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# An Overview of Medical Device Data Standards

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## ABSTRACT

Medical device trials are widely conducted in recent times, for different therapeutic and diagnostic reasons. The nature of device trials is different from traditional clinical trials, and involve different study design, ways of collecting and data standards. Over the last few years, SDTM domains have been identified to accommodate data for devices, which can be used alongside with other regular domains usually found in clinical trials. Additionally, there have been analysis data set proposals that are being currently used.

In this paper, we will see what medical devices are, what data standards exist for devices, and how different they are with example.

## MEDICAL DEVICES

A medical device is any device like a machine, instrument, apparatus or implant that is intended to diagnose, prevent, monitor or cure a disease/condition.

The FDA categorizes devices into 3 main classifications depending upon the level of risk associated with the device. The risk factors take into account the duration for which the device will be used, whether the device is surgically invasive and if the device contains any chemical or medicinal substances.

i) Class I – Class I devices are devices that are of the lowest risk. They have very low impact on a patient's health and are not invasive. Examples could be something like an elastic bandage that is used to treat a sprain, or a non-electric wheelchair. Class I devices are subject to the least level of regulatory controls.

ii) Class II – Class II devices are of a medium risk, they are simple devices too but more complicated and risky than Class II devices. Examples could be glucose test kits, syringes or powered wheelchairs. Class II devices need to go through more stringent regulatory controls than Class I, to prove their safety and efficacy.

iii) Class III – Class III devices are of the highest risk, and are considered to be the most complex devices. Examples could be pacemakers or stents implanted. These devices require very stringent regulatory controls, and rigorous requirements to prove safety and efficacy.

## DEVICE STANDARDS

Medical device trials are similar to pharmaceutical trials, in that they use similar clinical domains, including demographics, adverse events, medical history, vital signs and laboratory. While pharmaceutical drugs are submitted to the Center for Drug Evaluation and Research (CDER) division of the FDA for approval, medical devices are usually submitted to the Center for Devices and Radiological Health (CDRH). CDRH, which oversees the medical device program in FDA, encourages the use of data standards for submissions for medical devices.

CDISC has introduced a study data tabulation model implementation guide for medical devices. There are seven SDTM domains that are included in this guide:

1. Device Identifiers (DI)

2. Device-In-Use (DU)

3. Device Exposure (DX)

4. Device Events (DE)

5. Device Tracking and Disposition (DT)

6. Device-Subject Relationships (DR)

7. Device Properties (DO)

Looking at an example, let us assume there is a patient with a cardiovascular disorder, with restricted flow of blood in their tibial artery. For this patient, a peripheral vascular intervention is performed in the artery with a stent implantation. A month later, balloon angioplasty is performed to modify the vascular conduits and improve the blood flow.

The procedure (PR) domain includes the details of the procedure performed, along with the location and time of procedure

**Table 1: Procedures**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | prseq (Procedure Sequence) | prtrt (Name of Procedure) | prclas (Class of Procedure) | prloc (Location of Procedure) | prstdtc (Start Date/Time of Procedure) | prendtc (End Date/Time of Device Exposure) |
|---|---|---|---|---|---|---|---|---|
| STDY001 | PR | 01-1001 | 1 | STENT IMPLANTATION | PERIPHERAL VASCULAR INTERVENTION | ANTERIOR TIBIAL ARTERY | 2019-08-30 | 2019-08-30 |
| STDY001 | PR | 01-1001 | 2 | BALLOON ANGIOPLASTY | PERIPHERAL VASCULAR INTERVENTION | ANTERIOR TIBIAL ARTERY | 2019-09-30 | 2019-09-30 |

The Device Identifier (DI) domain is a study reference domain, that includes details of the device used in the study. There will be one record per device identifier per device in this domain. Every device will have a unique sponsor device identifier (SPDEVID) variable associated with it. This unique identifier variable will serve as a link to identify the device, and will be used in all other device domains.

