

Incorporating Digital Health Technology (DHT) Data in SDTM – Challenges and Examples

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Abstract: As digital health technologies (DHT) like wearables are increasingly used to capture data in clinical trials, sponsors face challenges in integrating and mapping this data to CDISC data standards for regulatory submissions. The diversity of data sources, high granularity, large volumes, use of software algorithms, and inclusion of supportive contextual data complicate this process. Current CDISC guidance offers limited examples, making standardization difficult. Some data may not fit clearly into existing SDTM domains, while other data presents challenges related to how it’s collected or reported by devices or vendors. This poster will examine some of the challenges in mapping DHT data, summarize the process used at Pfizer to determine the target mapping, and share examples illustrating these challenges.

What is DHT?

- A digital health technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for health care and related uses.
- DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions.
- Depending on the intended use of a DHT, the DHT may meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- The data collection may involve passive monitoring by the DHT or the acquisition of data while participants are actively interacting with the DHT.
- Common examples of DHTs: activity tracker bracelets/watches, mobile applications, continuous glucose monitoring devices.

Examples of DHT at Pfizer



- Daily symptoms
- Daily voice assessments
- Migraine episodes
- Platform, OS, app details



- Sleep & activity metrics (raw & derived)
- Device usage metrics
- Algorithm versions
- Data loss

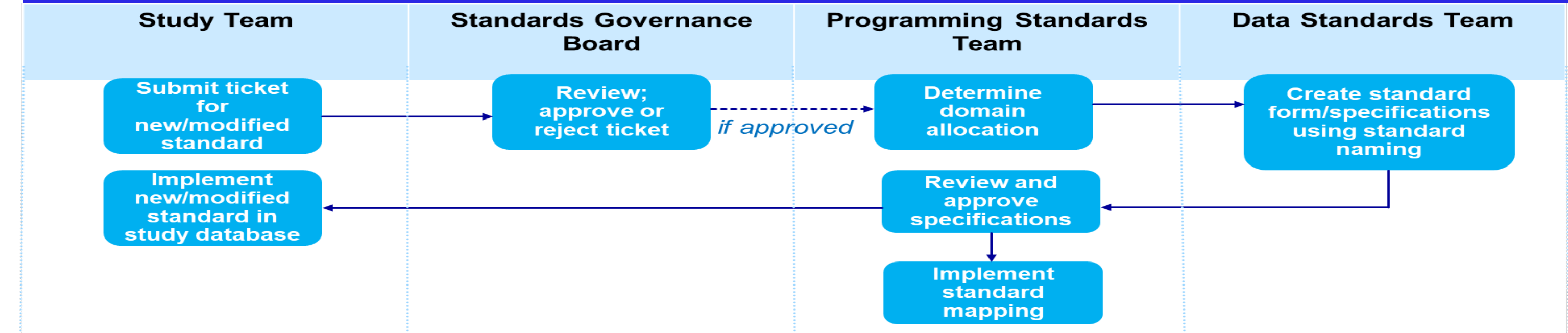


- ECG
- Vital signs
- Activity tracking
- Posture



- Gait parameters (raw, derived, estimated)
- Posture
- Spatial, temporal, and pressure data

Domain Allocation Process



Domain Allocation: process to determine the target SDTM domains for collected data so that standard CDASH-based naming conventions can be applied at collection to facilitate automation of SDTM mapping. If no standard exists, we will reference/use:

- Therapeutic Area User Guides
- Medical Device Implementation Guide
- Draft Domains
- Custom Domains

Challenges



Collection of device data and association to participants/results



Identifying appropriate target SDTM domains



Data from a single device may need to be mapped to multiple domains



Linking non-CRF data from the DHTs with related CRF data



Level of granularity of data (continuous raw data or aggregated)



Mapping of device/user issues, metrics, and other operational data

Examples

Nocturnal Scratch: atopic dermatitis study measuring frequency and duration of scratching and sleep quality using wrist-worn accelerometers

Device-collected Data:

Subject	Date	Total Sleep Time Minutes	Number of Wake Bouts Counts	Total Scratch Episodes Counts	Total Scratch Duration Minutes
1001	12/1/2018	601	15	220	14.3
1001	12/2/2018	455	15.5	200	15.95

Nervous System Findings (NV):

STUDYID	DOMAIN	USUBJID	SPDEVID	NTTESTCD	NTTEST	NVORRES	NVORRESU	NVLOC	NVLAT	NVMETHOD	NVANMETH	NVDTCT	NVENDTCT	NVEVINTX
ABC-123	NV	1001	Scratch sensor system	TST	Total Sleep Time	601	MINUTES	WRIST	BOTH	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	Sleep Period
ABC-123	NV	1001	Scratch sensor system	NNAWAKE	Number of Nighttime Awakenings	15		WRIST	BOTH	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	Sleep Period

Musculoskeletal System Findings (MK):

STUDYID	DOMAIN	USUBJID	SPDEVID	MKTESTCD	MKTEST	MKORRES	MKORRESU	MKLOC	MKLAT	MKMETHOD	MKANMETH	MKDTCT	MKENDTCT	MKEVINTX
ABC-123	MK	1001	Scratch sensor system	NSCRATCH	Number of Scratch Bouts	220		WRIST	BOTH	ACTIGRAPHY	PFIZER SCRATCH ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	SLEEP PERIOD
ABC-123	MK	1001	Scratch sensor system	DSRATCH	Duration of Scratch Bouts	14.3	MINUTES	WRIST	BOTH	ACTIGRAPHY	PFIZER SCRATCH ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	SLEEP PERIOD

Device Domains (DI, RELDEV):

