

Device Domains: Examples of their Use in Clinical Trials

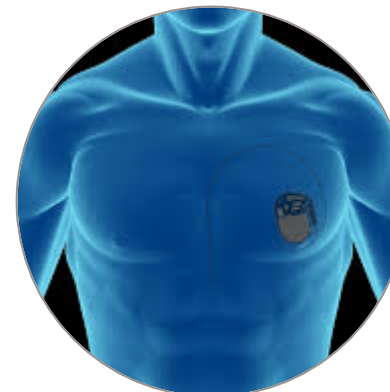
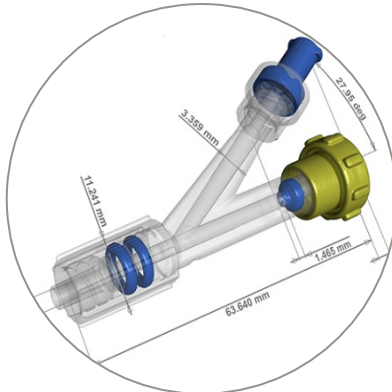
Oksana Voevutska
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PhUSE Annual Conference
Barcelona 2016

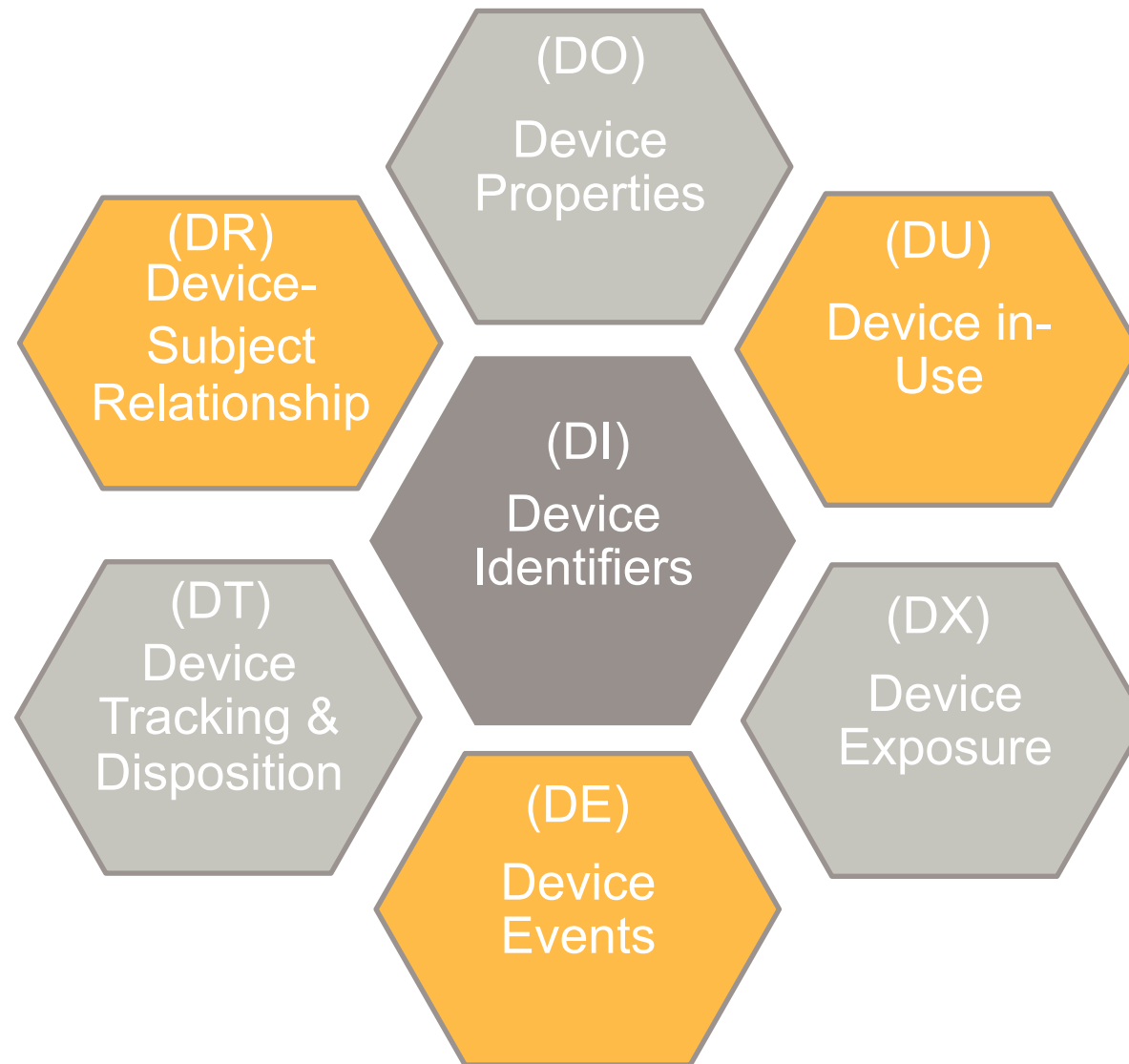
- Introduction
- Main Points of Device Domains
- First Use-Case
- Second Use-Case
- Challenges
- Conclusion



