CONSTRUCTING A DATA WAREHOUSE FOR NUTRITION CLINICAL STUDIES

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PhUSE Barcelona
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Learn and Innovate

- Design new studies
- Reference data
- Feed R&D
  - Substantiate results, new hypotheses

Learn more about our data

- Power to detect subtle differences
- Broader picture, beyond single study
- New dimensions, e.g. ingredients
“Bring health through food to as many people as possible”
THE FIRST 1000 DAYS
AN IMPACT ON LATER LIFE HEALTH

-9m to 24m
Critical window of opportunity to support healthy later life

CONCEPTION

TODDLERHOOD

ADULTHOOD

HEALTHY

DISEASE

Altered growth and development
Stunting
Allergy
Obesity
Coronary heart disease
Diabetes
Cognitive decline
A BABY IS NOT A SMALL ADULT
THE ORGANS OF A NEWBORN BABY STILL NEED TO DEVELOP

Immaturity of:

- DIGESTIVE SYSTEM
- GUT MICROBIOTICA
- IMMUNE SYSTEM
- METABOLISM
- BRAIN
- BONES
THE SCIENCE OF NUTRITION
DIFFERENCES IN ACTION REQUIRE SPECIFIC RESEARCH APPROACH

FOCUSED LARGE EFFECT ON SINGLE TARGET

CUMULATIVE EFFECTS ON MULTIPLE TARGETS
Analyses of secondary parameters leads to surprising and very interesting patterns!

Many exploratory endpoints and analyses

No NDAs, thus no external incentive to standardize clinical trial data across studies

Long-term follow-up in quite a number of studies

Open-minded culture, with standards and processes still developing and maturing

Not the standard Phase I-IV trials, and fewer trials for one product than in Pharma, but each trial investigates many outcomes
DATA STANDARDIZATION AND INTEGRATION

- Standardized raw data
- SDTM
- Product composition
- ADaM
- Standardized analysis-ready data

Individual raw study data
Study A
Study B
Study C

Study A
Study B
Study C
# GROWTH DATA – VITAL SIGNS (VS)

### Study A

<table>
<thead>
<tr>
<th>randomno</th>
<th>weightinf_W4</th>
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<th>headcirc_W4</th>
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### Study B

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<tr>
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<th>HEIGU</th>
<th>WEIG</th>
<th>WEIGU</th>
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### Study C

<table>
<thead>
<tr>
<th>VISIT USUBJID</th>
<th>VSTEST</th>
<th>VSORRES</th>
<th>VSORRESU</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Weight</td>
<td>grams</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>Height</td>
<td>cm</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Head circumference</td>
<td>cm</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>Weight</td>
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<td>5</td>
<td>1</td>
<td>Height</td>
<td>cm</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>Head circumference</td>
<td>cm</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>Weight</td>
<td>grams</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>Height</td>
<td>cm</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>Head circumference</td>
<td>cm</td>
</tr>
</tbody>
</table>
# GROWTH DATA – VITAL SIGNS (VS)

<table>
<thead>
<tr>
<th>Codelist Name</th>
<th>CDISC Submission Value</th>
<th>CDISC Synonym(s)</th>
<th>CDISC Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital Signs Test Code</td>
<td>VSTESTCD</td>
<td>VSTEST</td>
<td>The name given to the test that analyzes a particular set of vital signs including temperature, respiratory rate, heart beat (pulse), and blood pressure (NCI).</td>
</tr>
<tr>
<td>Vital Signs Test Code</td>
<td>WEIGHT</td>
<td></td>
<td>The vertical force exerted by a mass as a result of gravity. (NCI).</td>
</tr>
<tr>
<td>Vital Signs Test Code</td>
<td>HICIRC</td>
<td></td>
<td>A circumferential measurement of the head at the widest point.</td>
</tr>
<tr>
<td>Vital Signs Test Code</td>
<td>BODLENGTH</td>
<td></td>
<td>The linear extent in space from one end of the body to the other end, or the extent of the body from beginning to end.</td>
</tr>
</tbody>
</table>

