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

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Meet the Speakers

Swarupa Sudini

Title: Sr. Manager, Statistical Programming

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Swarupa has over 17 years of experience in clinical research, with a strong focus on CDISC SDTM standards. She is an active contributor to the CDISC SDS QRS, CT Relationships, and SDS Oncology teams. Currently, Swarupa currently works at Pfizer as a Senior Manager in the Submissions and Standards team, focused on end-to-end data standards implementation, governance, and automation.

Sandy VanPelt Nguyen

Title: Director, Statistical Programming

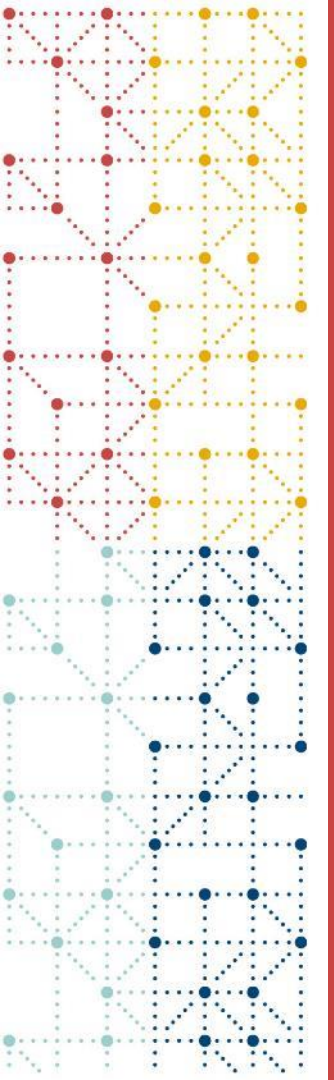
Organization: Pfizer

Sandy has been working in clinical research for over 20 years and has been involved with CDISC data standards almost as long. She is a lead for PHUSE's Optimizing the Use of Data Standards working group and participates in the CDISC Digital Health Technologies, Real World Data Lineage, and 360i teams. Sandy currently works at Pfizer as a Director in the Submissions and Standards team, focused on end-to-end data standards implementation, governance, and automation.

Disclaimer and Disclosures

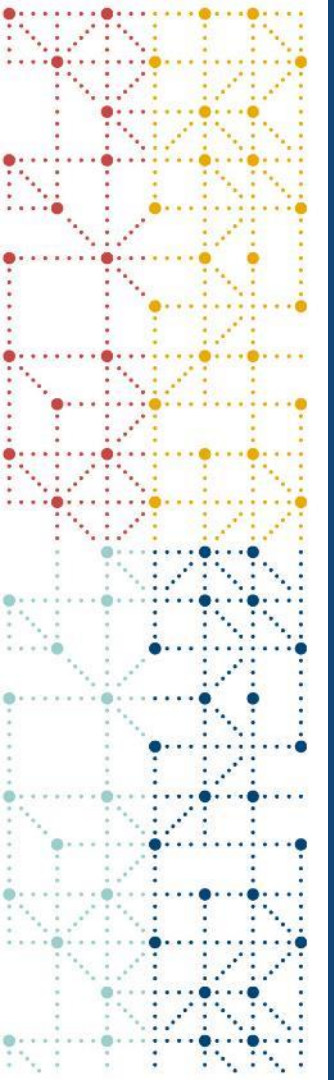
The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.

All data represented in examples here are fictitious and only provided for demonstration purposes.



Agenda

1. Introduction to DHTs
2. Data Flow
3. Challenges
4. Examples
5. CDISC DHT Team



DHTs and Data Flow at Pfizer

Digital Health Technologies (DHTs)

- A digital health technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for health care and related uses[1].
- 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

[1] FDA: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders https://www.fda.gov/media/155022/download)

eSource Data Flow

- Data is aggregated by vendor and transferred to Pfizer using the non-CRF data process.
- Programming Standards team determines SDTM domain allocation and coordinates with Data Standards (collection) to set up a standard CDASH-based file structure.
- Standard CDASH-based file structure allows us to standardize SDTM extraction and mapping programs with minimal manipulation.

