# Clinical Trials with Medical Devices

## Examples and Challenges in Statistical Programming


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PSDM 08-NOV-2022: Programming and Statistics in Medical Device Investigation

# Outline

- Characteristics Medical Devices in Clinical Trials
  - Pharma versus Medical Devices
- Standards in Medical Devices Studies
  - SDTM domains specific for Medical Devices
  - Challenges in applying standards compared to clinical trials in pharma
- Closing remarks

# Pharma versus Medical Devices

# Pharma versus Medical Devices


**Pharma**

- Disease process
- Molecular compounds
- Unanticipated effects of existing treatment
- New technologies

**Medical Devices**

- Unmet medical need
- Classifications
  - Class I
    - Surgical instruments, bandages, wheelchairs, latex gloves
  - Class II
    - Contact lenses, syringes, blood pressure cuffs
  - Class III
    - Pacemakers, breast implants, implanted prosthetics

# Pharma versus Medical Devices


**Pharma**

- In vitro
- In vivo

**Medical Devices**

- Prototype
  - Not for human use

# Pharma versus Medical Devices


**Pharma**

- Phase I: 20-100, healthy
  - Safety & dosage
- Phase II: up to 100, with disease
  - Efficacy & side effects
- Phase III: 300-3000, with disease
  - Efficacy & (less common) side effects
- Phase IV: Several thousand, with disease (post-marketing)
  - Long-term effects

**Medical Devices**

- Regulatory control based on classification
  - Class I least regulatory control
  - Class III most regulatory control
- Single arm with no control group is more common

# Pharma versus Medical Devices


**Pharma**

- New Drug Application (NDA)

