

CDISC-AdvaMed Device Project:

Building Consensus to Define Device CDASH and SDTM Standards

NEW DOMAIN DEFINITIONS

1. Device Identifiers (DI): Consistent unique sponsor-defined identifier that links data across domains.
2. Device Properties (DO): Important unvarying device characteristics that are not identifiers
3. Device-In-Use (DU): Measurements and settings intentionally set when the device is used that may vary between uses
4. Device Exposure (DX): Subject's exposure to a medical device under study
5. Device Events (DE): Reportable device-related occurrences such as malfunctions and calibrations
6. Tracking and Disposition (DT): Physical locations of device, either at each movement or just final status
7. Device-Subject Relationship (DR): Look-up table providing single consistent link between each device and subject

DEVICE IDENTIFIERS DOMAIN

#	STUDYID	DOMAIN	UDEVID
	Study ID	Domain Abbrev	Unique Device ID
1	ABC-123	DI	SL001
2	ABC-123	DI	SL001
3	ABC-123	DI	SL025
4	ABC-123	DI	SL025

#	DISEQ	DIPARMCD	DIPARM	DIVAL
	Record Sequence #	Device ID Short Name	Device ID Long Name	Device ID Value
1 cont.	1	TYPE	Device Type	Orthopedic Rod
2	2	SERIAL	Serial Number	268-449
3	1	TYPE	Device Type	Orthopedic Rod
4	2	SERIAL	Serial Number	274-962

NEW VARIABLE!

FACTS: DEVICE SL001

STUDY ID ABC-123
SER # 268-449

WHAT

THE MEDICAL DEVICE STANDARDS ARE DATA COLLECTION AND ELECTRONIC SUBMISSION STANDARDS FOR PMAs, 510Ks, BLAs, AND NDAs DEVELOPED IN A COLLABORATION BETWEEN CDISC, INDUSTRY, AND FDA.

THIS POSTER SHOWS HOW TO MODEL A SUBJECT'S DEVICE-RELATED DATA USING THE NEW CDISC DEVICE DOMAIN STANDARDS.

DEVICE EVENTS DOMAIN

#	STUDYID	DOMAIN	USUBJID	UDEVID	DETERM
	Study ID	Domain Abbrev	Subject ID	Unique Device ID	Event Name
1	ABC-123	DE	02-1024	SL001	Fissure

#	DEDECOD	DECAT	DESEV	DEACNDEV	DEDTTC	DESTDTTC
	Standard Event Name	Event Category	Event Severity	Action Taken With Device	Date Event Recorded	Date Event Started
1 cont.	FISSURE	Equipment Failure	Major	Returned to Sponsor	2011-04-17	2011-04-17

NEW VARIABLE!

FACTS: DEVICE SL001

DEVICE ID SL001
(ID ASSIGNED BY SPONSOR)
MALFUNCTION - FISSURE
RETURNED TO SPONSOR

DEVICE PROPERTIES DOMAIN

#	STUDYID	DOMAIN	UDEVID	DISEQ	DOPARMCD	DOPARM	DOVAL
	Study ID	Domain Abbrev	Unique Device ID	Properties Sequence #	Property Standard Name	Property Name	Property Value
1	ABC123	DO	SL001	1	MANUF	Manufacturer	Rods, Inc.
2	ABC123	DO	SL001	2	MANUFDAT	Date of Manufacture	2011-02-01
3	ABC123	DO	SL025	1	MANUF	Manufacturer	Rods, Inc.
4	ABC123	DO	SL025	2	MANUFDAT	Date of Manufacture	2011-02-08

FACTS: DEVICE SL025

MANUFACTURER = RODS, INC.
MANUFACTURE DATE
08, FEB 2011
DEVICE ID SL025
(ID ASSIGNED BY SPONSOR)

FACTS: DEVICE SL025

STUDY ID ABC-123
SER # 274-962

FACTS: DEVICE SL025

DEVICE ID SL025
(ID ASSIGNED BY SPONSOR)
LENGTH - 4CM

DEVICE IN-USE DOMAIN

#	STUDYID	DOMAIN	USUBJID	UDEVID	DUTESTCD	DUTEST	DUCORRES	DUCORRESU
	Study ID	Domain Abbrev	Subject ID	Unique Device ID	Device Setting Short Name	Device Setting Long Name	Setting Value	Setting Unit
1	ABC-123	DU	02-1024	SL025	ISLENGTH	In Situ Length	4	cm

#	DUTRESC	DUTRESN	DUTRESU	VISITNUM	VISIT	VISITDY	DUTDTC	DUTDY
	Standard Char Value	Standard Num Value	Standard Value Unit	Visit Num	Visit Name	Visit Study Day	Measurement Date	Measurement Study Day
1 cont.	4	4	cm	2	IMPLANTATION	1	2011-04-29	1

WHY

MOST DEVICE SUBMISSIONS TODAY ARE PAPER BASED
STANDARDISED ELECTRONIC SUBMISSION DATA FILES ARE MORE EFFICIENT TO CREATE AND REVIEW.

Subject 02-1024 at Site 02 in Study ABC-123 receives SuperLynx orthopedic rod from Rods, Co. in left femur. It is a telescoping rod adjustable to between 4 and 8 cm. The 1st rod (serial # 268-449, made 01Feb2011) is shipped from Sponsor to site 15Apr2011, arrives 17Apr2011. Rod has a fissure and is returned to Sponsor 18Apr2011. A 2nd rod (serial # 274-962, made 08Feb2011) is shipped 26Apr2011, has no malfunctions. It is implanted 29Apr2011, length set to 4 cm. Subject retains rod.

