Considerations in Conforming Data from Multiple Implantable Medical Devices to CDISC Standards Using SAS®

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ABSTRACT

Both pharmaceutical and medical device trial analyses are at the subject level, capturing a drug's or device's impact on the patient. Medical device trials are unique in that their analyses are also at the device level. Efficacy and safety data are affected by how each device is implanted and by the interactions of multiple related devices. Therefore, device-level analysis dataset (ADDL) is additionally required for device trials; similar to the required use of subject-level analysis dataset (ADSL).

It can be challenging and time-consuming to plan and create SDTM and ADaM data for the first time. However, once the ADaM data set is created, the SAS programs can be reused in reporting for multiple different device trials. This should result in substantial savings of both time and resources.

This paper addresses: 1) the need in device trials to have a SDTM dataset referred to as Device Exposure as Collected (DC), a counterpart to Exposure as Collected (EC) for drug development; 2) the use of BDS structure to develop Interim Device-Level Analysis Dataset (ADDLINT), which facilitates the creation of ADDL from the DC dataset; 3) the use of ADDL as the foundation for device clinical trial analysis.

Key Words: Implantable Medical Devices, SAS®, SDTMIG-MD, Device Exposure as Collected (DC), Interim Device-Level Analysis Dataset (ADDLINT), Device-Level Analysis Dataset (ADDL), Device Events, Device Survival

INTRODUCTION

Medical devices are designed for diagnostic and therapeutic uses. Medical devices do not have biochemical actions for primary intended purposes, but can be used to deliver drugs for therapeutic indications[6].

In addition to data collected similar to pharmaceutical clinical trials, other critical parts of the data in medical device clinical trials are the medical device data from the Case Report Forms (CRFs) and data downloaded from the devices. Implantable devices could have complicated data, due the required implant procedures, device follow-ups, system modifications and device events during the time the device is implanted. Some therapies require implantation of several devices connected mechanically, electronically and/or magnetically, in which case the therapies delivered are a joint function of those multiple devices. The interactions among those devices add another level of complexity, in addition to device-subject interactions.

CDISC standards are well accepted standards in the Pharmaceutical industry. However, those standards are still new in medical device area. The Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD) was released in 2012 for medical device data. The SDTMIG-MD has 7 device-specific models and provides standards to address the unique features and complexities of medical device data. Conforming to data standards like CDISC can make it easier for the FDA to review and analyze data[1, 2]. Recent FDA actions and the release of SDTM-MD standards should motivate medical device companies conform their studies to SDTM and ADaM standards.

Establishing a new path toward CDISC standards within in an organization using medical device data poses many challenges, especially under extremely tight timelines. The initial work of device companies is important in accumulating experiences and preparing for the eventual complete standardization of device data[3]. This paper will demonstrate the unique need for data standards for implantable medical device data. The paper will discuss the approaches for exposure data, as well as some of the challenges faced in mapping data to be consistent with CDISC standards.

DEVICE EXPOSURE AS COLLECTED (DC)

Based upon SDTMIG-MD, the Device Exposure (DX) records the details of a subject's direct interaction or contact with a medical device or the output from a medical device. It is similar to EX model in drug trials and is recognized in most cases as a derived summary dataset. DX records may be derived from collected data or determined from protocol definition.

The topic variable for DX is Name of Device Exposure or Output (DXTRT). It is defined as "Name of the device or the exposure outputs that are delivered or administered via the device. This should match the definitions as described in the trial summary domain and/or the protocol". SDTM-MD gives DXTRT examples (Table 1) such as hyaluronic acid, extracorporeal shock wave treatment and artificial cervical disc.