**Medical Devices**

- Depends on class
  - Premarket Notification
  - Premarket Approval Application

# Pharma versus Medical Devices

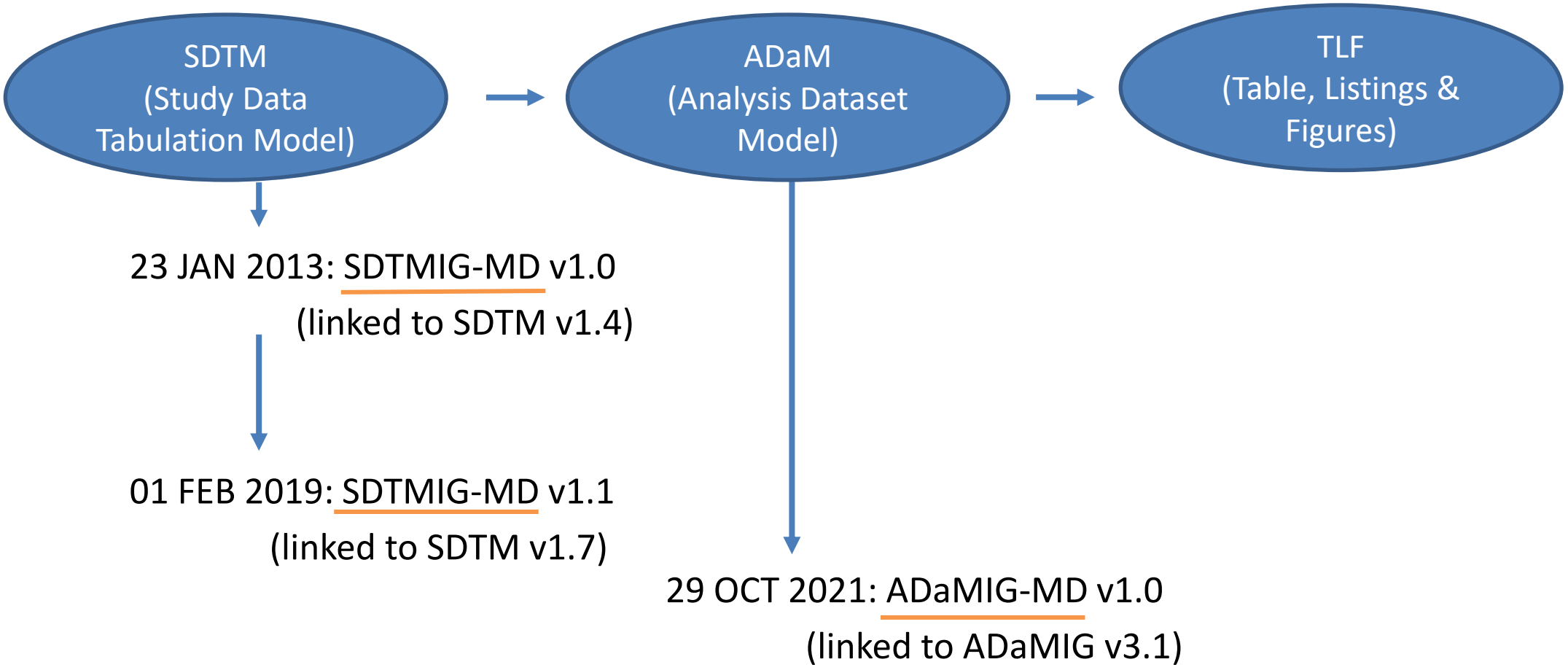

**Pharma**

- Active surveillance

**Medical Devices**

- Active surveillance

# Standards in Medical Devices



# SDTM in Medical Devices

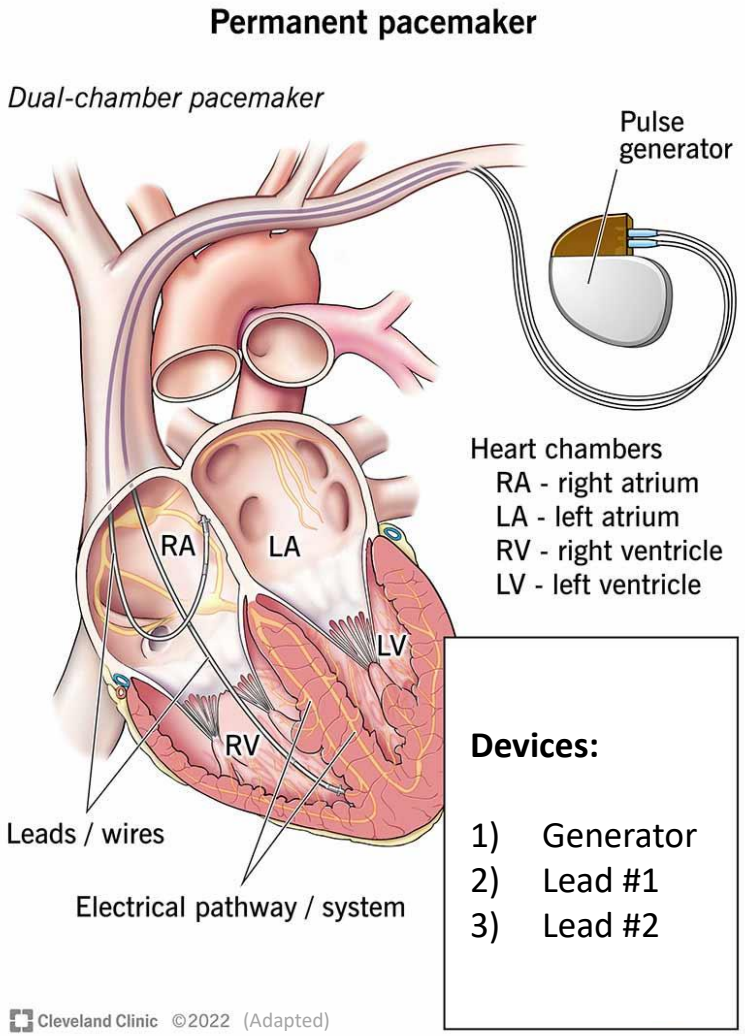
Device Specific domains in SDTM (7 domains)

- DI: Study Device Identifiers
  - 1 subject → multiple devices

**Need to capture device specific information!**

We need to be able to:

- Identify single devices (Lead)
- Identify device configuration (Pacemaker)
- Identify correct devices implanted per subject



# SDTM in Medical Devices

Device Specific domains in SDTM (7 domains)

- DI: Study Device Identifiers

**DI: Study Device Identifiers**

| STUDYID | DOMAIN | SPDEVID | DISEQ | DIPARMCD | DIPARM | DIVAL |
|---|---|---|---|---|---|---|
| *Study Identifier* | *Domain Abbreviation* | *Sponsor Device Identifier* | *Sequence Number* | *Device Identifier Element Short Name* | *Device Identifier Element Name* | *Device Identifier Element Value* |
| ABC-123 | DI | XYZ-789 | 1 | MANUF | Manufacturer | Rods, Co. |
| ABC-123 | DI | XYZ-789 | 2 | MODEL | Model | SuperLynx |
| ABC-123 | DI | XYZ-789 | 3 | SERIAL | Serial Number | 562987 |
| ABC-123 | DI | XYZ-789 | 4 | TYPE | Type of device | Telescoping orthopedic rod |
| … | … | … | … | … | … | … |

