PharmaSUG 2021 - Paper - MD-035

ADaM Implementation Guide for Medical Devices

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ABSTRACT

This paper presents the soon-to-be published ADaM Implementation Guide for Medical Devices-v1.0 (ADaMIG MD). The guide is intended to address the typical statistical analysis needs for clinical trials using medical devices.

Medical device data can be analyzed alone, or along with subject data. This drives the need for a new Class referred to as the Device Level Analysis Dataset (ADDL). The ADDL plays a role similar to the role of the ADSL, except that the identifier variable is the device identifier instead of the subject identifier. In the case of a device study, ADDL should be included. ADDL allows basic device-level information to be collected and merged with any other dataset containing the device identifier.

Medical device analysis also requires two other new Classes: Medical Device Basic Data Structure (MDBDS), and Medical Device Occurrence Data Structure (MDOCCDS). These two Classes are introduced to support the analysis when the device identifier is required, and the subject identifier is optional. A new SubClass under MDBDS, the Medical Device Time-to-event (MDTTE), is added for device survival analysis. These new Classes and SubClass have been registered in Controlled Terminology.

Along with the new metadata for the new Class and SubClass metadata, the conformance rules are provided. This paper also presents examples of how to use the Study Data Tabulation Model for Medical Devices (SDTM-MD) to create ADaM datasets for medical device analysis.

INTRODUCTION

In this paper, we will describe the rationale, metadata, and important variables from each of these proposed medical device ADaM standard structures. This new guide provides the ADaM standards to assist the special needs for medical device data analysis. It can be considered as a supplementary guide to the current published ADaM standards widely used for human drug and biologic clinical studies, and certainly are used for medical device clinical studies.

DEVELOPMENT OF ADAM IMPLEMENTATION GUIDE FOR MEDICAL DEVICES

The ADaMIG MD went through many iterations to reach this stage.

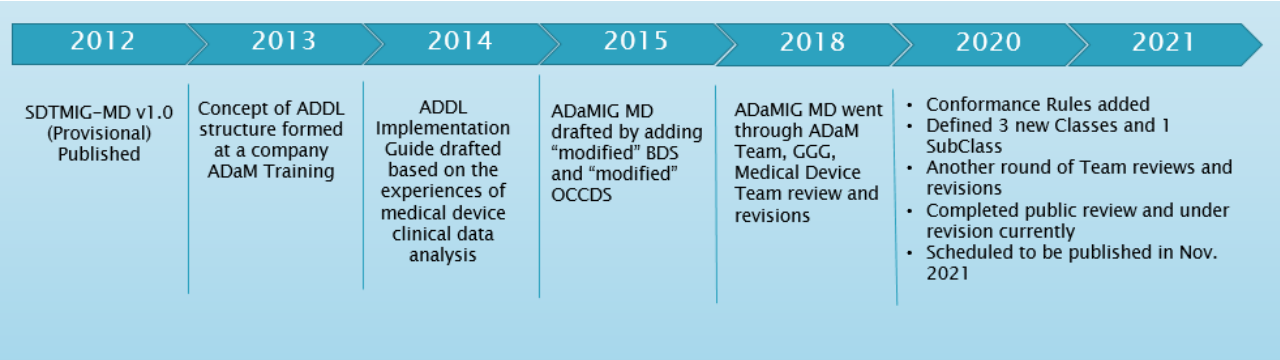

Figure 1. Timeline of ADaMIG MD development

Year 2012

- The release of "Study Data Tabulation Model Implementation Guide for Medical Devices. Version 1.0 Provisional" primed the thought to develop ADaM guide to serve the special analysis needs for medical device clinical data analyses.

Year 2013

- The concept of ADDL structure was formed at a company ADaM training.

Year 2014

- The use of the medical device clinical data in implementation of SDTMIG MD and initial practice of ADDL presented at PharmaSUG conference[2].
- ADDL Implementation Guide was drafted based on the initial practice and the paper.