DXTRT	DXSTDTC	DXENDTC
HYALURONIC ACID	2010-05-02T12:15	2010-05-02T12:17
EXTRACORPOREAL SHOCK WAVE TREATMENT	2010-05-02T12:15	2010-05-02T12:30
ARTIFICIAL CERVICAL DISC	2010-05-02T13:15	2010-05-09T13:17

Table 1. Examples of DXTRT, DXSTDTC and DXENDTC from SDTMIG-MD[6]

However, Start Date/Time of Device Exposure (DXSTDTC) and End Date/Time of Device Exposure (DXENDTC) for a device are not readily available from collected data. In most cases, DXSTDTC and DXENDTC are available at the final analysis or ADaM datasets, derived from actions collected on eCRF.

For the implantable device exposures, here are some examples for commonly collected intervention dates on eCRF:

1) Date of Device Implant (DEVIPDT)
2) Date of Device Turned-on (DEVONDT)
3) Date of Device Turned-off (DEVOFDT)
4) Date of Device Therapy Resumed (DEVRSDT)
5) Date of Device Modified (DEVMDDT)
6) Date of Device Repositioned (DEVRPDT)
7) Date of Device Abandoned/Capped (DEVCPDT)
8) Date of Device Explant (DEVXPDT)
9) Date of Other Device Exposure Related Action (DEVOTDT)

As shown in Figure 1, device interventions are collected in eCRF and the dates of first and last device exposure can be defined differently for each study. Dates of Device Implant, Device Turned-on and Device Therapy Resumed can all be considered in the algorithm for Date of First Exposure to Device. Similarly, Date of Last Exposure to Device can be requested with different derivative logics. In the case where a device is modified or repositioned more than one time, the earliest or latest date of several interventions may be used in the logic to derive Date of Last Exposure to Device.

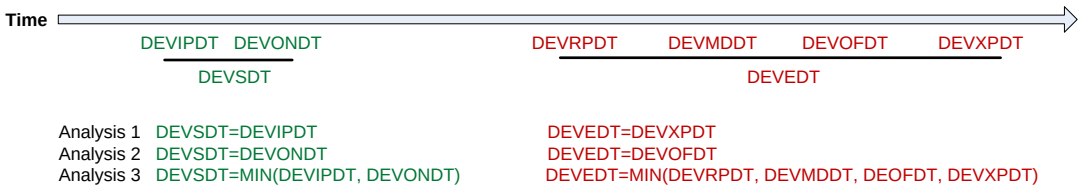

Figure 1. Dates of Device Interventions and Derivation Examples for Dates of First and Last Device Exposure

For traceability and transparency, all collected detail information should be presented in device exposure SDTM domain, representing the complete exposure history. Many dates collected may also be key analysis data points, in addition to first and last dates of device exposure. DX is not the domain to capture data as detailed as needed for analysis.

The SDTM team at CDISC recently released a model EC, Exposure as Collected (EC). The Exposure as Collected domain model reflects protocol-specified study treatment administrations, as collected. The parallel SDTM Dataset Device Exposure as Collected (DC) may be used for similar needs. The actual interventions as collected are mapped to DCTRT. The detailed 'one intervention collected on eCRF' is converted to one observation in the SDTM dataset. The benefit of this approach is to assure traceability from eCRF to SDTM and then to ADaM. It also provides flexibility for various analysis purposes as ADaM.

In reference to EC and considering the uniqueness of device trials this paper defines the DC as having the following characteristics:

- The Device Exposure as Collected domain model (DC) reflects protocol-specified study treatment administrations, as collected.
- DC could be used in all cases where collected device exposure information cannot or should not be directly represented in DX. For example, device implantation is considered start of device treatment; and various device modifications or electrical settings and changes collected could be considered as end of device treatment. All are needed for study analysis and preferred to be derived at ADaM level.
- For administrations given at a point in time (e.g., Device Therapy Turned-on), where only an administration date/time is collected, DCSTDTC should be copied to DCENDTC. However, if the start date/time of device implant and end date/time of device implant are both collected, then DCSTDTC and DCENDTC are populated with different values.