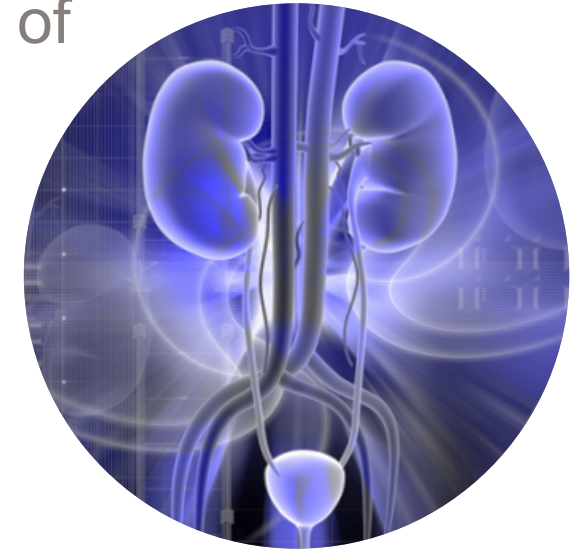
Medical Devices



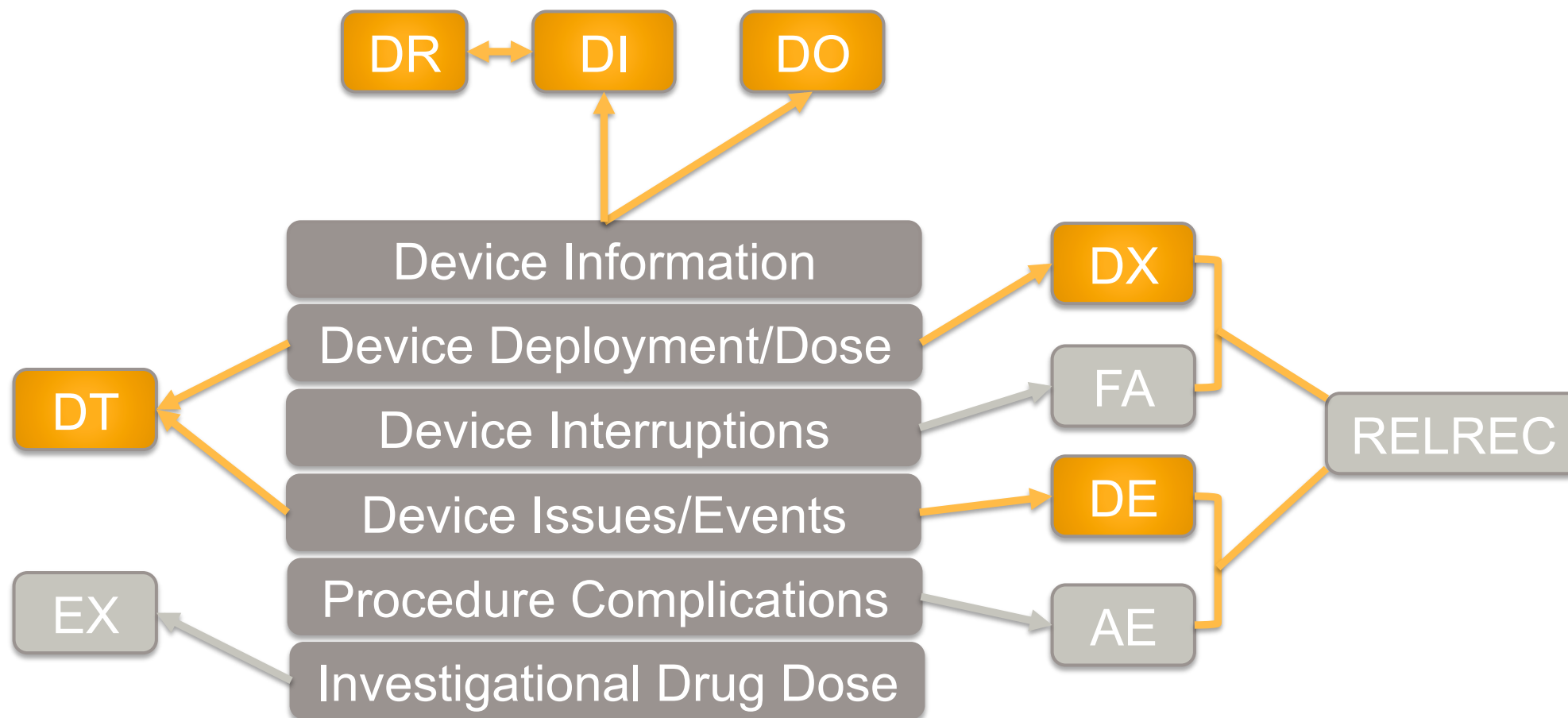
7 Device Domains



- The study is designed to evaluate the safety and efficacy of an investigational drug together with varying light dose activated by intra-urethral drug-activating device in male subjects.
- The study device is a customized catheter that consists of light-emitting diodes (LEDs).
- The light dose is delivered for a pre-programmed illumination time, commencing after intravenous administration of the investigational drug.