Year 2015

ADaMIG MD was drafted by adding the 'modified' BDS and the 'modified' OCCDS for medical device analysis use.

Year 2018

- ADaMIG MD went through ADaM team review, GGG review, Medical Device Team review in 2018.
- Presented the draft at PharmaSUG. This current paper is based on and updated 2018 paper[3].

2020 and 2021

- Added Conformance rules, created 3 new Classes, 1 SubClass.
- Went through another round of ADaM team review, GGG review, Medical Device Team review.
- At the writing of this paper the public review of this guide had just ended on April 2nd, 2021.
- After final updates and editing, ADaM IG-MD v1.0 is to be published in November 2021.

CONTROLLED TERMINOLOGY

The ADaM Model v2.1 describes the necessary analysis dataset metadata largely target at for pharmaceutical and biological industries. Currently there are only 3 ADaM dataset Classes and 2 SubClasses published at Define-XML Terminology that are related to existing ADaM models.

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
ADaM Basic Data Structure Subclass	TIME-TO-EVENT	TTE	A dataset containing data that is used for Time-to-Event analyses.
ADaM Occurrence Data Structure Subclass	ADVERSE EVENT		A dataset containing data that is used for adverse event analyses.

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
General Observation Class	BASIC DATA STRUCTURE	BDS; Basic Data Structure	An ADaM BDS dataset contains one or more records per subject, per analysis parameter, per analysis time point. Variables include the value being analyzed (e.g., AVAL) and the description of the value being analyzed (e.g., PARAM). Other variables in the dataset provide more information about the value being analyzed (e.g., the subject identification) or describe and trace the derivation of it (e.g., DTYPE) or support the analysis of it (e.g., treatment variables, covariates).
General Observation Class	OCCURRENCE DATA STRUCTURE	OCCDS; Occurrence Data Structure	The Occurrence Data Structure (OCCDS) is the ADaM data structure for occurrence analysis. Occurrence analysis is the counting of subjects with a record or term, and often includes a structured hierarchy of dictionary coding categories.
General Observation Class	SUBJECT LEVEL ANALYSIS DATASET	ADSL; Subject Level Analysis Dataset	The Subject-Level Analysis Dataset (ADSL) is a one-record-per-subject dataset which contains variables that describe subject demographic characteristics and group the subjects for analysis. ADSL is the primary source for subject-level variables included in other analysis datasets such as population flags and treatment variables.

Table 1. Define-XML Terminology Related to Existing ADaM Models

USUBJID is a required variable in published ADaM BDS, OCCDS and TTE structures. However, medical device analyses do not always require USUBJID. To solve this conflict in conformance rules, we developed new structures. With this ADaMIG MD guide, we have proposed and published three new Class and one SubClass as shown below. The table extracted from the Controlled Terminology file (dated 2021-03-26) showing the details of the new Class and Sub-Class designations.

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
ADaM Medical Device Basic Data Structure	MEDICAL DEVICE TIME-TO-EVENT	MDTTE	A dataset containing data that is used for medical device Time-to-Event analyses.
General Observation Class	DEVICE LEVEL ANALYSIS DATASET	ADDL; Device Level Analysis Dataset	The Device-Level Analysis Dataset (ADDL) is a one-record-per-device or one-record-per-subject-per-device dataset which contains variables that describe device characteristics and timing, and group the devices for analysis. ADDL is the primary source for device-level variables included in other analysis datasets.

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
General Observation Class	MEDICAL DEVICE BASIC DATA STRUCTURE	MDBDS; Medical Device Basic Data Structure	The Medical Device Basic Data Structure (MDBDS) supports the analysis needs by adding SPDEVID as a required key variable and USUBJID a conditionally required variable. See the BDS class for further details.
General Observation Class	MEDICAL DEVICE OCCURRENCE DATA STRUCTURE	MDOCCDS; Medical Device Occurrence Data Structure	The Medical Device Occurrence Data Structure (MDOCCDS) supports the analysis needs by adding SPDEVID as a required identifier and allowing USUBJID be a conditionally required variable. See the OCCDS class for further details.

