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2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION

MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Bringing SDTM to Medical Device

Practical Challenges, Implementation Strategies and a Glimpse on GF Domain

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Speaker

Graduated with the master's degree in Statistics and Data Science at "Università degli Studi di Firenze" in 2022.
He's actually working as Clinical Data Specialist at Aboca Italia in Sansepolcro. He's up to the Innovation & Medical Science department, where his main duties are the internalization and digitization of clinical trial data, starting from CSV files to SDTM. Everything is set to respect CDISC standards for clinical regulation.

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Agenda

1. The Context: Aboca and Medical Devices
2. Challenges and Process Flow
3. In-depth with Domains
4. Conclusions and Future Developments

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What is Aboca?

Aboca is an Italian healthcare company, founded in 1978 in Sansepolcro, Tuscany, focused on 100% natural and biodegradable products for health.

Our approach is based on scientific evidence and Systems Medicine, which studies how everything in the body is interconnected, much like nature itself.

We manage the entire supply chain, from organic cultivation to production, counting around 2,000 employees.

Finally, Aboca is also a Benefit Corporation, meaning it is legally committed to balancing profit with positive social and environmental impact and strongly interested in culture.

What is a Medical Device?

According to the EU Medical Device Regulation (MDR 2017/745), a medical device is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process;
- providing information by means of in vitro examination of specimens derived from the human body.

Unlike medicinal products (drugs), medical devices do not achieve their principal intended action by pharmacological, immunological or metabolic means — even if they may be assisted by them.

More of MD

Risk Class	Description	Typical examples
Class I (low risk)	Non-invasive or minimally invasive devices, simple use, low impact on the body	Bandages, manual wheelchairs, reading glasses
Class IIa (low-to-medium risk)	Invasive for short-term use, or with more complex functions but not high risk	Hearing aids, dental fillings, contact lenses, cough syrup
Class IIb (medium-to-high risk)	Longer-term invasive, active therapeutic devices, or those with higher potential impact if malfunctioning	Infusion pumps, long-term invasive surgical devices, eye lubricant (artificial tears)
Class III (high risk)	Highest-risk devices, usually life-supporting, implantable, or with critical safety concerns	Pacemakers, heart valves, hip and knee replacements, injectable gel for aesthetic use

EU Regulation 2023/607

- Amends MDR (2017/745) and IVDR (2017/746).
- All devices must be re-evaluated and certified in accordance with the new rules, which are stricter, especially regarding claims and clinical evidence.
- Conditionally extends transition periods for legacy devices (2027/2028).
- Removes the “sell-off” deadline.

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MD vs. Drug

	MD	Drug
Phases	Feasibility studies, pre-market, post-market	Phase I, Phase II, Phase III, Phase IV
Number of patients	Generally low	Generally high, especially in Phase III
Goals	Security, technical performance, usability	Clinical endpoints
Legislation	ISO 14155, MDR 2017/745	Regulation EU No 536/2014
Timing	Generally faster studies	Longer and more expensive studies
Duties	Mandatory only for high-risk class or innovative devices	Always mandatory for new molecules

Since medical device studies were mostly based on patient diaries and surveys rather than objective parameters, and did not require submission, we had to face several challenges

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Challenges

- **Standardization gap**: absence of formal CDISC procedures for legacy studies and new projects
- **Data quality**: structural data errors prevented linear mapping
- **Closed studies**: constraints on making modifications necessitated workarounds
- **CROs difference**: inconsistent data and limited process control

Benefits

- **Efficiency**: harmonizing data facilitates the production of a Data Transfer Agreement (DTA) to be sent to CROs.
- **Consistency and quality across studies**: standardized mapping enables comparisons and integration of data
- **Long-term reusability**: standardized data becomes reusable for future projects, saving time and resources
- **Regulatory compliance**: improving data quality reduces audit risk and accelerates regulatory submissions

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Process Flow

Close work with the clinical team
Define goals, expectations, and timelines

Establish internal standards and tools for consistency across studies
Define controlled terminology