Examples of DHT at Pfizer

Mobile App

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

Activity Trackers

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

Wearable Patch

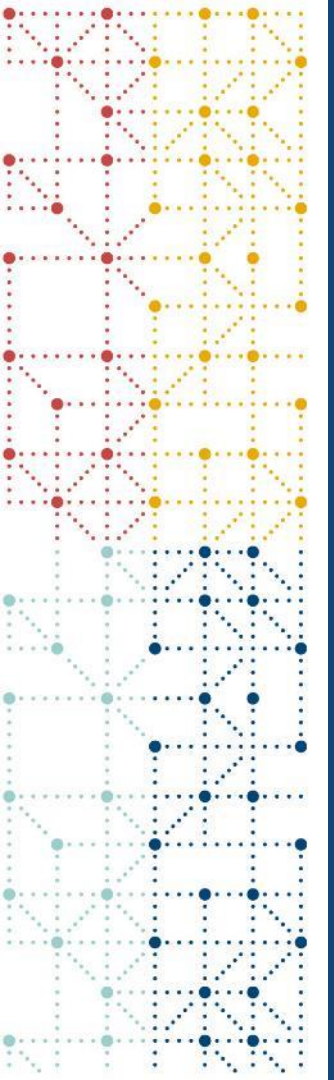
- ECG
- Vital signs
- Activity tracking
- Posture

Insole Device

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

Device Assessments

- Multiple devices may be assessed in a trial and compared for accuracy, reliability, ease of use/comfort, etc.
- Additional data may be collected beyond what the device itself collects/provides
  - Device data may be compared to “traditionally” collected data for accuracy
  - Device monitoring – device issues, syncing, upload/download status
  - Study may use questionnaires to assess comfort/use factors



Challenges and Examples

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

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

Level of granularity of data

Gait & Physical Activity data Example

e-Data

STUDY	SUBJECT	VISIT	CATEGORY	SUB-CAT	SPDEVID	DEVTYPE	PROCEDURE	DATE OF COLL	LOC	ACMTEST	RESULT	UNIT
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Single Limb Support Duration	0.190867475	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Double Support Duration	0.102842699	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Swing Duration	0.667083016	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Stance Duration	0.747797779	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Stride Length	0.04	m
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Step Duration	0.504635666	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Stride Duration	0.780439629	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Average Cadence	0.070867475	/min
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:14:19	FOOT	Gait Speed	0.02	m/sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	SLOW WALK	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-14T14:14:19	FOOT	Data Loss	0.871163163	fraction of 1
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Single Limb Support Duration	40.16513928	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Double Support Duration	21.91953968	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Swing Duration	40.20087319	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Stance Duration	62.14287681	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Stride Length	1.167348924	m
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Step Duration	0.5109375	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Stride Duration	1.0234375	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Average Cadence	58.6259542	/min
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Gait Speed	1.140680587	m/sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	OUTSIDE LAB	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T15:08:59	FOOT	Data Loss	0.253350555	fraction of 1
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Single Limb Support Duration	41.66278611	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Double Support Duration	22.5141205	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Swing Duration	41.02351979	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Stance Duration	64.60148021	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Stride Length	1.115201843	m
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Step Duration	0.5234375	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Stride Duration	1.05625	sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Average Cadence	56.80473373	/min
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Gait Speed	1.032863015	m/sec
XYZ123	1001	VISIT1	PHYSICAL ACTIVITY	ACTIVITY BLOCK 1	1234	FEETME-INSOLES	PHYSICAL ACTIVITY MONITORING	2020-12-04T14:39:04	FOOT	Data Loss	0.596548586	fraction of 1

Gait & Physical Activity data Example (Cont.)

SDTM Transformations

STUDYID	DOMAIN	USUBJID	SPDEVID	PRREFID	PRTRT	PRCAT	PRSCAT	PRLOC	VISIT	PRSTDTC
XYZ123	PR	1001	1234	10010001V1SLOWWALKFEETMEINSOLES	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	FOOT	VISIT1	2020-12-04T14:14:19
XYZ123	PR	1001	1234	10010001V1OUTSIDELABFEETMEINSOLES	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	OUTSIDE LAB	FOOT	VISIT1	2020-12-04T15:08:59

FAPR

STUDYID	DOMAIN	USUBJID	SPDEVID	FAREFID	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	VISIT	FADTC
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESSingleDuration	Single Limb Support Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.1908675	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESDoubleDuration	Double Support Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.1028427	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESSwingDuration	Swing Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.667083	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESStanceDuration	Stance Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.7477978	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESStrideLength	Stride Length	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.04	m	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESStepDuration	Step Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.5046357	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESStrideDuration	Stride Duration	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.7804396	sec	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESAverageCadence	Average Cadence	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.0708675	/min	VISIT1	2020-12-04T14:14:19
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESGaitSpeed	Gait Speed	PHYSICAL ACTIVITY MONITORING	PHYSICAL ACTIVITY	SLOW WALK	0.02	m/sec	VISIT1	2020-12-04T14:14:19

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
XYZ123	DI	1234	1	DEVTYPE	Device Type	FEETME-INSOLES