In below DI dataset, the device details are included like the type and model of the stent and catheter. The spdevid DEV1 is taken to represent the stent device and DEV2 is taken to represent the balloon catheter device. In the following device domains, only the spdevid will be used, and not the device names, to link the device data

**Table 2: Device Identifier**

| studyid (Study Identifier) | domain (Domain) | spdevid (Sponsor Device Identifier) | diparmcd (Device Identifier Short Name) | diparm (Device Identifier Element Name) | dival (Device Identifier Element Value) |
|---|---|---|---|---|---|
| STDY001 | DI | DEV1 | TYPE | Device Type | STENT |
| STDY001 | DI | DEV1 | MODEL | Model | Stent01 |
| STDY001 | DI | DEV2 | TYPE | Device Type | BALLOON CATHETER |
| STDY001 | DI | DEV2 | MODEL | Model | Balloon01 |

The Device Properties (DO) is a findings domain, that records all properties and characteristics of the devices used. For example, below dataset records the length, diameter and material used for both the devices DEV1 and DEV2

**Table 3: Device Properties**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | spdevid (Sponsor Device Identifier) | dotestcd (Device Property Short Name) | dotest (Device Property Test Name) | doorres (Result or Finding in Original Units) | doorresu (Original Units) |
|---|---|---|---|---|---|---|---|
| STDY001 | DO | 01-1001 | DEV1 | LEN | Length | 16 | mm |
| STDY001 | DO | 01-1001 | DEV1 | DIAM | Diameter | 3.2 | mm |
| STDY001 | DO | 01-1001 | DEV1 | MATR | Material | Bare Metal | |
| STDY001 | DO | 01-1001 | DEV2 | LEN | Length | 150 | cm |
| STDY001 | DO | 01-1001 | DEV2 | DIAM | Diameter | 3.0 | mm |
| STDY001 | DO | 01-1001 | DEV2 | MATR | Material | Metal Alloy | |

The Device-In-Use (DU) is a findings domain, with information on measurements of usage of device. This may seem similar to the Device Properties (DO) domain but is actually different. The difference is that DO measurements are of the measurements of the device, that will never change and remain the same. Whereas the DU measurements are of the device in use and may vary depending on the usage of the device

**Table 4: Device-In-Use**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | spdevid (Sponsor Device Identifier) | dutestcd (Device-In-Use Test Short Name) | dutest (Device-In-Use Test Name) | duorres (Result or Finding in Original Units) | duorresu (Original Units) | dudtc (Date/Time Device Used with Test/Setting) |
|---|---|---|---|---|---|---|---|---|
| STDY001 | DU | 01-1001 | DEV1 | PRES | Pressure | 15.5 | atm | 2019-08-30 |
| STDY001 | DU | 01-1001 | DEV2 | PRES | Pressure | 15.0 | atm | 2019-09-30 |

The Device Exposure (DX) domain is an interventions domain, that includes details on the exposure of a subject to a device. The device exposure domain is similar to the Exposure (EX) domain in pharmaceutical data. The DX dataset below has the details of the device frequency, route of exposure, location, and start and end time of the exposure to the devices for the subject

**Table 5: Device Exposure**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | spdevid (Sponsor Device Identifier) | dxtrt (Name of Device Exposure or Output) | dxdosfrq (Frequency of Device Exposure) | dxroute (Route of Device Exposure) | dxloc (Location of Device Exposure) | dxstdtc (Start Date/Time of Device Exposure) | dxendtc (End Date/Time of Device Exposure) |
|---|---|---|---|---|---|---|---|---|---|
| STDY001 | DX | 01-1001 | DEV1 | Stent | Once | Intravenous | ANTERIOR TIBIAL ARTERY | 2019-08-30 | 2019-10-12 |
| STDY001 | DX | 01-1001 | DEV2 | Balloon Catheter | Once | Intravenous | ANTERIOR TIBIAL ARTERY | 2019-09-30 | 2019-09-30 |

One of the devices used for the subject experiences a device failure. This is taken in the Device Events (DE) domain, an events domain, that has details on the device malfunctions. Below dataset includes the category and reported terms for the device events, along with the time of the event

**Table 6: Device Events**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | spdevid (Sponsor Device Identifier) | decat (Category of Device Event) | dedecod (Device Events Dictionary-Derived Term) | determ (Reported Term for Device Event) | desev (Severity of Device Event) | dedtc (Date/Time of Device Event) |
|---|---|---|---|---|---|---|---|---|
| STDY001 | DE | 01-1001 | DEV1 | Failure | Stent Compression | Stent blockage | Minor | 2019-10-12 |

