Paper FC10

CDISC for the Medical Device and Diagnostic Industry

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ABSTRACT

In May, 2006 a CDISC SDTM Device sub-team was formed. This sub-team's purpose is to address issues pertaining to the medical device and diagnostic industry. This sub-team is made of industry experts, CDISC representatives and FDA representatives. Specifically this sub-team will determine how well medical device and diagnostic data fits with the current SDTM model and identify gaps (what kind of data does not fit into the current SDTM model). These gaps exist because medical device and diagnostic data may contain information about instruments, assays and specimens that do not fit into the current SDTM model. The team will develop domains to fill-in these gaps and produce an implementation guideline.

INTRODUCTION

In this paper, unless noted otherwise, I will use the term "medical device" to refer to both medical devices (e.g., heart stents) and diagnostic assays (e.g., testing blood for presence of HIV).

The medical device industry is different than the pharmaceutical industry in many respects. The paper by Campbell (2006) summarizes the following differences:

- A medical device is anything that is not either a drug or a biologic product.
- The mechanism of action for medical devices is usually physical, whereas the mechanism of action for pharmaceutical products are usually chemical or biological.
- Medical devices can be therapeutic, diagnostic or something else, whereas pharmaceutical products are usually therapeutic.
- Medical devices are invented, whereas drugs (new chemical entities) are generally discovered.
- Medical devices can be altered during clinical development and once on the market a newer, improved version may be in development. Consequently, the life-cycle of a medical device may only be as short as a couple of years. In contrast, drugs are usually on the market for many years.
- Medical devices are approved through the Premarket Approval (PMA) application process and a single confirmatory study is often sufficient for approval. In contrast, drugs are approved through the New Drug Application (NDA) process and drug development is characterized by Phases I through IV clinical trials.
- There are more than 25,000 medical device companies registered with the FDA. In contrast, there are relatively few pharmaceutical companies.
- There are tens of thousands of medical devices, whereas the number of drug numbers in the thousands.
- Medical device companies are usually small (the median size is less than 50 employees), whereas pharmaceutical companies tend to be large.

Another difference between medical devices and drugs is that medical devices are generally submitted to CDRH (Center for Devices and Radiologic Health) or CBER (Center for Biologics Evaluation and Research) at the FDA. Pharmaceutical companies generally submit drugs for approval to CDER (Center for Drug Evaluation and Research) or CBER at the FDA.

Finally, a difference that I personally find interesting is that medical device clinical trials can be completed in just a few weeks. I previously worked for a company that conducted vaccine and therapeutic clinical trials and typically these clinical trials lasted months and sometimes even years. So, generally there is less time for the SAS programming to be completed for a medical device clinical trial versus a therapeutic drug clinical trial. However, in some of the medical device clinical trials that I work on there are not any adverse events, medical history or concomitant medications. Most of the data is laboratory data. So, even though the length of the clinical trial may be short there is generally fewer types of data to process in order to produce the summary tables, listings and graphs.

CDISC

CDISC (Clinical Data Interchange Standards Consortium) is a volunteer, non-profit organization committed to developing industry standards for an electronic submission to the FDA. Further information regarding CDISC can be found on their website (www.cdisc.org).

In 2004, CDISC released the production version of the standards for submitting clinical trial data to the FDA. This study data tabulation model (SDTM) specifically addresses data that is typically called CRF or source data. The current SDTM Implementation Guide can be found at http://www.cdisc.org/models/sds/v3.1/index.html. The paper by Kenny and Litzsinger (2005) provides some good information about the SDTM model:

- The purpose of SDTM is to guide the organization, structure and format of tabulation data (source data that is collected during the clinical trial) to be submitted to the FDA.
- SDTM organizes observations collected about participants in a clinical trial.
- These observations are organized into domains because they share a common topic.
- There are three classes of domains: interventions, events and findings.
- There are also special purpose domains, such as comments and demographics.

There are currently more than 40 domains in the SDTM Implementation Guide. Each domain is identified by a unique two-letter code (e.g., AE for Adverse Events) that becomes the first two letters of variables (e.g., AEREL) in that particular domain.

CDISC SDTM DEVICE SUB-TEAM

The current CDISC SDTM Device sub-team represents companies that make the following types of medical devices:

- Biologic implants
- Cardiac Devices
- Cataract and refractive surgical equipment
- Contact lenses
- Defibulators
- Electronic leads for pacemaker software
- Implantable pumps
- In-vitro diagnostics
- Orthopaedic implants
- Pacemakers
- Stents

The CDISC SDTM Device sub-team also includes representatives from CDISC and CDRH (a branch of the FDA).

TEAM MISSION AND GOALS

The purpose of this CDISC SDTM Device sub-team is to determine how well medical device data fits into the current SDTM model. The team will identify gaps (data that does not currently fit into the SDTM model) and then develop new domains and an implementation guide to fill-in these gaps.

WHY DEVICES?

Medical device data can have data about instruments, assays and specimens that do not currently fit into SDTM. Here are three examples of medical device data for which no domain exists in SDTM:

Data about a device (instrument) may include:

- A description of the device
- Instrument type (e.g., stent, nucleic acid detection instrument)
- Instrument serial number
- Instrument software version
- Relative position
- Delivery procedure

Data about an assay may include:

- Assay type (e.g., HIV, Hepatitis B, Hepatitis C)
- Assay lot number

Data about specimens may include:

- Sample ID
- Position in the run (a run designates a set of specimens and controls that are assayed together)
- Run number
- Result

Here is an example of the type of data that might be found in a heart stent clinical trial. All of the data in this example might fit into a domain about the device (instrument).

Instrument Type	*Instrument Serial Number*	*Instrument Software Version*	*Relative Position*	*Device Procedure*
Stent	123456	4.5.1	Distal to primary	Shaft, Balloon, Blade

Here is an example of the type of data that might be found in a diagnostic assay clinical trial. The data is this example fits into three categories. The variable Instrument Serial Number fits with data about devices (instruments), the variables Type of Assay and Assay Lot Number fit with data about assays and the variables Run Number, Sample ID, Position in the Run and Result fit with data about specimens.

Run Number	**Sample ID**	*Instrument Serial Number*	*Type of Assay*	*Assay Lot Number*	*Position in Run*	**Result**
101	1001	123456	HIV	1	3	Positive
101	1002	123456	HIV	1	4	Negative
.	.	.	.		.	.
.	.	.	.		.	.
.	.	.	.		.	.
102	1048	456789	HIV	2	24	Negative

The problem in these two examples is that some of the variables do not currently fit anywhere in the SDTM model. This is what the sub-team is calling gaps in the SDTM model. Therefore, the goal of this team is to create domains that will handle these types of data thus allowing medical device companies to submit data that conforms to SDTM standards.

CONCLUSION

The medical device and diagnostic industry is different from the pharmaceutical industry. Currently some of the data collected in medical device and diagnostic clinical trials do not fit into the current CDISC SDTM model. Therefore, a CDISC SDTM Device sub-team was formed in May, 2006 to identify gaps and to come up with domains and an implementation guide. The work to identify gaps is currently in progress. Once this sub-team's work is completed then medical device companies will be able to submit data that complies with CDISC SDTM guidelines.

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