STUDYID	DOMAIN	USUBJID	SPDEVID	DEREFID	DETERM	DEDECOD	DECAT	VISIT	DESTDTC
XYZ123	DE	1001	1234	10010001V1SLOWWALKFEETMEINSOLESDataLoss	Device Data Loss	Device Data Issue	MALFUNCTION	VISIT1	2020-12-04T14:14:19

FADE

STUDYID	DOMAIN	USUBJID	SPDEVID	FAREFID	FATEST	FAOBJ	FACAT	FASCAT	FAORRES	FAORRESU	VISIT	FADTC
XYZ123	FA	1001	1234	10010001V1SLOWWALKFEETMEINSOLESDataLoss	Amount of Data loss	Device Data Issue	PHYSICAL ACTIVITY	SLOW WALK	0.8711632	fraction of 1	VISIT1	2020-12-04T14:14:19

CRF & eDATA Example

MENSTRUAL CYCLE CRF		
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

STUDYID	DOMAIN	USUBJID	RPSPID	RPGRPID	RPTESTCD	RPTEST	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

e-Data

STUDY	SUBJECT	DATE OF COLL	SPDEVID	LOCATION	CATEGORY	TEST	RESULT	UNIT	EVAL	DEVTYPE	TRADENAM	MANUF
ABC234	1001	2024-01-01T09:30:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	35.0598023	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-01T09:31:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	34.87848856	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-01T09:32:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	34.04824848	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-01T09:33:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	35.44244938	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-01T09:34:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	32.24911394	C		WEARABLE	EmbracePlus	EMPATICA
....	....	....	....	....	....	....	....	....		....	....	....
....	....	....	....	....	....	....	....	....		....	....	....
ABC234	1001	2024-01-03T09:38:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	34.71985395	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-03T09:39:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	33.91677987	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-03T09:40:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	34.51597354	C		WEARABLE	EmbracePlus	EMPATICA
ABC234	1001	2024-01-03T09:41:00	1111	WRIST JOINT	VITAL SIGNS MONITORING	Skin Temperature	35.45149701	C		WEARABLE	EmbracePlus	EMPATICA
....	....	....	....	....	....	....	....	....		....	....	....
....	....	....	....	....	....	....	....	....		....	....	....
ABC234	1001	2024-01-03T00:00:00	2222		MIGRAINE MONITORING	Moderate Migraine Episode Date	2024-01-03		SUBJECT	APP	MIRA	

SDTM Transformations

STUDYID	DOMAIN	USUBJID	SPDEVID	VSTESTCD	VSTEST	VSCAT	VSORRES	VSORRESU	VSLOC	VSDTC
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	35.0598	C	WRIST JOINT	2024-01-01T09:30:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	34.8785	C	WRIST JOINT	2024-01-01T09:31:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	34.0482	C	WRIST JOINT	2024-01-01T09:32:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	35.4424	C	WRIST JOINT	2024-01-01T09:33:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	32.2491	C	WRIST JOINT	2024-01-01T09:34:00
....	....	....		....	....	....	....	....	....	....
....	....	....		....	....	....	....	....	....	....
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	34.7199	C	WRIST JOINT	2024-01-01T09:38:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	33.9168	C	WRIST JOINT	2024-01-01T09:39:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	34.516	C	WRIST JOINT	2024-01-01T09:40:00
ABC234	VS	1001	1111	TEMP	Temperature	VITAL SIGNS MONITORING	35.4515	C	WRIST JOINT	2024-01-01T09:41:00

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

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
ABC234	DI	1111	1	DEVTYPE	Device Type	Wearable
ABC234	DI	1111	2	MANUF	Manufacturer	EMPATICA
ABC234	DI	1111	2	TRADENAM	Trade Name	EmbracePlus
ABC234	DI	2222	1	DEVTYPE	Device Type	APP
ABC234	DI	2222	2	TRADENAM	Trade Name	MIRA

Dashboard/Device Monitoring Example

e-Data

Study	Subject	Category	Device Name	Status	State	Device Battery	Memory Usage	Data Downloa	Phone Battery	Last Worn State	Upload Info Date	Data Uploaded	Serial	Connection Type	App Version	Firmware
ABC123	1001	Device Status Activity	Actigraph	Issue!	Collecting Data	64%	36%	100%	80%	Not Worn	4/8/2025 5:01:57 AM	93%	STM2E24247751	BLE - UploadOnly: Apple	CentrePoint Connect 2.0.0.167	2.1.0.106
ABC123	1001	Device Status Activity	Actigraph	Ok	Collecting Data	66%	36%	100%	55%	Worn	4/8/2025 3:00:58 AM	94%	STM2E24247751	BLE - UploadOnly: Apple	CentrePoint Connect 2.0.0.167	2.1.0.106