The example in Table 2 shows two types of medical devices (from Medical Device Component or Accessory Terminology FDA CDRH[10]). Generator is defined as "An engine designed to produce electricity or a device designed to produce a vapor or gas". Wire is "A metal strand designed for signal or power transmission or for structural or other purpose.". Table 2 only shows the variables discussed in this paper.

Subject VENUSIAN1 has 3 generators (GENERATOR-X, GENERATOR-Y and GENERATOR-Z) and two wires (WIRE-1 and WIRE-2) implanted during the study. DCGRPID ties together a block of related records in DC domain for a subject. Here DCGRPID indicates which generator the wire is linked or connected to. WIRE-1 is connected to GENERATOR-Y from 2999-12-01 to 3011-06-06. When GENERATOR-Y explanted, WIRE-1 is then connected to GENERATOR-Z. WIRE-2 is connected to GENERATOR-X until that generator explanted on 3014-02-01.

Even though DCGRPID grouped the linked devices, the interventions of generators are not readily usable yet. We will link the generator interventions to its linked wire in interim analysis dataset discussed in the following section.

USUBJID	SPDEVID	DCCAT	DCGRPID	DCTRT	DCSTDTC
VENUSIAN1	GENERATOR-X	GENERATOR	GENERATOR-X	NEW IMPLANT	3000-01-01
VENUSIAN1	GENERATOR-X	GENERATOR	GENERATOR-X	THERAPY STARTED	3000-01-15
VENUSIAN1	GENERATOR-X	GENERATOR	GENERATOR-X	MODIFIED	3010-09-19
VENUSIAN1	GENERATOR-X	GENERATOR	GENERATOR-X	MODIFIED	3015-10-17
VENUSIAN1	GENERATOR-X	GENERATOR	GENERATOR-X	THERAPY SUSPENDED	3016-07-08
VENUSIAN1	GENERATOR-Y	GENERATOR	GENERATOR-Y	NEW IMPLANT	2999-12-15
VENUSIAN1	GENERATOR-Y	GENERATOR	GENERATOR-Y	THERAPY STARTED	2999-12-15
VENUSIAN1	GENERATOR-Y	GENERATOR	GENERATOR-Y	REPOSITIONED	3008-04-01
VENUSIAN1	GENERATOR-Y	GENERATOR	GENERATOR-Y	REPOSITIONED	3010-03-03
VENUSIAN1	GENERATOR-Y	GENERATOR	GENERATOR-Y	EXPLANTED WITH REPLACEMENT ON THE SAME DATE	3011-06-06
VENUSIAN1	GENERATOR-Z	GENERATOR	GENERATOR-Z	REPLACEMENT IMPLANT ON THE SAME DATE	3011-06-06
VENUSIAN1	GENERATOR-Z	GENERATOR	GENERATOR-Z	THERAPY STARTED	3011-06-06
VENUSIAN1	WIRE-1	WIRE	GENERATOR-Y	NEW IMPLANT	2999-12-01
VENUSIAN1	WIRE-1	WIRE	GENERATOR-Z	CONNECTED TO NEW GENERATOR	3011-06-06
VENUSIAN1	WIRE-1	WIRE	GENERATOR-Z	REPOSITIONED	3012-05-05
VENUSIAN1	WIRE-2	WIRE	GENERATOR-X	NEW IMPLANT	3000-01-01
VENUSIAN1	WIRE-2	WIRE	GENERATOR-X	MODIFIED	3013-11-15
VENUSIAN1	WIRE-2	WIRE	GENERATOR-X	EXPLANTED WITHOUT REPLACEMENT	3014-02-01

Table 2. Device Exposure as Collected Domain (DC)

INTERIM DEVICE-LEVEL ANALYSIS DATASET (ADDLINT) IN BDS STRUCTURE

DC is ready to be transformed into ADaM analysis dataset with date of first device exposure and date of last device exposure, if the device data did not have generator-wire interactions that affects and defines the wire therapy.