Any adverse event that arises out of the device malfunction is taken into the regular Adverse Events (AE) dataset. As a result of the stent malfunction, the subject undergoes restenosis with the corresponding symptoms. This results in the stent being explanted or taken out. The AE dataset has information on the date the adverse event occurred, and the action taken following it

**Table 7: Adverse Events**

| studyid (Study Identifier) | domain (Domain) | usubjid (Unique Subject Identifier) | aespid (Sponsor-Defined Identifier) | aedecod (Dictionary-Derived Term) | aeterm (Event Verbatim Term) | aeacndev (Other Action Taken for AE) | aestdtc (Event Start Date/Time) | aeendtc (Event End Date/Time) |
|---|---|---|---|---|---|---|---|---|
| STDY001 | AE | 01-1001 | 1 | Restenosis | Chest pain | Stent explanted | 2019-10-12 | 2019-10-12 |
| STDY001 | AE | 01-1001 | 1 | Restenosis | Shortness of breath | Stent explanted | 2019-10-12 | 2019-10-12 |

The two events domain, DE and AE can be linked with the related records (RELREC) domain. This is to identify the adverse event that occurred with the corresponding device DEV1 or the stent

**Table 8: Related Records**

| studyid (Study Identifier) | rdomain (Related Records Domain) | usubjid (Unique Subject Identifier) | idvar (Identifier Variable) | idvarval (Value of Identifier Variable) | relid (Related Records Identifier) |
|---|---|---|---|---|---|
| STDY001 | DE | 01-1001 | SPDEVID | DEV1 | 1 |
| STDY001 | AE | 01-1001 | AESPID | 1 | 1 |

The Device Tracking and Disposition (DT) domain is also an events domain, that tracks the sequence of events from shipping of a device, to implanting on and explanting from a patient. Unlike the disposition (DS) dataset in pharmaceutical trials, that records status of a subject at a given time point, the DT domain records the status of the device at the end of the clinical trial

**Table 9: Device Tracking and Disposition**

| studyid (Study Identifier) | domain (Domain) | spdevid (Sponsor Device Identifier) | dtterm (Reported Term for the Tracking Event) | dtparty (Part Responsible for the Device) | dtprtyid (Responsible Party Identifier) | dtstdtc (Start Date/Time of Device Tracking Event) |
|---|---|---|---|---|---|---|
| STDY001 | DT | DEV1 | SHIPPED | SITE | 01 | 2019-08-27 |
| STDY001 | DT | DEV1 | IMPLANTED | SUBJECT | 1001 | 2019-08-30 |
| STDY001 | DT | DEV1 | EXPLANTED | SITE | 01 | 2019-10-12 |
| STDY001 | DT | DEV1 | SHIPPED | SPONSOR | | 2019-10-14 |
| STDY001 | DT | DEV2 | SHIPPED | SITE | 01 | 2019-09-28 |
| STDY001 | DT | DEV2 | INTERVENTION | SUBJECT | 1001 | 2019-09-30 |

The Device-Subject Relationships (DR) domain is a relationships domain, like the RELREC dataset. Here the link is between the device and the subject that has used or has been exposed to the device

**Table 10: Device-Subject Relationships**

| studyid<br>(Study Identifier) | domain<br>(Domain) | usubjid<br>(Unique Subject Identifier) | spdevid<br>(Sponsor Device Identifier) |
|---|---|---|---|
| STDY001 | DR | 01-1001 | DEV1 |
| STDY001 | DR | 01-1001 | DEV2 |

## CONCLUSION

There are many medical devices being used for different reasons, ranging from a common testing kit, a CT scan machine or even a wearable. Medical devices, like pharmaceutical drugs also have standards that are being widely implemented in studies. Although device standards have not been made mandatory, it is very like to become the requirement in the near future. The standard clinical domains used in pharmaceutical trials, are used in medical device trials too. In addition, the seven domains for devices can be used to accommodate all possible device information. This will help to standardize the data and make it suitable for submission purposes.

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

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