Table 2. Define-XML Terminology Related to ADaMIG MD

ADAM STRUCTURES FROM ADAMIG MD AND OTHER ADAM DOCUMENTS

Any published ADaM structures can be used for medical device data analysis. The new Medical Device ADaM IG only adds to those existing structures and to supplement the special device data analysis needs. The table below shows the relationship between the ADAM dataset structures, and the new structures provided in the ADaMIG MD. Note that some of the structures are currently under review and not yet published.

Other Published ADaM Structures		New Structures in ADaMIG MD v1.0	
Class	**SubClass**	**Class**	**SubClass**
ADSL			
BDS	TTE (define XML CT)	MDBDS	MDTTE
	ADNCA (not published)		
OCCDS	ADAE (define XML CT)	MDOCCDS	
		ADDL	

Table 3. Available ADaM Structures from Other ADaM Documents and ADaMIG MD

The following table summarizes the usages of ADaM Structures from the other published ADaM documents and from the ADaMIG MD. There are two sets of analyses for medical device studies. One is the analysis regarding the subjects, another is the analysis regarding the devices. The analysis regarding the subjects can only be done, if the subject data is collected.

	Other Published ADaM Structures	ADaMIG MD Structures
Intentions	Analyses regarding the subjects and the interactions between the subjects and devices	Analyses of the devices with or without regard to the subjects
Conditions	Subject data must be collected, and linkage between the subjects and the devices is most likely collected	1. Subject data not collected or not linked with devices OR 2. Additional analysis of the devices with or without regard to the subjects
Examples	1. Summary of subject demographics 2. Summary of subject clinical events or adverse events 3. Time-to-Events regarding the subjects, such as subject survival analysis while using the devices	1. Summary of the different types of device models used 2. Summary of subject age at the Date of First Exposure to Device 3. Summary of device events or device malfunctions 4. Time-to-Event regarding the devices, such as device survival analysis

Table 4. The usages of Structures from Other Published ADaM Documents and ADaMIG MD

SUBJECT-LEVEL ANALYSIS DATASET (ADSL)

ADSL and its related metadata are required in a CDISC-based submission of data for a drug clinical trial. This is also true for most medical device clinical trials when subject data are collected along with medical device data. In such cases, the treatment variables must be included in ADSL as documented in the sponsor's SAP. For example, Date of First Exposure to Treatment (TRTSDT) could be defined as the earliest Date of First Exposure to Device (DEVSDT) of multiple devices used for a subject. In another study, it might be more appropriate to assign DEVSDT of the main device, such as pacemaker generator, to TRTSDT.

However, when multiple devices are used for a subject, ADDL is a more appropriate place for the detailed treatment content. We will discuss this in ADDL section.

ADSL is required for medical device studies only when subject information is collected and needs to be reported. This is different from pharmaceutical and biologic studies in which ADSL is always required. If ADSL is not included, then an explanation should be included in the Analysis Data Reviewers Guide (ADRG). Therefore, in a medical device study, ADSL is a “conditionally-required” dataset.

DEVICE-LEVEL ANALYSIS DATASET (ADDL)

Medical devices can be analyzed by device alone or with regard to subject. When the relationship between subjects and devices is not collected or the subject data is not collected, then ADSL cannot be created and ADDL must be included.

The ADDL dataset plays a role like the ADSL dataset, except that the identifier of interest is the device identifier rather than the subject identifier. Similar to the ADSL design, an ADDL dataset allows basic device-level information to be collected and merged with any other dataset containing the device identifier, including other ADaM datasets and SDTM datasets. ADDL is a source for device-level variables

used in other ADaM datasets, such as device-specific demographic, characteristic and treatment timing variables.

