

Types of Devices in Therapeutic Area User Guides

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ABSTRACT

Thirty-seven unique Therapeutic Area User Guides (TAUGs) have been published as of 2020. Thirty of these TAUGs either have examples of device data or mention device data. Of the twenty-three TAUGs which have examples of medical device data, there are twenty-one types of device data in these TAUGs. The most frequent types of device data are imaging, diagnostic tests and lab tests. These examples of device data would be useful in the next Medical Device SDTM Implementation Guide (SDTMIG-MD), particularly for ancillary devices used in pharmaceutical studies. Better examples of device data from medical device companies is needed from medical device companies for the next SDTMIG-MD. It is also suggested that reference documents for imaging, diagnostic tests and lab tests be developed to provide better consistency of presentation of device data in the TAUGs.

INTRODUCTION

Previously it has been shown that twenty-two out of twenty-six Therapeutic Area User Guides (TAUGs) either have example of medical device data or mention medical device data (Smoak, 2018). Overall, the examples of device data in the TAUGs are good with minor exceptions. Since the previous paper was published there are now thirty-seven unique TAUGs which have been published. By unique, I mean that multiple versions are counted once. For example, the Alzheimer TAUG has two versions, but I count only the most recent version. Of these thirty-seven published TAUGs, now thirty of them have either example of device data or mention device data (see Table 1). The number thirty is derived by there being thirty-seven TAUGs listed in Table 1 and seven of them do not have examples of device data or mention device data.

	DI	DO	DU	DX	DT	DE	DR	PR without DI Domain	Could Have Device Domains	None
Acute Kidney Injury (v1)										X
Alzheimer's (v2)	X	X	X							
Asthma (v1)	X		X							
Breast Cancer (v1)								X	DI, DO, DT	
Cardiovascular (v1)	X							X	DI, DU	
CDAD (v1)	X									
Colorectal (v1)	X	X					X			
COPD (v1)									DI, DU	
COVID-19	X									
Diabetes (v1)	X									
Diabetic Kidney Disease (v1)										X
Duchenne Muscular Dystrophy (v1)	X		X	X					DI	
Dyslipidemia (v1)										X

Ebola (v1)	X										
Heart Failure (v1)								X	DI, DU		
Hepatitis C (v1)									DI		
HIV (v1)	X	X	X	X					DI		
Huntington Disease (v1)	X	X	X								
Influenza (v1.1)	X							X	DI		
Kidney Transplant (v1)	X										
Major Depressive Disorder (v1)								X	DI		
Malaria (v1)	X										
Multiple Sclerosis (v1)	X		X								
Pain (v1.1)											X
Parkinson's (v1)	X	X	X	X		X	X				
Polycystic Kidney Disease (v1)	X	X	X				X				
Post Traumatic Stress Disorder (v1)	X	X	X				X	X	DI, DU		
Prostate Cancer (v1)								X	DI		
Psoriasis (v1)	X	X							DI		
QT Studies (v1)	X	X									
Rheumatoid Arthritis (v1)									DI, DE		
Schizophrenia (v1.1)											X
Traditional Chinese Medicine – CAD-Angina (v1)											X
Traumatic Brain Injury (v1)	X	X	X								
Tuberculosis (v2)	X										
Vaccines (v1)											X
Virology (v2.1)	X										
Totals	23	10	10	3	0	1	4	7	13		7

Table 1 – Summary of Device Data in TAUGs

This paper will focus on the types of device data which are represented in the TAUGs.

TYPES OF DEVICE DATA IN THE TAUGS

Table 2 lists the types of device data found in the TAUGs. This only includes TAUGs which have actual examples of device data and not TAUGs which only mention device data.

