PharmaSUG 2019 - Paper DS-088

Pacemaker Guy: De-Mystifying a Business Use Case for SDTM and Medical Device Domains

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ABSTRACT

Medical-device standards can be applied to even the most complicated clinical research studies with medical devices. There are many papers written on how to map certain kinds of data like exposure data or lab data using SDTM-based standards. Not has been written however, on how to represent medical-device data using these standards.

In developing medical-device standards, considerations were made for simple and complex data points when mapping to the SDTM standards. Just like in pharmaceutical and biological products; one needs to plan for the unexpected with medical device studies.

This paper will take the reader through a subject experience by showing the mappings of the data but also illustrate the procedure(s) and how to visually map the data. The goal is to leave the participant/reader with a curiosity to want to map their own medical device data to standards sooner than what the current expectation is. The more the Medical Device Industry uses the standards the more we can influence the regulatory agencies and their tools for Medical Device domains.

INTRODUCTION

Most readers have probably not seen a medical-device clinical study with the collection database configured to CDISC SDTM Standards. This paper will demonstrate the real-life business case for utilizing the CDISC SDTMIG and SDTMIG-MD domains. It's no longer just a concept. It can be done!

THE NEED FOR CDISC FOR MEDICAL DEVICES

Currently, the Center for Devices and Radiologic Health (CDRH) accepts data in any format (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/data-standards-and-terminology-standards-information-submitted-cdrh). This means that CDRH will accept data that conforms to CDISC standards such as SDTM and ADaM.

This concept of the FDA being able to more quickly analyze data when standards are used is supported by the Gartner report (https://www.cdisc.org/system/files/all/article/PDF/2014%20Business%20Case_Executive%20Summary.pdf). This business case for CDISC standards shows up to a 75% savings of the time and resources for study conduct and analysis when CDISC standards are implemented at earlies stages of planning a clinical trial. Thus, the statement on the CDRH webpage is correct that they would be able to review and analyze data more quickly if medical device sponsors submitted data in CDISC-conforming formats.

Recently, CDRH put a notice in the Federal Register to end paper submissions (https://www.federalregister.gov/documents/2018/09/13/2018-19865/medical-device-submissions-amending-premarket-regulations-that-require-multiple-copies-and-specify). This would be a good move as one of the authors (Carey Smoak) was involved in a medical device submission in which more than 42,000 women were screened. The amount of paper submitted to CDRH was staggering.

Finally, in 2014 a CDRH statistician gave a presentation in 2014 at an AdvaMed Statistical Issues conference (Nair 2014). After this presentation, the CDISC team took each point in this presentation and showed how CDISC could solve the problems mentioned by the CDRH statistician. The CDISC solutions for CDRH issues have been presented at a CDISC conference (Nair et al 2015).

Thus, there is a clear pathway for CDRH to not only encourage sponsors to submit CDISC conforming data, but also in the future to require sponsors to submit data in such a format. This paper will illustrate for medical device sponsors how to implement CDISC standards using a pacemaker (investigational product) as an example.

The table below summarizes the issues and the solutions that CDISC can provide.

	CDRH Issue	CDRH Reviewer Request	CDISC Solution
Protocol Deviations	Hard to identify, determine impact	• Summary tables by type of deviation (major / minor) • Protocol deviations by investigational site	• SDTM: designed to facilitate summary table production • CDASH: defines deviation data capture, including narratives; facilitates categorization
Data Traceability	Lack of data traceability leads to inability assess data validity	• Provide mechanism to trace each data point from the study report back to the CRF	• ADaM, SDTM, associated define-xml and CDASH-conformant CRFs are specifically designed for this: hyperlink each variable to associated algorithm(s), source dataset(s), controlled terms and annotated CRF(s).

Missing Data	May impact validity of conclusions, or choice of statistical model	• Show why and when data are missing (missed visits, value not recorded, etc.)
		• No undisclosed data omissions; justify all data omissions
		• Clearly note all imputed data
			• SDTM and ADaM define-xml:
			  • Origin of each variable is defined as collected, derived, or imputed.
			  • Algorithms for all derivations and imputations included.
			  • Can show what data were included or omitted and why.
			• CDASH can indicate what data were missing, with associated dates.