A generator can be physically implanted in the subject, but is not therapeutically active if its therapy is not turned on. i.e. there is no therapy delivered to the subject. A wire is therapeutically active, only when it is connected to the generator and the generator therapy is turned on.

DC needs to be transformed into an interim analysis dataset ADDLINT following BDS format, where the connections between generators and wires are represented. The interaction between generator and wire is linked by a simple SAS code:

```
PROC SQL;
      CREATE TABLE WIRE_GEN AS
      SELECT DISTINCT W.USUBJID,W.DCCAT, W.SPDEVID, W.DCGRPID, G.DCTRT, G.DCSTDTC
      FROM DC (WHERE=(DCCAT="WIRE")) AS W
            LEFT JOIN
           DC (WHERE=(DCCAT="GENERATOR")) AS G
      ON W.USUBJID=G.USUBJID AND W.DCGRPID=G.DCGRPID
      ORDER BY 1,2;
QUIT;
```

The resulting dataset is then processed into BDS data. BDS for medical devices requires Unique Device Identifier (SPDEVID), in addition to Study Identifier (STUDYID) and Unique Subject Identifier (USUBJID), as identifier variables. PARAM describes the dates of interventions for wires or generators to which the wires are linked., Descriptive and qualifying information is included to describe unambiguously and sufficiently the contents of AVAL. Generator abbreviation (G1, G2, and G3) is included to indicate the identity of the generator. If multiple interventions occurred to the same device, a sequential numeric suffix (DATE OF G2 REPOSITIONED 1, DATE OF G2 REPOSITIONED 2) is added to PARAM.

The resulting ADDLINT holds all the required information so the compound criteria and logics may be applied to create analysis datasets per Statistical Analysis Plan (SAP). For example, wire DEVSTDT is defined as the later of dates for wire implant and linked generator therapy turned-on at ADDL. A SAS program can be set to process the records sharing same SPDEVID.

USUBJID	SPDEVID	DCSTDTC	PARAM	PARAMCD	AVAL
VENUSIAN1	WIRE-1	2999-12-01	DATE OF WIRE IMPLANT 1	WIPDT1	2999-12-01
VENUSIAN1	WIRE-1	2999-12-15	DATE OF G2 IMPLANT 1	G2IPDT1	2999-12-15
VENUSIAN1	WIRE-1	2999-12-15	DATE OF G2 TURNED-ON 1	G2ONDT1	2999-12-15
VENUSIAN1	WIRE-1	3008-04-01	DATE OF G2 REPOSITIONED 1	G2RPDT1	3008-04-01
VENUSIAN1	WIRE-1	3010-03-03	DATE OF G2 REPOSITIONED 2	G2RPDT2	3010-03-03
VENUSIAN1	WIRE-1	3011-06-06	DATE OF G2 EXPLANT 1	G2XPDT1	3011-06-06
VENUSIAN1	WIRE-1	3011-06-06	DATE OF G3 IMPLANT 1	G3IPDT1	3011-06-06
VENUSIAN1	WIRE-1	3011-06-06	DATE OF G3 TURNED-ON 1	G3ONDT1	3011-06-06
VENUSIAN1	WIRE-1	3011-06-06	DATE OF WIRE TURNED-ON 1	WONDT1	3011-06-06
VENUSIAN1	WIRE-1	3012-05-05	DATE OF WIRE REPOSITIONED 1	WRPDT1	3012-05-05
VENUSIAN1	WIRE-2	3000-01-01	DATE OF G1 IMPLANT 1	G1IPDT1	3000-01-01
VENUSIAN1	WIRE-2	3000-01-01	DATE OF WIRE IMPLANT 1	WIPDT1	3000-01-01
VENUSIAN1	WIRE-2	3000-01-15	DATE OF G1 TURNED-ON 1	G1ONDT1	3000-01-15
VENUSIAN1	WIRE-2	3010-09-19	DATE OF G1 MODIFIED 1	G1MDDT1	3010-09-19
VENUSIAN1	WIRE-2	3013-11-15	DATE OF WIRE MODIFIED 1	WMDDT1	3013-11-15
VENUSIAN1	WIRE-2	3014-02-01	DATE OF WIRE EXPLANT 1	WXPDT1	3014-02-01
VENUSIAN1	WIRE-2	3015-10-17	DATE OF G1 MODIFIED 2	G1MDDT2	3015-10-17
VENUSIAN1	WIRE-2	3016-07-08	DATE OF G1 TURNED-OFF 1	G1OFDT1	3016-07-08