Type of Device	Example	TAUG	DI	DO	DU	DX	DT	DE	DR
Imaging	MRI	Alzheimer's Disease (v2)	X	X	X				

	MRI	Huntington's Disease (v1)	X	X	X				
	MRI	Parkinson's Disease (v1)	X	X	X				X
	MRI	Polycystic Kidney Disease (v1)	X	X	X				X
	MRS (Magnetic Resonance Spectroscopy)	Huntington's Disease (v1)	X	X	X				
	MRS	Parkinson's Disease (v1)	X	X	X				X
	PET	Huntington's Disease (v1)	X	X	X				
	PET	Parkinson's Disease (v1)	X	X	X	X			X
	DXA	Duchenne Muscular Dystrophy (v1)	X		X				
	DXA	HIV (v1)	X		X				
	Optical Coherence Tomography (OCT)	Multiple Sclerosis (v1)	X						
	CT	Traumatic Brain Injury (v1)	X	X					
	X-ray	Tuberculosis (v2)	X						
CSF	Collection of CSF	Alzheimer's Disease (v1)	X	X					
	Collection of CSF	Huntington's Disease (v1)	X	X					
Pulmonary Function	Peak Flow Meter	Asthma (v1)	X						
	Peak Flow Meter	Influenza (v1.1)	X						
	Spirometry and reference equation	Asthma (v1)	X	X					
Cardiovascular	Balloon angioplasty	Cardiovascular (v1)	X						
	Pacemaker	Cardiovascular (v1)	X						
	ECG	QT Studies (v1)	X	X					

DNA Mutation Kit	DNA MSI mutation testing	Colorectal Cancer (v1)	X	X					X
Diabetes Devices	Glucose meter	Diabetes (v1)	X						
Assistive Devices	Powered wheelchair	Duchenne Muscular Dystrophy (v1)	X			X			
Musculoskeletal Assessments	Grip dynamometer, Pinch gauge and Force transducer	Duchenne Muscular Dystrophy (v1)	X						
Assistive Ventilation Devices	CPAP and Chest Cuirass	Duchenne Muscular Dystrophy (v1)	X						
	Nasal Cannula	COVID-19 (v1)	X						
	Oxygen Delivery Face Mask	COVID-19 (v1)	X						
Diagnostic Test	qRT-PCR	Ebola (v1)	X						
	RT-PCR kit	Virology (v2.1)	X						
	Rapid Influenza Diagnostic Test	Influenza (v1.1)	X						
	Rapid Influenza Diagnostic Test	Virology (v2.1)	X						
	NA Inhibition Assay	Influenza (v1.1)	X						
	NA Inhibition Assay	Virology (v2.1)	X						
	Nucleic Acid Amplification Test	Tuberculosis (v2)	X						
	Real Time-PCR Assay kit	CDAD (v1)	X						
	SARS-CoV-2 Viral Load	COVID-19 (v1)	X						
Lab	Plate reader for IgM (ELISA)	Ebola (v1)	X						
	Multiplex assay for anti-HLA	Kidney Transplant (v1)	X						
	G6PD activity	Malaria (v1)	X						

	Interferon-gamma release assay	Tuberculosis (v2)	X						
	Lipoarabinomannan antigen test kit	Tuberculosis (v2)	X						
	Blood Gas Analyzer for arterial blood gas panel	COVID-19 (v1)	X						
Vaginal Ring	Drug measurement	HIV (v1)	X	X	X	X			
Seroreactivity	Assay kit	HIV (v1)	X						
Crossmatch	Flow cytometer	Kidney Transplant (v1)	X						
Brain electrical activity	Visual Evoked Potential (VEP)	Multiple Sclerosis (v1)	X		X				
Functional neurosurgery	Deep Brain Stimulation (DBS)	Parkinson's Disease (v1)	X		X			X	X
Sleep Study Devices	Polysomnography - PSG device	Post Traumatic Stress Disorder (v1)	X	X	X				X
Protective Devices	Seat belts, airbags, helmets and body armor	Traumatic Brain Injury (v1)	X						
	Personal Protective Equipment (PPE)	COVID-19	X						
Mycobacterial Susceptibility (MB/MS)	Mycobacterial Detection System	Tuberculosis (v2)	X						
	Sputum decontamination kit	Tuberculosis (v2)	X						
Stool Collection Device	Stool collection device for stool count/volume	CDAD (v1)	X						

