SDTM – Just a Walk in the (Theme) Park,
Exploring SDTM in the Most Magical Place on Earth

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ABSTRACT

By now, most in the industry know the basic concepts of SDTM, now let us infuse some magic and take a virtual vacation to look at SDTM from a perspective inspired by one of the happiest places on earth. Some of the basic as well as more complicated pieces of SDTM can be shown in examples of things encountered during a day at a theme park in Central Florida.

With a little imagination, we can equate our virtual vacation to a clinical trial. Come along as our vacationers (subjects) take part in our vacation (study) where they will experience various rides and attractions (treatments). We will take a look at how these experiences could be mapped to SDTM, from describing the plan of the virtual vacation in the TDM through capturing the events of the day in SDTM domains.

Within this trip, we will look at some more common but important domain examples such as DM, AE, VS and more.

Additionally, we will take a look at some more advanced concepts in SDTM in areas within our vacation example such as the usage of EX vs EC, basic trial design strategies to use in TDM creation, EDC and external data to support core study data, as well as a few applicable device domains.

We will take a look at these concepts in a new and creative way as we explore SDTM with a magical twist.

INTRODUCTION

There is still at times a reaction or hesitation, even a little panicked look when TDM, RELREC, EC and device domains are mentioned. There is a little uncertainty felt while individuals work to gain more experience and comfort in these areas. The goal of this paper is to step away from thinking of clinical trials and take a look at these domains in a completely different way in relation to a fun filled theme park vacation.

For the purposes of this exercise, we will be changing our mindset and language from clinical trial speak to vacation lingo.

Vacation=Study

Guest=Subject

Ride=Treatment

Thrill level=Dose level

Our objective is to take a no pressure look at TDM, device, and other SDTM domains while highlighting some variables and concepts of interest. We will go to our happy place on vacation where we are nice and relaxed and take a look at some examples of these SDTM structures as applied to our vacation.

THE SETUP - TRIAL DESIGN DOMAINS

First, we need a plan. For a study, that is the protocol; for a vacation, the itinerary. The trial design model datasets (TDM) help to summarize this design and structure. One by one, those domains will give a great overview of this vacation.

TS – TRIAL SUMMARY

First, a subset of the parameters from the Trial Summary (TS) domain shows key information about the premise. The planned duration is 34 days which includes up to 30 days for screening plus 4 active vacation days of the park visits with rides. Just a subset of the parameters that would appear in TS have been included to show the basic setup of the vacation. It will be single arm, open label, with 3 planned guests without age restrictions as seen in the parameter values displayed. There are 4 variables in TS that deserve some additional attention. Those are: Parameter Null Flavor (TSVALNF), Name of the Reference Terminology (TSVCDREF), Parameter Value Code (TSVALCD), and Version of the Reference Terminology (TSVCDVER).

TSVALNF is the Parameter Null Flavor. This field is present to provide some reasoning when TSVAL is missing. In the example below, since guests both young and old can participate in this vacation, there is not a maximum age that can be listed in the TSVAL for TSPARMCD=AGEMAX. Instead, the null flavor (TSVALNF) is set to PINF which indicates positive infinity.

TSVCDREF is the Name of the Reference Terminology. This could be CDISC for CDISC terminology lists, an ISO list for dates, durations or country, or other sources such as SNOMED. TSVALCD is the parameter value code which is the code associated with the value in TSVAL. When pulling the value from CDISC terminology, note that both the code list and value have codes. TSVALCD is the code associated with the particular value. When using CDISC terminology, TSVCDVER is used to specify the version that was used since it is updated quarterly.

Table 1 is a partial TS domain describing our vacation plan.

STUDYID	DOMAIN	TSSEQ	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
DIS123	TS	1	LENGTH	Planned Trial Length	P34D			ISO 8601	
DIS123	TS	1	PLANSUB	Planned Number of Subjects	3				
DIS123	TS	1	RANDOM	Trial is Randomized	N		C49487	CDISC	2016-09-30
DIS123	TS	1	TBLIND	Trial Blinding Schema	OPEN LABEL		C49659	CDISC	2016-09-30
DIS123	TS	1	TRT	Investigational Therapy or Treatment	FUN				
DIS123	TS	1	FCNTRY	Planned Country of Investigational Site(s)	USA		USA	ISO 3166	
DIS123	TS	1	INTMODEL	Intervention Model	SINGLE GROUP		C82640	CDISC	2016-09-30
DIS123	TS	1	AGEMIN	Planned Minimum Age of Subjects	P0Y			ISO 8601	
DIS123	TS	1	AGEMAX	Planned Maximum Age of Subjects		PINF		ISO 21090	

