

INTRODUCTION

LivaNova (LN) is a global leader medical device company and heart valves (HV) are a key product in its portfolio.

We are showing the creation of Study Data Tabulation Model (SDTM) Medical Device (MD) domains in a real case from LivaNova HV clinical studies.

Not all device-related data need to be stored in MD datasets since also traditional SDTM can properly contain device data.

The purpose of this project is the design of a map to link device-related data to the appropriate domain.

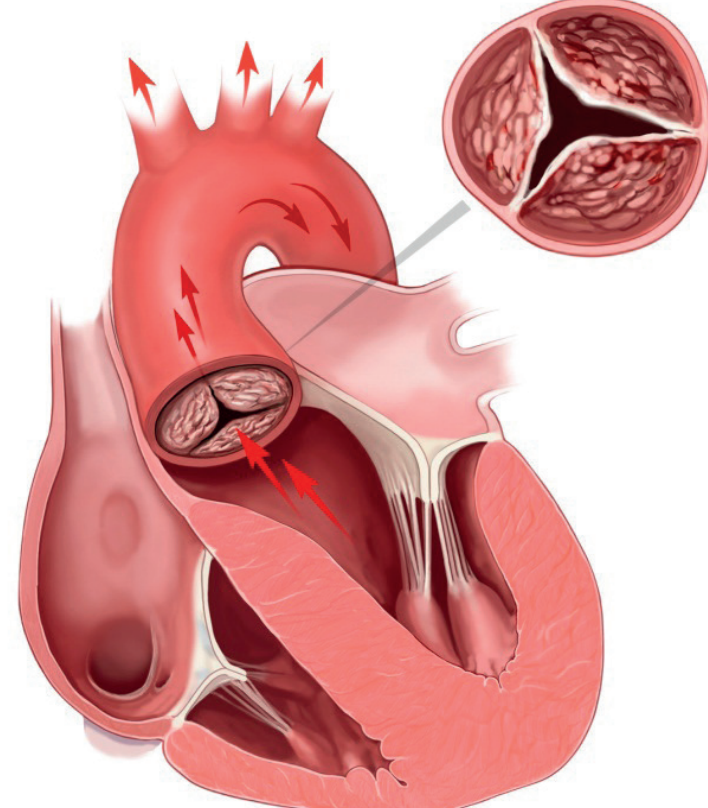


FIG. 1 A native valve affected by aortic stenosis

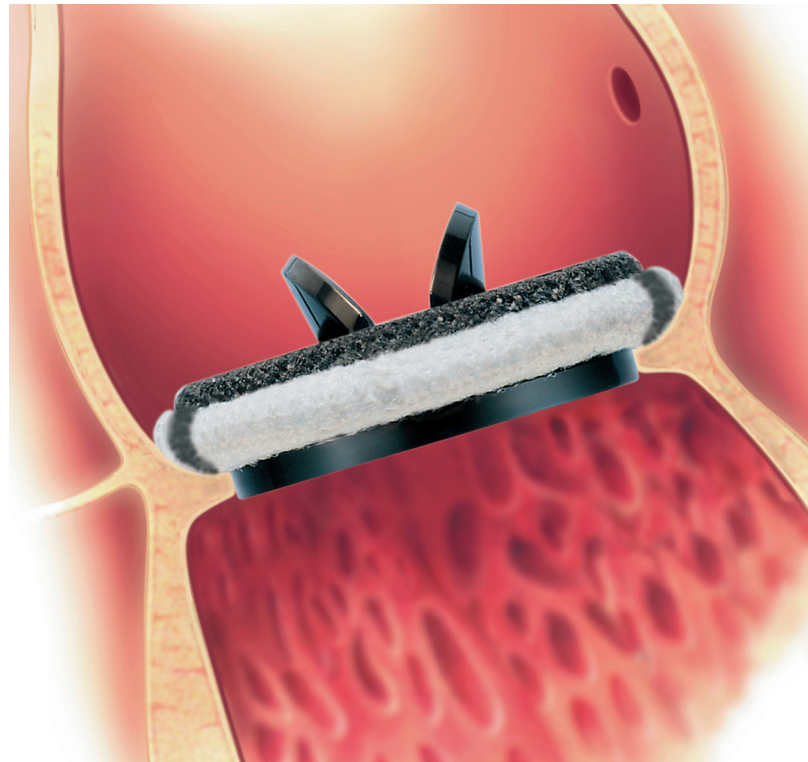


FIG. 2 LN CARBOMEDICS valve placement

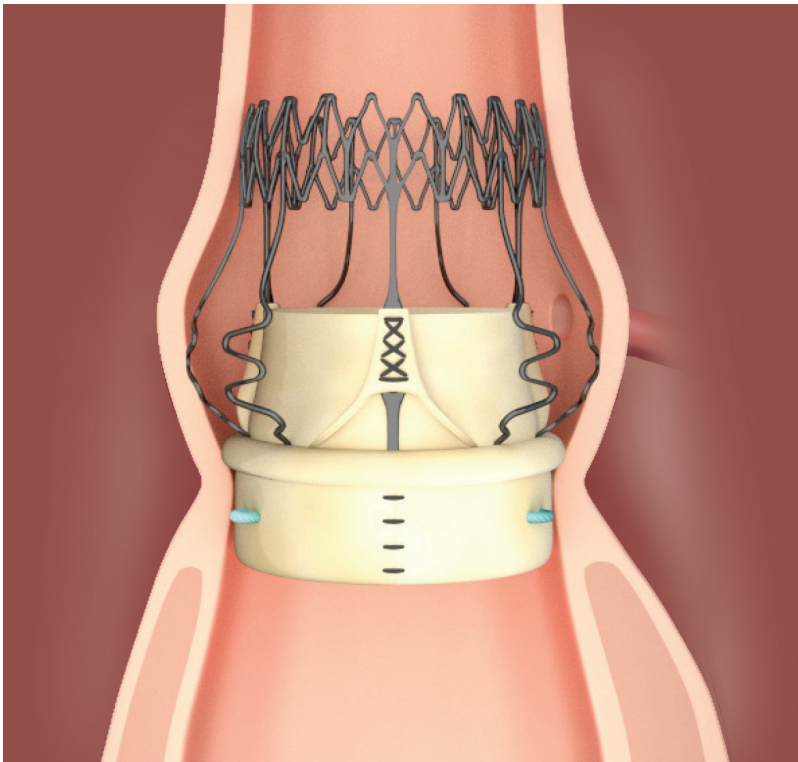


FIG. 3 LN PERCEVAL valve placement