Map variables of interest
- ODM generation
- SDTM mapping

Data Flow

Excel/CSV file
- First line contains names
- | as separator

ODM file
- Field for Subject ID
- Field for StudyEvent

SDTM mapping

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Special Purpose

Domain	Main variables
DM	SUBJID, RFSTDTC, RFENDTC, RFICDTC, RFPENDTC, SITEID, AGE, AGEU, SEX, RACE, COUNTRY
SV	VISITNUM, VISIT, SVPRESP, SVOCCUR, SVSTDTC, SVENDTC

Event

Domain	Main variables
AE	AETERM, AEMODIFY, AELLT, AELLTCD, AEDECOD, AEPTCD, AEHLT, AEHLTCD, AECAT, AEPRESP, AESEV, AESER, AEACN, AEACNOTH, AEREL, AEOUT, AESCONG, AEDISAB, AESDTH, AESHOSP, AESLIFE, AESINTV, AECONTRT, AESTDTC, AEENDTC, AESTRF, AEENRF
DS	DSTERM, DSDECOD, DSCAT, DSSTDTC, KIT, STS, CLSR
MH	MHTERM, MHDECOD, MHCAT, MHPRESP, MHOCCUR, MHSTAT, MHREASND, MHSTDTC, MHENDTC, MHENRF, MHSTRF

Findings

Domain	Main variables
DA	DATESTCD, DATEST, DAORRES, DAORRESU, DASTRESC/DASTRESN, DASTRESU, DASTAT, DAREASND, VISITNUM, VISIT, DADTC
GF	GFTESTCD, GFGENREF, GFORRES
IE	IETESTCD, IETEST, IECAT, IEORRES, IETRESC, VISITNUM, VISIT, IEC
LB	LBTESTCD, LBTEST, LBCAT, LBORRES, LBORRESU, LBORNRLO, LBORNRHI, LBSTRESC/LBSTRESN, LBSTRESU, LBSTNRLO, LBSTNRHI, LBSTAT, LBREASND, LBSPEC, LBLOBXFL, VISITNUM, VISIT, LBDTC
QS	QSTESTCD, QSTEST, QSCAT, QSORRES, QSSTRESC, VISITNUM, VISIT, QSDTC, QSDY, QSTPT
VS	VSTESTCD, VSTEST, VSORRES, VSORRESU, VSSTRESC/VSSTRESN, VSSTRESU, VSSTAT, VSREASND, VISITNUM, VISIT, VSDTC, VSBLFL
XC	XCTESTCD, XCTEST, XCORRES, XCSTAT, XCREASND, XCDTC, SYM

Interventions

Domain	Main variables
CM	CMTRT, CMDECOD, CMCAT, CMSCAT, CMPRESP, CMOCCUR, CMSTAT, CMREASND, CMINDIC, CMDOSE/CMDOSETXT, CMDOSU, CMDOSFRM, CMDOSFRQ, CMROUTE, CMSTDTC, CMENDTC, CMSTRF, CMENRF

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The Challenge

Spreadsheet (26 items)

SDTM

Randomization
Information needed to assign participants to study groups

Premature Discontinuation
Tracks participants who stop the study early before completing all planned visits

Cycles Status
Tracks each participant's progress through every treatment cycle

Cycle Closure
Tracks when each treatment cycle is formally completed

The Solution

	Randomization	Premature Discontinuation	Cycle Status	Cycle Closure
DSTERM	"	Reported Disposition Term	"	"
DSDECOD	Standardized Disposition Term	Standarduized Disposition Term	"	Standardized Disposition Term
DSCAT	Disposition Category	Disposition Category	Disposition Category	Disposition Category
DSSTDTC	Disposition Start Date	Disposition Start Date	"	Disposition Start Date
KIT	New non-standard Variable 1	"	"	"
CLSR	"	"	"	New non-standard Variable 2
STS	"	"	New non-standard Variable 3	"