Table 1. TS Domain

TA – TRIAL ARMS

This vacation is planned to have 5 elements: screening followed by 4 planned ride (treatment) elements. Each ride will have a thrill level increase. Starting with a very mild and slow ride, first is DINOSAUR LOW level, then increasing to DINOSAUR HIGH, DARK COASTER and finally maxing out with DARK FREE FALL.

To further describe each ride element:

DINOSAUR LOW includes an informative and slow paced ride teaching about energy as well as a visit back in time to the dinosaur age while learning about fossil fuels.

DINOSAUR HIGH element will have the subjects experience a ride that is fast paced at times and transports the riders back to the time of the dinosaurs with a few encounters with the now extinct giants that almost always elicit a scream or two or a least a jump of surprise.

DARK COASTER element will involve a ride on a space coaster where a few screams and some giggles of giddy excitement are common as this coaster twists and turns in the dark.

DARK FREE FALL element will include an otherworldly elevator ride that causes screams from the riders that are heard from the ride queue and the area outside of the building.

Table 2 is a visualization of the TA domain.

STUDYID	DOMAIN	ARMCD	ARM	TAETORD	ETCD	ELEMENT	BRANCH	TATRANS	EPOCH
DIS123	TA	V	VACATION	1	SCRN	SCREEN	ASSIGNED TO ARM VACATION		SCREENING
DIS123	TA	V	VACATION	2	R1	DINOSAUR LOW			OPEN LABEL TREATMENT 1
DIS123	TA	V	VACATION	3	R2	DINOSAUR HIGH			OPEN LABEL TREATMENT 2
DIS123	TA	V	VACATION	4	R3	DARK COASTER			OPEN LABEL TREATMENT 3
DIS123	TA	V	VACATION	5	R4	DARK FREE FALL			OPEN LABEL TREATMENT 4

Table 2. TA Domain

TE – TRIAL ELEMENTS

Further definition of each of these 5 elements can be seen in the TE domain where TESTRL and TEENRL/TEDUR define the rules for the start and end of each element. Either TEENRL or TEDUR need to be populated for a given element. The SCREEN element begins at time of ticket purchase which is equivalent to informed consent being given. SCREEN will last through the interval of entering personal information per participant, selecting ride passes and preparing for vacation. Each of the four ride elements begins upon experiencing the scheduled ride and is scheduled to last one day.

Table 3 is a visualization of the TE domain.

STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
DIS123	TE	SCRN	SCREEN	TICKET PURCHACE	SCREENING ASSESSMENTS AND FASTPASS SELECTION COMPLETE, UP TO 30 DAYS AFTER START OF ELEMENT	
DIS123	TE	R1	DINOSAUR LOW	EXPERIENCE DINOSAUR LOW		P1D
DIS123	TE	R2	DINOSAUR HIGH	EXPERIENCE DINOSAUR HIGH		P1D
DIS123	TE	R3	DARK COASTER	EXPERIENCE DARK COASTER		P1D
DIS123	TE	R4	FREE FALL	EXPERIENCE DARK FREE FALL		P1D

Table 3. TE Domain

TV – TRIAL VISITS

There is one visit planned for each of the elements. In TV, TVSTRL defines the start of the visit and TVENRL defines the end of the visit. Visit 1 – SCREEN can be thought of as a virtual visit where tickets are purchased online and personal data is entered. Each of visits 2-5 are different park visits on different dates that begin upon arrival at the entrance gate and end upon exiting the park at park close time.

Table 4 is a visualization of the TV domain.