Scheme of Mapping Device-Specific Data



Device Data aCRF Page 1

DI - Device Identifiers

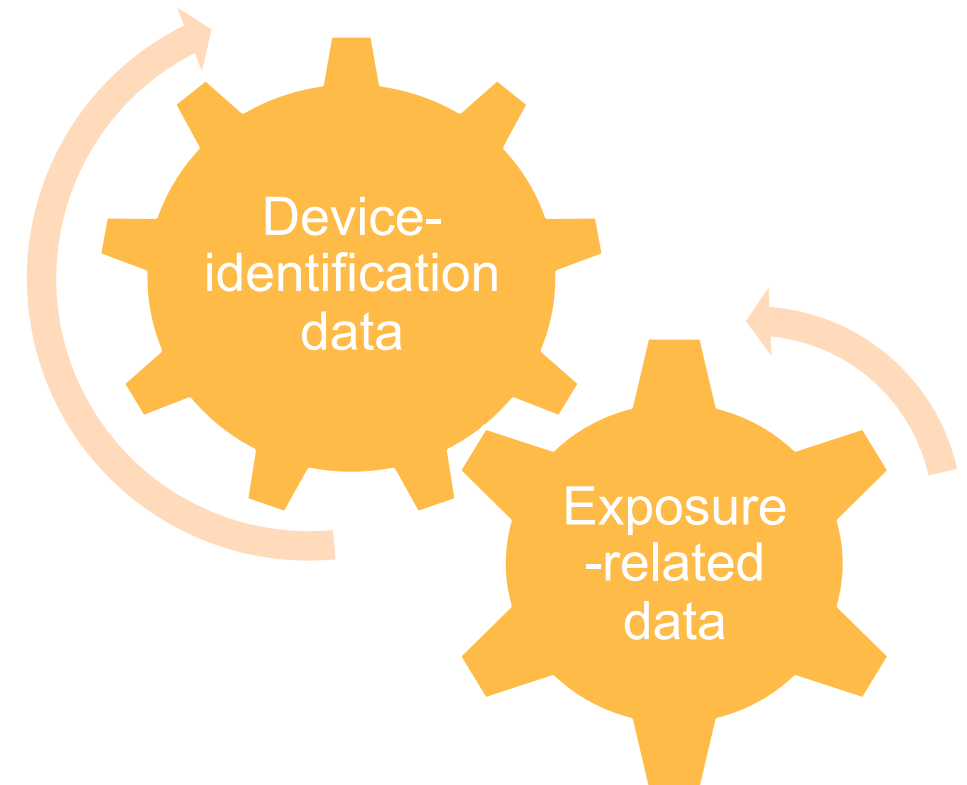
DT - Device Tracking and Disposition

DX - Device Exposure

Form: Drug Activator Use

Device pack ID number:	SPDEVID	①
	DIVAL where DIPARM=Pack Number	
Model number	DIVAL where DIPARM=Model	②
Serial number	DIVAL where DIPARM=Serial Number	③
Drug activator insertion date/time	DXSTDTC where DXTRT=Drug Activator	④
	DTSTDTC where DTTERM=DEPLOYED	
Drug activator device activation date/time	DXSTDTC where DXTRT=Drug Activator Light	⑤
Light dose (J/cm)	DXDOSE	⑥
	DXDOSU	
Drug activation stop date/time	DXENDTC where DXTRT=Drug Activator Light	⑦
Drug activator device removal date/time	DXENDTC where DXTRT=Drug Activator	⑧

Includes



Device Data aCRF Pages 2 & 3

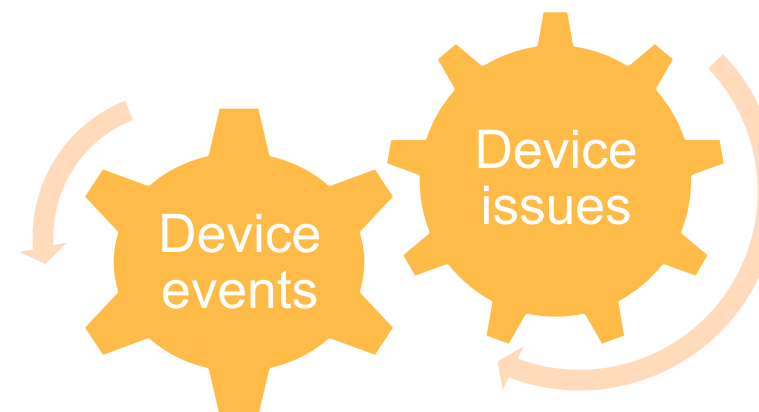
DE - Device Events

DT - Device Tracking and Disposition

Form: Device Clinical Incident Report

Date issue occurred	DTSTDTC where DTTERM='RETURNED TO MANUFACTURER'	①
	DESTDTC	
Description of issue	DETERM	②
Device pack ID number:	SPDEVID	③
Will the device be disinfected and returned to manufacturer	Yes ☐ No ☐	④
	DTTERM='RETURNED TO MANUFACTURER' if 'Yes'	
	SUPPDE.QVAL where SUPPDE.QNAM='DEVRTN'	
Was there an unexpected adverse reaction?	Yes ☐ No ☐	⑤
	SUPPDE.QVAL where SUPPDE.QNAM='UNEXP AE'	