The label of the ADDL dataset is "Device-Level Analysis Dataset". In a study, there is only one dataset in the Class "DEVICE LEVEL ANALYSIS DATASET", and its name is ADDL. Any other datasets with one record per device and subject combination would be members of other Classes.

If the subject data is collected in a study, ADDL is structured as one record per device per subject, such as in the case of a subject exposed to multiple devices. ADDL can also be thought of as one record per subject per device, when a device being used by more than one subject. ADDL contains one record per device and subject combination, regardless of the type of clinical trial design using a medical device.

In a one-device-per-subject clinical study, a separate ADDL dataset may not be necessary since the device characteristics could be accommodated in ADSL. However, if a clinical study involves multiple devices per subject or multiple subjects per device, an ADDL dataset becomes essential. To be consistent, a developer may choose to create an ADDL dataset for all trials in which medical devices are analyzed.

When the study is only about the device, and subject information is not collected, then ADDL is one record per device. This is the case ADDL and its related metadata are required in a CDISC-based submission of data from a clinical trial even if no other analysis datasets are submitted.

ADDL STRUCTURE

An ADDL contains one record per device per subject. Sponsor-specified Device Identifier (SPDEVID) is a required identifier and subject identifier (USUBJID) is conditionally required, depending on whether subject information is collected and relevant to the analysis. The relationship between a subject and a device is usually defined in the SDTM DR dataset. For studies where subject data is not collected or the analysis is only about the device, the device identifier is the sole key variable for the ADDL structure.

The variable USUBJID can be included for two different reasons. The first is when multiple devices are used on the same subject, such as the implantable cardioverter defibrillator (ICD) and related leads that deliver the therapies from the defibrillator. USUBJID can also be included when multiple subjects use the same device, such as an X-ray machine that is used for many subjects. The combination of USUBJID and SPDEVID become the unique identifiers for records in datasets.

Here are some examples of the ADDL dataset metadata.

When there is not subject data collected or subject data is not required to be analyzed, the ADDL is on record per SPDEVID and there is USUBJID is not required.

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset
ADDL	Device-Level Analysis Dataset	addl.xpt	one record per device	SPDEVID

Table 5. ADDL when the only identifier is SPDEVID

When subject data are collected and analyzed, and one device is used for more than one subject, it is easier to read the data by sorting the ADDL by SPDEVID and then by USUBJID.

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset
ADDL	Device-Level Analysis Dataset	addl.xpt	one record per device per subject	SPDEVID, USUBJID

Table 6. ADDL Sorted by Device and Subject

In other cases, if multiple devices are used in one subject, it is easier to read the data by sorting with USUBJID first then by SPDEVID.

Dataset Name	Dataset Description	Dataset Location	Dataset Structure	Key Variables of Dataset
ADDL	Device-Level Analysis Dataset	addl.xpt	one record per subject per device	USUBJID, SPDEVID

Table 7. ADDL Sorted by Subject and Device

Similar to ADSL, ADDL was designed so that its data can be combined with other device datasets, such as SDTM and/or ADaM. With ADSL, the merge or join key is simply USUBJID. With ADDL, the merge or join key is at least SPDEVID, plus conditionally USUBJID, when USUBJID is included in ADDL.

Examples are provided in the soon to be released ADaMIG MD v1.0.

ADDL VARIABLES

As with all ADaM datasets, ADDL should include all variables from input SDTM datasets and corresponding supplemental qualifiers that are needed for analysis or traceability. Most of the source data needed for ADDL can be found in SDTM domains DI (Device Identifiers), DR (Device-Subject Relationships), PR (Procedures), and DX (Device Exposure). Additional study or therapeutic-specific variables may be added as needed but should follow the standard variable naming conventions described in the ADaMIG.

Identifier Variables

The most important identifiers for the ADDL standard structure are SPDEVID and USUBJID. SPDEVID is copied from SDTM DI dataset and is required. USUBJID when available from SDTM DR domains is conditionally required. One other identifier, SITEID, is also required in the proposed ADDL, even if it is the same value across all rows in the dataset.