STUDYID	DOMAIN	VISITNUM	VISIT	ARMCD	ARM	TVSTRL	TVENRL
DIS123	TV	1	SCREEN			TICKET PURCHACE AND ENTRY OF PERSONAL DATA	DAY PRIOR TO PARK ARRIVAL
DIS123	TV	2	COUNTRIES PARK			ARRIVAL AT ENTRANCE GATE OF COUNTRIES PARK	PARK CLOSE
DIS123	TV	3	ANIMAL PARK			ARRIVAL AT ENTRANCE GATE OF ANIMAL PARK	PARK CLOSE
DIS123	TV	4	MAGIC PARK			ARRIVAL AT ENTRANCE GATE OF MAGIC PARK	PARK CLOSE
DIS123	TV	5	STUDIO PARK			ARRIVAL AT ENTRANCE GATE OF STUDIO PARK	PARK CLOSE

Table 4. TV Domain

TI – TRIAL INCLUSION/EXCLUSION CRITERIA

Essentially, any guest with a ticket is welcome on this vacation, so TI is not presented for this example.

ELECTRONIC DATA CAPTURE

Just as there is electronic data capture (EDC) in studies, there is EDC occurring on our vacation primarily through two devices worn around the wrist.

Almost every guest now uses a wristband as a ticket to the park and possibly also for a room key, payment method and other. For the purpose of our vacation, our band contains key information that is entered both at ticket purchase and throughout the visits. First, our pass purchase is tracked. Most importantly, this answers the question if we have indeed bought a ticket and effectively given consent to participate in the vacation. Birth date is also stored to determine age and if a ticket is needed. Birth date

can also be read by cast members who can wish you a happy birthday on your special day. Additionally, this device tracks our ride reservations and ride arrivals.

The other common adornment seen on individuals is a fitness tracker/biometric style device. This device serves as both a digital pedometer as well as a tracker of our heart rate as it changes over the course of the day and as impacted by our various planned rides.

As we move through the domain examples, we will see where the data captured by these devices would be stored in SDTM as well as how we would capture information about these EDC devices themselves.

COMMON DOMAINS

We have seen how we can use the TDM domains to capture the plan for our vacation. Next, we will see how just a small part of some of our daily activities and actual events that occurred on this vacation would fit into common SDTM.

DM – DEMOGRAPHICS

Demographics (DM) contains the basic demographic and some overall study summary information for our vacationers. Information such as birthdate, age and identifier can be sourced from our EDC band from information entered upon ticket purchase. As the bands are worn in the parks, each entry to the park (our visit starts) are recorded as well as rides with reservations are tracked by automatic readers at the individual rides. Both of these would then feed into DM RFSTDTC (reference start date/our first ride), RFENDTC (reference end date/our last visit), RFXSTDTC (treatment start date/first ride), and RFXENDTC (treatment end date/last ride). Each of our 3 guests will have one record in DM. USUBJID M3 has some interesting points to be considered within the demographic information. Age is less than 3 years which means that this little vacationer does not need a ticket yet. This information will come up again within the device domains. Also, RFXENDTC is only 3 days after RFSTDTC, not 4 days as expected, so we can see that M3 did not ride all of the rides as planned for this vacation.

Table 5 is a partial view of the DM domain containing variables of interest.

STUDYID	DOMAIN	USUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	INVNAM	AGE	AGEU	ARMCD	ARM	ACTARMCD	ARM
DIS123	DM	M1	2017-05-01	2017-05-04	2017-05-01	2017-05-04	M. MOUSE	29	YEARS	V	VACATION	V	VACATION
DIS123	DM	M2	2017-05-01	2017-05-04	2017-05-01	2017-05-04	M. MOUSE	29	YEARS	V	VACATION	V	VACATION
DIS123	DM	M3	2017-05-01	2017-05-03	2017-05-01	2017-05-03	M. MOUSE	2	YEARS	V	VACATION	V	VACATION

Table 5. DM Domain

AE – ADVERSE EVENTS

Our guests were very fortunate on this trip and the only injury or illness on this trip was a mild scream induced sore throat for guest M1. Adverse Event (AE) contains a single event that started on day 2. This mild sore throat was non-serious, but determined to be ride related, but dose was not changed. Though it is known that the event was related to day 2 ride, DINOSAUR HIGH screams, as the subsequent day's thrill rides continued, the sore throat did not resolve. Since the event was ongoing at the end of the vacation reference period, AEENRF was able to be used and set to ONGOING. If the vacation reference period specifically was not used for the determination of whether event was ONGOING, other AE variables AEENRTPT and AEENTPT would have been used to define the status and the reference period used.