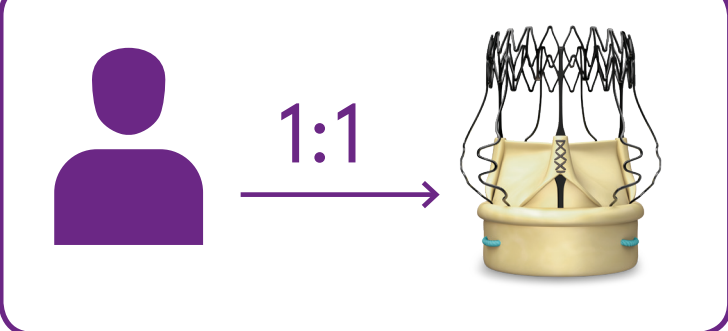
STUDY OVERVIEW



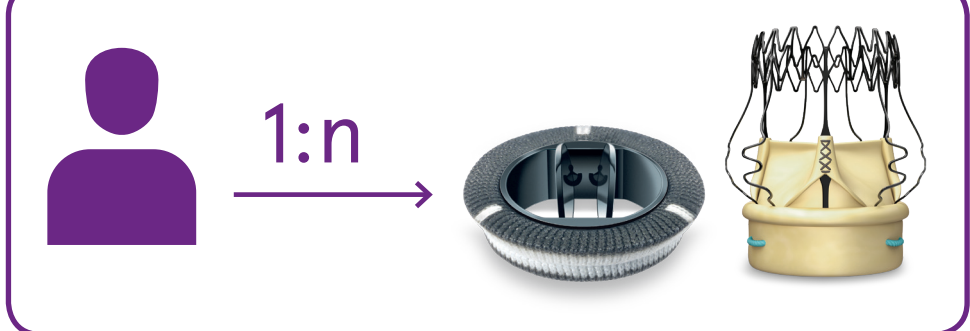
The objective of LN HV clinical studies is typically to evaluate safety and efficacy on implanted patients. Key device-related steps are:

- Implant details
- HV characteristics
- Adverse Events
- Device Deficiencies
- Explant

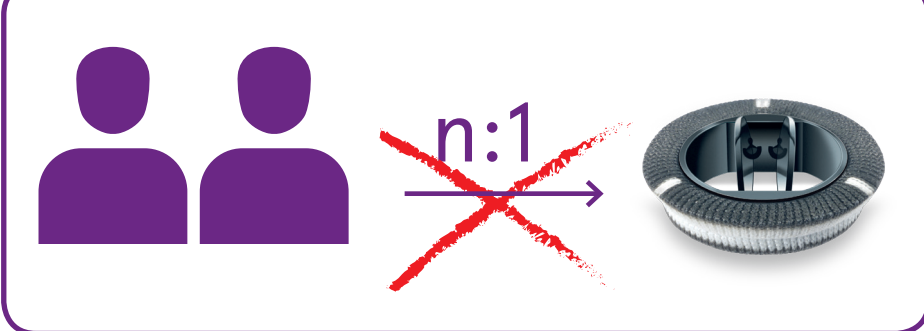
How to map data collected in these phases into SDTM domains?



1:1



1:n



n:1

	Implant details	HV characteristics	Adverse Events	Device Deficiencies	Explant
DI		✓			
DR	✓	✓			
DX	✓				✓
DO	✓	✓			
DE	✓			✓	✓
DT	✓				✓
PR	✓				✓
AE			✓		

SDTM-MD

By definition, the Device In-Use (DU) domain contains properties of the device that can vary over the course of the study. Due to the nature of HVs, DU is not used.

