CDISC Standards: Creating Clarity from Confusion

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CDISC
Learning Outcomes

- Describe Exposure as Collected (EC), its uses and its relationship to Exposure (EX)?
- Differentiate relative timing variables and their Controlled Terminology
- Use the “generally not used” variables appropriately
- Identify the kinds of data can and should not go in Medical History (MH)
Part 1: Exposure as Collected and as Reported
**Definitions**

**EC (Exposure as Collected)**
- Information known during study conduct
- May include things that were planned and did not happen
- Contains collected data

**EX (Actual Exposure)**
- Information known after the study is complete
- Intended only for things that happened
- Usually mostly derived
Examples of EC and EX

<table>
<thead>
<tr>
<th>Description</th>
<th>EC</th>
<th>EX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Double blind study</td>
<td>Blinded data: 2 tablets</td>
<td>Unblinded data: 250 mg/day</td>
</tr>
<tr>
<td>Missed doses</td>
<td>Missed: 4 tablets</td>
<td>Taken: 750 mg</td>
</tr>
<tr>
<td>Calculated dosage</td>
<td>20 mg/kg (subject weighs 75 kg)</td>
<td>1,500 mg/day</td>
</tr>
</tbody>
</table>
Case 1: Dosing One Pill at a Time

EC

Exposure

Day 3
Was Study Treatment Administered?

[ ] No
[ ] Yes, if "Yes", please provide the following.

Date Administered
03 May 2013

Assigned
Derived from ECSTDTC

<table>
<thead>
<tr>
<th>ECPRESPh</th>
<th>ECOCCUR</th>
<th>EPOCH</th>
<th>ECSTDTC</th>
<th>ECENDTC</th>
<th>ECSTDY</th>
<th>ECENDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>Y</td>
<td>TREATMENT</td>
<td>2013-05-03</td>
<td>2013-05-03</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
### Case 1: Dosing One Pill at a Time

**Randomization Code**

**EC**

<table>
<thead>
<tr>
<th>ECPRESP</th>
<th>ECOCCUR</th>
<th>EPOCH</th>
<th>ECSTDTC</th>
<th>ECENDTC</th>
<th>ECSTDY</th>
<th>ECENDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>Y</td>
<td>TREATMENT</td>
<td>2013-05-03</td>
<td>2013-05-03</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

**EX**

- **DRUG X**: 1000 mg TABLET QD ORAL
- **EPOCH**: TREATMENT
- **EXSTDT**: 2013-05-03
- **EXENDT**: 2013-05-03
Part 2: Relative Timing Variables
### Medical History

Did the subject report any clinically significant medical history conditions within [protocol-specified time period] prior to the study?

- No [MHYN]
- Yes - (please complete the form)

<table>
<thead>
<tr>
<th>Line #</th>
<th>Condition</th>
<th>Start Date</th>
<th>End Date</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hypertension</td>
<td>May 2015</td>
<td>Dec 2017</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Medical History Table**

- **MHTERM**: Hypertension
- **MHSTDTC**: 2015-05
- **MHENDAT**: 2017-12
Not So Nice Timing Situation

As of when???

Prior and Concomitant Medications

Were any medications taken? Include medications that were taken within [protocol-defined time period] before or during study treatment.

- **No**
- **Yes**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Start Date</th>
<th>End Date</th>
<th>Ongoing</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benedryl &amp; Sudafed</td>
<td>23 MAY 2013</td>
<td></td>
<td>Yes</td>
<td>Seasonal allergies</td>
</tr>
</tbody>
</table>
First Solution: Study Reference Period

Usually first day on treatment

Usually last day on treatment
When Did the CM End Compared to This Period?

- First Day
- Last Day

- BEFORE
- DURING
- AFTER
- DURING/AFTER
- UNKNOWN

VALUES ⇒ --ENRF
What is the Status of the Non-Study Med on This Date?

VALUES FOR –xxTPT ⇒ Date, Visit Name, Any Timepoint

VALUES ⇒ --STRTP

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What is the Status of the Non-Study Med on This Date?

**Coincident:** ended on the same day as the reference date; Ongoing: it was ongoing on the reference date

**Values for** –xxTPT ⇒ Date, Visit Name, Any Timepoint

**Before** (bound by when started) **AFTER**

**Coincident Ongoing**

**Values ⇒** --ENRTPT (influenced by when observation made)
Part 3: Using “Generally Not Used” Variables
What is in the SDTM IG?

7. Any identifiers, timing variables, or events general observation class qualifiers may be added to the MH domain, but the following Qualifiers would generally not be used in MH: --SER, --ACN, --ACNOTH, --REL, --RELNST, --OUT, --SCAN, --SCONG, --SDISAB, --SDTH, --SHOSP, --SLIFE, --SOD, --SMIE.

This was meant to be helpful!

It means we had no use case at that time

Use them if you have a use case
Part 4: What Data Can Go in Medical History?
Understanding the Medical History (MH) domain

Generally accepted definition of MH

• “A record of information about a person’s health. …allergies, illnesses, surgeries, immunizations, and results of physical exams and tests.”* i.e., all relevant past personal experience

SDTMIG definition of MH

• “An events† domain that contains data that includes the subject's prior medical history at the start of the trial”**

SDTM definition of “Event”

• Something that happens; may or may not happen to everyone, may be planned or unplanned

**NCI-EVS controlled terminology
†SDTM definition of “events”
What Domain to Use for Prior Information?

Two considerations: content and timing

CM  Dose, Units, Method
PR  Dose, Units, Indication
LB  Results, Units
MH  Conditions

Time  Study Start

AE
Thank you for Attending!

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