Table 6 is a partial example of AE containing variables of interest.

STUDYID	DOMAIN	USUBJID	AESEQ	AETERM	AESEV	AESER	AEACN	AEREL	AESTDTC	AEENDTC	AESTDY	AEENDY	AEENRF
DIS123	AE	M1	1	SORE THROAT	MILD	N	DOSE NOT CHANGED	RELATED	2017-05-02		2		ONGOING

Table 6. AE Domain

VS – VITAL SIGNS

As thrill level is increased from ride to ride, it is of interest to see how this impacts heart rate. This snippet from Vital Signs (VS) domain shows how we can compare across rides. Heart rate is measured at 1 minute pre-ride and then 30 seconds and 5 minutes post-ride for each planned ride. For each record with time point (VSTPT) defined, the elapsed time (VSELTM) has been used to show the amount of time in ISO8601 format before or after dose. Time point reference (VSPTPREF) was set to RIDE TIME to specify that the time points described are relative to the point in time that the ride was ridden. Variable VSRFTDTC can be used to store the actual date/time of the RIDE TIME. Comparing heart rate from DINOSAUR LOW and DINOSAUR HIGH rides, the post treatment 2 (DINOSAUR HIGH) heart rate (VSORRES) shows a greater increase from pre-ride heart rate than the post treatment 1 (DINOSAUR LOW) heart rate.

Table 7 is a partial example of VS with variables of interest.

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VISITNUM	VISIT	VSDY	VSTPT	VSTPTNUM	VSELTM	VSPTPREF
DIS123	VS	M1	2	HR	Heart Rate	75	beats/min	2	COUNTRIES PARK	1	1 MIN PRE-RIDE	1	-PT1M	RIDE TIME
DIS123	VS	M1	3	HR	Heart Rate	76	beats/min	2	COUNTRIES PARK	1	30 SECONDS	2	PT30S	RIDE TIME
DIS123	VS	M1	4	HR	Heart Rate	75	beats/min	2	COUNTRIES PARK	1	5 MINUTES	3	PT5M	RIDE TIME
DIS123	VS	M1	5	HR	Heart Rate	73	beats/min	3	ANIMAL PARK	2	1 MIN PRE-RIDE	1	-PT1M	RIDE TIME
DIS123	VS	M1	6	HR	Heart Rate	84	beats/min	3	ANIMAL PARK	2	30 SECONDS	2	PT30S	RIDE TIME
DIS123	VS	M1	7	HR	Heart Rate	74	beats/min	3	ANIMAL PARK	2	5 MINUTES	3	PT5M	RIDE TIME

Table 7. VS Domain

EX – EXPOSURE AND EC – EXPOSURE AS COLLECTED

Now it is time to track the rides! The difference between Exposure (EX) and Exposure as Collected (EC) is an area that may not be completely clear to all. The two domains differ in a few key areas.

First, as the name states, EC is the exposure information as collected. EX is the exposure in protocol-specified units. If the protocol for example stated that subjects were to experience a certain thrill level on each ride, however, data was collected to summarize how many times each ride was ridden to get to that thrill level, then EX would show units in terms of the THRILL LEVEL and EC would show units in terms of number of RIDES. In EX for DARK COASTER record, the thrill level administered (EXDOSU) is 6 (EXDOSE). However, EC documents that this consisted of 2 rides (ECDOSE/ECDOSU).

Second, EX shows only treatments that were given. Any missed doses would not be present in EX. However, EC contains the fields that provide the ability to capture information about missed doses. USUBJID M3 contains records in EX for only DINOSAUR LOW and DINOSAUR HIGH rides. EC for M3 contains an additional record for DARK COASTER documenting that this guest was not able to ride (ECOCCUR=N). Further details can be found in SUPPEC in a parameter showing that the reason for the ECOCCUR=N value is that the subject did not meet the height requirement for that ride.

Note that in both EX and EC, xxLNKID fields have been created. These xxLNKID fields can be used to uniquely identify the treatment records such that the relationship between EX and EC can be defined easily. Each domain's xxLNKID has been created in both cases as 'E' for 'exposure' plus the date without dashes. Since there was only one ride per date per guest, this is enough to uniquely and consistently identify the pairing of the records between the two domains. RELREC can then be used to document this relationship. RELREC can be used to show relationships between records or datasets. Because this relationship is showing the dataset level linkage, there is only one row per dataset necessary in RELREC to show the type of relationship and the keys needed to make this relationship. Since there is only one instance of each xxLNKID per subject, RELREC describes that there is a ONE to ONE relationship based on xxLNKID values. Also, since this is describing a dataset level relationship, USUBJID and IDVARVAL are null since we are not making a patient level or specific record level link.

