Device Domains: Examples of their Use in Clinical Trials

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Agenda

● Introduction
● Main Points of Device Domains
● First Use-Case
● Second Use-Case
● Challenges
● Conclusion
7 Device Domains

- **(DO)** Device Properties
- **(DU)** Device in-Use
- **(DI)** Device Identifiers
- **(DE)** Device Events
- **(DR)** Device-Subject Relationship
- **(DT)** Device Tracking & Disposition
- **(DX)** Device Exposure
First Use-Case

- The study is designed to evaluate the safety and efficacy of an investigational drug together with varying light dose activated by intra-urethral drug-activating device in male subjects.

- The study device is a customized catheter that consists of light-emitting diodes (LEDs).

- The light dose is delivered for a pre-programmed illumination time, commencing after intravenous administration of the investigational drug.
Scheme of Mapping Device-Specific Data

Device Information
- Device Deployment/Dose
- Device Interruptions
- Device Issues/Events
- Procedure Complications
- Investigational Drug Dose

DX
FA
DE
AE
RELREC

DR ↔ DI ↔ DO

DT
EX
### Form: Drug Activator Use

<table>
<thead>
<tr>
<th>Device Data Identifier</th>
<th>Device Tracking and Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DI - Device Identifiers</strong></td>
<td><strong>DT - Device Tracking and Disposition</strong></td>
</tr>
<tr>
<td><strong>DX - Device Exposure</strong></td>
<td><strong>Includes</strong></td>
</tr>
</tbody>
</table>

- **Device pack ID number:** DIVAL where DIPARM=Pack Number
- **Model number:** DIVAL where DIPARM=Model
- **Serial number:** DIVAL where DIPARM=Serial Number
- **Drug activator insertion date/time:** DXSTDTC where DXTRT=Drug Activator
- **Drug activator device activation date/time:** DXSTDTC where DXTRT=Drug Activator Light
- **Light dose (J/cm):** DXDOSE, DXDGSU
- **Drug activation stop date/time:** DXENDTC where DXTRT=Drug Activator Light
- **Drug activator device removal date/time:** DXENDTC where DXTRT=Drug Activator

**Includes**

- **Device-identification data**
- **Exposure-related data**
Device Data aCRF Pages 2 & 3

Includes

Device events

Device issues

**JE - Device Events**
**DT - Device Tracking and Disposition**

*Form: Device Clinical Incident Report*

Date issue occurred

Description of issue

Device pack ID number:

Will the device be disinfected and returned to manufacturer?

Was there an unexpected adverse reaction?

If yes, specify AE number

**FA - Findings About**

*Form: Drug Activator Interruptions*

Date/time of pausing

Date/time of resumption

Reason for pausing
<table>
<thead>
<tr>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>SPDEVID</th>
<th>DISEQ</th>
<th>DIPARMCD</th>
<th>DIPARM</th>
<th>DIVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20000</td>
<td>1</td>
<td>MANUF</td>
<td>Manufacturer</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20000</td>
<td>2</td>
<td>MODEL</td>
<td>Model</td>
<td>ABC123</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20000</td>
<td>3</td>
<td>PACK</td>
<td>Pack Number</td>
<td>20000</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20000</td>
<td>4</td>
<td>SERIAL</td>
<td>Serial Number</td>
<td>A745631</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20000</td>
<td>5</td>
<td>TYPE</td>
<td>Type of Device</td>
<td>TBD</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20001</td>
<td>1</td>
<td>MANUF</td>
<td>Manufacturer</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20001</td>
<td>2</td>
<td>MODEL</td>
<td>Model</td>
<td>ABC123</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20001</td>
<td>3</td>
<td>PACK</td>
<td>Pack Number</td>
<td>20001</td>
</tr>
<tr>
<td>AB1001</td>
<td>DI</td>
<td>20001</td>
<td>4</td>
<td>SERIAL</td>
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<td>A852746</td>
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<tr>
<td>AB1001</td>
<td>DI</td>
<td>20001</td>
<td>5</td>
<td>TYPE</td>
<td>Type of Device</td>
<td>TBD</td>
</tr>
</tbody>
</table>
DO contains the device structural and functional properties that are not required for identification in the study and which correlate to device effectiveness and safety at the end of the study.

It has a relatively free format in comparison with other device domains and accept a wide variety of data.
Includes 2 kinds of records:
• deployment of the catheter
• light treatment provided via that catheter
### DT – Device Tracking and Disposition

<table>
<thead>
<tr>
<th>DOMAIN</th>
<th>SPDEVID</th>
<th>DTSEQ</th>
<th>DTTERM</th>
<th>DTDECOD</th>
<th>DTPARTY</th>
<th>DTPRTYID</th>
<th>DTCAT</th>
<th>DTSTDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>DT</td>
<td>30252</td>
<td>1</td>
<td>SHIPPED</td>
<td>SHIPPED</td>
<td>SITE</td>
<td>104</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>30252</td>
<td>2</td>
<td>DEPLOYED</td>
<td>DEPLOYED</td>
<td>SUBJECT</td>
<td>1047016</td>
<td></td>
<td>2016-03-24</td>
</tr>
<tr>
<td>DT</td>
<td>30252</td>
<td>3</td>
<td>RETURNED TO MANUFACTURER</td>
<td>RETURNED TO MANUFACTURER</td>
<td>MANUFACTURER</td>
<td>2016-03-24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>30253</td>
<td>1</td>
<td>SHIPPED</td>
<td>SHIPPED</td>
<td>SITE</td>
<td>102</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>30253</td>
<td>2</td>
<td>DEPLOYED</td>
<td>DEPLOYED</td>
<td>SUBJECT</td>
<td>1029012</td>
<td></td>
<td>2015-09-14</td>
</tr>
</tbody>
</table>

