Multiple Dates Concept
* Overview and Proposed Implementation Approach *

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

DC CDISC User Network
March 21, 2012 Meeting
Outline

- Background – The Journey
- The Multiple Dates Concept
  - An Example
- Your Input Needed…Please!
- Next Steps
Background

**Purpose:** The CDISC SDS Multiple Dates Subteam will provide guidance for representing different dates related to a single stated "topic" (event, intervention or finding) in the SDTM/SDTMIG

**Deliverables:**
- Identification of new domains and/or variables and/or controlled terminology as appropriate for inclusion in the SDTM/SDTMIG
- SDTMIG examples and assumptions (general or domain specific)
- SDTMIG CDISC Notes
Background

The Problem

- Events have “start” and “stop” dates
  - Start & stop may not be well defined
- Dates that may or may not mean start or stop may be collected
  - Diagnosis date
  - Date of confirmatory test
  - Date of symptom onset
  - Date of first treatment
  - Date of most recent episode
- These dates do not have a distinct term
Background

- Other Aspects
  - “Extra” dates may be associated with a Finding
    - Severity of most recent episode
    - Disease stage at some point in time
  - Similar issue with “interventions” and “findings”
    - Steps in surgery
    - Sample preparation
  - Agreed to focus on Events case first
Background

- **Solutions Considered**
  - Add new timing variables
  - Single parent record with dates in SUPP
  - Multiple records in MH
    - Characterize records w/SCAT or SUPP—

- **More possible solutions**
  - New DS-like domain for stages or disease state changes
  - Various Findings About structures
  - Events About
Multiple Dates (MDt) Concept

- Current concept:
  - *Multiple Dates* refers to “additional points in time (dates, not duration) within the continuum of an intervention or event”
  - Often seen in “long-term”, “chronic”, “progressive-type” conditions

- What it is…
  - interested in what happens at those times
  - What we knew about condition/event then
  - having a descriptor on a date (e.g., onset, diagnosis) that enables us to know where we put “___” date(s) and relate it(Them)
  - A date w/ description but no other qualifier

- What it is not…
  - Not about addressing how to handle more, or additional data (collected or not), such as Severity, related to those Dates & Descriptors

- Why it needs representation…
  - Haven’t found where “dates” go best
Multiple Dates (MDt) Concept

Guiding principles/assumptions:
- New Domain not necessary
- New variables not needed
- Multiple Dates should be represented using the Findings About (FA) representation of dates using the result fields in FA Findings structure (FAORRES, FASTRESN, FASTRESC) unequivocally support this use
- Sponsor must create a parent event record to which the multiple date records can be related.
  - The sponsor should identify the appropriate Parent domain(s) based on the topic of the data
Multiple Dates (MDt) Concept

- The following references reconcile the use of FA with the date represented in –ORRES:
  - Dates are generally used only as timing variables to describe the timing of an event, intervention, or collection activity, but there may be occasions when it may be preferable to model a date as a result (--ORRES) in a Findings dataset. *(Section 4.1.4.9, page 44)*.

  - It is intended, as its name implies, to be used when collected data represent "findings about" an Event or Intervention that cannot be represented within an Event or Intervention record or as a Supplemental Qualifier to such a record *(Section 6.4.1, Page 194)*. Examples include the following:
    - Data or observations that have different timing from an associated Event or Intervention as a whole.
    - Data or observations about an Event or Intervention which have Qualifiers of their own that can be represented in Findings variables.
MDt Example

RA History (CRF Sample)

Date of sx onset: _______
No. swollen/tender joints: __
Date of clin dx: _________  Functional class: ___
Date confirmed by imaging: ______ Method: ___
Date of most recent flare: _________  Severity: ___
MDt Example

RA History (CRF Sample)

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>FASEQ</th>
<th>FATESTCD</th>
<th>FATEST</th>
<th>FAOBJ</th>
<th>FAORRES</th>
<th>FADTC</th>
<th>FAMETHD</th>
<th>FASEV</th>
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<tbody>
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<td>FA</td>
<td>ABC123-01001</td>
<td>1</td>
<td>SYMPTOC</td>
<td>Date Symptom Onset</td>
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<td>2008-10-10</td>
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<td>ABC123</td>
<td>FA</td>
<td>ABC123-01001</td>
<td>2</td>
<td>DIAGNOC</td>
<td>Date Diagnosed</td>
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<td>2007-12</td>
<td>2008-10-10</td>
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<tr>
<td>3</td>
<td>ABC123</td>
<td>FA</td>
<td>ABC123-01001</td>
<td>3</td>
<td>CONFDOC</td>
<td>Date Confirmed by Imaging</td>
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<td>2008-01-10</td>
<td>2008-10-10</td>
<td>X-RAY</td>
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<td>FLREATOC</td>
<td>Date Most Recent Flare</td>
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<td>2008-01-15</td>
<td>2008-10-10</td>
<td>MILD</td>
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<td>FA</td>
<td>ABC123-01001</td>
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<td>No. Swollen/Tender Joints</td>
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<tr>
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<td>FA</td>
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<td>6</td>
<td>FNCTCLS</td>
<td>Functional Class</td>
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<td>2007-12</td>
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</table>
# MDt Example

<table>
<thead>
<tr>
<th>Other Topics/Domains</th>
<th>Types of MDts</th>
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<tbody>
<tr>
<td>Oncology</td>
<td>Date of Metastasis</td>
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<tr>
<td></td>
<td>Date of Diagnosis</td>
</tr>
<tr>
<td>Depression</td>
<td>Date of Diagnosis</td>
</tr>
</tbody>
</table>

- Oncology Date of Metastasis
- Date of Diagnosis
- Depression Date of Diagnosis
Your Input Needed…Please!

- In the form of feedback
  - Is the model making sense?
  - Are there other options not yet considered?
  - Are you comfortable with Dates in ----RES fields?

- In the form of examples
  - Do you have sample CRFs we can use to model?
  - Do you know of other types of MDt?
Next Steps

- Harmonize MDt approach with TA Mappings/Domains
  - As related to Date handling
  - In Common examples

- Publish MDT
  - Public comment period (TBA)
  - Include as part of SDTM-IG 3.1.4 (3Q12)
Q&A