Table 8 shows the EX data set.

STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXDOSE	EXDOSU	EXSTDTC	EXENDTC	EXSTDY	EXENDY
DIS123	EX	M1	1	E20170501	DINOSAUR LOW	0.5	THRILL LEVEL	2017-05-01	2017-05-01	1	1
DIS123	EX	M1	2	E20170502	DINOSAUR HIGH	2	THRILL LEVEL	2017-05-02	2017-05-02	2	2
DIS123	EX	M1	3	E20170503	DARK COASTER	6	THRILL LEVEL	2017-05-03	2017-05-03	3	3
DIS123	EX	M1	4	E20170504	DARK FREE FALL	8	THRILL LEVEL	2017-05-04	2017-05-04	4	4
DIS123	EX	M2	1	E20170501	DINOSAUR LOW	0.5	THRILL LEVEL	2017-05-01	2017-05-01	1	1
DIS123	EX	M2	2	E20170502	DINOSAUR HIGH	2	THRILL LEVEL	2017-05-02	2017-05-02	2	2
DIS123	EX	M2	3	E20170503	DARK COASTER	6	THRILL LEVEL	2017-05-03	2017-05-03	3	3
DIS123	EX	M2	4	E20170504	DARK FREE FALL	8	THRILL LEVEL	2017-05-04	2017-05-04	4	4
DIS123	EX	M3	1	E20170501	DINOSAUR LOW	0.5	THRILL LEVEL	2017-05-01	2017-05-01	1	1
DIS123	EX	M3	2	E20170502	DINOSAUR HIGH	2	THRILL LEVEL	2017-05-02	2017-05-02	2	2

Table 8. EX Domain

Table 9 displays the EC data set.

STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECTRT	ECPRESP	ECOCCUR	ECDOSE	ECDOSU	ECSTDTC	ECENDTC	ECSTDY	ECENDY
DIS123	EC	M1	1	E20170501	DINOSAUR LOW	Y	Y	1	RIDES	2017-05-01	2017-05-01	1	1
DIS123	EC	M1	2	E20170502	DINOSAUR HIGH	Y	Y	1	RIDES	2017-05-02	2017-05-02	2	2
DIS123	EC	M1	3	E20170503	DARK COASTER	Y	Y	2	RIDES	2017-05-03	2017-05-03	3	3
DIS123	EC	M1	4	E20170504	DARK FREE FALL	Y	Y	2	RIDES	2017-05-04	2017-05-04	4	4
DIS123	EC	M2	1	E20170501	DINOSAUR LOW	Y	Y	1	RIDES	2017-05-01	2017-05-01	1	1
DIS123	EC	M2	2	E20170502	DINOSAUR HIGH	Y	Y	1	RIDES	2017-05-02	2017-05-02	2	2
DIS123	EC	M2	3	E20170503	DARK COASTER	Y	Y	2	RIDES	2017-05-03	2017-05-03	3	3
DIS123	EC	M2	4	E20170504	DARK FREE FALL	Y	Y	2	RIDES	2017-05-04	2017-05-04	4	4
DIS123	EC	M3	1	E20170501	DINOSAUR LOW	Y	Y	1	RIDES	2017-05-01	2017-05-01	1	1
DIS123	EC	M3	2	E20170502	DINOSAUR HIGH	Y	Y	1	RIDES	2017-05-02	2017-05-02	2	2
DIS123	EC	M3	3	E20170503	DARK COASTER	Y	N			2017-05-03	2017-05-03	3	3

Table 9. EC Domain

Table 10 shows the SUPPEC data.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
DIS123	EC	M3	ECSEQ	3	ECREASOC	Reason for Occur Value	DOES NOT MEET HEIGHT REQUIREMENT

Table 10. SUPPEC Data

Table 11 shows the RELREC data set.