Table 3. Interim Device-Level Analysis Dataset (ADDLINT) in BDS structure

DEVICE-LEVEL ANALYSIS DATASET (ADDL)

As we have seen previously, device data with multiple observations for a device in BDS structure (ADDLINT) is not analysis ready ADaM dataset. A one record per device per subject dataset such as Device-Level Analysis Dataset (ADDL) with the key characteristic and exposure details is required for most device analysis, in addition to subject level analysis dataset (ADSL).

Why do we need ADDL? The answer is that the analysis has to be done at the device level, in addition to analysis at subject level. Here are some examples of device level analysis:

- Summary of device follow-up by device type and by device model.
- Summary of device events by device manufacturer.
- Device time-to-event, such as from date of first exposure to the earliest of date of device explant, device reposition and other device problems.
- Adverse events related to devices.
- Age of the subject at the first exposure to a device. If there are multiple devices implanted at different dates/times, there will be more than one subject age. The age at first exposure to a device may be different from the age at ADSL, which is the age of the subject on the date of the study's initiation or the date of the subject's consent.

The characteristics of ADDL are:

- One record per medical device per subject.
- ADDL is used to provide the variables that describe attributes of a device. This allows simple combining with any other dataset, including SDTM domains and analysis datasets.
- ADDL is a source for device-level variables used in other analysis datasets. It contains device-level variables that are important in describing a device in a trial, such as SPDEVID/ASPDEVID, device implant data, device modification data and device explant data.
- ADDL contains the age of subject at beginning of a device intervention.
- If needed, ADDL also has subject demographic information, stratification and subgrouping variables, important trial related dates, etc.
- ADDL and its related metadata, along with ADSL, should be required in a CDISC-based submission of data from a clinical trial, even if no other analysis datasets are submitted.

In this paper, we illustrate the creation of ADDL, focusing on the dates of device interventions. Similar to any other treatment analysis dataset in pharmaceutical clinical trials, the date a subject is first exposed to a device and the date a subject is last exposed to a device are the pivotal points of a trial. Efficacy, device event and adverse event analysis are defined by those dates.

The date of first exposure to a device is usually the date of device implant or the combination of dates for device implant and device therapy turned-on, depending on analysis needs and sponsor and regulatory requirements. To retain traceability, ADDL has all the analysis relevant dates regarding a device and the dates that contributed to the creation of the relevant dates. Table 4 shows the definition examples for some of the ADDL variables.

Variable Name	Variable Label	Examples
DEVIPDT	Date of Device Implant	1). Date of generator implant. 2). Date of wire implant
DEVXPDT	Date of Device Explant	1). Date of generator explant. 2). Date of wire explant
DEVONDT	Date of Device Turned-on	1). The date generator therapy turned-on. 2). Therapy for a wire is turned on by turning on linked generator's therapy.
DEVOFDT	Date of Device Turned-off	1). The date generator therapy turned-off. 2). Therapy for a wire is turned off by turning off linked generator's therapy.
DEVRPDT	Date of Device Repositioned	An implantable device could be surgically repositioned for therapeutic justification. The device may be repositioned multiple times during the course of a study. That information is usually stored at DC and ADDLINT. How to populate the DEVRPDT at ADDL is sponsor's and regulator's decision. 1). Date of generator repositioned. 2). Date of wire repositioned