# SDTM in Medical Devices

Device Specific domains in SDTM (7 domains)

- DI: Study Device Identifiers
- DO: Device Properties
- DU: Device In-Use

} Device Specific Domains (not related to the subject)

**DO: Device Properties**

| STUDYID | DOMAIN | SPDEVID | DOSE | DOORRESU |
|---|---|---|---|---|
| *Study Identifier* | *Domain Abbreviation* | *Sponsor Device Identifier* | *Sequence Number* | Original Units |
| ABC-123 | DO | XYZ-789 | | T |
| ABC-123 | DO | XYZ-789 | | T |
| … | … | … | … | … |

MRI scanner

# SDTM in Medical Devices

MRI scanner

Device Specific domains in SDTM (7 domains)

- DI: Study Device Identifiers
- DO: Device Properties
- DU: Device In-Use

} Device Specific Domains (not related to the subject)

→ Domains related to the subject

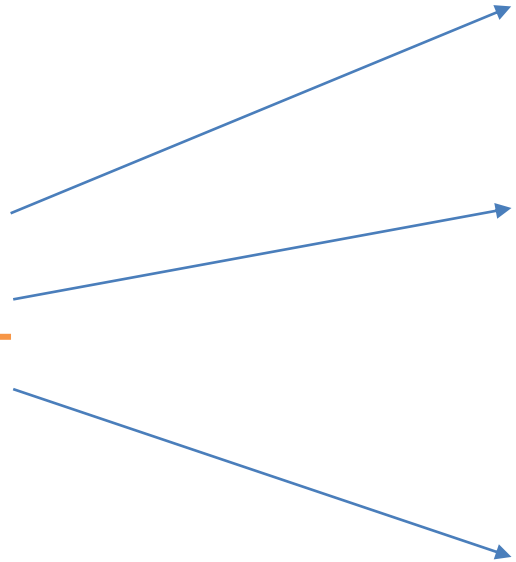
**DU: Device In-Use**

| STUDYID | DOMAIN | USUBJID | SPDEVID | DUSEQ | DUTESTCD | DUTEST | DUORRES | DUORRESU |
|---|---|---|---|---|---|---|---|---|
| *Study Identifier* | *Domain Abbreviation* | *Unique Subject Identifier* | *Sponsor Device Identifier* | *Sequence Number* | *Device In-Use Test Short Name* | *Device In-Use Test Name* | *Result or Finding in Original Units* | Original Units |
| ABC-123 | DU | S00001 | XYZ-789 | 1 | MRISTR | MRI Strength | 1.0 | T |
| ABC-123 | DU | S00002 | XYZ-789 | 1 | MRISTR | MRI Strength | 1.2 | T |
| … | … | … | … | … | … | … | … | … |

# SDTM in Medical Devices

Device Specific domains in SDTM (7 domains)

- DI: Study Device Identifiers
- DO: Device Properties
- DU: Device In-Use
- DR: Device-Subject Relationships
- DT: Device Tracking and Disposition
- DX: Device Exposure
- DE: Device Events



Overview of all devices linked per subject

Shipment
Deployment
Return
Destruction

Information about exposure time from subject to a device

# SDTM in Medical Devices

DE: Device Events domain

*To fill in the gap between adverse events and device malfunction not leading to an adverse event*

| STUDYID | SUBJID | SPDEVID | DESEQ | DETERM | DEDECOD | DECAT |
|---|---|---|---|---|---|---|
| *Study Identifier* | *Unique Subject Identifier* | *Sponsor Device Identifier* | *Sequence Number* | *Reported Term for Device Event* | *Device Events Dictionary-Derived Term* | *Category of Device Event* |
| ABC-123 | SUBJ-001 | XYZ-789 | 1 | Internal communication failure | Communications failure | Equipment Failure |
| … | … | … | … | … | … | … |

# Closing remarks

- Phases in clinical trials in medical devices are fundamentally different from those in pharma

- Huge variety in medical devices (pumps, stents, pacemakers, surgery assistant devices)
  - Device specific information needs to be collected in a standardized manner
  - 1 subject can (and usually will) have multiple devices
  - Besides adverse event, report on device events as well

- Before programming: think about what level the data is required and create datasets accordingly
  - Subject level / Device level

- Implement guidelines from CDISC (even though not always required!):
  - Improves transparency within a study
    consistency across studies
    comparison across studies

# Thank you! Questions?

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