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<thead>
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<th>Codelist Name</th>
<th>CDISC Submission Value</th>
<th>CDISC Synonym(s)</th>
<th>CDISC Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Units for Vital Signs Results</td>
<td>VSRESU</td>
<td></td>
<td>The unit used to record and describe the result of a test investigating a vital sign. (NCI).</td>
</tr>
<tr>
<td>Units for Vital Signs Results</td>
<td>cm</td>
<td></td>
<td>A basic unit of length equal to one hundredth of a meter or approximately 0.393700787 inch.</td>
</tr>
<tr>
<td>Units for Vital Signs Results</td>
<td>g</td>
<td></td>
<td>A metric unit of mass equal to one one thousandth of a kilogram. (NCI).</td>
</tr>
</tbody>
</table>

**VISIT USUBJID** | **VSTEST** | **VSORRES** | **VSORRESU**
---|---|---|---
1 | Dg.1.C/A-056-41-2201 | Weight | 35.40 | grams |
2 | Dg.1.C/A-056-41-2201 | Height | 50.0 | cm |
3 | Dg.1.C/A-056-41-2201 | Head Circumference | 33.0 | cm |
4 | Dg.1.C/A-056-41-2201 | Weight | 41.00 | grams |
5 | Dg.1.C/A-056-41-2201 | Height | 54.5 | cm |
6 | Dg.1.C/A-056-41-2201 | Head Circumference | 36.0 | cm |
7 | Dg.1.C/A-056-41-2201 | Weight | 47.80 | cm |
8 | Dg.1.C/A-056-41-2201 | Height | 56.0 | cm |
9 | Dg.1.C/A-056-41-2201 | Head Circumference | 37.5 | cm |

**DOMAIN USUBJID** | **VSTESTCD** | **VSTEST** | **VSORRES** | **VSORRESU** | **VISIT**
---|---|---|---|---|---
1 | Dg.1.C/A-056-41-2201 | BODLENGTH | Body Length | 50.0 | cm | Vist 1 |
2 | Dg.1.C/A-056-41-2201 | HICIRC | Head Circumference | 33.0 | cm | Vist 1 |
3 | Dg.1.C/A-056-41-2201 | WEIGHT | Weight | 35.40 | g | Vist 1 |
4 | Dg.1.C/A-056-41-2201 | BODLENGTH | Body Length | 54.5 | cm | Vist 2 |
5 | Dg.1.C/A-056-41-2201 | HICIRC | Head Circumference | 36.0 | cm | Vist 2 |
6 | Dg.1.C/A-056-41-2201 | WEIGHT | Weight | 41.00 | g | Vist 2 |
7 | Dg.1.C/A-056-41-2201 | Height | 56.0 | cm |
8 | Dg.1.C/A-056-41-2201 | HEADCIRC | Head Circumference | 37.5 | cm | Vist 3 |
9 | Dg.1.C/A-056-41-2201 | WEIGHT | Weight | 47.80 | g | Vist 3 |
### Product Composition As Data

#### Planned Treatment (ARM/TRT01P)

<table>
<thead>
<tr>
<th>Unique Product Identifier</th>
<th>Unique Product Full Description</th>
<th>Product Characteristics Space Delimited List From CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFLP00</td>
<td>Low Protein Cow's Milk Infant Formula with a protein content of 1.8 g/100kcal</td>
<td>PROT1.8</td>
</tr>
<tr>
<td>CFLP10</td>
<td>Modified Low Protein Cow's Milk Infant Formula with a protein content of 1.8 g/100kcal with ferment and scGOS/lcFOS</td>
<td>PROT1.8 PREB10 PREB20 FERM</td>
</tr>
</tbody>
</table>

#### Analysis Record Flag (ANLzzFL)

<table>
<thead>
<tr>
<th>Product Characteristic</th>
<th>Product Characteristic Category</th>
<th>Product Characteristic Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRDCHAR</td>
<td>CHARCAT</td>
<td>CHARDESC</td>
</tr>
<tr>
<td>PREB10</td>
<td>Prebiotics</td>
<td>Prebiotics lcFOS</td>
</tr>
<tr>
<td>PREB20</td>
<td>Prebiotics</td>
<td>Prebiotics scGOS</td>
</tr>
<tr>
<td>PROT1.8</td>
<td>Protein</td>
<td>Protein at 1.8g/100kcal</td>
</tr>
</tbody>
</table>
What is the effect of ingredient xx on growth across all studies? (and I want a p-value)