If yes, specify AE number	DESPID	⑥

Includes



FA - Findings About

Form: Drug Activator Interruptions

FAOBJ='DRUG ACTIVATOR INTERRUPTIONS'

Date/time of pausing	FAORRES where FATESTCD='INTPUDTC'	①
Date/time of resumption	FAORRES where FATESTCD='INTREA'	②
Reason for pausing	FAORRES where FATESTCD='INTREDTC'	③

DI – Device Identifiers

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
AB1001	DI	20000	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20000	2	MODEL	Model	ABC123
AB1001	DI	20000	3	PACK	Pack Number	20000
AB1001	DI	20000	4	SERIAL	Serial Number	A745631
AB1001	DI	20000	5	TYPE	Type of Device	TBD
AB1001	DI	20001	1	MANUF	Manufacturer	Manufacturer
AB1001	DI	20001	2	MODEL	Model	ABC123
AB1001	DI	20001	3	PACK	Pack Number	20001
AB1001	DI	20001	4	SERIAL	Serial Number	A852746
AB1001	DI	20001	5	TYPE	Type of Device	TBD



DO – Device Properties

STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOORRES	DOORRESU
AB1001	DO	20000	1	BALVOL	Balloon Volume	5-10	mL
AB1001	DO	20000	2	LEDDIA	LED Array Diameter	1.2	mm
AB1001	DO	20000	3	LEWINDOW	Light Emitting Window	25	mm
AB1001	DO	20000	4	WAVELEN	Light Wavelength	660	nm

DO contains the device structural and functional properties that are not required for identification in the study and which correlate to device effectiveness and safety at the end of the study.

