

1. Table of Contents

1.	Table of Contents	1
2.	Purpose	1
3.	Form Naming Guidelines	1
4.	Variable or Field Naming Guidelines:.....	2
5.	Numeric codes for Codelist Items	3

2. Purpose

The purpose of the Variable Naming Standards document is to detail the criteria when developing names for forms and variables and the coding associated with them. These standards were developed using Clinical Data Acquisition Standards Harmonization (CDASH) guidance and apply to databases and data sets developed prospectively in the Data Management and Analysis Center (DMAC) at Cincinnati Children's Hospital and Medical Center (CCHMC). CDASH establishes a standard way to collect data consistently across studies and sponsors/investigators so that data collection formats and structures provide clear traceability of the data into data models (like the Study Data Tabulation Model (SDTM)), delivering more transparency to regulators and others who conduct data review. If the DMAC does not develop the database, these guidelines should be followed where practical.

More information can be found here: <https://www.cdisc.org/standards/foundational/cdash>

3. Form Naming Guidelines

For the following forms, use the following dataset name and prefix for fieldnames:

CLASS	FORM	DATASET NAME (DOMAIN)	PREFIX FOR FIELD NAMES*
EVENTS	Adverse Events	AE	ae-
EVENTS	Disposition/End of Study	DS	ds-
EVENTS	Medical History	MH	mh-
EVENTS	Protocol Deviation	DV	dv-
FINDINGS	Death Details	DD	dd-
FINDINGS	Drug Accountability	DA	da-
FINDINGS	ECG Test Results	EG	eg-
FINDINGS	Eligibility Criteria	IE	ie-
FINDINGS	Laboratory Test	LB	lb-
FINDINGS	Pharmacokinetics (PK) Concentrations	PC	pc-
FINDINGS	Physical Examination	PE	pe-
FINDINGS	Questionnaires, Ratings, and Scales	QS	qs-
FINDINGS	Reproductive System Findings	See below**	See below**

FINDINGS	Disease Response and Clinical Classification	RS	rs-
FINDINGS	Respiratory System Findings	RE	re-
FINDINGS	Subject Characteristics	SC	sc-
FINDINGS	Vital Signs	VS	vs-
INTERVENTIONS	Concomitant Medications	CM	cm-
INTERVENTIONS	Exposure as Collected	EX	ex-
INTERVENTIONS	Meal Data	ML	ml-
INTERVENTIONS	Procedures	PR	pr-
INTERVENTIONS	Substance Use	SU	su-
SPECIAL-PURPOSE	Demographics	DM	dm-

*Note: Some fields/variables do not always follow this general rule. These are listed in the next section.

**Questionnaires, ratings, and scales (QRS) are standardized and often validated instruments, and the data collected using them are represented in domains including Questionnaires (QS), Disease Response and Clin Classification (RS), and Functional Tests (FT). See the SDTMIG or the QRS web page (<https://www.cdisc.org/foundational/qrs>) for complete information on these domains. CDISC publishes supplemental specifications called QRS supplements, including example annotated CRFs (aCRFs) for many of these instruments. Please reach out to a Data Management Lead if adding a new questionnaire, rating, or scale in your study for further guidance.

4. Variable or Field Naming Guidelines:

Use these general guidelines when defining fields/field names when possible:

- Use ddMONyyyy format for dates whenever possible; otherwise, use mmddyyyy
- Limit field name to 8 characters
- Do not use underscores

4.1. Common Variables Naming Guidelines

Use the following field names for these common fields:

FIELD	FIELD NAME
Study Id	studyid
Subject ID	subjid
Site ID	siteid
Visit Name	visit
Visit Number	visitnum
Date of Visit	visdat
MRN	mrn
Date of Birth	brthdat
Date of Birth /mon	brthmdat
Date of Birth /day	brthddat
Date of Birth /yr	brthydat
Date of Death	dthdat

Date of Death /mon	dthmdat
Date of Death /day	dthddat
Date of Death /yr	dthydat
Gender	sex
Ethnicity	ethnic
Race	race
Age	age
Age Unit	ageu
Height	height
Weight	weight
Systolic Blood Pressure	sysbp
Diastolic Blood Pressure	diabp
Temperature	temp

It is important to note that the variables listed above do NOT follow the normal convention of adding a two-character domain/form ID.

4.2. Suffixes for Variable Naming

Use the following suffix when defining field names for these field types:

FIELD TYPE	SUFFIX	FIELD TYPE	SUFFIX
Date	-dat	BMI	-bmi
Time	-tim	Heart Rate	-hrt
Start Date	-stdat	Education	-edus
		(Subject/Parent)	-edup
End Date	-endat	Insurance	-ins
Time/min	-mtim	Income	-inc
Time/hr	-htim	Circumference	-circ
Date/mon	-mdat	Zip Code	-zip
Date/day	-ddat		
Date/yr	-ydat		

5. Numeric codes for Codelist Items

Use the following codes for these codelist items:

Codelist Items	Codes
Positive	1
Negative	0
Yes	1
No	0
Selected	1

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Programming Standards—Variable Naming

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Not Selected/Not Reported	0
Missing	1's (length of code should be 1 digit larger than longest code in the codelist)
Not Applicable	2's (length of code should be 1 digit larger than longest code in the codelist)
Unknown	3's (length of code should be 1 digit larger than longest code in the codelist)
Refused	4's (length of code should be 1 digit larger than longest code in the codelist)
Not Done	5's (length of code should be 1 digit larger than longest code in the codelist)
Other	9's (length of code should be 1 digit larger than longest code in the codelist)
Male	1
Female	2
Hispanic	1
Non-Hispanic	2
American Indian or Alaska Native	1
Asian	2
Black or African American	3
Native Hawaiian or Other Pacific Islander	4
White	5