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Mission Possible: A Proposed SDTM Domain 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 has been working on a model to fill-in the gaps in SDTM for medical device and diagnostic companies. The focus has been on developing a domain that would contain information (metadata) about devices and not on results from devices. The sub-team has come up with a model that is currently being reviewed by industry experts. The proposed model is based on a custom Finding Observation Class domain. The advantage of this proposed model is that it is simple and extensible.

INTRODUCTION

There is a need to develop an SDTM (Study Data Tabulation Model) domain to help medical device and diagnostic companies to be able to submit data to the FDA. Currently, such companies may have a hard time figuring out how to submit their data using the latest version of SDTM (termed version 3.0 – see Wood and Guinter 2007). In fact, in my own personal experience, we have been submitting data to CDRH (Center for Devices and Radiological Health) at the FDA using version 2.0 of SDTM because of the trouble with fitting device data into version 3.0 of SDTM. However, at some point in time, CDRH will require medical device and diagnostic companies to submit data in the current 3.0 version of SDTM. Therefore, the work of this sub-team is relevant and necessary to assist medical device and diagnostic companies to be able to submit data that is compliant with version 3.0 of SDTM.

In May of 2006, a CDISC SDTM Device sub-team was formed. The sub-team's mission was to identify gaps in SDTM. The term "gaps" is defined as device data that does not currently fit into the SDTM version 3.0 (Smoak 2007). The sub-team has been diligently working to identify these gaps since its inception.

The SDTM Device sub-team has identified several types of device data that does not fit into version 3.0 of SDTM. Three general areas of data have been identified:

- in-vitro diagnostics (e.g., testing blood for presence of HIV)
- implantable devices (e.g., heart stents)
- imaging devices (e.g., diagnostic imaging)

MISSION POSSIBLE: A PROPOSED DOMAIN

Once the gaps are identified then the sub-team's mission is to develop SDTM domain(s) that would help fill-in these gaps. The decision of this sub-team was to focus on data about devices (metadata) and not on results (measurements) from devices. The reason for this decision is that results from devices should be able to fit into a current Findings Observation Class domain (e.g., ECG, Labs, Microbiology, etc.) or into a custom Findings Observation Class domain. Therefore, the focus of this sub-team has been on properties or characteristic about a device.

The device sub-team is proposing that data about a device be fitted into a custom Findings Observation Class domain. The Findings Observation Class domain is described in another PharmaSUG paper (Wood and Guinter 2007) as: "Observations resulting from planned evaluations (e.g., lab tests, ECGs, microscopic findings. One record per finding result or measurement." So, what the SDTM Device sub-team is proposing is a custom Findings domain to describe data about devices, i.e., metadata about devices.

A custom Findings Observation Class domain has the following variables:

- short test code (--TESTCD)
- longer test name (--TEST)
- original result (--ORRES)
- original units (--ORRESU)
- character result in standard format (--STRESC)
- numeric result in standard format (--STRESN)
- standard units (--STRESU)

Device data might look like the following (based on a custom Findings Observation Class domain), where DP

standard for Device Properties:

Domain	DPTESTCD	DPTEST	DPORRES
DP	DPMODEL	Model Number	ABCDEF
DP	DPSNUM	Serial Number	123456
DP	DPSVER	Software Version	1.2.3

NEXT STEPS

The next steps for the device sub-team is as follows:

- Further develop a list of controlled terminology for the test code (DPTESTCD). Of course, this list is extensible (expandable).
- Further review of the domain by device industry experts and the FDA.
- Publish the proposed domain on the CDISC website for public comment.
- Explore the possibility of doing a pilot submission of device data to the FDA using the proposed model.
- Develop an implementation guideline for the proposed domain.
- Incorporate the proposed domain into SDTM.

At each step the proposed domain will be evaluated and refined as needed.

CONCLUSION

In May, 2006 a CDISC SDTM Device sub-team was formed. This sub-team has been working on a model to fill-in the gaps in SDTM for medical device and diagnostic companies. The focus has been on developing a domain that would contain information (metadata) about devices and not on results from devices. The sub-team has come up with a model for that is currently being reviewed by industry experts. The proposed model is based on a custom Findings Observation Class domain. The advantage of this model is that it is simple and extensible.

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