Patient Accountability	Hard to determine accountability for all subjects	• Provide patient accountability charts with discussions of missing data	• CDASH and SDTM: The Disposition domain captures status of each subject at each defined time point, which can be used to produce accountability charts; see also “Missing Data” box.
Missing Coding Tools	Hard to identify, determine impact	• Include Proc Format program that creates the format catalog	• Controlled Terminology contains standard values and "formats" • define-XML contains customized ones and external terms.
Trial Data Issues		• Include electronic datasets in PMA submission • Adverse event listings for medical reviewers • Study endpoints analysis dataset(s) and raw data to minimize complicated manipulations and merges required to validate results • Analysis datasets to support key effectiveness/safety analyses • Include basic Demographics variables and important covariates in analysis datasets • Define/README file for datasets and program files • Document datasets and code sufficiently	• SDTM and ADaM provide subject- and device-level tabulation and analysis datasets • Data transmitted in SAS® transport files • Standardized AE data support listings from data visualization tools • ADaM defines key effectiveness / safety analyses and datasets, and permits inclusion of any/all relevant variables • ADaM datasets are “one proc away” from running analyses • Define-xml provides structure to document all datasets

Table 1. CDRH Issues and CDISC Solutions

NARRATIVE ABOUT “PACEMAKER GUY”

The study subject, “Pacemaker Guy”, was randomized to participate in a single-blind (subject was blinded) study, testing the new design “Right Ventricle Pacing Lead” (see Figures 1 and 2). The marketed pacemaker has a stable generator of a cardiac pacemaker with two leads (right atrium and right ventricle). The subject signed the Informed Consent, was randomized at screening, and passed. The subject returned the next day for the surgery. Surgery went as planned, and subject was discharged the following day after satisfactory ECG.

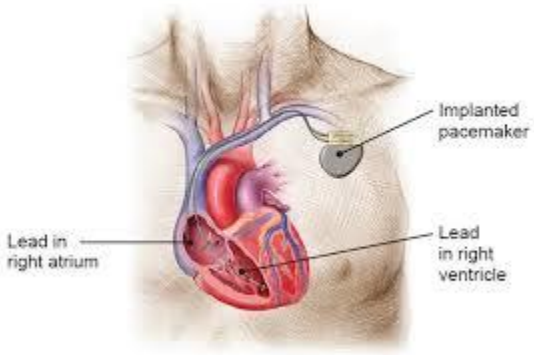

Figure 1. Implanted Pacemaker

Figure 2. Pacemaker (Generator and Two Leads)

During Follow-up on Day 8, subject complains of fatigue three days prior for follow-up visit. ECG and examination detects bradycardia. Further testing via radiography and fluoroscope detects the “study” lead has migrated. The next day the subject is admitted for an unscheduled hospitalization and surgery to reposition the lead.

During the replacement surgery, surgeon finds that study lead is abraded, it is replaced and repositioned. Noticed crack in insulation - could be too small to see but body fluids could seep in and cause it to either sense incorrectly or fire incorrectly (failure to be effectively mode, rather than safety).

If this malfunction was identified in a clinical setting or in a clinical trial; the clinical site should return to manufacturer for engineering review - site may not be able to ID problem - may only see an anomaly.

On Day 10, the subject was discharged, and examinations are satisfactory. Returns on Day 18 and all is fine.

Full Title	Cardiac Pacemaker, testing a new design of right ventricle pacing lead.
Protocol Number	CDISCLWO
Short Title	Right ventricle pacing lead.
Sponsor	ANYCOM
Indication	bradycardia
Study Devices	Cardiac pacemaker w/ 2 leads, one in the right ventricle and one in right atrium
Regulatory Classification	III
Study Device Description	The marketed pacemaker has stable generator, but the study is testing a new design of right ventricle pacing lead. The green lead is the current marketed design and the yellow lead is the component under study. Subjects are randomized to one of the two colors. The ARMs are SINGLE BLIND YELLOW LEAD and SINGLE BLIND GREEN LEAD, with associated ARMCDs of YELLOW LEAD and GREEN LEAD.
Study Design	One Site
Sample Size	One Subject
Study Population	Adult patient with bradycardia
Geographic Area	United States
Study Duration	Up to 2 weeks
Procedure Description	Implantable pulse generator
Primary Objective	Efficacy of pacing lead
Primary Endpoints & Follow-up Intervals	Non-inferiority versus Standard of care
Schedule of Assessments	See next Table