- Power to detect subtle differences
- Broader picture, beyond single study
- New dimensions, e.g. ingredients
SPECIFIC DOMAINS IN NUTRITION CLINICAL STUDIES

- Typical:
  - GI-tolerance
  - Microbiota data
  - Food intake
  - Parent data
# Glycemic Index Chart

## Glycemic Index Chart

Low Glycemic (55 or Below)  High Glycemic (70 or Higher)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pizza</td>
<td>33</td>
<td>Bagel, Plain</td>
<td>33</td>
<td>Broccoli</td>
<td>10</td>
<td>Cherries</td>
<td>22</td>
<td>Yogurt, Plain</td>
<td>14</td>
</tr>
<tr>
<td>Chocolate Bar</td>
<td>69</td>
<td>White Rice</td>
<td>38</td>
<td>Pepper</td>
<td>10</td>
<td>Apple</td>
<td>48</td>
<td>Yogurt, Low Fat</td>
<td>14</td>
</tr>
<tr>
<td>Pound Cake</td>
<td>54</td>
<td>White Spaghetti</td>
<td>38</td>
<td>Lettuce</td>
<td>10</td>
<td>Orange</td>
<td>43</td>
<td>Whole Milk</td>
<td>30</td>
</tr>
<tr>
<td>Popcorn</td>
<td>55</td>
<td>Sweet Potato</td>
<td>44</td>
<td>Mushrooms</td>
<td>10</td>
<td>Grapes</td>
<td>46</td>
<td>Soy Milk</td>
<td>21</td>
</tr>
<tr>
<td>Energy Bar</td>
<td>58</td>
<td>White Bread</td>
<td>46</td>
<td>Onions</td>
<td>10</td>
<td>Kiwi</td>
<td>52</td>
<td>Sesame Milk</td>
<td>22</td>
</tr>
<tr>
<td>Soda</td>
<td>72</td>
<td>Brown Rice</td>
<td>55</td>
<td>Green Peas</td>
<td>48</td>
<td>Banana</td>
<td>56</td>
<td>Chocolate Milk</td>
<td>35</td>
</tr>
<tr>
<td>Doughnut</td>
<td>76</td>
<td>Pancakes</td>
<td>67</td>
<td>Carrots</td>
<td>69</td>
<td>Pineapple</td>
<td>66</td>
<td>Yogurt, Fruit</td>
<td>36</td>
</tr>
<tr>
<td>Jelly Beans</td>
<td>80</td>
<td>Wheat Bread</td>
<td>80</td>
<td>Beets</td>
<td>64</td>
<td>Watermelon</td>
<td>72</td>
<td>Custard</td>
<td>43</td>
</tr>
<tr>
<td>Pretzels</td>
<td>83</td>
<td>Baked Potato</td>
<td>85</td>
<td>Onions</td>
<td>75</td>
<td>Dates</td>
<td>103</td>
<td>Ice Cream</td>
<td>60</td>
</tr>
</tbody>
</table>

Glycemic Index values obtained from [www.lowglycemic.com](http://www.lowglycemic.com), [www.nutritiondata.com](http://www.nutritiondata.com) and [www.diabeticcarb.com](http://www.diabeticcarb.com)
GI TOLERANCE

CRF example

Visit 1 – Baseline

Gastrointestinal tolerance

Does the child / the subject suffer from:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Absent</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burping</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flatulence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colic (cramps)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regurgitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Average number of stools per day:

What is the average consistency of the stools?

- Watery
- Soft, puddinglike
- Soft, formed
- Dry, formed
- Dry, hard pellets
**GI TOLERANCE**

**CRF example**

**Visit 1 – Baseline**

**Gastrointestinal tolerance**

Does the child / the subject suffer from:

<table>
<thead>
<tr>
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Average number of stools per day: □□

What is the average consistency of the stools?