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The Result

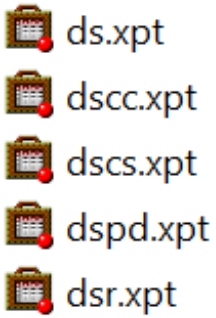
Resulting file after SDTM mapping

DSCS	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DSDECOD	DS.DSCAT
DSCC	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DSDECOD	DS.DSCAT
DSPD	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DSDECOD	DS.DSCAT
DSR	STUDYID	DOMAIN	USUBJID	DS.DSSEQ	DS.DSGRPID	DS.DSREFID	DS.DSSPID	DS.DSTERM	DS.DSDECOD	DS.DSCAT

Transformation

☑ **Additionally generate a merged dataset for 'split' domain datasets**

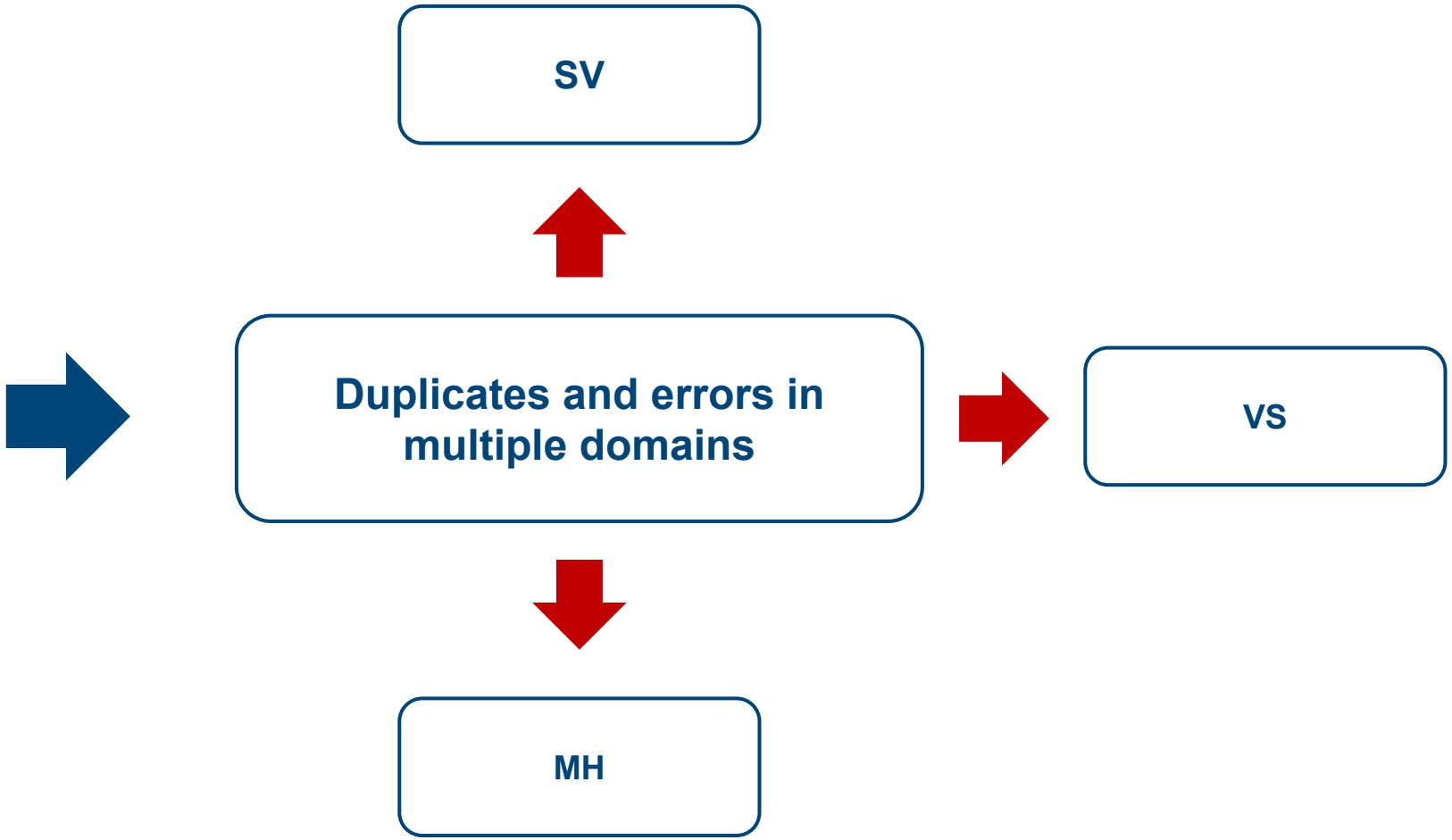
Ready for submission (or loading)