Variable Name	Variable Label	Examples
DEVMDDT	Date of Device Modified	The device modification or maintenance could be done surgically or externally depending on the type of device. A device may be modified multiple times during the course of a study. That information is usually stored at DC and ADDLINT. How to populate the DEVMDDT at ADDL is sponsor's and regulator's decision. 1). Date of generator modified. 2). Date of wire modified.
DEVSDT	Date of First Exposure to Device	How to populate DEVSDT is sponsor's and regulator's decision. 1). Date of subject first exposure to generator. DEVSDT=max(generator DEVIPDT, generator DEVONDT) in the example provided. 2). Date of subject first exposure to wire. DEVSDT=max(linked generator DEVIPDT, linked generator DEVONDT, wire DEVIPDT) in the example provided.
DEVEDT	Date of Last Exposure to Device	How to populate DEVEDT for a study is sponsor's and regulator's decision. 1). Date of subject last exposure to generator. DEVEDT=min(generator DEVXPDT, generator DEVOFDT) in the example provided 2). Date of subject last exposure to wire. DEVEDT=min(wire DEVXPDT, linked generator DEVOFDT, linked generator DEVXPDT) in the example provided.

Table 4. Examples of Dates and their Definitions in ADDL

To create ADDL from ADDLINT, the vertical ADDLINT in BDS format is transposed to horizontal structure first:

```
PROC TRANSPOSE DATA=ADDLINT OUT=TRANS_ADDLINT(DROP=_NAME_);
      BY USUBJID SPDEVID ;
      ID PARAMCD;
      IDLABEL PARAM;
      VAR AVAL;
RUN;
```

After further SAS processing on the transposed dataset, the final ADDL dataset is created. Table 5 shows only the SPDEVID and the date variables under discussion.

SPDEVID	DEVSDT	DEVEDT	DEVIPDT	DEVXPDT	DEVONDT	DEVOFDT	DEVRPDT	DEVMDDT
GENERATOR-X	3000-01-15	3016-07-08	3000-01-01	.	3000-01-15	3016-07-08	.	3010-09-19
GENERATOR-Y	2999-12-15	3011-06-06	2999-12-15	3011-06-06	2999-12-15	.	3008-04-01	.
GENERATOR-Z	3011-06-06	.	3011-06-06	.	3011-06-06	.	.	.
WIRE-1	2999-12-15	.	2999-12-01	.	2999-12-15	.	3012-05-05	.
WIRE-2	3000-01-15	3014-02-01	3000-01-01	3014-02-01	3000-01-15	3016-07-08	.	3013-11-15

Table 5. DEVICE-LEVEL ANALYSIS DATASET (ADDL)

DEVICE EVENT ANALYSIS DATASET (ADDE)

Therapeutic effect is available when a device is implanted and therapy turned-on. However, adverse events and device events can occur and are expected to be reported when a device is implanted and not explanted regardless of whether the device therapy is on or off. Therefore, the dates of device-subject interactions for analysis should be presented in ADDL. ADDL is then merged with other SDTM domain or ADaM data to create analysis datasets.

The DETERM in Table 6 are selected examples from Medical Device Problem Codes by FDA-CDRH[10]. DE domain shows the device events and their related devices, as indicated by SPDEVID. DESTDTC is the date an event occurs.

USUBJID	SPDEVID	DETERM	DESTDTC
VENUSIAN1	GENERATOR-X	MISFIRE	3009-07-02
VENUSIAN1	GENERATOR-X	BATTERY ISSUE	3010-01-01
VENUSIAN1	GENERATOR-Y	POWER CONDITIONING ISSUE	2998-02-08
VENUSIAN1	WIRE-1	BENT	3013-07-07

Table 6. SDTM: Device Events (DE)

In Table 6, Generator-Y has a device event occurrence on 2998-02-08. When DE and ADDL merged by USUBJID and SPDEVID, it shows the device event is before date of device implant in subject on 2999-12-15. If it is queried and validated as data entry error, then that event and device will be excluded from ADDE in Table 7.