Phototherapy	UVB Light Box and UV Bulb	Psoriasis (v1)	X	X					
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Table 2 – Types of Device Data in TAUGs

The classification is arbitrary and there are certainly other ways to classify the devices. The classification of the devices can be summarized as:

- Imaging – thirteen examples in ten TAUGs
- CSF Collection – two examples in two TAUGs
- Pulmonary Function – three examples in two TAUGs
- Cardiovascular – three examples in two TAUGs
- DNA Mutation Kit – one example in one TAUG
- Diabetic Devices – one example in one TAUG
- Assistive Devices – one example in one TAUG
- Musculoskeletal Assessments – one example in one TAUG
- Assistive Ventilation Devices – three examples in two TAUGs
- Diagnostic Test – nine examples in six TAUGs
- Lab – six examples in five TAUGs
- Vaginal Ring – one example in one TAUG
- Seroreactivity – one example in one TAUG
- Crossmatch – one example in one TAUG
- Brain electrical activity – one example in one TAUG
- Functional neurosurgery – one example in one TAUG
- Sleep study devices – one example in one TAUG
- Protective devices – two examples in two TAUGs
- Mycobacterial Susceptibility (MB/MS) – two examples in one TAUG
- Stool collection device – one example in one TAUG
- Phototherapy – one example in one TAUG

Twenty-one types of devices are found in the TAUGs, with the most frequent being imaging (n=13), diagnostic tests (n=9) and lab (n=6)

USEFULNESS OF DEVICE TYPES

I can see two uses of categorizing the types of devices found in the TAUGs.

First, the examples of device data found in the TAUGs could be added to the next version of the Medical Device SDTM Implementation Guide (SDTMIG-MD). The examples in the TAUGs would particularly be useful for ancillary devices used by pharmaceutical companies since the TAUGs have a pharmaceutical orientation. This may mean that the examples in the TAUGs are not fully useful for medical device companies. Yes, they would show the implementation of the seven SDTM domains for medical device data. But approval of a medical device entails more detailed data for approval of a product than an ancillary device used in a pharmaceutical study. Thus, better examples of device data from medical device companies are needed for the next SDTMIG-MD.

Second, this list of types of device data, especially the most frequent ones (imaging, diagnostic tests and lab tests) may be best served by having their own source document that the TAUGs then refer to. For example, an imaging reference document could be developed and then the TAUGs would reference the imaging document. This would ensure consistency in the presentation of imaging data in the various TAUGs.

Furthermore, thirteen TAUGs only mention device data, but do not provide examples. Also, seven TAUGs mention device data in the PR domain, but do not identify the device in the DI domain. Thus, reference documents for device data could help these TAUGs with presenting device data. For example, the Breast Cancer TAUG mentions using imaging devices for tumor identification. If an imaging reference document was developed, then the Breast Cancer TAUG could potential use examples from the reference document.

CONCLUSION

There is a vast array of types of devices represented in the TAUGs, but the most frequent ones are imaging devices, diagnostic devices and lab devices. It would be useful to create reference documents for these most frequent types of devices. This should make it easier for new TAUG that are under development to reference these documents. It would also help to standardize the presentation of device data in the TAUGs. A further use of this paper would be to include better examples of device data in the next version of the SDTM Implementation Guide for Medical Devices (SDTMIG-MD).

REFERENCES

Smoak CG. 2018. A Critique of the Use of the Medical Device SDTM Domains in Therapeutic Area User Guides. *Proceedings of the Pharmaceutical Software Users Group*, Seattle, WA. Available at: https://www.lexjansen.com/cgi-bin/xsl_transform.php?x=pharmasug2018#PharmaSUG2018-md008

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