It has a relatively free format in comparison with other device domains and accept a wide variety of data.



Row	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXDOSE	DXDOSU	DXDOSFRQ
1	DX	AB1001-1011010	20306	1	Drug Activator	1	U	ONCE
2	DX	AB1001-1011010	20306	2	Drug Activator Light	75	J/cm	ONCE
3	DX	AB1001-1011011	20314	1	Drug Activator	1	U	ONCE
4	DX	AB1001-1011011	20314	2	Drug Activator Light	150	J/cm	ONCE

Row	DXROUTE	DXLOC	DXSTDTC	DXENDTC	DXSTDY	DXENDY
1	URETHRAL	PROSTATE GLAND	2016-02-18T10:05	2016-02-18T12:38	1	1
2	URETHRAL	PROSTATE GLAND	2016-02-18T10:36	2016-02-18T12:33	1	1
3	URETHRAL	PROSTATE GLAND	2016-03-04T09:04	2016-03-04T12:02	1	1
4	URETHRAL	PROSTATE GLAND	2016-03-04T09:39	2016-03-04T11:49	1	1

Includes 2 kinds of records:

- deployment of the catheter
- light treatment provided via that catheter

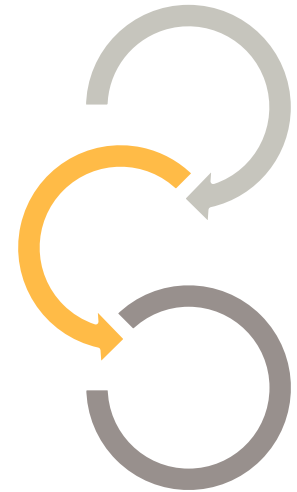


DT – Device Tracking and Disposition

DOMAIN	SPDEVID	DTSEQ	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTCAT	DTSTDTC
DT	30252	1	SHIPPED	SHIPPED	SITE	104		
DT	30252	2	DEPLOYED	DEPLOYED	SUBJECT	1047016		2016-03-24
DT	30252	3	RETURNED TO MANUFACTURER	RETURNED TO MANUFACTURER	MANUFACTURER			2016-03-24
DT	30253	1	SHIPPED	SHIPPED	SITE	102		
DT	30253	2	DEPLOYED	DEPLOYED	SUBJECT	1029012		2015-09-14

There are three main stages of a device:

- shipment to the site
- deployment to the subject
- in case of issues, return to the manufacturer, otherwise, disposal



DE – Device Events

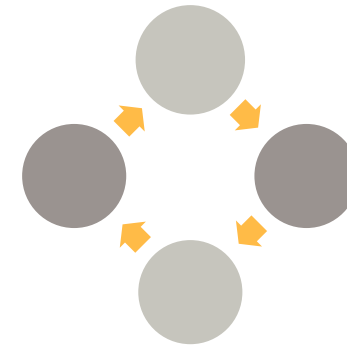
Row	DOMAIN	USUBJID	SPDEVID	DESEQ	DESPID	DETERM
1	DE	AB1001-1016001	20002	1		THE DEVICE WAS FLASHING ERROR AND WOULDN'T RESTART.
2	DE		20228	1		STERILE PACKAGING BREACHED
3	DE	AB1001-1047016	30252	1		CATHETER DID NOT ROTATE BACK APPROPRIATELY
4	DE	AB1001-1013042	30267	1	2	SUBJECT EXPERIENCED PAIN FROM CATHETER AND WAS REMOVED EARLY
5	DE	AB1001-1013065	30297	1	1	COMPLICATION WITH PLACEMENT OF DEVICE
6	DE	AB1001-1066016	30312	1		THE PATIENT INFORMED STUDY COORDINATOR THAT HE HAD SHIFTED AND HIT THE DEVICE, WHEN CHECKED THE DEVICE WAS MOVED

