

4 Device Domains

4.8 Device-Device Relationships

Some devices have components and it is important to record those relationships. In some cases relationship between a device and a component device may be physical and relatively permanent. In other cases, the top-level device may be a logical device, consisting of devices used together to perform a test or intervention.

reldev.xpt, Device-Device Relationships — Version x.x. One record per relationship parameter

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Definition	Implementation Notes	Core
STUDYID	Study Identifier	Char		Unique identifier for a study.	Unique identifier for a study.	Req
SPDEVID	Sponsor Device Identifier	Char		Sponsor-defined identifier for a device.	It must be unique for each tracked unit of the device under study, and can be at whatever level of granularity the device should be identified (e.g., model or serial number, or combination of identifiers) as defined in DI.	Req
PARENT	Parent Sponsor Device Identifier	Char		The sponsor-defined identifier for the “parent” device, the device of which the device named in SPDEVID is a component.	Must be a value of SPDEVID as defined in DI.	Exp
LEVEL	Device Level	Num		Represents the hierarchy level of the device named in SPDEVID, where 1 is the highest level.	Should be a positive integer. The device at the top level has a level of 1. A direct component of a level 1 device has a level of 2, etc.	Req
PARMCD	Relationship Parameter Short Name	Char		Short name for the relationship parameter.		Perm
PARM	Relationship Parameter	Char		A parameter that describes properties of the relationship between the component device named in SPDEVID and the parent device named in PARENT.	Examples: Quantity, Connection Type, Connection Location	Perm
VAL	Relationship Parameter Value	Char		The value of the parameter described in PARM.		Perm

4.8.1 Assumptions for Device-Device Relationships Dataset

1. The Device-Device Relationships Dataset is a relationship dataset that links device components to “parent” devices.
2. As a relationship dataset, this does not have a Topic variable.
3. As a relationship dataset, this dataset does not include variables such as DOMAIN and SEQ which are present in all general observation class domains. RDOMAIN is not needed, since it is expected that all records in this domain will link back to records in DI.
4. PARENT is not populated for a device at the Level 1
5. PARM, PARMCD, and VAL are populated only if there are properties of the relationship that need to be represented.
6. If the relationship between a device and a component has multiple properties, then the dataset will contain a record for each of these as a parameter.

4.8.2 Examples for Device-Device Relationships Dataset

Example 1

This example shows the types of devices used to obtain ECG data for a particular study. Although multiple ECG machines were used, they were all of the same type, so identifiers were assigned to the type of machine, rather than to individual devices. There were two separate devices used to obtain the ECG data: an ECG machine that recorded data from the subject, and a second device that performed further processing of the ECG data from the first machine, and also allowed manual over-reading of the ECG data. Because these two machines were used together to produce the results in the ECG domain, the combination of the two devices is treated as a composite device, and the combination is given its own unique sponsor ID.

- Row 1:** Shows the sponsor device identifier for the composite ECG Device. This is the device whose identifier appears in the EG dataset where subject data are represented. Further information about what this device consisted of is provided in the Device-Device Relationships dataset, below.
- Rows 2-5:** Show the characteristics of the ECG machine, which has been given an SPDEVID value of “2.”
- Rows 6-10:** Show the characteristics of the machine which performs further processing of the ECG data from the first machine. This device has been given an SPDEVID value of “3.”

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Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC-123	DI	1	1	TYPE	Device Type	Composite ECG Device
2	ABC-123	DI	2	1	TYPE	Device Type	ECG Machine
3	ABC-123	DI	2	2	MANUF	Manufacturer	Acme
4	ABC-123	DI	2	3	MODEL	Model	XYZ 2000
5	ABC-123	DI	2	4	SFTWRVER	Software/Firmware Version	3.6
6	ABC-123	DI	3	1	TYPE	Device Type	ECG Analyzer
7	ABC-123	DI	3	2	MANUF	Manufacturer	Acme
8	ABC-123	DI	3	3	MODEL	Model	ECG Wizard
9	ABC-123	DI	3	4	SFTWRVVER	Software Type	12SL algorithm
10	ABC-123	DI	3	5	SFTWRVER	Software/Firmware Version	12B

The relationships between the two ECG machines and their combination is a simple one, which requires no additional parameters to describe the relationship, so the permissible variables PARMCD, PARM, and VAL are not included in the Device-Device Relationship dataset.

SDTMIG-MD Draft Dataset: Device-Device Relationships (RELDEV)

- Row 1:** Shows that the device with SPDEVID = 1 has no parent and thus is at Level 1.
- Row 2:** Shows that the device with SPDEVID = 2 is a part of the composite device with SPDEVID = 1. Since the device with SPDEVID = 1 is at Level 1, this device is at Level 2.
- Row 3:** Shows that the device with SPDEVID = 3 is also a part of the composite device with SPDEVID = 1 and thus is also at Level 2.

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Row	STUDYID	SPDEVID	PARENT	LEVEL
1	ABC	1		1
2	ABC	2	1	2
3	ABC	3	1	2

Example 2

This example shows the components of a cardiac pacing device. There is information about the nature of the relationship between a device and its components that is needed, so the Device-Device Relationship Dataset includes the parameters PARMCD, PARM, and VAL.

- Row 1:** Shows that the device with SPDEVID = LSKKDH23 has no parent and thus is at Level 1.
- Row 2-3:** Show that the device with SPDEVID = 237YALU is a part of the composite device with SPDEVID = LSKKDH23. There are two records for this relationship because there are two properties of the relationship of this component to its parent that are considered to be important in describing the relationship, and have been recorded. Row 3 shows that ten of the type of device with SPDEVID = 237YALU are components of the parent device. Row 4 shows that the connections of these components to the parent have “Connection Type” = “Active.”
- Row 4:** Shows that the device with SPDEVID = 29384LHS is also a part of the composite device with SPDEVID = LSKKDH23 and thus is also at Level 2. This relationship has one property, “Connection Location,” which is “Slot 3.”

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Row	STUDYID	SPDEVID	PARENT	LEVEL	PARMCD	PARM	VAL
1	ABC	LSKKDH23		1			
2	ABC	237YALU	LSKKDH23	2	QTY	Quantity	10
3	ABC	237YALU	LSKKDH23	2	CONNTYPE	Connection Type	Active
4	ABC	29384LHS	LSKKDH23	2	CONNLOC	Connection Location	Slot 3