Device Grouping Variables and Timing and Status Flag Variables

In addition to any grouping variables copied from SDTM, the ADaMIG MD guide proposed standard names for Device Grouping and Timing variables. For more information about creating ADaM-compliant timing variables, refer to Timing Variable Conventions and Date and Time Imputation Flag Variables in the ADaMIG.

Definition of Date of First Exposure to Device and Date of Last Exposure to Device are described in a statistical analysis plan. For example, one device study may define device implant date as device exposure start date and device explant as device exposure end date. However, another study may define device therapy turned on as device exposure start date and therapy turned off date as device exposure end date. Sometimes, the earliest date of all procedure events, such as device turned off, device explant, device modification, device re-positioned and subject last visit, is considered as device exposure end date.

Note that most or all device exposure information is included in ADDL. In fact, if ADDL has all the information needed to do all device exposure analysis, a separate device exposure analysis dataset may not be needed. However, if multiple records per device are needed in a device exposure analysis dataset, this additional information does not belong in ADDL. Instead, it should be put into a BDS structure, which captures the detail actions take with the devices. Thus, often considered as one record per action taken on the device.

Device-based Demographic Variables

In addition to demographics variables from ADSL, for the device-level analysis, the age of the subject at date of first exposure to each device is often needed. Subjects with multiple devices, it might be useful to capture the age of the subject at the start of each device exposure. AGEDST is the proposed name for the age of the subject at the start of the device, and this is a permissible variable.

Other ADSL and SDTM Variables

Include in ADDL any ADSL variables, SDTM variables, or any other derived variables needed for analysis or for traceability. Be aware that only subjects with a device record would have an analysis record in ADDL. Additional variables could include flags that denote whether a device was implanted, explanted, etc., which would enable counting for summary tables.

ADDL EXAMPLE

The following example shows a few rows of an ADDL with multiple devices per subject:

Row	USUBJID	SPDEVID	MODEL	MODELG1	MODELG1N	TYPEGR1	BRTHDT	AGEDST
	Unique Subject Identifier	Sponsor Device Identifier	Model	Device Model Group 1	Device Model Group 1 (N)	Device Type Group 1	Date of Birth	Subject Age at First Exposure to Device
1	1001	G003	Model 1	Model A	1	GENERATOR	1940-01-01	59
2	1001	G2002	Model 2	Model A	1	GENERATOR	1940-01-01	71
3	1001	W0101	Model 123	Model B	2	WIRE	1940-01-01	59

Row	DEVSDT	DEVEDT	DEVIPDT	DEVXPDT	DEVONDT	DEVOFDT	DEVRPDT	DEVMDDT
	Date of First Exposure to Device	**Date of Last Exposure to Device**	**Date Device Implanted**	**Date Device Explanted**	**Date Device Turned On**	**Date Device Turned Off**	**Date Device Repositioned**	**Date Device Modified**
1	1999-12-01	2011-06-06	1999-12-01	2011-06-06	1999-12-15	2011-03-03	2008-04-01	
2	2011-06-06		2011-06-06		2011-06-06			
3	1999-12-01		1999-12-01		1999-12-15			2014-05-05

Table 8. Example ADDL Dataset

Additional variables, not shown above, could include flags that denote whether a device was implanted, explanted, etc., which would enable counting for summary tables.

MEDICAL DEVICE OCCURRENCE DATA STRUCTURE (MDOCCDS)

The proposed Medical Device version of OCCDS is very similar to the current ADaM OCCDS structure. The only differences have to do with the identifier requirements.

MDOCCDS STRUCTURE AND VARIABLES

The current ADaM OCCDS structure requires USUBJID, which as explained above may not be collected in medical device studies. In the proposed Medical Device version of OCCDS, the variable SPDEVID is required, and the USUBJD requirement has been changed to conditionally required.