SPDEVID	DEVSDT	DEVEDT	DEVIPDT	DEVXPDT	DEVOND	DEVOFDT	DEVRPDT	DEVMDDT	DETERM	DESTDT	ASTDT
GENERATOR-X	3000-01-15	3016-07-08	3000-01-01	.	3000-01-15	3016-07-08	.	3010-09-19	MISFIRE	3009-07-02	3009-07-02
GENERATOR-X	3000-01-15	3016-07-08	3000-01-01	.	3000-01-15	3016-07-08	.	3010-09-19	BATTERY ISSUE	3010-01-01	3010-01-01
WIRE-1	2999-12-15	.	2999-12-01	.	2999-12-15	.	3012-05-05	.	BENT	3013-07-07	3013-07-07

Table 7. ADaM: Device Events Analysis Dataset (ADDE)

TIME-TO-EVENT ANALYSIS DATASET (ADTTE)

This section shows merging ADDL with ADDE to create Time to First Device Event analysis dataset. The ADDL is merged with ADDE by USUBJID AND SPDEVID. The resulting dataset have the dates for the device events as collected from eCRF and also the dates for different device interventions. ADT is defined as the earliest date of all device events from ADDE and device interventions contributing to DEVEDT from ADDL. If there is no device event and device intervention, the End of Study Date from ADSL is used for censoring.

```
DATA ADTTE;
       MERGE SUG.ADDL(IN=A) SUG.ADDE;
       BY USUBJID SPDEVID;
       IF A;
       PARAM='TIME TO FIRST DEVICE EVENT (DAYS)';
       PARAMCD='TTFDE';
       STARTDT=DEVSDT;
       ADT=MIN(DEVEDT,ASTDT,EOSDT);
       AVAL=ADT-STARTDT;
       /*Date from ADDE has the highest priority*/
       IF ASTDT ^=. AND (DEVEDT >= ASTDT OR DEVEDT=.) THEN DO;
              CNSR=0;
              EVENTDESC=DETERM;
              SRCDOM="ADDE";
       END;
       /*Within the dates contributing to DEVEDT, here is priority rank*/
       ELSE IF DEVEDT ^=. THEN DO;
              CNSR=0;
              SRCDOM="ADDL";
              IF DEVEDT=DEVXPDT THEN EVENTDESC='DEVICE EXPLANTED';
              ELSE IF DEVEDT=DEVOFDT THEN EVENTDESC='DEVICE TURNED-OFF';
       END;
       ELSE IF EOSDT^=. THEN DO;
              CNSR=1;
              EVENTDESC='END OF STUDY';
              SRCDOM="ADSL";
       END;
RUN;

/*Select the earliest date:*/
DATA SUG.ADTTE;
SET ADTTE;
BY USUBJID SPDEVID AVAL;
IF FIRST.SPDEVID;
RUN;
```

Table 8 illustrates the ADTTE data where SRCDOM has the value of ‘ADDE’, ‘ADDL’ and ‘ADSL’, a typical integration of subject level and device level data points in device trials.

SPDEVID	DEVSDT	DEVEDT	DEVXPDT	EOSDT	DETERM	ASTDT	STARTDT	ADT	PARAM	PARAMCD	AVAL	CNSR	EVENTDESC	SRCDOM
GENERATOR-X	3000-01-15	3016-07-08	.	3015-05-18	MISFIRE	3009-07-02	3000-01-15	3009-07-02	TIME TO FIRST DEVICE EVENT (DAYS)	TTFDE	3455	0	MISFIRE	ADDE
GENERATOR-Y	2999-12-15	3011-06-06	3011-06-06	3015-05-18		.	2999-12-15	3011-06-06	TIME TO FIRST DEVICE EVENT (DAYS)	TTFDE	4190	0	DEVICE EXPLANTED	ADDL
GENERATOR-Z	3011-06-06	.	.	3015-05-18		.	3011-06-06	3015-05-18	TIME TO FIRST DEVICE EVENT (DAYS)	TTFDE	1442	1	END OF STUDY	ADSL
WIRE-1	2999-12-15	.	.	3015-05-18	BENT	3013-07-07	2999-12-15	3013-07-07	TIME TO FIRST DEVICE EVENT (DAYS)	TTFDE	4952	0	BENT	ADDE
WIRE-2	3000-01-15	3014-02-01	3014-02-01	3015-05-18		.	3000-01-15	3014-02-01	TIME TO FIRST DEVICE EVENT (DAYS)	TTFDE	5130	0	DEVICE EXPLANTED	ADDL