STUDYID	DOMAIN	SPDEVID	DIPARMCD	DIPARM	DIVAL
ABC-123	DI	Scratch Sensor System	DEVTYPE	Device Type	Kinesiology ambulatory recorder system
ABC-123	DI	Right Sensor	DEVTYPE	Device Type	Kinesiology ambulatory recorder
ABC-123	DI	Right Sensor	WEARLOC	Wear Location	Right Wrist
ABC-123	DI	Left Sensor	DEVTYPE	Device Type	Kinesiology ambulatory recorder
ABC-123	DI	Left Sensor	WEARLOC	Wear Location	Left Wrist

Device Status Monitoring (ZD):

STUDYID	SPDEVID	PARENT	LEVEL
ABC-123	Scratch Sensor System		1
ABC-123	Right Sensor	Scratch Sensor System	2
ABC-123	Left Sensor	Scratch Sensor System	2

Vital Signs Monitoring: study to detect changes in vital signs across different phases of menstrual cycle, identify and characterize migraine episodes

CRF Menstrual Data:

Cycle	Start Date	End Date
1	2024-01-01	2024-01-04
2	2024-02-01	2024-02-05
3	2024-03-01	2024-03-04

Device-collected Data:

STUDY	SUBJECT	DATE OF COLL	SPDEVID	LOCATION	TEST	RESULT	UNIT	EVAL	DEVTYPE	TRADENAM	MANUF
ABC234	1001	2024-01-01T09:30:00	1111	WRIST JOINT	Skin Temperature	35.09	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-01T09:31:00	1111	WRIST JOINT	Skin Temperature	34.87	C		WEARABLE	EmbracePlus	EMPATICA
...	...	...	...	...	...	...	...	...	...	...	...
ABC234	1001	2024-01-03T09:40:00	1111	WRIST JOINT	Skin Temperature	34.51	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-03T09:41:00	1111	WRIST JOINT	Skin Temperature	35.45	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-03T00:00:00	2222		Moderate Migraine Episode Date				SUBJECT	APP	MIRA

Vital Signs (VS):

STUDYID	DOMAIN	USUBJID	SPDEVID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSLOC	VSDTC
ABC234	VS	1001	1111	EMP	Temperature	35.09	C	WRIST JOINT	2024-01-01T09:30:00
ABC234	VS	1001	1111	EMP	Temperature	34.87	C	WRIST JOINT	2024-01-01T09:31:00
...	...	...	...	...	...	...	...	...	...
ABC234	VS	1001	1111	EMP	Temperature	34.51	C	WRIST JOINT	2024-01-03T09:40:00
ABC234	VS	1001	1111	EMP	Temperature	35.45	C	WRIST JOINT	2024-01-03T09:41:00

Reproductive System Findings (RP):

STUDYID	DOMAIN	USUBJID	RPSPID	RPGRPID	RPTSTCD	RPTST	RPORRES
ABC234	RP	1001	1	1	MCYSTDTC	Start Date of Menstrual Cycle	2024-01-01
ABC234	RP	1001	2	1	MCYENDTC	End Date of Menstrual Cycle	2024-01-04
ABC234	RP	1001	3	2	MCYSTDTC	Start Date of Menstrual Cycle	2024-02-01
ABC234	RP	1001	4	2	MCYENDTC	End Date of Menstrual Cycle	2024-02-05
ABC234	RP	1001	5	3	MCYSTDTC	Start Date of Menstrual Cycle	2024-03-01
ABC234	RP	1001	6	3	MCYENDTC	End Date of Menstrual Cycle	2024-03-04

Clinical Events (CE):

STUDYID	DOMAIN	USUBJID	SPDEVID	CETERM	CESEV	CESTDTC
ABC234	CE	1001	2222	Migraine	MODERATE	2024-01-03

Device/Dashboard Monitoring: study evaluating device/dashboard monitoring processes for real-time data gap identification

Device-collected Data:

Study	Subject	Category	Device Name	Device Battery	Memory Usage	Last Worn State	Data Uploaded	Serial	Upload Info Date
ABC123	1001	Device Status Activity	Actigraph	64%	96%	Not Worn	93%	STM2E24247751	4/8/2025 5:01

Device Status Monitoring (ZD):

STUDYID	DOMAIN	USUBJID	SPDEVID	ZDTESTCD	ZDTEST	ZDORRES	ZDORRESU	ZDUTC
ABC123	ZD	1001	STM2E24247751	DEVBUISG	Device Battery Usage	64%		2025-04-08T05:01
ABC123	ZD	1001	STM2E24247751	MEMUSG	Memory Usage	96%		2025-04-08T05:01
ABC123	ZD	1001	STM2E24247751	DUPLOAD	Data Uploaded	100%		2025-04-08T05:01
ABC123	ZD	1001	STM2E24247751	LASTWORN	Last Worn State	Not Worn		2025-04-08T05:01

Device Identifiers (DI):

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
ABC123	DI	STM2E24247751	1	DEVTYPE	Device Type	Wearable
ABC123	DI	STM2E24247751	2	MANUF	Manufacturer	Actigraph
ABC123	DI	STM2E24247751	3	SERIAL	Serial Number	STM2E24247751

Summary

As demonstrated here, mapping DHT data to CDISC standards presents several challenges, which can result in additional time and resource expenditures and inconsistent approaches across organizations. While some of the existing CDISC guidance can be drawn upon to support this work, more guidance and examples would be beneficial to support standardization across industry. To that effect, Pfizer has been participating in the CDISC DHT team, which has been working diligently to define and develop key DHT concepts, common semantics, and best practices. Multiple examples based on digital endpoints from the DiME (Digital Medicine Society) library have been modeled in SDTM, including device domains, and will be made available along with other resources in a CDISC DHT portal, which should help alleviate some of the challenges experienced with this data.