MAPPING SDTM DOMAINS

The Sponsor Device Identifier (SPDEVID) is the only variable always required in MD domains. The Unique Subject Identifier (USUBJID) is required only in DR and DX domains. Even if into the CRF human subjects and valves data are already linked, the data must be rearranged in the proper domains using CDISC structure.

DI DEVICE IDENTIFIERS

DOMAIN	SPDEVID	DIPARMCD	DIPARM	DIVAL
DI	ABC1234	DEVTYPE	Device Type	Valve
DI	ABC1234	MANUF	Manufacturer	LivaNova PLC
DI	ABC1234	MODEL	Model Identifier	Perceval
DI	ABC1234	SERIAL	Serial Number	ABC1234
DI	ABC1234	VALVENUM	Valve Number	2
DI	ABC1234	MANSITE	Manufacturer Site	Vancouver

CDISC Controlled Terminology

LivaNova SDTM Library

In case that serial number is not available, SPDEVID is derived by concatenating other information, such as subject ID and valve number.

DO DEVICE PROPERTIES

DOMAIN	SPDEVID	DOTESTCD	DOTEST	DOORRES
DO	XYZ9999	LVLVSIZE	Labeled Valve Size	S (21mm)
DO	ABC1234	LVLVSIZE	Labeled Valve Size	M (23mm)
DO	DEF5678	LVLVSIZE	Labeled Valve Size	L (25mm)

DE DEVICE EVENTS

DOMAIN	SPDEVID	USUBJID	DETERM	DECAT	DEACNDEV	DESTDTC
DE	XYZ9999	ITA1001	Sizing, positioning or deployment difficulties	VALVE NOT IMPLANTED	Another Valve Used	2018-09-27
DE	DEF5678	USA6001	Material Deformation	DEFICIENCY	Explant	2018-10-16

DE domain could contain reasons for not implanting the valve or general device deficiencies.

AE ADVERSE EVENTS

DOMAIN	USUBJID	AETERM	AEREL	SPDEVID
AE	ITA1001	Myocardial infarction	RELATED	ABC1234
AE	ITA1001	Acute kidney injury	NOT RELATED	
AE	USA6001	Aortic regurgitation	RELATED	DEF5678

AEREL column ("Relationship to Study Treatment") refers to the relationship to the HV. SPDEVID is populated for valve-related AEs to ensure traceability.

DR DEVICE- SUBJECT RELATIONSHIP

DOMAIN	USUBJID	SPDEVID
DR	ITA1001	XYZ9999
DR	ITA1001	ABC1234
DR	USA6001	DEF5678

DX DEVICE EXPOSURE

DOMAIN	USUBJID	SPDEVID	DXTRT	DXMETHOD	DXSTDTC	DXENDTC
DX	ITA1001	ABC1234	VALVE	SURGICAL	2018-09-27	
DX	USA6001	DEF5678	VALVE	SURGICAL	2018-03-16	2018-10-16

Implant date

Explant date

DT DEVICE TRACKING AND DISPOSITION

DOMAIN	SPDEVID	DTTERM	DTPARTY	DTPRTYID	DTSTDTC
DT	XYZ9999	NOT IMPLANTED	SITE	ITA1	2018-09-27
DT	ABC1234	IMPLANTED	SUBJECT	ITA1001	2018-09-27
DT	DEF5678	IMPLANTED	SUBJECT	USA6001	2018-03-16
DT	DEF5678	EXPLANTED	SPONSOR	LIVANOVA	2018-10-16

The not implanted valves (NOT IMPLANTED or EXPLANTED) could remain in the site or return to LivaNova PLC.

PR PROCEDURE

DOMAIN	USUBJID	PRTRT	PRCAT	PRSTDTC	PRENDTC	SPDEVID
PR	ITA1001	Skin-to-skin	Implant Procedure	2018-09-27T09:07	2018-09-27T13:05	ABC1234
PR	ITA1001	Extracorporeal circulation	Implant Procedure	2018-09-27T10:26	2018-09-27T12:18	ABC1234
PR	ITA1001	Cross clamp	Implant Procedure	2018-09-27T10:44	2018-09-27T12:05	ABC1234
PR	ITA1001	Valve Implant	Implant Procedure	2018-09-27T11:00	2018-09-27T11:55	ABC1234
PR	ITA1001	CABG	Implant Concomitant Procedure	2018-09-27	2018-09-27	

CONCLUSIONS AND FUTURE DEVELOPMENT

For medical devices FDA submissions CDSIC SDTM are not yet mandatory, but LivaNova SDM department is adopting CDISC Standards also for internal purposes, e.g.: process and terminology standardization, pooling analyses.

LivaNova SDTM Library has already been enhanced with cardiac surgery terminology, and in the future it will expand to neuromodulation as well.

REFERENCES

1) "Study Data Tabulation Model (SDTM)" Version 1.7, www.cdisc.org.

2) "Study Data Tabulation Model Implementation Guide: Human Clinical Trials (SDTMIG)" Version 3.3, www.cdisc.org.

3) "Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)" Version 1.1, www.cdisc.org.