- Watery
- Soft, puddinglike
- Soft, formed
- Dry, formed
- Dry, hard pellets
GENERAL OBSERVATION CLASSES (SDTM-IG 2.1)

- The **Interventions** class captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., exposure to study drug), coincident with the study assessment period (e.g., concomitant medications), or self-administered by the subject (such as use of alcohol, tobacco, or caffeine).

- The **Events** class captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).

- The **Findings** class captures the observations resulting from planned evaluations to address specific tests or questions such as laboratory tests, ECG testing, and questions listed on questionnaires.
GI TOLERANCE

CRF example

Visit 1 – Baseline

Gastrointestinal tolerance

Does the child / the subject suffer from:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Absent</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>☒</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Burping</td>
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<tr>
<td>Regurgitation</td>
<td></td>
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</tbody>
</table>

CEOCCUR='N'

<table>
<thead>
<tr>
<th>SYMPTOM</th>
<th>CATEGORY</th>
<th>LEVEL</th>
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</thead>
<tbody>
<tr>
<td>NAUSEA</td>
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<td>Y</td>
</tr>
<tr>
<td>VOMITING</td>
<td>GASTROINTESTINAL TOLERANCE</td>
<td>Y</td>
</tr>
<tr>
<td>BURPING</td>
<td>GASTROINTESTINAL TOLERANCE</td>
<td>Y</td>
</tr>
<tr>
<td>FLATULENCE</td>
<td>GASTROINTESTINAL TOLERANCE</td>
<td>Y</td>
</tr>
</tbody>
</table>
### GI TOLERANCE

**CRF example**

---

**Visit 1 – Baseline**

**Gastrointestinal tolerance**

Does the child / the subject suffer from:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Absent</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tr>
<td>Nausea</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Average number of stools per day:

- [ ]

What is the average consistency of the stools?

- [ ] Watery
- [ ] Soft, puddinglike
- [ ] Soft, formed
- [ ] Dry, formed
- [ ] Dry, hard pellets
FINDINGS ABOUT (FA)

- A dataset used to capture the findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier.

- Criteria 1) data that do not describe an Event or Intervention as a whole, 2) data (“about” an Event or Intervention) having Qualifiers that can be represented in Findings variables (e.g., units, method), and 3) data (“about” an Event or Intervention) that indicate the occurrence of related symptoms or therapies.

- FAOBJ: Used to describe the object or focal point of the findings observation that is represented by FATEST. Examples: an event such as VOMIT where the volume of Vomit is being measured by a VOLUME test.

---

6 Domain Models Based on the General Observation Classes

6.4 Findings About Events or Interventions

Findings About (FA)

FA – Description/Overview for Findings About Domain Model

A dataset used to capture the findings about an event or intervention that cannot be represented within an event or intervention record or as a supplemental qualifier.

FA – Specification for Findings About Domain Model

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>SDXML Elements</th>
<th>Expected Occurrences</th>
<th>CDISC Notes</th>
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</thead>
<tbody>
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<td>Study Identifier</td>
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<td>Idnt</td>
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<tr>
<td>NMAID</td>
<td>Domain Identification</td>
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</tr>
<tr>
<td>CMID</td>
<td>Unique Subject Identifier</td>
<td>Chri</td>
<td>Idnt</td>
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</tr>
<tr>
<td>FDSEQ</td>
<td>Sequence Number</td>
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<tr>
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<td>Chri</td>
<td>(FADDTHCD)</td>
<td>Topic</td>
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## GI TOLERANCE

### Visit 1 – Baseline

**Gastrointestinal tolerance**

<table>
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<tr>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>FATESTCD</th>
<th>FATEST</th>
<th>FAOBJ</th>
<th>FAORRES</th>
<th>FAORRESU</th>
</tr>
</thead>
<tbody>
<tr>
<td>FA</td>
<td>YYY-321-001</td>
<td>A_COUNT</td>
<td>Average Count</td>
<td>STOOL</td>
<td>3</td>
<td>1/DAY</td>
</tr>
<tr>
<td>FA</td>
<td>YYY-321-001</td>
<td>A_CONSIS</td>
<td>Average Consistency</td>
<td>STOOL</td>
<td>WATERY</td>
<td></td>
</tr>
</tbody>
</table>