Table 2. Protocol Details

SCHEDULE OF EVENTS

	Visit 1	Visit 2	Visit 3	Visit 4	Unscheduled	Visit 5
	Screening (Day -1>1)	**Implant Proced**	**Discharge (Day 3)**	**Follow-up (Day 30)**	**System Modification (Day 31)**	**Follow-up 2 (Day 61)**

			ure (Day 2)				
SDTM	**Study Assessments**						
DS	Informed Consent	X					
DS	Randomization	X					
PR	Procedure for Pacemaker		X				
AE	AE				X		
DS	Discharge			X			
CE/PR/HO/HE	Radiography				X	X	
PR/HO/HE	Procedure 2 for replacement					X	
DS	Discharge 2						X
EG	ECG		X			X	
DI/DO/DT	The device as is at the site	X					
DU/DX/DR/DT	The device as implanted in the subject		X				
DX/DE/DT	The device malfunction					X	
DT	The device as shipped back to the sponsor after being explanted						X

Table 3. Schedule of Events for Pacemaker Guy

LLUSTATION OF MEDICAL DEVICE DOMAINS FOR PACEMAKER GUY

DEVICE IDENTIFIERS (DI)

The DI domain provides a method of identifying each device and component uniquely, and this is accomplished by creating a SPDEVID for each. Generally, the data for this domain will be derived, but there may be cases where it is collected on a CRF.

STUDYID	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
CDISCLWO	LWO001	1	DEVTYPE	Device Type	IMPLANTABLE PACING SYSTEM
CDISCLWO	LWO001	2	MANUF	Manufacturer	RELIABLE CARDIOVASCULAR SOLUTIONS, INC.
CDISCLWO	LWO003-01	3	DEVTYPE	Device Type	IMPLANTABLE PACEMAKER PULSE-GENERATOR
CDISCLWO	LWO003-01	4	MANUF	Manufacturer	RELIABLE CARDIOVASCULAR SOLUTIONS, INC.
CDISCLWO	LWO003-01	5	MODEL	Model	RELIABLE PM GENERATOR
CDISCLWO	LWO003-01	6	SERIAL	Serial Number	629PAF
CDISCLWO	LWO002-01	7	DEVTYPE	Device Type	RV PACING LEAD
CDISCLWO	LWO002-01	8	MANUF	Manufacturer	RELIABLE CARDIOVASCULAR SOLUTIONS, INC.
CDISCLWO	LWO002-01	9	MODEL	Model	RELIABLE RV ELECTRODE
CDISCLWO	LWO002-01	10	SERIAL	Serial Number	258TRED
CDISCLWO	LWO002-02	11	DEVTYPE	Device Type	RA LEAD
CDISCLWO	LWO002-02	12	MANUF	Manufacturer	RELIABLE CARDIOVASCULAR SOLUTIONS, INC.

Table 4. Device Identifiers - di.xpt

DEVICE PROPERTIES (DO)

The DO domain represents characteristics of the device that do not change over the course of the study. Typically, the properties recorded here are ones that are important for understanding the data. The characteristics recorded for this study are the length of the leads, the range of lead impedance, and the expiration date for the generator. Using too short a lead is a possible contributing factor to why the lead dislodged, and the impedance data defines the range within which the impedance for each lead can be set. Expiration dates are also often tracked. This domain will almost always be derived, with the information coming from the protocol or manufacturing records (e.g., device expiration date). The derivation is usually done in the SDTM dataset environment, and it is very unlikely that the source would be a CRF.

STUDYID	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOORRES	DOORRESU
CDISCLWO	LWO002-01	1	LENGTH	LENGTH	50	CM
CDISCLWO	LWO002-01	2	LIMPRNGU	LEAD IMPEDANCE UPPER RANGE	1000	OHMS
CDISCLWO	LWO002-01	3	LIMPRNGL	LEAD IMPEDANCE LOWER RANGE	300	OHMS
CDISCLWO	LWO003-01	4	EXPDTC	EXPIRATION DATE	10/25/2025	

Table 5. Device Properties - do.xpt

DEVICE IN-USE (DU)

The DU domain represents data describing settings for devices as used with individual subjects. Typical settings for a pacemaker are electrical signal width and electrical signal amplitude.