There is only one other variable in the proposed MDOCCDS that is different from the current ADaM OCCDS: ASEQ. The CDISC Notes in the current ADaM OCCDS structure explain that this assigned sequence number ASEQ must be unique within a subject (USUBJID). In the proposed MD OCCDS, sequence number uniqueness is instead required within the combination of SPDEVID and USUBJID, if the latter is collected.

Because of these changes to the dataset identifiers, dataset metadata is affected. In the proposed MDOCCDS, SPDEVID is a key variable.

MDOCCDS EXAMPLE

The following example shows a few rows of a MDOCCDS dataset containing device events or malfunctions:

Row	USUBJID	SPDEVID	DEVSDT	DEVEDT	DETERM	DESTDTC	ASTDT
1	1001	G003	1999-12-01	2011-06-06	POWER CONDITIONING ISSUE	2009-12-28	2009-12-28
2	1001	W0101	1999-12-01		BENT	2013-08-08	2013-08-08

Table 9. Example MDOCCDS for Device Events Analysis

Note that:

1. Variables USUBJID and SPDEVID are keys that would be used to merge or join input datasets ADDL and SDTM DE.
1. Variables DEVSDT and DEVEDT would be copied from ADDL.
2. Variables DETERM and DESTDTC would be copied from SDTM DE.
3. Variable ASTDT is a numeric date, derived from the character DESTDTC.
4. This example dataset contains just device events from SDTM domain DE.
5. This type of dataset could be used to produce a summary table of device events.

MEDICAL DEVICE BASIC DATA STRUCTURE (MDBDS)

The proposed Medical Device version of BDS is very similar to the current ADaM BDS structure. The only differences have to do with the identifier requirements.

MDBDS STRUCTURE AND VARIABLES

The Basic Data Structure, as described in the ADaM model document and ADaMIG, is structured as one or more records per subject, per analysis parameter, and per timepoint (optional). It is the analysis of subject and parameter. USUBJID is a required variable. The use of BDS can support many analyses involving medical devices and subjects.

The unique need for medical device studies is the device-focused analysis when subject data is not collected or not associated to a SPDEVID. The very similar version of general BDS is MDBDS with the modification by adding SPDEVID as a required variable and SUBJID a conditionally required. Hence the structure is one or more records per subject (optional), per device, per analysis parameter, and per timepoint (optional).

Another variable in the proposed MDBDS that is different from the current ADaM BDS: ASEQ. The CDISC Notes in the current ADaM BDS structure explain that this assigned sequence number ASEQ must be unique within a subject (USUBJID). A similar requirement is needed for device studies, so in the proposed MDBDS, sequence number uniqueness is required within the combination of USBJID (optional) and SPDEVID.

The Time-to-Event dataset for medical devices is based on this new Class. The MDBDS supports device data analysis, when subject data were not collected or could not be linked to device data.

MDBDS EXAMPLE

The following example shows a few rows of a MDBDS dataset for time-to-device-event analysis:

Row	USUBJID	SPDEVID	PARAM	PARAMCD	STARTDT	ADT	AVAL	CNSR

1	1001	G003	TIME TO FIRST DEVICE EVENT (MONTHS)	TTFDE	1999-12-01	2011-06-06	138	0
2	1001	G2002	TIME TO FIRST DEVICE EVENT (MONTHS)	TTFDE	2011-06-06	2016-08-10	62	1
3	1001	W0101	TIME TO FIRST DEVICE EVENT (MONTHS)	TTFDE	1999-12-01	2013-08-08	164	0

Row	EVENTDESC	SRCDOM	SRCVAR	SRCSEQ
1	DEVICE REPOSITIONED	ADDATES	ADT	2
2	END OF STUDY	ADDATES	ADT	10
3	DEVICE BENT	ADDATES	ADT	8

Table 10. Example MDBDS for Time-to-Device-Event Analysis

Notes:

