COVAL_CIGARETTES_SUTRT		5.1	Smoking History Comments		[protocol-specified targeted question]	[protocol-specified targeted question]		



CDASH Variable	Order	Question Text	Prompt	Type	Controlled Terminology Code List Name	Permissible Values	Pre-Populated Value	Query Display	List Style	Hidden
SUCAT	1	What is the category of the substance used?	Substance Use Category	Text			Smoking Tobacco History	Prompt		Yes
TOBACCO_SUNCF	2	Has the subject ever used tobacco?	Usage	Text	(NCF)	Never; Current; Former			radio	
TOBACCO_SUENDAT	3	What was the end date of tobacco use?	End Date	Date				Prompt		
CIGARETTES_SUDSTXT	4	What was the amount of cigarettes consumed?	Cigarettes Amount	Num						
CIGARETTES_SUDOSU	5	What was the unit for the amount of cigarettes consumption?	Unit	Text	(UNIT)		Pack Year			Yes

CDASH Variable	Order	Question Text	Prompt
SUCAT	1	What is the category of the substance used?	Substance Use Category
CIGARETTES_SUNCF	2	Has the subject ever used tobacco?	Usage
CIGARETTES_SUENDAT	3	What was the end date of tobacco use?	Date Ended
COVAL_CIGARETTES_SUDSTXT	4	Describe the subjects smoking history?	Smoking History Description
CIGARETTES_SUDSTXT	5	What was the amount of cigarettes consumed?	Cigarettes Amount
CIGARETTES_SUDOSU	6	What was the unit for the amount of cigarettes consumption?	Unit
COVAL_CIGARETTES_SUTRT	7	Comments on the smoking history of the subject.	Smoking History Comments

CDASH Conformance Score			
	Base	Reviewed	Status
	80%	93%	Pass
	Variables	Fields	Terminology
Base	60%	80%	100%
Reviewed	100%	80%	100%

DDC Variable	Src Variable	DDC Order	DDC Prompt	Src Prompt	IG Metadata Table	Model Metadata Table	Variable Sponsor Comment	Field Sponsor Comment
CIGARETTES_SUNCF	TOBACCO_SUNCF		Cigarette Usage	Usage	([Substance]) Usage	Usage	No action needed. Conformant. More specific, consider updating standard CRF.	No action needed. Conformant to domain metadata
CIGARETTES_SUENDAT	TOBACCO_SUENDAT		Date Ended	End Date	End Date	([Intended/Planned/Actual]) ([End/Discharge/Stop]) Date	No action needed. Conformant. More specific, consider updating standard CRF.	No action needed. Not conformant but semantically equivalent.
COVAL_CIGARETTES_SUDSTXT		3.1	Smoking History Description		[protocol-specified targeted question]	[Protocol-specified Targeted Question]		
COVAL_CIGARETTES_SUTRT		5.1	Smoking History Comments		[protocol-specified targeted question]	[protocol-specified targeted question]		



Site(Global) DDC Standard eCRFs

- If the site(s) implemented a DDC eCRF version control system they could provide the sponsor with the DDC eCRF ID. The sponsor would be able to review if this DDC eCRF was in line with expectations.

General eCRF Standards Versioning Process

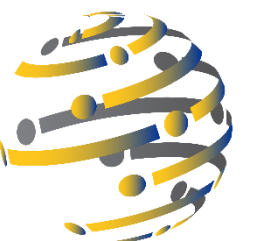
- DM-01-001

Site(Global) DDC Standard eCRFs

- If the site(s) implemented a DDC eCRF version control system they could provide the sponsor with the DDC eCRF ID. The sponsor would be able to review if this DDC eCRF was in line with expectations.

General eCRF Standards Versioning Process

- **DM-01-001**
- **<Domain>-<Major Version>-<Minor/Administrative Version>**



Standards Versioning

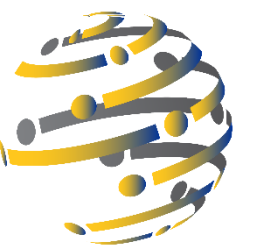
- When do you create a new version of the CRF?