The “Cycle” Problem

Spreadsheet

Subject	Cycle
001-0001	1
002-0017	1
005-0007	1
006-0002	1
007-0019	1
009-0001	1
011-0027	1
012-0008	1
012-0009	1
012-0009	2



Relative pathing

SV

```
$TEMP = xpath(/StudyEventData[./FormData/ItemGroupData/ItemData[@ItemOID='IT.SV.F3' and @ Value='1']]/@StudyEventOID/);

if($TEMP=='SE.V-1') {
$SV.VISITNUM=-1;
} elsif($TEMP=='SE.V0') {
$SV.VISITNUM=0;
} elsif($TEMP=='SE.V1') {
$SV.VISITNUM=1;
} else {
$SV.VISITNUM=999;
}
```

CYCLE 1

```
$TEMP = xpath(/StudyEventData[@StudyEventOID='SE.U-1'][../@SubjectKey='012-0009']
                    [./FormData/ItemGroupData/ItemData[@ItemOID='IT.SV.F3' and @ Value='2']]/@StudyEventOID/);

if($TEMP=='SE.V-1') {
$SV.VISITNUM=-1;
} elsif($TEMP=='SE.V0') {
$SV.VISITNUM=0;
} elsif($TEMP=='SE.V1') {
$SV.VISITNUM=1;
} else {
$SV.VISITNUM=999;
}
```

CYCLE 2

VS

```
$TEMP = xpath(../../../@StudyEventOID);

if($TEMP=='SE.V-1') {
$VS.VISITNUM=-1;
} elsif($TEMP=='SE.V0') {
$VS.VISITNUM=0;
} elsif($TEMP=='SE.V1') {
$VS.VISITNUM=1;
} else {
$VS.VISITNUM=999;
}
```

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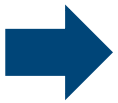
GF Domain

```
GeneName|Subj|Visit|Value
TC0100006437.hg.2|001-0001|0|5.71
TC0100006437.hg.2|001-0001|1|5.93
TC0100006476.hg.2|001-0001|0|8.16
TC0100006476.hg.2|001-0001|1|7.88
TC0100006479.hg.2|001-0001|0|7.36
```

Complete sample
90 MB



Small sample
(4 subjects)
6 MB

BATCH EXECUTION

java –Xms1024 –Xmx8192 –jar *SDTM Executor Name.jar* –DEFINEVERSION *Executor Version*
–DEFINELOCATION *define.xml path\define.xml file name .xml* –STUDYID *Study Name* –ODMVERSION *ODM Version*
–METADATAFILELOCATION *ODM metadata file path\file name .xml (Must be located in the same folder as the Executor)*
–CLINICALDATAFILELOCATION *ODM clinical data file path\file name .xml (Must be located in the same folder as the Executor)*
–GENERATESASXPT –SASXPTDIRECTORYLOCATION *Output file path*

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Conclusion and Tips

- Collaborate with the same CRO: using similar CRFs reduces mapping complexity and supports reusability
- Data quality and sensitivity must be carefully considered and confirmed before broader implementation
- Maintain collaborative document and apply consistent variable usage to ensure efficiency and consistency
- AI tools could improve version control by creating a knowledge base and enabling reuse across projects

In the Future

- Adjustment and enhancement of SDTM datasets to ensure submission compliance, with a focus on the EX/EC domain
- Optimization of the current DTA delivered to the CRO through the integration of CDASH terminology to ensure CDISC submission readiness, followed by analysis based on ADaM standards
- Design and implementation of a CDISC mapping solution for wearable-generated data, intended for data capture only (not for product administration), initially targeting stress and heart rate endpoints

Special thanks to
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Thank you all for your attention!

Questions?