The CDISC vision is to inform patient care & safety through higher quality medical research.
The New SDTMIG 3.1.4

What’s Different from Previous Versions

Presented by Dan Godoy (SDS Team Co-Lead)
Agenda

- Background
- Progress-to-Date
- SDTM 3.1.4 - What’s Different?
  - Key Features & Examples
- Q&A
Background
Background

- SDTMIG has traditionally been a single document
  - 1 Table of Content (at top)
  - Numbering schema has been static, at 4 levels
    - Inconsistent domain numbering of domain sub-sections
    - Forcing new domains to be “appended”
  - Maintenance of pagination & references has been challenging
    - Done after everything is inserted
    - QC takes longer than it should

- Document has become extremely large and difficult to update
Background

- SDS Team had become too large and inefficient
  - 80+ members per meeting, difficult to maintain focus
  - Lots of moving pieces to review in single meeting
  - Bottom Line: 4+ years since last release

- SDTMIG 3.1.3 was 1st attempt to mitigate challenges
  - Several post-3.1.2 publications tied to new release
    - Enhanced Trial Design
    - Oncology domains
    - Amendment 1 – Updates to DM & AE
  - Annotations were “quick win”, but impossible to maintain for next release
  - Lots of single documents needed for simple read
  - Numbering schema no longer useful
# Background

**New Operating Model rationale: It is a complex environment**

<table>
<thead>
<tr>
<th>SDTM Area</th>
<th>Code</th>
<th>Title</th>
<th>Foundational Standards Implementation Guides (IGs)</th>
<th>Therapeutic Area Project User Guides (UGs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Findings NEC</td>
<td>DA</td>
<td>Drug Accountability</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DD</td>
<td>Death Details</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MI</td>
<td>Microscopic Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MO</td>
<td>Morphology Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PE</td>
<td>Physical Exam</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RP</td>
<td>Reproductive System Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SC</td>
<td>Subject Characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SS</td>
<td>Subject Status</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| = Released | = Draft | = Provisional |

© CDISC 2012
Progress to-date
## Progress to-date

<table>
<thead>
<tr>
<th></th>
<th>SDTM v1.3</th>
<th>SDTMIG v3.1.3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timing</strong></td>
<td>Two-week public review April</td>
<td>July 2012</td>
</tr>
<tr>
<td></td>
<td>Final Posting July 2012</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria</strong></td>
<td>Material had undergone public review and comments have been addressed.</td>
<td></td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td>SDTM 1.2</td>
<td>SDTMIG 3.1.2</td>
</tr>
<tr>
<td></td>
<td>Amendment 1 variables</td>
<td>Amendment 1 updates to DM and AE</td>
</tr>
<tr>
<td></td>
<td>Oncology data items (LNKID, LNKGRP, ACPTFL, EVALID)</td>
<td>Oncology domains (TU, TR, RS)</td>
</tr>
<tr>
<td></td>
<td>SEND data items (additions to Tables 2.2.1-2.2.5 and DM), POOLDEF, Trial Sets</td>
<td>Enhanced TS</td>
</tr>
<tr>
<td></td>
<td>Enhanced TS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RELSUB, RSUBJID</td>
<td></td>
</tr>
</tbody>
</table>
# Progress to-date

<table>
<thead>
<tr>
<th></th>
<th>SDTM v1.4</th>
<th>SDTMIG v3.1.4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timing</strong></td>
<td>Summer 2013</td>
<td></td>
</tr>
<tr>
<td><strong>Criteria</strong></td>
<td>Material Publicly Reviewed in 3 Batches (Batch 3 available in early Fall ’13)</td>
<td></td>
</tr>
<tr>
<td><strong>Content</strong></td>
<td>◆ SDTM 1.3</td>
<td>◆ SDTMIG 3.1.3</td>
</tr>
<tr>
<td></td>
<td>◆ New Device variables</td>
<td>◆ Death Details (DD)</td>
</tr>
<tr>
<td></td>
<td>◆ New EX variables</td>
<td>◆ Exposure as Collected (EC) and EX enhancements</td>
</tr>
<tr>
<td></td>
<td>◆ Associated Person NSID</td>
<td>◆ Healthcare Encounters (HO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Immunogenicity domains (IS/SR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Microscopic Findings (MI)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Morphology (MO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Procedures (PR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Reproductive Details (RD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Subject Status (SS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Associated Person IG (AP IG)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ Virology User Guide (VR, VF, VP)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>◆ PGx User Guide</td>
</tr>
</tbody>
</table>

© CDISC 2012
SDTMIG 3.1.4 – What’s Different?
SDTMIG 3.1.4 - What’s Different?

- No more annotations like the ones in SDTMIG 3.1.3
SDTMIG 3.1.4 - What’s Different?

- Modular approach

SDTMIG 3.1.4 Portfolio

Section 1-4
Section 5 TOC
Section 6 TOC
Section 7 TOC
...
Appendices

Section 5 TOC
DM Domain
CO Domain
SE Domain
SV Domain

Section 6 TOC
Interventions TOC
Events TOC
Findings TOC

Appendices
SDTMIG 3.1.4 - What’s Different?

- Numbering schema simplified – down to just Section number
SDTMIG 3.1.4 - What’s Different?

- Simpler numbering schema = Removal of references
SDTMIG 3.1.4 - What’s Different?

- Ability to re-order alphabetically
SDTMIG 3.1.4 - What’s Different?

- Ability to easily insert new domains
SDTMIG 3.1.4 - What’s Different?

- Every Domain will have consistent sub-sections
  - Purpose – Description of intended use and related background
  - Specification – table of variables
  - Assumptions – all clarifications, caveats, rules, exceptions, etc.
  - Examples
- Purpose will match Controlled Terminology
- Domains will be issued as topic sets, for instance
  - Pharmacokinetics – PP & PC
  - Microbiology – MB & MS
  - Exposure – EX & EC
- Consistent headers and footers
- Page Numbers relative to individual document
SDTMIG 3.1.4 - What’s Different?

SDTM Publications & Schedule

- New Versions of SDTM and SDTM-IG released 1-to 2 times a year
  - SDTM 1.3 and SDTM-IG 3.1.3 targeted for May July ‘12
  - SDTM 1.4 and SDTM-IG 3.1.4 targeted for Summer-Fall ‘13

- New domains/vars will be posted for comments as they become available

- New versions will link all previously published domains from last version
  - Enables Provisional standards
  - Useful for setting validation rules
  - E.g., SDTM 1.3 and SDTM-IG 3.1.3 linked Amendment 1
Q&A
Thank You!

- Interested in Joining the SDS Team?
  - Register through Volunteer link on CDISC website
  - Contact:
    Dan Godoy (GodoyD@MedImmune.com)
    Barrie Nelson (BarrieN@amgen.com)