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
DIS123	EC		ECLNKID		ONE	1
DIS123	EX		EXLNKID		ONE	1

Table 11. RELREC Data

DEVICE DOMAINS

It is now time to come back to our two EDC devices and explore the device domains. SDTM for Medical Devices applies for both devices under study as well as ancillary devices. Both of our devices are ancillary devices, that is, they are used to collect information, but the devices themselves are not under study.

DI – DEVICE IDENTIFIERS

The Device Identifiers (DI) domain identifies the unique devices of interest. For this identification a new variable was necessary and the Sponsor Device Identifier (SPDEVID) has been created. SPDEVID is present in all of the device domains to identify which of the defined devices is the subject of the data captured on that record. Note that USUBJID is not present in this domain as this data is about the device and is not related to a particular subject. Our DI example identifies 3 devices of interest: 2 Ticket

Trackers and 1 Fitness Tracker. To uniquely identify each device with a unique SPDEVID, records have been provided to document the device type as well as the device serial number. Note also that there are only 2 Ticket Trackers identified for our 3 guests. As noted when we reviewed the demographic data in DM, due to age, subject M3 does not require a ticket so does not need the electronic pass.

Table 12 shows the DI data of interest.

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
DIS123	DI	MB1	1	TYPE	Device Type	TICKET TRACKER
DIS123	DI	MB1	2	SERIAL	Serial Number	1234-AB56-YZ01
DIS123	DI	MB2	1	TYPE	Device Type	TICKET TRACKER
DIS123	DI	MB2	2	SERIAL	Serial Number	1234-AB56-YZ02
DIS123	DI	FB1	1	TYPE	Device Type	FIT TRACKER
DIS123	DI	FB1	2	SERIAL	Serial Number	FB12345

Table 12. DI Domain

DO – DEVICE PROPERTIES

The Device Properties (DO) domain stores those characteristics about a device that do not vary, but are not used to identify the device. This domain may not always be applicable. To further describe the properties of the 3 devices related to this vacation, a parameter has been created to store the color of each device.

Table 13 contains the DO dataset variables of interest.

STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOORRES	DOORRESU
DIS123	DO	MB1	1	COLOR	Color	PINK	
DIS123	DO	MB2	1	COLOR	Color	BLUE	
DIS123	DO	FB1	1	COLOR	Color	BLACK	

Table 13. DO Domain

DR – DEVICE-SUBJECT RELATIONSHIPS

Now that we have sufficiently described each unique device and its static characteristics, we need to know how the devices relate to each of our guests. The Device-Subject Relationships (DR) domain contains both the device identifier (SPDEVID) and subject identifier (USUBJID) and this is the domain that makes the link(s) between device(s) and subject(s). Device MB1 is associated only with subject M1. Device MB2 is associated with only subject M2. However, device FB1 is associated with both subjects M1 and M2.

Table 14 shows the data in the DR domain.

STUDYID	DOMAIN	USUBJID	SPDEVID
DIS123	DR	M1	MB1
DIS123	DR	M1	FB1
DIS123	DR	M2	MB2
DIS123	DR	M2	FB1

Table 14. DR Domain

DU – DEVICE IN-USE

The Device In-Use (DU) domain contains the properties or settings that could be changed, unlike DO which shows properties that will not change during the vacation. DU can show how each device is customized per use and per guest. Device FB1 will be the focus of this example. The wristband of the

device has several notches which can be used in sizing to get appropriate fit. On the two visits when M1 used device FB1, the band was adjusted to use notch number 3 to get a snug fit for proper use. When the same device FB1 was used for guest M2, only the second notch was needed to get a snug fit on the wristband.

Table 15 shows the variables of interest in the DU domain.

STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM
DIS123	DU	M1	FB1	1	NOTCH	BAND NOTCH	3	NOTCHES	3	3	NOTCHES	2
DIS123	DU	M1	FB1	2	NOTCH	BAND NOTCH	3	NOTCHES	3	3	NOTCHES	3
DIS123	DU	M2	FB1	1	NOTCH	BAND NOTCH	2	NOTCHES	2	2	NOTCHES	4
DIS123	DU	M2	FB1	2	NOTCH	BAND NOTCH	2	NOTCHES	2	2	NOTCHES	5

Table 15. DU Domain

DX – DEVICE EXPOSURE

Data in DR and DU has already shown that there is a relationship of device FB1 to both guests M1 and M2 at multiple visits. The Device Exposure (DX) domain further identifies each guest's direct interaction and exposure to the device. Specifically here, the DXTRT has been defined as the LED light emitted by the device that is reflected onto the skin to determine the measurements. M1 was exposed to the device for the first two days and M2 was exposed on the third and fourth day. Though the device is worn around the wrist of both guests M1 and M2, note the laterality, stored in DXLAT, allows for the further identification of location. M1 wore the band on the left wrist while M2 wore the band on the right wrist.

