THE IMPLEMENTATION OF SDTM STANDARDS FOR NON-SUBMISSION PURPOSES

Paul Vervuren, Nutricia Research
Lieke Gijsbers, OCS Life Sciences

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AGENDA

• Background
• Project scope
• Deliverables and submission standards
• SDTM implementation challenges
• Project approach
• Conclusions
BACKGROUND

• Value of data for future research

• SDTM legacy conversion project for early life infant nutrition studies

• Twenty-one infant nutrition clinical studies selected
  • Based on business relevance, features of the study
DATA TO INSIGHT PATHWAY

SDTM

ADaM

Study A

Study B

Study C

Learn more about our data

- Power to detect subtle differences
- Broader picture, beyond single study
- New dimensions, e.g. ingredients
PROJECT SCOPE

- Initial
  - Demographics
  - Subject characteristics
  - Vital signs
  - Adverse events
  - Gastrointestinal tolerance
  - Concomitant medication

- Scope extension
  - Based on ‘economics’
PROJECT SCOPE

- Raw data inventory based on:
  - Protocol
  - CRF
  - Datasets

- Informed decision
## Regulatory submission (FDA) components

<table>
<thead>
<tr>
<th>Regulatory submission (FDA) components</th>
<th>Nutricia project</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDTM dataset</td>
<td>Required</td>
</tr>
<tr>
<td>Trial design tables</td>
<td>Nice-to-have; not included</td>
</tr>
<tr>
<td>Define.xml</td>
<td>Desired; not included</td>
</tr>
<tr>
<td>Annotated CRF</td>
<td>Required</td>
</tr>
<tr>
<td>Reviewer Guides (RG)</td>
<td>Nice-to-have; not included</td>
</tr>
<tr>
<td>Study Data Standardization Plan</td>
<td>Not used and not considered relevant at this point</td>
</tr>
<tr>
<td>Legacy Data Conversion Plan and Report</td>
<td>Not used; documented in mapping design and specifications</td>
</tr>
<tr>
<td>SAS transport files</td>
<td>Not used</td>
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SOME SDTM IMPLEMENTATION CHALLENGES

• Specific nutrition concepts not entirely addressed in CDISC standards
  • No standard domain available to represent gastrointestinal tolerance data
  • Limited terminology for faecal microbiology parameters, only 4 standard terms vs. 66 parameters in our studies

• Variable length restrictions in CDISC standards
  • --TEST: "Clostridium Histolyticum Group and Clostridium Lituseburense Group"
    • >40 characters
  • --TESTCD: "CHIS150CLIT135"
    • >8 characters
SOME SDTM IMPLEMENTATION CHALLENGES

• CRFs of legacy studies not designed with SDTM in mind
  • Date of first intake of study formula not always captured; how to populate RFXSTDTC (Date/Time of First Study Treatment)?

• Data issues
  • Data collected via paper CRF and diaries; need for exception handling
SOME SDTM IMPLEMENTATION CHALLENGES

- Substantial variation in study design, CRF, dataset structure and naming conventions.
PROJECT APPROACH

• SDTM implementation outsourced from Nutricia Research to OCS Life Sciences

• Tuned approach early in the project
  • From ‘delivery’ model to ’delivery-and-collaboration’ model
  • Regular meetings with Nutricia domain experts to make the best implementation choices
LESSONS LEARNED / RECOMMENDATIONS

• SDTM is a usable standard for non-submission purposes
  • Best to strive for full conformance
  • Other submission components applicable to varying degrees
  • Some SDTM requirements outdated (8 char. limitation)

• Outsourcing SDTM conversion can be successful
  • Seek close collaboration and have SDTM expertise on both sides
  • Spend time pre-analysing the data structure and variability
Thank you!

Paul Vervuren  
Nutricia Research  
paul.vervuren@danone.com

Lieke Gijsbers  
OCS Life Sciences  
lieke.gijsbers@ocs-consulting.com