- **FAOBJ='STOOL'**
  - **FATEST='Average Count'**
    - Average number of stools per day: 3
  - What is the average consistency of the stools?
    - **FAOBJ='STOOL'**
      - **FATEST='Average consistency'**
        - Soft, puddinglike
        - Soft, formed
        - Dry, formed
        - Dry, hard pellets

- **FAORRES**
  - WATERY
Updates over time
(MAY 2016)

- **Content Standards**
- **Technical Standards**
- **Semantics**
- **Therapeutic Areas**

### 2010
- ODM v1.3.1
- BRIDG v3.0.3
- Alzheimer v1.0
- SDM.XML v1.0
- SDTM v1.3
- SDTM Device IG v3.1.3
- AdAm Val. Checks v1.1
- PRM Toolset v1.0
- CDASH UG v1.1
- SAE IG
- ADaM MD Guide
- Dataset-xml v1.0

### 2011
- BRIDG v3.0.1
- SDTM v1.3
- SDTM IG v3.1.3
- AdAm Val. Checks v1.1
- CDASH UG v1.1
- ADaM MD Guide
- SAE IG

### 2012
- BRIDG v3.0.2
- SDTM v1.3
- SDTM IG v3.1.3
- AdAm Val. Checks v1.1
- CDASH UG v1.1
- ADaM MD Guide

### 2013
- BRIDG v3.1
- SDTM v1.4
- SDTM IG v3.2
- AdAm Val. Checks v1.1
- CDASH UG v1.1
- ADaM MD Guide

### 2014
- BRIDG v3.2
- SDTM v1.4
- SDTM IG v3.2
- AdAm Val. Checks v1.1
- CDASH UG v1.1
- ADaM MD Guide

### 2015
- BRIDG v3.3.2
- SDTM v1.5
- SDTM IG v3.3
- AdAm Val. Checks v1.1
- CDASH UG v1.1
- ADaM MD Guide

### 2016
- BRIDG v4.0
- ADaM IG v1.1
- ADaM Validation Checks v1.3
- Protocol Concept Guide
- SEND IG v3.1
- ADaM IG v2.0

**Kindly provided by:**
Peter van Reusel
Business & Decision Life Sciences

**Therapeutic Areas:**
- Pain
- Devices
- Parkinson’s Disease
- Tuberculosis
- Tuberculosis
- Alzheimer v1.1
- Virology v1.0
- PKD
- Influenza
- Diabetes
- QT Studies
- Cardiovascular
- Multiple Sclerosis
- Diabetes PKD
- Dyslepidemia
- COPD
- Breast cancer v1.0
- Diabetic Kidney Disease v1.0
- SEND IG v3.1
- Define.xml IG Validation
- PROTOCOL.XML v1.0
- SEND DART v1.0
- SDTM v3.4 Batch 1
- CTR-XML v1.0
- RDF UG v1.0
- RDF RG v1.0
- Define.xml v2.1
- ADaM OCCDS v1.0
- ADaM Validation Checks v1.3
- SDTM Device IG v2.0
- ADaM IG v1.2
- ADaM IG 2.0
- SDTM Pharmacogenomics IG v1.0
- SAE IG v2.0
- CDASH v2.0
- CDASH v1.2
- CDASH v1.0
- Define.xml v2.1
- ADaM IG v1.2
- ADaM IG 2.0
WHAT DOES THE FUTURE LOOK LIKE?

Leverage value and increase capabilities

- Build on cross-functional collaborations and R&D data strategy
- Streamline with upstream standardization (CDASH/SDTM)
- Enable controlled data sharing and usage for Nutricia Research R&D community
- Incorporate & explore new sources of data

There’s more to come…
THANK YOU

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John Roth
Remco van der Meer
Michael Auld
Lieke Gijsbers
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