SDTM Transformations

Variables ‘Status’ thru ‘Data Uploaded’ are mapped to Custom Findings Domain: Device Status Monitoring(ZD)

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
ABC123	DI	DSHB001	1	DEVTYPE	Device Type	Dashboard
ABC123	DI	PHN001	1	DEVTYPE	Device Type	Phone App
ABC123	DI	STM2E24247751	1	DEVTYPE	Device Type	Wearable
ABC123	DI	STM2E24247751	2	MANUF	Manufacturer	Actigraph
ABC123	DI	STM2E24247751	3	SERIAL	Serial Number	STM2E24247751

STUDYID	DOMAIN	USUBJID	SPDEVID	DUTESTCD	DUTEST	DUORRES
ABC123	DU	1001	DSHB001	SFTWRVER	Software Version	2.1.0.106
ABC123	DU	1001	PHN001	SFTWRVER	Software Version	CentrePoint Connect 2.0.0.167
ABC123	DU	1001	PHN001	CONTYPE	Connection Type	....

CDISC DHT Standards Development

CDISC DHT Team

- CDISC and the Digital Medicine Society (DiMe) have partnered to develop shared standards and common semantics of data across different DHTs.
- Standards development has been focused in the following areas:
  - Key DHT Concepts in clinical research
  - Device Attributes that contextualize collected data
  - Digital Endpoints collected using DHTs
  - Best Practices for using CDISC standards and DiMe resources with DHTs in clinical research.
- Several endpoints have been modeled in SDTM.
- Goals for 2025:
  - Finalize Key Concepts
  - CDISC Portal planning
  - Continue to assess and model use cases

Nocturnal Scratch CDISC DHT Example

STUDYID	DOMAIN	USUBJID	SPDEVID	NVTEST	NVORRES	NVORRESU	NVLOC	NVMETHOD	NVANMETH	NVDTC	NVENDTC	NVEVINTX
ABC-123	NV	1001	Scratch Sensor System	Total Sleep Opportunity	658	MINUTES	WRIST	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	
ABC-123	NV	1001	Scratch Sensor System	Total Sleep Time	601	MINUTES	WRIST	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	Sleep Period
ABC-123	NV	1001	Scratch Sensor System	Sleep Efficiency	91.489	%	WRIST	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	Sleep Period
ABC-123	NV	1001	Scratch Sensor System	Number of Nighttime Awakenings	15		WRIST	ACTIGRAPHY	PFIZER SLEEP ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	Sleep Period

STUDYID	DOMAIN	USUBJID	SPDEVID	MKSEQ	MKTEST	MKORRES	MKORRESU	MKLOC	MKMETHOD	MKANMETH	MKDTC	MKENDTC	MKEVINTX
ABC-123	MK	1001	Scratch Sensor System	44	Number of Scratch Bouts	220		WRIST	ACTIGRAPHY	PFIZER SCRATCH ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	SLEEP PERIOD
ABC-123	MK	1001	Scratch Sensor System	45	Duration of Scratch Bouts	14.3	MINUTES	WRIST	ACTIGRAPHY	PFIZER SCRATCH ALGORITHM	2018-12-01T12:00	2018-12-02T11:59	SLEEP PERIOD

Nocturnal Scratch CDISC DHT Example (Cont.)

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC-123	DI	Scratch Sensor System	1	DEVTYPE	Device Type	Kinesiology ambulatory recorder system
2	ABC-123	DI	Right Sensor	1	DEVTYPE	Device Type	Kinesiology ambulatory recorder
3	ABC-123	DI	Right Sensor	2	MANUF	Manufacturer	Someone
4	ABC-123	DI	Right Sensor	3	WEARLOC	Wear Location	Right Wrist
5	ABC-123	DI	Left Sensor	1	DEVTYPE	Device Type	Kinesiology ambulatory recorder
6	ABC-123	DI	Left Sensor	2	MANUF	Manufacturer	Someone
7	ABC-123	DI	Left Sensor	3	WEARLOC	Wear Location	Left Wrist

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

Conclusion

- Collection, acquisition, and mapping of DHT data can be challenging
- While medical device IG and TAUGs are helpful, more guidance is needed
- Sponsors can contribute to CDISC DHT team to share knowledge and experience, support and enhance standards development and guidance

CDISC DHT Team is accepting volunteers: https://www.cdisc.org/volunteer/form

Thank You!

Contact the presenters for more information:

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