DEVICE-SUBJECT RELATIONSHIPS DOMAIN

#	STUDYID	USUBJID	UDEVID
	Study ID	Subject ID	Unique Device ID
1	ABC-123	02-1024	SL025

FACTS: DEVICE SL025

STUDY ID ABC-123
SUBJECT 02-1024
DEVICE ID SL025
(ID ASSIGNED BY SPONSOR)

DEVICE EXPOSURE DOMAIN

#	STUDYID	DOMAIN	USUBJID	UDEVID	DXTRT	DXDOSE	DXDOSU
	Study ID	Domain Abbrev	Subject ID	Unique Device ID	Exposure Description	Exposure Dose	Dose Unit
1	ABC-123	DX	02-1024	SL025	SuperLynx Orthopedic Rod	1	Rod

#	DXLOC	DXSTDTTC	DXENDTTC	DXSTDY	DXENDY
	Device Location	Exposure Start	Exposure End	Start Study Day	End Study Day
1 cont.	LEFT FEMUR	2011-04-29		1	

FACTS: DEVICE SL025

DEVICE ID SL025
(ID ASSIGNED BY SPONSOR)
IMPLANTED 29, APR 2011
INTO LEFT FEMUR
NOT EXPLANTED

DEVICE TRACKING AND DISPOSITION DOMAIN

#	STUDYID	DOMAIN	UDEVID	DTTERM	DTDECODE
	Study ID	Domain Abbrev	Unique Device ID	Device Tracking Event Name	Standard Tracking Name
1	ABC-123	DT	SL001	Shipment	SHIPPED
2	ABC-123	DT	SL001	Shipment	SHIPPED
3	ABC-123	DT	SL025	Shipment	SHIPPED
4	ABC-123	DT	SL025	Implantation	IMPLANTED

FACTS: DEVICE SL025

DEVICE ID SL025
(ID ASSIGNED BY SPONSOR)
SHIPPED TO SITE ON
26, APRIL 2011
IMPLANTED INTO SUBJECT
02-1024 ON
29, APRIL 2011

#	DTPLOC	DTPLOCSP	DTTCAT	DTTDTTC	DTSTDTTC	DTSTDY
	Device Physical Location	Physical Location Specifc	Tracking Category	Date Tracking Event Recorded	Date Tracking Event Occurred	Tracking Event Study Day
1 cont.	SITE	02	INTERIM	2011-04-15	2011-04-15	
2 cont.	SPONSOR		FINAL	2011-04-18	2011-04-18	
3 cont.	SITE	02	INTERIM	2011-04-26	2011-04-26	
4 cont.	SUBJECT	02-1024	CURRENT	2011-04-29	2011-04-29	1

NEW VARIABLE!

WHAT NEXT

PUBLIC REVIEW COMPLETED
9 MARCH 2012 ADDRESS PUBLIC REVIEW COMMENTS AND PUBLISH SDTM STANDARD ON CDISC.ORG
COMPLETE DATA COLLECTION FIELD DESIGN, METADATA, AND CONTROLLED TERMINOLOGY DEVELOPMENT.
CONFIRM CONSISTENCY WITH OTHER STANDARDS
(SHARE)

LEADERSHIP TEAM

CAREY SMOAK - ROCHE MOLECULAR SYSTEMS, INC.
CARY.SMOAK@ROCHE.COM

KIT HOWARD - KESTREL CONSULTANTS, INC.
KIT@KESTRELCONSULTANTS.COM

FRED WOOD - OCTAGON RESEARCH SOLUTIONS
FWOOD@OCTAGONRESEARCH.COM

RHONDA FACILE - NCI-EVS, CDISC, LM
RFACILE@CDISC.ORG

BOB PEARSALL - SENSORS FOR MEDICINE AND SCIENCE, INC.
MAUREEN LYDEN - BIOSTAT INTERNATIONAL, INC.

PAUL FRANSON - MEDTRONIC

JENNIFER DUGGAN - ST. JUDE MEDICAL

MARC MUCATEL - W. L. GORE

PARAG SHIRALKAR - eCLINICAL

JENNIE TEDROW - BOSTON SCIENTIFIC

AMY MALLA - FDA-CBER, LYNN HENLEY - FDA-CDRH

ADDITIONAL PARTICIPATING COMPANIES

ABBOTT, ADVAMED, ALCON LABS
ALLERGAN, BAYER, BECTON DICKINSON
BIOCLINICA, BIOMET, EMERGO GROUP
BUCKLER BIOMEDICAL SCIENCES, BUSINESS BRIDGE
EDWARDS LIFESCIENCES, CDISC, CLEVELAND CLINIC
COVIDIEN, eCLINICAL SOLUTIONS, DEXCOM
FDA-CBER, FDA-CDER, FDA-CDRH
GENPROBE, HARVARD CLINICAL RESEARCH INSTITUTE, INNOVENTZ
JOHNSON & JOHNSON, NATIONAL CANCER INSTITUTE
PRA INTERNATIONAL, PREMIER RESEARCH, SMITH & NEPHEW
STRYKER, SYNERACT, TRIREME MEDICAL