Table 16 displays the records and variables of interest from the DX domain.

STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXLOC	DXLAT	DXSTDTC	DXENDTC	DXSTDY	DXENDY
DIS123	DX	M1	FB1	1	LED LIGHT	WRIST JOINT	LEFT	2017-05-01	2017-05-02	1	2
DIS123	DX	M2	FB1	1	LED LIGHT	WRIST JOINT	RIGHT	2017-05-03	2017-05-04	3	4

Table 16. DX Domain

DE – DEVICE EVENTS

Device Events (DE) stores events that occur that are about the device. Here, the charge on device FB1's battery has been depleted (DETERM) on study day 2 (DESTDY). Note that the record also contains a reference to USUBJID=M1. This indicates that the device was in use by M1 when this event occurred. USUBJID is expected and not required in this domain as an event could have occurred without being related to a guest. Also of interest in DE is new field Action Taken with Device (DEACNDEV). This stores the action taken specifically with the device. In this case, the action taken on the device was that FB1's battery was charged.

Table 17 displays the variables of interest from the DE domain.

STUDYID	DOMAIN	USUBJID	SPDEVID	DESEQ	DETERM	DEACNDEV	VISITNUM	DESTDTC	DEENDTC	DESTDY	DEENDY
DIS123	DE	M1	FB1	1	CHARGE DEPLETED	CHARGED	3	2017-05-02	2017-05-02	2	2

Table 17. DE Domain

DT – DEVICE TRACKING AND DISPOSITION

Device Tracking and Disposition (DT) stores information about where the device is located and who is accountable for the device. Two new variables have been introduced to aid in storing this information. Party Responsible for the Device (DTPARTY) and Responsible Party Identifier (DTPRTYID) identify who is accountable for the device after the action in DTTERM has been taken. DTPARTY is the type of party, for example: SPONSOR, SITE, or SUBJECT. DTPRTYID then further identifies the specific party with detail of the site number or subject number responsible. Looking at the tracking of FB1, it was shipped to guest M1 prior to the vacation. M1 remained accountable for FB1 until loaning it to M2 on day 3 of vacation. M2 then returned the borrowed device back to M1 at the end of the vacation.

Table 18 displays the records and variables of interest from the DT domain.

STUDYID	DOMAIN	SPDEVID	DTSEQ	DTTERM	DTPARTY	DTPRTYID	DTCAT	DTSTDTC
DIS123	DT	FB1	1	SHIPPED	GUEST	M1		2017-04-14
DIS123	DT	FB1	2	LOANED	GUEST	M2		2017-05-03
DIS123	DT	FB1	3	RETURNED	GUEST	M1		2017-05-05

Table 18. DT Domain

CONCLUSION

As our theme park adventure concludes, let us take a look back through our fond memories of this trip. We showed how our vacation itinerary could be outlined using the trial design domains and touched on some of the key fields used to store that planned information. We then took a look at things which actually did occur during our vacation and how some of that information would fit into the SDTM domains. Finally, we worked through the device domain structures and saw how they would be used to document the information about our wrist worn EDC devices. After walking through this vacation scenario, hopefully you are now a little more comfortable with these domains and the key variables within. Let your fears center around things like roller coasters and free fall rides because you are now ready to let go of any lingering SDTM fears of TDM, EX/EC and device domains.

REFERENCES

Study Data Tabulation Model Version 1.4

Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.2

Study Data Tabulation Model Implementation Guide for Medical Devices Version 1.0 (provisional)

Available at: http://www.cdisc.org

RECOMMENDED READING

- *Study Data Tabulation Model Version 1.4*

- *Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.2*

- *Study Data Tabulation Model Implementation Guide for Medical Devices Version 1.0 (provisional)*

CONTACT INFORMATION

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