Planning DataFax Studies for CDISC Compliance

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Why Do We Need Data Standards? 1 of 3

- It takes approximately 15 years for a typical drug to go through the clinical development process!

- Such slowness is expensive, consuming both financial and human resources, which reduces the total research that can be done.

- An inefficient clinical development process is not just expensive but harmful to patients worldwide.
Clinical trial designs have become larger and more complex over the past generation.

The ability to electronically collect, archive, and manipulate large amounts of data with relative ease has led to more data being collected, which tends to make analyses increasingly complex and more time intensive to duplicate.

Clinical trial documentation (e.g. Protocols, CSRs, SAPs, etc.) have correspondingly grown in length and complexity.
Largest benefits are still primarily hypothetical.

Perhaps the greatest potential benefit is easier meta-analyses. The FDA wants to be able to do sophisticated data mining on the ocean of clinical data it processes.

It is hoped that better data standards will permit easier combination of clinical trial data with patient data. This is in its infancy.

Personalized/genetic medicine will drive data to be used in a more sophisticated way.
What is CDISC? 1 of 3

- “CDISC is an open, multidisciplinary, non-profit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.”
What is CDISC? 2 of 3

- CDISC has high-level cross-pollination with some of the largest pharmaceutical companies and CROs.

- CDISC’s board of directors includes current executives from Sanofi, Quintiles, GlaxoSmithKline, and AstraZeneca.

- CDISC is part of growing ecosystem of interconnected groups working to streamline the clinical development process, e.g. C-Path, TransCelerate, IHE, etc.
The Clinical Data Interchange Standards Consortium (CDISC) was founded in 1997.

Development of standards has been driven primarily using collaborative, consensus-based working groups.

Most important data standards – ODM, CDASH*, SDTM, ADaM – have been available for a decade.
SDTM

- **Standard Data Tabulation Module**
- Standard structure for data tabulations
- Observations described by a series of variables
- Collected in domains: collection of logically related observations with a common topic
Domains

- Currently 44+ domains
  - DM: Demographics
  - VS: Vital Signs
  - LB: Laboratory Test Results
  - CM: Concomitant Medications
  - AE: Adverse Events
  - Etc.
# Laboratory CRF

## Test Study

<table>
<thead>
<tr>
<th>Participant Identification #:</th>
<th>Sample Collection Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Haematology (HAE)

**Instructions:** For each result, if applicable, record a DAIDS Grade from 1–4. If result does not fall within grades 1–4, record as 0.

<table>
<thead>
<tr>
<th>N/A</th>
<th>Haematology:</th>
<th>DAIDS Grade (1–4)</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>. . , x 10^12</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>. . , . . , pl.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>. . , . . , .</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>. . , x 10^14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>. . , . . , x 10^12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>. . , x 10^12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>(lymphocytes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>. . , x 10^12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>. . , x 10^12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>. . , x 10^12</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At Screening: Record all findings on Baseline Medical History Log, if applicable.

**Version 1, 05-05-015**
Setup: Previous DataFax Versions
Output: List View

- One row per record
What CDISC Wants: SDTM Format

- One row per result

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>LBSEQ</th>
<th>LBTESTCD</th>
<th>LBTEST</th>
<th>LBCAT</th>
<th>LBSCAT</th>
<th>LBORRES</th>
<th>LBORRESU</th>
<th>LBORNRLO</th>
<th>LBORNRHI</th>
<th>LBSTRES</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>ABC</td>
<td>LB</td>
<td>ABC-001-001</td>
<td>1</td>
<td>ALB</td>
<td>Albumin</td>
<td>CHEMISTRY</td>
<td>30</td>
<td>g/L</td>
<td>35</td>
<td>50</td>
<td>3.0</td>
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</tr>
<tr>
<td>2</td>
<td>ABC</td>
<td>LB</td>
<td>ABC-001-001</td>
<td>2</td>
<td>ALP</td>
<td>Alkaline Phosphatase</td>
<td>CHEMISTRY</td>
<td>398</td>
<td>IU/L</td>
<td>40</td>
<td>160</td>
<td>398</td>
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</tr>
<tr>
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<td>LB</td>
<td>ABC-001-001</td>
<td>3</td>
<td>ALP</td>
<td>Alkaline Phosphatase</td>
<td>CHEMISTRY</td>
<td>350</td>
<td>IU/L</td>
<td>40</td>
<td>160</td>
<td>350</td>
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</tr>
<tr>
<td>4</td>
<td>ABC</td>
<td>LB</td>
<td>ABC-001-001</td>
<td>4</td>
<td>ALP</td>
<td>Alkaline Phosphatase</td>
<td>CHEMISTRY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>374</td>
</tr>
<tr>
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<td>ABC</td>
<td>LB</td>
<td>ABC-001-001</td>
<td>5</td>
<td>WBC</td>
<td>Leukocytes</td>
<td>HEMATOLOGY</td>
<td>5.9</td>
<td>10^9/L</td>
<td>4</td>
<td>11</td>
<td>5.9</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>ABC</td>
<td>LB</td>
<td>ABC-001-001</td>
<td>6</td>
<td>LYMLE</td>
<td>Lymphocytes</td>
<td>HEMATOLOGY</td>
<td>DIFFERENTIAL</td>
<td>6.7</td>
<td>%</td>
<td>25</td>
<td>40</td>
<td>6.7</td>
</tr>
<tr>
<td>7</td>
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<td>LB</td>
<td>ABC-001-001</td>
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<td>10^9/L</td>
<td>2</td>
<td>8</td>
<td>5.1</td>
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<tr>
<td>8</td>
<td>ABC</td>
<td>LB</td>
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<td>8</td>
<td>PH</td>
<td>pH</td>
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<td></td>
<td>5.0</td>
<td>9.0</td>
<td>7.5</td>
<td></td>
</tr>
</tbody>
</table>
How to Achieve This in DataFax?

- Previous versions: mapping behind the scenes (e.g., in SAS)
- 2014.1: modules!
- Think of a module as a domain
Setup: 2014.1 Using Modules
Output: List View: Modules

- Much closer to what we need
- One row per result
- Pulls lab data from different plates
- Less mapping behind the scenes
Data records are exported in ASCII plain text format
- Records can be exported by plate

- Or across plates by module
DFsas: Modules

- In the process of implementing this – coming soon!
Questions?