There are three main stages of a device:
- shipment to the site
- deployment to the subject
- in case of issues, return to the manufacturer, otherwise, disposal
## DE – Device Events

<table>
<thead>
<tr>
<th>Row</th>
<th>DE</th>
<th>USUBJID</th>
<th>SPDEVID</th>
<th>DES EQ</th>
<th>DES PID</th>
<th>DETERM</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DE</td>
<td>AB1001-1016001</td>
<td>20002</td>
<td>1</td>
<td></td>
<td>THE DEVICE WAS FLASHING ERROR AND WOULDN'T RESTART.</td>
</tr>
<tr>
<td>2</td>
<td>DE</td>
<td>20228</td>
<td>1</td>
<td></td>
<td></td>
<td>STERILE PACKAGING BREACHED</td>
</tr>
<tr>
<td>3</td>
<td>DE</td>
<td>AB1001-1047016</td>
<td>30252</td>
<td>1</td>
<td></td>
<td>CATHETER DID NOT ROTATE BACK APPROPRIATELY</td>
</tr>
<tr>
<td>4</td>
<td>DE</td>
<td>AB1001-1013042</td>
<td>30267</td>
<td>1</td>
<td>2</td>
<td>SUBJECT EXPERIENCED PAIN FROM CATHETER AND WAS REMOVED EARLY</td>
</tr>
<tr>
<td>5</td>
<td>DE</td>
<td>AB1001-1013065</td>
<td>30297</td>
<td>1</td>
<td>1</td>
<td>COMPLICATION WITH PLACEMENT OF DEVICE</td>
</tr>
<tr>
<td>6</td>
<td>DE</td>
<td>AB1001-1066016</td>
<td>30312</td>
<td>1</td>
<td></td>
<td>THE PATIENT INFORMED STUDY COORDINATOR THAT HE HAD SHIFTED AND HIT THE DEVICE, WHEN CHECKED THE DEVICE WAS MOVED</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Row</th>
<th>DEDECOD</th>
<th>DECAT</th>
<th>DEDT DTC</th>
<th>DEDT DY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>COMPUTER SOFTWARE ISSUE</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2015-01-06</td>
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</tr>
<tr>
<td>2</td>
<td>DELIVERED AS UNSTERILE PRODUCT</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2015-08-27</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>DIFFICULT TO REMOVE</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2016-03-24</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>NOT APPLICABLE</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2015-10-21</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>DIFFICULT TO POSITION</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2016-01-18</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>UNINTENDED MOVEMENT</td>
<td>DEVICE CLINICAL INCIDENT REPORT</td>
<td>2016-02-22</td>
<td>1</td>
</tr>
</tbody>
</table>
RELREC has 2 kinds of relationships:

- one-to-one
  (adverse events and device issues)
- one-to-many
  (drug interruptions with light doses)
The objective of the study is:

- Evaluating the benefit of adding a mobile application and wearable activity monitor to the standard of care of knee
- Demonstrating the impact on increasing the mobility of knee
- Determining the percent change in amount of steps per day per patient

Medical device is a set of 3 items:

- Wearable activity monitor
- Smartphone
- Mobile application downloaded on the mobile
Scheme of Mapping Mobile-Specific Data

- **DR**: 1 subject may have more than 1 device combinations
- **DT**: Shipment to the site → Returned to the sponsor → Lost → Destroyed
- **DI**: Mobile serial number, model, manufacturer → Tracker serial number, model, manufacturer → Application name
- **DO**: Application version → Tracker battery life
- **DE**: Application program issue → Battery issue → Charging issue → Connection issue → Loss of Data

Device Information → Device Tracking → Device Issues
Mobile Study Specific

- Unusual for medical sphere devices obtain the data
- Study is unique in the objective of the trial (impact of using the latest technologies such as mobile application)
- SPDEVID represents a unique key created manually to display combination of mobile and wearable activity monitor identifiers
- Neither EX or DX are applicable
- Collected pain and mood assessment responses by the mobile application do not have any place in the Device Domains, so were mapped in the QS domain
Challenges

- Often issue of data collection problems with creating SPDEVID
- Unclear what DIPARMCDs should be created there is a need to involve the sponsor participation
- Not freely available access to GMDN DIPARMCD=TYPE issue
  - DEDECOD is based on Device Problem Codes list difficulties with decoding DETERM
- Could be no data to create EX and DX OpenCDISC error
  - Not all device data fit Device Domains need to find the best place in other SDTMIG models
• Devices are getting increasingly used in medical world. Standardization of collected data for medical device trials is important for efficient data analysis.

• Seven Device Domains were designed to cover different information such as identifiers, characteristics and settings used for each device in the study, details of device deployment or drug exposure and the recording of disposition events or other device-related events such as malfunction.

• The device domains should be used when the investigational product under study is a medical device or if a device is used as an instrument to obtain the measurements or results of the study.

• The SDTM Device Domain model is robust and useful to those who are working in the device area. However there are still challenges with mapping such data.
Questions?

Thank You for Your Attention!

Please feel free to contact:

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