1. This time-to-device-event dataset looks very similar to a typical time-to-event dataset found in drug and biologic studies. The only difference here is the inclusion of SPDEVID.
2. SRCDOM for all rows is ADDATES. This idea of using an intermediate dataset called ADDATES to collect all the dates that could be used as events or censoring was first published in the Prostate Cancer Therapeutic Area User Guide v1.1

The example ADDATES for the above time-to-device-event dataset is:

Row	USUBJID	SPDEVID	ASEQ	ADT	ADTDESC	ADTDESCD	SRCDOM	SRCVAR	SRCSEQ
1	1001	G003	1	1999-12-01	Date of First Exposure to Device	DEVSDT	ADDL	DEVSDT	1
2	1001	G003	2	2008-04-01	Date Device Repositioned	DEVRPDT	ADDL	DEVRPDT	1
3	1001	G003	3	2009-12-28	Date of Device Event	ASTDT	ADDE	ASTDT	1
4	1001	G003	4	2011-03-03	Date Device Turned Off	DEVOFDT	ADDL	DEVOFDT	1
5	1001	G003	5	2011-06-06	Date Device Explanted	DEVXPDT	ADDL	DEVXPDT	1
6	1001	G2002	6	2011-06-06	Date of First Exposure to Device	DEVSDT	ADDL	DEVSDT	2
7	1001	W0101	7	1999-12-01	Date of First Exposure to Device	DEVSDT	ADDL	DEVSDT	3
8	1001	W0101	8	2013-08-08	Date of Device Event	ASTDT	ADDE	ASTDT	2
9	1001	W0101	9	2014-05-05	Date of Device Modified	DEVMDDT	ADDL	DEVMDDT	3
10	1001		10	2016-08-10	End of Study Date	EOSDT	ADSL	EOSDT	.

Table 11. Example ADDATES Intermediate Dataset

Note that:

1. All rows are specific to a single device, other than row 10 which is the end of study date (used for censoring)
2. Variable ASEQ is created within this intermediate dataset for the sole purpose of being used as a reference in the time-to-device-event dataset. Notice that row 1 in Figure 6 points to ADDATES sequence number 2, which is the row the describes the device repositioning. Whenever one ADaM dataset is used as input to another ADaM dataset, the variable ASEQ in the predecessor dataset is used to provide traceability.
3. While many BDS variables are used in ADDATES, some required BDS variables are not included,

such as PARAM, PARAMCD, and either AVAL or AVALC. As an intermediate dataset not being used directly for analysis, these standard and required BDS variables are not needed.

CONCLUSION

This paper summarizes soon-to-be released ADaM Implementation Guide for Medical Devices (ADaMIG-MD) v1.0. It provides the rationale for development of the standard, and describes new structures, such as ADDL, and MDBDS, MDOCCDS and ADTTE. With no published standard that addresses the special medical device data analysis needs, we hope the near future publication will be a welcome industry standard.

REFERENCES

1. All CDISC documents referenced in this paper can be downloaded from https://www.cdisc.org/ or https://wiki.cdisc.org/.

2. Article in conference proceedings Julia Yang. 2014. "Considerations in Conforming Data from Multiple Implantable Medical Devices to CDISC Standards Using SAS®" available at https://www.lexjansen.com/pharmasug/2015/DS/PharmaSUG-2015-DS03.pdf

3. Article in conference proceedings Sandra Minjoe, Julia Yang and Priya Gopal. 2018. "ADaM for Medical Devices: Extending the Current ADaM Structures" available at https://www.pharmasug.org/proceedings/2018/MD/PharmaSUG-2018-MD02.pdf

ACKNOWLEDGMENTS

We would like to express our gratitude to Becky DeBus, Sandra Minjoe, John Troxell and Priya Gopal for their contributions to the different stages of the ADaMIG MD development. Our special thanks also go to ADaM Team and Medical Device Team at CDISC for the kind reviews and comments.

RECOMMENDED READING

- *ADaMIG MD to be published is available at https://wiki.cdisc.org/display/ADAMIGMD/ADaMIG+for+Medical+Devices*

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