Domain Models Based on the General Observations Classes

FINDINGS

URINARY SYSTEM — UR

ur.xpt, Urinary System — Findings, Version 3.1.5. One record per Urinary System Detail or finding per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	UR	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
URSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
URGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
URREFID	Reference ID	Char		Identifier	Internal or external Urinary System record identifier.	Perm
URSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
URTESTCD	Urniary SystemTest Short Name	Char	(URTESTCD)	Topic	Short name of the measurement, test, or examination described in URTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in URTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g."1TEST"). URTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: RBLDFLW, etc.	Req
URTEST	Urniary SystemTest Name	Char	(URTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in URTEST cannot be longer than 40 characters. Examples: Renal Blood Flow, etc.	Req

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
URCAT	Category for Urinary Systems	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
URSCAT	Subcategory for Urinary System	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perm
URORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the Urinary System test as originally received or collected.	Exp
URORRESU	Original Units	Char		Variable Qualifier	Original units in which the data were collected. The unit for URORRES. Examples: YEARS.	Exp
URSTRESC	Character Result/Finding in Standard Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from URORRES in a standard format or standard units. URSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in URSTRESN. For example, if a test has results “NONE”, “NEG”, and “NEGATIVE” in URORRES and these results effectively have the same meaning; they could be represented in standard format in URSTRESC as “NEGATIVE”.	Exp
URSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from URSTRESC. URSTRESN should store all numeric test results or findings.	Exp
URSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for URSTRESC and URSTRESN.	Exp
URSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a Urinary System test was not done. Should be null if a result exists in URORRES.	Perm
URREASND	Reason Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with URSTAT when value is NOT DONE.	Perm
URBLFL	Baseline Flag	Char	(ND)	Record Qualifier	Indicator used to identify a baseline value. The value should be “Y” or null.	Exp

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
URDRVFL	Derived Flag	Char	(ND)	Record Qualifier	Used to indicate a derived record. The value should be Y or null. Records which represent the average of other records or which do not come from the CRF are examples of records that would be derived for the submission datasets. If URDRVFL=Y, then URORRES may be null, with URSTRESC and (if numeric) URSTRESN having the derived value.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
URDTC	Date/Time of Measurements	Char	ISO 8601	Timing		Exp
URDY	Study Day of Urinary System	Num		Timing	1. Study day of Urinary System observation, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

6.3.14.1 ASSUMPTIONS FOR URINARY SYSTEM DOMAIN MODEL

1. UR Definition: This domain captures all Urinary System details in a study related to the subject in a FINDINGS domain. Many of the findings proposed originated in legacy data conversions. Any new prospective Urinary System tests need to be proposed with the CDISC Terminology Committee for formal inclusion.
2. The following Qualifiers would not generally be used in UR: --MODIFY, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --NRIND, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV, --LLOQ.
3. Terminology
    3.1. Controlled Terminology for the UR domain URTESTCD and URTEST values is being submitted for consideration to the CDISC Terminology Team.

6.3.14.2 EXAMPLES FOR URINARY SYSTEM DOMAIN MODEL

Example 1:

The example below shows 1 subject (USUBJID=2324-P0001) who had UR results based on a PKD MRI image. These results fields are mapped to UR (Urinary System) domain as in the following data example. The standard controlled terminology for URTESTCD, URTEST, URLOC, URLAT, and URMETHOD is represented in the table.

Rows 1-3: Display Renal Blood Flow measurements based on URMETHOD=PARA-AMINO HIPPURIC ACID CLEARANCE and URLOC= KID

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ROW	STUDYID	DOMAIN	USUBJID	URSEQ	URTESTCD	URTEST	URORRES	URORRESU	URSTRESC	URSTRESN	URSTRESU
1	STUDY01	UR	2324-P0001	7	RBLDFLW	Renal blood flow	20	mL	20	20	mL
2	STUDY01	UR	2324-P0001	8	RBLDFLW	Renal blood flow	10	mL	10	10	mL
3	STUDY01	UR	2324-P0001	9	RBLDFLW	Renal blood flow	10	mL	10	10	mL

ROW	URLOC	URLAT	URMETHOD	VISITNUM
1 (cont)	KIDNEY	BILATERAL	PARA-AMINO HIPPURIC ACID CLEARANCE	1
2 (cont)	KIDNEY	LEFT	PARA-AMINO HIPPURIC ACID CLEARANCE	2
3 (cont)	KIDNEY	RIGHT	PARA-AMINO HIPPURIC ACID CLEARANCE	3

Appendix A: Representations and Warranties, Limitations of Liability, and Disclaimers

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