STUDYID	USUBJID	SPDEVID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DULOC
CDISCLWO	CDISCLWO-018-03	LWO002-01	SIGW	ELECTRICAL SIGNAL WIDTH	0.3	MS	HEART, VENTRICLE
CDISCLWO	CDISCLWO-018-03	LWO002-01	SIGAMP	ELECTRICAL SIGNAL AMPLITUDE	1.5	VOLTS	HEART, VENTRICLE

Table 6. Device In-Use - du.xpt

DEVICE EXPOSURE (DX)

This example includes records of the subject's direct interaction or contact with the medical device under study. This example of the DX dataset is derived from the PR domain, as the device exposure data are captured on the procedures/surgery form. Because the first lead was removed, and the replacement implanted during the same surgery, the start date of second procedure is the end date of the exposure record for the removed lead.

STUDYID	USUBJID	SPDEVID	DXTRT	DXLOC	DXSTDTC	DXENDTC
CDISCLWO	CDISCLWO-018-03	LWO003-01	IMPLANTABLE PACEMAKER PULSE-GENERATOR	CHEST	6/9/2015	
CDISCLWO	CDISCLWO-018-03	LWO002-01	RV PACING LEAD	HEART, VENTRICLE	6/9/2015	6/16/2015
CDISCLWO	CDISCLWO-018-03	LWO002-02	RA LEAD	HEART, ATRIUM	6/9/2015	
CDISCLWO	CDISCLWO-018-03	LWO002-03	RV PACING LEAD	HEART, VENTRICLE	6/16/2015	

Table 7. Device Exposure - dx.xpt

DEVICE SUBJECT RELATIONSHIP (DR)

The DR domain represents the relationships among all devices and all subjects. It is intended to be a "look-up" table or index, allowing Programing functions to find associated data even if the corresponding ID variables are not present. For example, if the Vital signs dataset (which usually does not have the device identifier, SPDEVID) needed to be merged

with the Device Events dataset (which may not have the USUBJID), the DR table can provide that connection. This domain will almost always be derived, as it is most likely that the information can be obtained from another CRF (e.g., DX, PR), rather than being collected.

STUDYID	USUBJID	SPDEVID
CDISCLWO	CDISCLWO-018-03	LWO001
CDISCLWO	CDISCLWO-018-03	LWO002-01
CDISCLWO	CDISCLWO-018-03	LWO002-02
CDISCLWO	CDISCLWO-018-03	LWO003-01

Table 8. Device Subject Relationship - dr.xpt

DEVICE EVENT (DE)

The DE is represented in this example as a free text field (in DETERM), a coded value (in DEDECOD), and a numeric FDA-required codelist value (in DEPROBCD). The value in DEDECOD (not shown in the table below due to space limitation) is the code derived from the FDA's Problem Code List, and the FDA code portion (DEPROBCD) is stored in SUPPDE since it's a non-standard variable but is required by the FDA. See the STDMIG-MD for a link to the FDA's Problem Code List.

The end date is not always applicable for a device event. For example, when the abraded lead is discovered, that would mark the beginning of the event, as that is when it is first identified. The lead is explanted, and never repaired, so there isn't an end date for such an event. As a result, data capture allows for the user to enter an NA (not applicable) to indicate that there is no relevant end date, but the event isn't really ongoing (i.e., it will never have an end date), but this is not relevant to the assessment of the device performance. When moving the data from CDASH into the SDTM datasets, the end date value of NA is not transferred, as it is an administrative field that is used for data cleaning. For cases where there is no end date, no further action is taken in creating the SDTM datasets; the apparent inconsistency of having no end date and no ongoing status in relative timing variables can be addressed in the Study Data Reviewer's Guide.

STUDYID	USUBJID	SPDEVID	DETERM	DECAT	DEACNDEV	DESTDTC	MIDS
CDISCLWO	CDISCLWO-018-03	LWO002-01	LOW IMPEDANCE	EQUIPMENT FAILURE	EXPLANTED	6/16/2015	
CDISCLWO	CDISCLWO-018-03	LWO002-01	INSULATION ABRASION	EQUIPMENT FAILURE	EXPLANTED	6/16/2015	
CDISCLWO	CDISCLWO-018-03	LWO002-01	LEAD DISLODGEMENT	EQUIPMENT FAILURE	EXPLANTED	6/16/2015	AESURG1

Table 9. Device Events - de.xpt

DEVICE TRACKING (DT)

The DT domain represents the data showing how the device and/or its components physically move throughout the study. The sponsor will decide whether faulty components are returned; in this case, all components represented in Device Events will be returned if removed from the subject. Generally, the "location" represents a party who is legally responsible for the device from a tracking/disposition perspective, rather than an individual or geographical location. Here, the sponsor sends the pacemaker (generator and two leads) to the site, who implants it into the subject. When the subject presents with bradycardia, one lead is removed and returned to the sponsor, while another lead is implanted.