Row	DEDECOD	DECAT	DESTDTCT	DESTDY
1	COMPUTER SOFTWARE ISSUE	DEVICE CLINICAL INCIDENT REPORT	2015-01-06	1
2	DELIVERED AS UNSTERILE PRODUCT	DEVICE CLINICAL INCIDENT REPORT	2015-08-27	
3	DIFFICULT TO REMOVE	DEVICE CLINICAL INCIDENT REPORT	2016-03-24	1
4	NOT APPLICABLE	DEVICE CLINICAL INCIDENT REPORT	2015-10-21	2
5	DIFFICULT TO POSITION	DEVICE CLINICAL INCIDENT REPORT	2016-01-18	1
6	UNINTENDED MOVEMENT	DEVICE CLINICAL INCIDENT REPORT	2016-02-22	1



Relationship Domains: RELREC and DR

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
AB1001	AE	AB1001-1013042	AESEQ	1		DEAE1
AB1001	DE	AB1001-1013042	DESEQ	1		DEAE1
AB1001	AE	AB1001-1013065	AESEQ	1		DEAE1
AB1001	DE	AB1001-1013065	DESEQ	1		DEAE1
AB1001	DX	AB1001-1039005	DXSEQ	2		DXFA1
AB1001	FA	AB1001-1039005	FAGRPID	INT_V3		DXFA1
AB1001	DX	AB1001-1054006	DXSEQ	2		DXFA1
AB1001	FA	AB1001-1054006	FAGRPID	INT_V3		DXFA1



RELREC has 2 kinds of relationships:

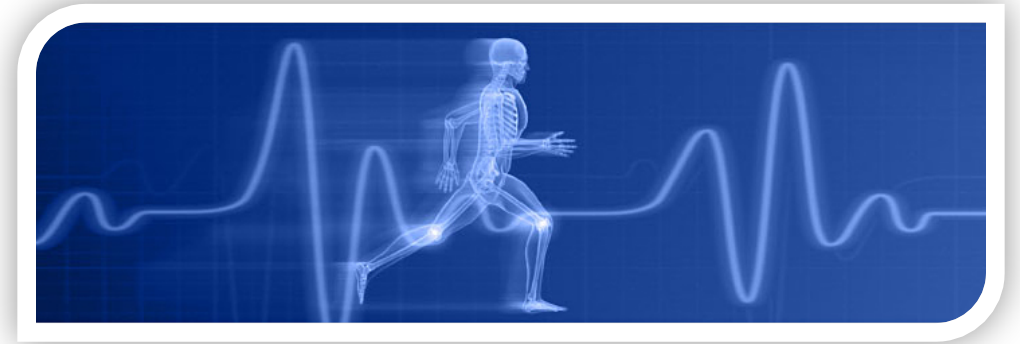
- one-to-one
(adverse events and device issues)
- one-to-many
(drug interruptions with light doses)

DR – Device-Subject Relationship

STUDYID	DOMAIN	USUBJID	SPDEVID
AB1001	DR	AB1001-1011010	20306
AB1001	DR	AB1001-1011011	20314

The objective of the study is:

