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Biography

- Carey is a co-founder and co-leader of the CDISC Medical Device team.
- Carey has 36 years of experience with using SAS software.
- He has been involved in more than 20 products that have been cleared / approved by the FDA.
- He has 60 publications to his credit and is a frequent speaker at conferences.

A Critique of the Use of the Medical Device SDTM Domains in Therapeutic Area User Guides

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Section 1: Method



TAUGs

- The purpose of the Therapeutic Area User Guides (TAUGs) is to facilitate solutions using the various CDISC standards for specific diseases or conditions.
 - Typically, the TAUGs provide advice, examples, and explanations regarding the use of CDASH, SDTM, and/or ADaM standards within the context of the specific therapeutic area.
 - TAUGs can be found on the CDISC website at:
 - www.cdisc.org/standards/therapeutic-areas

TAUGs Included

- Alzheimer's (v2)
- Asthma (v1)
- Breast Cancer (v1)
- Cardiovascular (v1)
- Chronic Hepatitis C (v1)
- COPD (v1)
- Diabetes (v1)
- Diabetic Kidney Disease (v1)
- Duchenne Muscular Dystrophy (v1)
- Dyslipidemia (v1)
- Ebola (v1)
- Influenza (v1)
- Kidney Transplant (v1)
- Malaria (v1)
- Major Depressive Disorder (v1)
- Multiple Sclerosis (v1)
- Pain (v1.1)
- Parkinson's (v1)
- Polycystic Kidney Disease (v1)
- Prostate Cancer (v1)
- QT Studies (v1)
- Rheumatoid Arthritis (v1)
- Schizophrenia (v1.1)
- Traumatic Brain Injury (v1)
- Tuberculosis (v2)
- Virology (v2.1)

Method

- All of the TAUGs available on the CDISC website were downloaded
 - Those in public review or are current being developed are not included
- I looked for examples of device domains in the TAUGs
 - I noticed that there were TAUGs that also mentioned device data but did not give examples
- I compiled this information (device examples and mentioned device data, but no examples) into a table
 - The compiled table is an appendix in the PhUSE paper

Section 2: Results



Results

Table 1 – TAUGs and Device Domains

DI	DO	DU	DX	DT	DE	DR	PR without DI	Could have Device Domain	None
16	5	7	2	0	1	2	5	8	4

Results

- Twenty-two of the 26 TAUGs published as of this writing have examples of device data.
- There is both diversity and similarity of device data across the TAUGs.
- The diversity of device data is clear when looking at the examples of device data in the compiled table that I put together.
- The similarity of device data is less apparent in the compiled table, but eight of the TAUGs mention imaging data and six mention diagnostic assay tests.

Results

- Table 1 details some of the differences in the TAUGs with respect to examples of device data. The differences in device data in the TAUGs are detailed here:
- Sixteen of the TAUGs have actual examples of device data:
 - These sixteen TAUGs are identified in Table 1 in the column for “DI”

Results

- Eight of the TAUGs mention device data, but do not provide examples:
 - These eight TAUGs are identified in Table 1 in the column for “Could Have Device Domains”
 - Five of the eight TAUGs have PR domains which mention a device, but do not identify the device in DI (see column “PR without DI” in Table 1). Examples of PR without DI include:

Results

- The Influenza TAUG has a PR example that mentions assistive ventilation devices, but no example of device data. In contrast, the Duchenne MD TAUG has a PR example of assistive ventilation devices and the DI domain identifies the devices.
- The Major Depressive Disorder TAUG identifies Deep Brain Stimulation (DBS) in a PR domain, but no device data examples. In contrast, the in the Parkinson's TAUG, DBS is identified in a PR domain and there are examples of device data for five of the device domains.

Results

- Two of the eight TAUGs could add device data for the examples that they mention:
 - The Chronic Hepatitis C TAUG could add DI example data for the viral load assessments mentioned in the TAUG.
 - The Rheumatoid Arthritis TAUG could add DE where it mentions that DE could be modeled for medications which are injected using a syringe or autoinjector. Additionally, DI could be added to identify the syringe or autoinjector used.

Results

- One of the eight TAUGs could borrow identical examples from another TAUG.
 - The Asthma and COPD TAUGs have the same peak flow meter and spirometry examples.
 - However, the Asthma TAUG shows examples of DI and DU whereas the COPD TAUGs omits these examples of DI and DU.

Results

- Two of the TAUGs fall into both categories (actual examples of device data and mention device data, but do not provide examples):
 - For the Cardiovascular TAUG, there are two examples with device data and one without device data.
 - Examples with device data: Balloon angioplasty and pacemaker implantation
 - Example without device data: Implantation of stents is identified in PR, but no examples of device data are provided.

Results

- For the Duchenne Muscular Dystrophy TAUG there are four examples with actual device data and three examples without device data.
 - Examples with device data are: Assistive devices (powered wheelchair), imaging, musculoskeletal assessments and assisted ventilation devices
 - Examples without device data are: Cardiac assessments, muscle biopsy and Pulmonary Function Tests

Results

- Other differences for similar device examples across the TAUGs:
 - Eight TAUGs mention the use of imaging devices, but six of the eight provide imaging device examples:
 - The six TAUGs that have imaging device examples are: Alzheimer's, Duchenne MD, Multiple Sclerosis, Parkinson's, Polycystic Kidney Disease and Traumatic Brain Injury
 - The two TAUGs which do not have examples of imaging device data are: Breast Cancer and Prostate Cancer

Results

- Six of the TAUGs mention diagnostic assay tests (such as PCR assays), but five of the six provide diagnostic assay examples:
 - The five TAUGs that have diagnostic assay test examples are: Ebola, Influenza, Malaria, Tuberculosis and Virology
 - The one TAUG which does not have examples of diagnostic assay tests is: Chronic Hepatitis C

Section 3: Conclusion



Conclusion

- While TAUGs may not be required to provide examples for every type of data that they mention, it would be helpful to pharma companies to see correct implementation of the device domains in the TAUGs.
 - I personally get questions from pharma companies about implementation of the device domains and I have personally seen incorrect implementation of device domains by pharma companies.
 - Hopefully, good examples in TAUGs would help with this problem of incorrect implementation of device domains by pharma companies.

Conclusion

- I realize that people who work on the TAUGs are very dedicated to producing the best TAUGs possible.
 - This analysis of the TAUGs with respect to device data is not intended to put down their efforts.
 - Rather it is intended to open further discussion and, hopefully good solutions to the problem.
 - Part of the problem lies with the lack of device experts to spend time on reviewing the TAUGs. Over the past several months, the Medical Device Team has done a better job of reviewing TAUGs. It would be even better to have device experts involved in the development of TAUGs.

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