STUDYID	SITEID	SPDEVID	DTTERM	DTDECOD	DTPARTY	DTPRTYID	DTSTDTC
CDISCLWO	18	LWO003-01	SHIPPED	SHIPPED	SITE	18	5/23/2015
CDISCLWO	18	LWO002-01	SHIPPED	SHIPPED	SITE	18	5/23/2015
CDISCLWO	18	LWO002-02	SHIPPED	SHIPPED	SITE	18	5/23/2015
CDISCLWO	18	LWO002-03	SHIPPED	SHIPPED	SITE	18	5/23/2015
CDISCLWO	18	LWO003-01	IMPLANTED	IMPLANTED	SUBJECT	018-03	6/9/2015
CDISCLWO	18	LWO002-01	IMPLANTED	IMPLANTED	SUBJECT	018-03	6/9/2015
CDISCLWO	18	LWO002-02	IMPLANTED	IMPLANTED	SUBJECT	018-03	6/9/2015
CDISCLWO	18	LWO002-01	EXPLANTED	EXPLANTED	SITE	18	6/16/2015

CDISCLWO	18	LWO002-03	IMPLANTED	IMPLANTED	SUBJECT	018-03	6/16/2015
CDISCLWO	18	LWO002-01	SHIPPED	SHIPPED	SPONSOR		6/29/2015

Table 10. Device Tracking and Disposition – dt.xpt

ILLUSTATION OF SDTMIG STANDARD DOMAINS FOR PACEMAKER GUY

DEMOGRAPHICS (DM)

STUDYID	USUBJID	DOMAIN	SITEID	SUBJID	SEX	RACE	AGE	ETHNIC	ARM
CDISCLWO	CDISCLWO-018-03	DM	18	018-03	M	CAUCASIAN	63	HISPANIC OR LATINO	

Table 11. Demographics

DISPOSITION (DS)

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD
CDISCLWO	DS	CDISCLWO-018-03	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED
CDISCLWO	DS	CDISCLWO-018-03	2	COMPLETED	COMPLETED
CDISCLWO	DS	CDISCLWO-018-03	3	RANDOMIZED	RANDOMIZED
CDISCLWO	DS	CDISCLWO-018-03	4	COMPLETED	COMPLETED
CDISCLWO	DS	CDISCLWO-018-03	5	COMPLETED	COMPLETED

DSCAT	EPOCH	DSSTDTC	DSSTDY
PROTOCOL MILESTONE		2015-06-02	-7
DISPOSITION EVENT	SCREENING	2015-06-02	-7
PROTOCOL MILESTONE		2015-06-02	-7
DISPOSITION EVENT	PROCEDURE	2015-06-09	9
DISPOSITION EVENT	FOLLOW-UP	2015-06-23	15

Table 12. Disposition

ADVERSE EVENTS (AE)

STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AEDECOD
CDISCLWO	AE	CDISCLWO-018-03	52	1	INCISION SITE PAIN	INCISION SITE PAIN
CDISCLWO	AE	CDISCLWO-018-03	53	2	FATIGUE	FATIGUE
CDISCLWO	AE	CDISCLWO-018-03	54	3	BRADYCARDIA	BRADYCARDIA
CDISCLWO	AE	CDISCLWO-018-03	55	4	SYSTEMIC INFECTION	SYSTEMIC INFECTION

AESEV	AESER	AESCONG	AESDISAB	AESDTH	AESHOSP	AESLIFE
MODERATE	N	N	N	N	N	N
MILD	N	N	N	N	N	N
MODERATE	Y	N	N	N	Y	N
MODERATE	Y	N	N	N	N	N

AESMIE	AESINTV	AEACNDEV	AEACNOTH	AEREL	AERLPRT	AERLPRC
N	N	MULTIPLE	CIPRO	MULTIPLE	NOT RELATED	RELATED
N	N	MULTIPLE		MULTIPLE	NOT RELATED	NOT RELATED
N	Y	MULTIPLE		MULTIPLE	NOT RELATED	NOT RELATED
N	Y	MULTIPLE	HOT COMPRESS	MULTIPLE	NOT RELATED	POSSIBLY RELATED