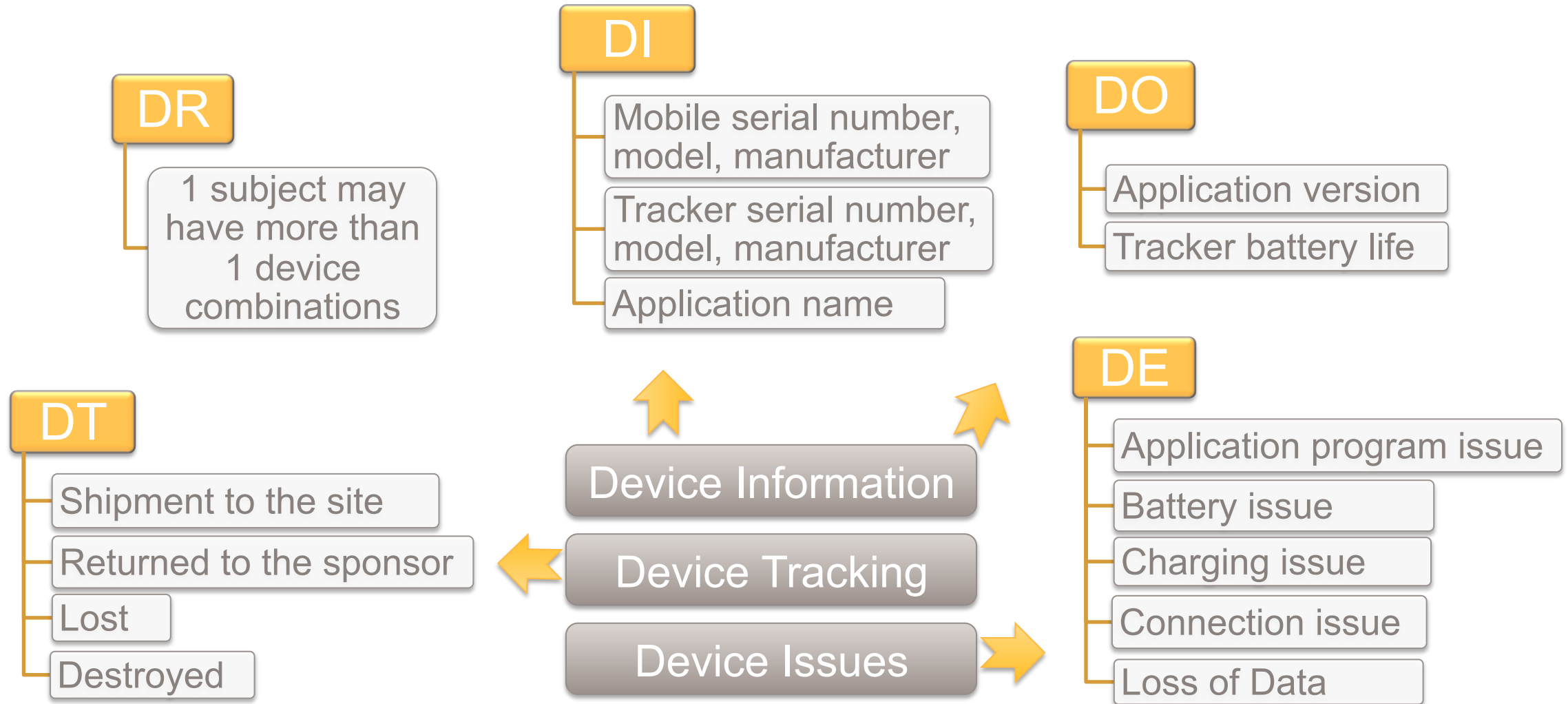
- Evaluating the benefit of adding a mobile application and wearable activity monitor to the standard of care of knee
- Demonstrating the impact on increasing the mobility of knee
- Determining the percent change in amount of steps per day per patient



Medical device is a set of 3 items:

- Wearable activity monitor
- Smartphone
- Mobile application downloaded on the mobile

Scheme of Mapping Mobile-Specific Data



- Unusual for medical sphere devices obtain the data
- Study is unique in the objective of the trial (impact of using the latest technologies such as mobile application)
- SPDEVID represents a unique key created manually to display combination of mobile and wearable activity monitor identifiers
- Neither EX or DX are applicable
- Collected pain and mood assessment responses by the mobile application do not have any place in the Device Domains, so were mapped in the QS domain

- 
- Often issue of data collection → problems with creating SPDEVID
 - Unclear what DIPARMCDs should be created → there is a need to involve the sponsor participation

- 
- Not freely available access to GMDN → DIPARMCD=TYPE issue
 - DEDECOD is based on Device Problem Codes list → difficulties with decoding DETERM

- 
- Could be no data to create EX and DX → OpenCDISC error
 - Not all device data fit Device Domains → need to find the best place in other SDTMIG models

- Devices are getting increasingly used in medical world. Standardization of collected data for medical device trials is important for efficient data analysis.
- Seven Device Domains were designed to cover different information such as identifiers, characteristics and settings used for each device in the study, details of device deployment or drug exposure and the recording of disposition events or other device-related events such as malfunction.
- The device domains should be used when the investigational product under study is a medical device or if a device is used as an instrument to obtain the measurements or results of the study.
- The SDTM Device Domain model is robust and useful to those who are working in the device area. However there are still challenges with mapping such data.

Questions?

Thank You for Your Attention!

Please feel free to contact:

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