




Domain PROCEDURES pr.xpt

CDISC German User Group Meeting
Leverkusen 26. Februar 2013

Interventions: The Interventions class captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., exposure to study drug), coincident with the study assessment period (e.g., concomitant medications), or self-administered by the subject (such as use of alcohol, tobacco, or caffeine).

Interventions domains



		Variablen (total / req. / exp. / perm.)	Key
●CM STDTC	Concomitant medication	37 / 5 / 0 / 32	STUDYID, USUBJID, --TRT, --
●SU STDTC	Substance use	35 / 5 / 0 / 30	STUDYID, USUBJID, --TRT, --
●EX STDTC	Exposure	44 / 5 / 4 / 35	STUDYID, USUBJID, --TRT, --
●EC STDTC	Exposure as collected	45 / 5 / 4 / 36	STUDYID, USUBJID, --TRT, --
●PR STDTC	Procedures	42 / 5 / 1 / 36	STUDYID, USUBJID, --TRT, --

Procedures domain pr.xpt: Details

One record per recorded procedure per occurrence per subject

The Procedures domain model reflects collected details describing a subject's therapeutic and diagnostic procedures. Measurements obtained from procedures are to be represented in their respective Findings domain(s).

SDTMIG 3.1.2 "Surgery (SG) might be consolidated with Procedure domain(s)."

- Topic variable = PRTRT
- Synonym qualifier = PRDECOD
- Grouping qualifier = PRCAT, PRSCAT
- Identifier Variables = STUDYID, DOMAIN, USUBJID, PRSEQ, PRGRPID, PRSPID, PRLNKID
- Record Qualifier = PRESP, OCCUR, STAT, REASND, INDC, DOSE, DOSTXT, LOC

Procedures domain pr.xpt: Assumptions

Procedure type(s)

- disease screening
mammogram
- endoscopic examinations
arthroscopy
- diagnostic tests
biopsy
- therapeutic procedures
dialysis
- surgical procedures
hysterectomy

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRSTDTC
	1XYZ	PR	XYZ1001		1 Wisdom Teeth Extraction	2010-06-08
	2XYZ	PR	XYZ1001		2 Reset Broken Arm	2010-08-06
	3XYZ	PR	XYZ1001		3 Prostate Examination	2010-12-12
	4XYZ	PR	XYZ1001		4 Endoscopy	2010-12-12
	5XYZ	PR	XYZ1001		5 Heart Transplant	2011-08-29