AEUNANT	AEOUT	AESTDTC	AEENDTC	*AESTDY*	*AEENDY*	MIDS	RELMIDS	MIDSDTC
Y	RECOVERED/ RESOLVED	2015-06-11	2015-06-13	3	5	AESURG1	DURING	6/13/2015
N	RECOVERED/ RESOLVED	2015-06-13	2015-06-17	5	9			
N	RECOVERED/ RESOLVED	2015-06-13	2015-06-17	5	9	AESURG1	DURING	6/13/2015
N	RECOVERED/ RESOLVED	2015-06-13	2015-06-30	5	22			

SUPPAE Dataset for AEACNDEV and AEREL

QNAM	QLABEL	QVAL
AEACNPG	Action Taken with Pulse Generator	NONE
AEACNRV	Action Taken with RV Pacing Lead	REPLACED LEAD
AERELPG	Causality of Pulse Generator	NOT RELATED
AERELRV	Causality of RV Pacing Lead	RELATED

Table 13. Adverse Events

PROCEDURES (PR)

In the following example, the non-standard variable PRREAS is used in the parent domain for illustrative purposes. In actuality, PRREAS would go in the supplemental qualifier domain for PR.

STUDYID	DOMAIN	USUBJID	SPDEVID	PRSEQ	PRTRT	PRDECOD
CDISCLWO	PR	CDISCLWO-018-03	LWO001	1	IMPLANTATION	IMPLANTATION
CDISCLWO	PR	CDISCLWO-018-03		2	RADIOGRAPH	RADIOGRAPHY
CDISCLWO	PR	CDISCLWO-018-03	LWO002-01	3	EXPLANTED	EXPLANTATION
CDISCLWO	PR	CDISCLWO-018-03	LWO002-03	4	IMPLANTED	IMPLANTATION

PRINDC	PRREAS	PRLOC	VISITNUM	VISIT	VISITDY
ATRIAL FIBRILLATION			2	PROCEDURE	1
BRADYCARDIA		CHEST	4.1	UNSCHEDULED	9
BRADYCARDIA	LEAD ABRASION		4.1	UNSCHEDULED	9
BRADYCARDIA	IMPLANT REPLACEMENT LEAD		4.1	UNSCHEDULED	9

PRSTDTC	PRENDTC	PRSTDY	PRENDY
2015-06-09	2015-06-09	1	1
2015-06-17	2015-06-17	9	9
2015-06-17	2015-06-17	9	9
2015-06-17	2015-06-17	9	9

Table 14. Procedures

ECG TEST RESULTS (EG)

STUDYID	USUBJID	DOMAIN	EGTESTCD	EGTEST	EGORRES	EGDTC
CDISCLWO	CDISCLWO-018-03	EG	EGINTP	Interpretation	BRADYCARDIA	2015-06-17
CDISCLWO	CDISCLWO-018-03					

Table 15. ECG Test Results

CONCLUSION

This paper has shown that there is a way forward to implement CDISC Standards in a practical real-life situation in a medical-device environment. From this Pacemaker Guy example, there is no mystery. One can collect medical device data and have links with the subject data.

REFERENCES

Nair R, Lu L. "Good Practice in PMA Submissions for Efficient Regulatory Decision Making." *Presented at the 7th Annual FDA/MTLI Medical Device and Diagnostics Statistical Issues Workshop*, Washington, DC, April 29-30, 2014. http://www.cdisc.org/system/files/all/Education/Good%20Practice%20in%20PMA%20Submissions%20for%20Efficient%20Regulatory.pdf

Nair R, Howard K, Smoak C, Wood F. "How Can CDISC Help CDRH?" Poster presented at the PhUSE Annual Computational Science Symposium, Silver Springs, MD, March 15-17, 2015. http://www.phusewiki.org/docs/CSS2015Presentations/PP16FINAL.pdf

Smoak C, Wood F, Facile R, Howard K. "Seven New SDTM Domains for Medical Devices." *Proceedings of the Pharmaceutical Industry SAS® Users Group,* San Francisco, CA, May 13-16, 2012. http://www.lexjansen.com/pharmasug/2012/DS/PharmaSUG-2012-DS05.pdf

ACKNOWLEDGMENTS

The authors would like to gratefully acknowledge the work of the Medical Device CDASH and Leadership teams for their contributions to Pacemaker Guy. Amongst the people who helped to develop the concept of Pacemaker Guy we would like to acknowledge the contribution of Kit Howard who has co-led this team for many years. We would also like to acknowledge the contributions of Henry Friend, Paul Franson and others who worked on the Pacemaker Guy concept.

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