ID	Name	Description
DM-01-001	Demographics	Demographics CRF

Standards Versioning

- When do you create a new version of the CRF? **Changed codelist values**

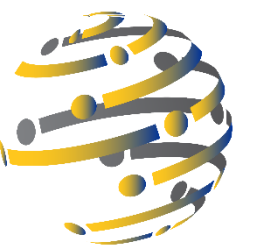
ID	Name	Description	Variables Used
DM-01-001	Demographics	Demographics CRF	AGEU defaulted to years
DM-02-001	Demographics Pediatrics	Demographics CRF for Pediatrics Studies CRF captures age in weeks	AGEU can be set to a radio button



Standards Versioning

- When do you create a new version of the CRF? **Frequent change expected**

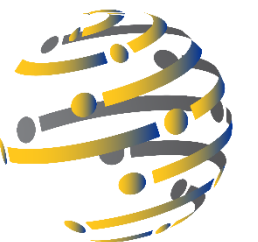
ID	Name	Description	Variables Used
DM-01-001	Demographics	Demographics CRF	AGEU defaulted to years
DM-02-001	Demographics Pediatrics	Demographics CRF for Pediatrics Studies CRF captures age in weeks	AGEU can be set to a radio button
DM-03-001	Demographics - EU	Demographics CRF that does not include the US Race and Ethnicity Variables	"AMERICAN INDIAN OR ALASKA NATIVENATIVE" and "HAWAIIAN OR OTHER PACIFIC ISLANDER" RACE codelist values removed: "BLACK OR AFRICAN AMERICAN" changed to "BLACK" ETHNIC codelist is not included.



Standards Versioning

- When do you create a new version of the CRF? **Frequent change expected**

ID	Name	Description	Variables Used
DM-01-001	Demographics	Demographics CRF	AGEU defaulted to years
DM-02-001	Demographics Pediatrics	Demographics CRF for Pediatrics Studies CRF captures age in weeks	AGEU can be set to a radio button
DM-03-001	Demographics - EU	Demographics CRF that does not include the US Race and Ethnicity Variables	“AMERICAN INDIAN OR ALASKA NATIVENATIVE” and “HAWAIIAN OR OTHER PACIFIC ISLANDER” RACE codelist values removed: "BLACK OR AFRICAN AMERICAN" changed to "BLACK" ETHNIC codelist is not included.
DM-04-001	Demographics New Zealand	Captures the Ethnicity Required by New Zealand	New Zealand specific ethnicities



Types of DDC Data

- A clinical site using a DDC system will be collecting 3 general types of data
 1. CRF data
 2. Administrative Site Data
 3. Personally Identifying Information (PII)

Type	Variable	Prompt	CRF Design Comment
CRF	AGE	Age	The DDC site will derive AGE from BRTHDAT
Site	COVAL_CIGARETTES_ SUDSTXT	Smoking History Description	Used by the site for Pack Year calculations
PII	FRSTNAME_SCORRES	First Name	Not to be provided to the sponsor due PII

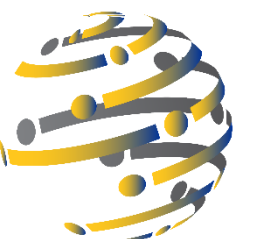
Managing Personally Identifying Information (PII)

- CDM has extensive experience managing “Blinded Data” e.g. Unblinded Data Managers, Unblinded CRAs and Unblinded Site Staff.
- A data privacy team could be setup to manage and review this data.

SCDM GCDMP Data Privacy (2009-04): Data Privacy Focus Areas: Appropriate Redaction of Personal Data

- *Redaction is the act of obscuring or removing text from a document before releasing the document to other personnel or departments.*

Type	Variable	Variable Prefix	DDC CDASH VNC Variables
CRF	AGE	C__	C__AGE
Site	COVAL_CIGARETTES_SUDSTXT	S__	S__COVAL_CIGARETTES_SUDSTXT
PII	FRSTNAME_SCORRES	P__	P__FRSTNAME_SCORRES



- > ECG QT Correction Model Data (QT)
- > Environmental and Social Factors (ER)
- > Gastrointestinal System Findings (GI)
- > Product Accountability (DA)
- > Whole-Body System (WB)
- > Related Devices (RELDEV)
- > Genomic Findings (GF)
- > Domain Template Instructions
- ▼ SDTM Draft Domains Under Construction
 - > Common Metadata for Physiology Morphology
 - > **Site Summary (SI)**
 - > Subject Biomarkers (SB)
 - > Trial Test Lookup
 - > Ophthalmic Examinations (OE)
 - > Biospecimen Events (BE)
 - > Biospecimen Findings (BS)
 - > PGx Biomarker and Subject Biomarker Domains - PB and SB
 - > Pharmacogenomics/Genetics Methods and Supporting Information (PG)
 - > Related Specimens (RELSPEC)
 - > Trial Time Points (TT)
 - > Cell Phenotype Findings (CP)
 - > Integumentary System Findings (IG)
 - > Demographics as Collected (DC)
 - > SDTM Section 3.2.2(new) Demographics as Collected
 - > QRS Reference (QX)
 - > Subject Visits (SV)

Separate PI Domain?