Table 8. Time-to-event analysis dataset (ADTTE)

CONCLUSION

This paper provides considerations in the planning and the implementation of SDTM and ADaM for medical device data. As shown in Figure 2, ADDL along with ADSL merges with other SDTM or ADaM datasets to create device level analysis datasets, such as ADDE and ADTTE. Clinical trial needs and regulatory requirements determine how the data are defined and presented in CDISC standards for submission. The SDTM domain DC is a standard format for hosting the device exposure data as collected. ADDL is the pivotal for device level analysis datasets. DC and ADDL may become useful additions to the CDISC standards for device trials.

The CDISC Device ADaM sub-team is working on developing ADDL implementation guidelines. Before the standards are published, the opinions and approaches in this paper are intended to facilitate further discussions, hopefully leading to better solutions for medical device data standards.

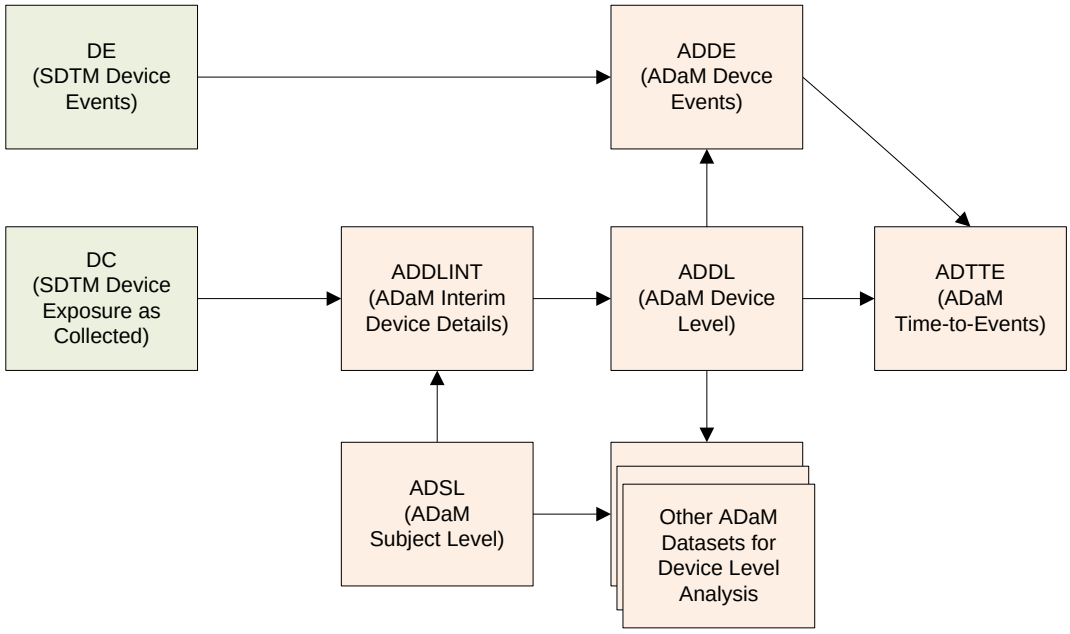

Figure 2. ADDL for the Device Level Analysis

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DISCLAIMER

The views expressed in this paper are those of the author and are not intended to reflect the views of the author’s employer.

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