- PII could be stored in a separate domain to SC to possibly help reduce issues with incorrect transferred PII data.

CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission...
SC	Subject Characteristics	A findings domain that contains subject-related data not collected in other domains.
PI	Personally Identifying Information	A findings domain that contains personally identifying information that would not usually be submitted to the sponsor or regulatory agency.

- There is currently not PI domain
 - PB, PC, PE, PF, PG, POOLDEF, PP, PROJECT
- A Site Summary (SI) domain was developed for site data.
- [SDTM Draft Domains Home](#) (SDS Team Member Access)



FDA Projected Benefits of using eSource

II. BACKGROUND

- *Capturing source data electronically and transmitting it to the eCRF should:*
 - *Eliminate unnecessary duplication of data*
 - *Reduce the possibility for transcription errors*
 - *Encourage entering source data during a subject's visit, where appropriate*
 - *Eliminate transcription of source data prior to entry into an eCRF*
 - *Facilitate remote monitoring of data*
 - *Promote real-time access for*
 - *Facilitate the collection of a*

INDUSTRY COLLABORATORS

Novartis - Memorial Sloan Kettering

- EHR export -> sponsor data warehouse
- Local lab and vitals domain

VALUE

- Manual data entry **reduced** by **20%**
- Query rate **reduced** by **50%**
- Transcription errors **0**

Eli Lilly - Memorial Sloan Kettering & Yale

- EHR -> EDC
- Local lab domains

- Data latency **reduced** from **20.4 to 3.5 days**
- Transcription errors **reduced** from **0.7% to 0**
- Site effort **reduced** by **8 hours/patient/study**
- Monitoring activity **reduced** by **2 hours/patient/study**

Duke University School of Medicine

- Internal EHR -> internal EDC

- Time saved **37% total time** between traditional EDC vs eSource, 1 FTE, 65% total keystrokes
- Data Quality - 9% error rate to **0**



eSource/Direct Data Capture in Industry

- [TransCelerate](#) provides a good overview of eSource and defines the related terms.
- The SCDM is leading an [eSource consortium](#) and addressing industry challenges.
- CDISC is working on HL7 FHIR [initiative](#)
- The European Innovative Medicines Initiative (IMI) has relevant projects.
- Source Data Capture from Electronic Health Records (EHRs): Using Standardized Clinical Research Data – ([OneSource](#))
- Others



Non-CRF

The collection and transfer of electronic data from internal sponsor sources or external vendors into data repositories/warehouses without into a Case Report Form (CRF).



Devices and Apps

The collection and management of clinical data from non-site personnel, wearables, and sensors.



DDC

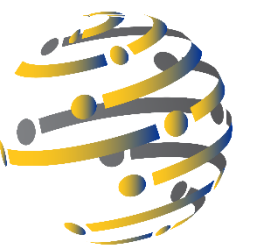
The direct entry of clinical data by site staff into a mobile application or EDC system.



EHR

The collection and reuse of data for use in clinical research from site/patient electronic health record systems.

<https://www.transceleratebiopharmainc.com/assets/esource-solutions/>



SCDM-01 Site 01 Subject 001

Collection Date	15 / SEP / 2020
First Name	Eanna
Last Name	Kiely
Birth Date	15 / SEP / 2020
Age	-----
Age Unit	Years
Sex	<input checked="" type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown <input type="radio"/> Undifferentiated
What is the subject's address?	Alt Buch 40B
Town	Berlin
State (Abbreviation)	
ZIP Code	13125
Phone No.	+4917657816593
Email Address	eanna.kiely@clinbuild.com
Ethnicity	<input type="radio"/> Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported
Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input checked="" type="checkbox"/> White <input type="checkbox"/> Other
Specify Other Race	Irish

Any Questions?

- Thank you
- Please feel free to contact with any questions or comments

