CDISC 360 Update: Evolution of the CDISC Standards

Peter Van Reusel, CDISC Chief Standards Officer
Agenda

1. CDISC 360 Intro
2. Project Approach
3. Project Status
4. Achievements so far
1. CDISC 360 Intro
Today we are here

CDISC Standards in the Clinical Research Process
Defined structures

- CDISC Foundational models provide much needed structure
  - Normative Content
  - 2 dimensional (tables, columns)
  - Standard to represent data

- The information itself is not defined
  - We do not need new structures
  - We need to define
    - Entities
    - Semantics (meaning)
    - Relationships between information
    - Rules in the data lifecycle
Why do we need to evolve?

• Data structures are known, but data meaning lacks full definition
• Standards are incomplete
  • protocol content, data collection instruments, analysis/endpoint definition
• Current clinical data standards are implemented inconsistently
  • Across studies and organizations
• Limited process automation in data processing
  • Study build, study conduct, and study reporting
  • Much manual programming needed in these processes
  • Some automation, but lack of fully-scaled automation

• Too much time needed for study specification
• High level of standards expertise needed
How do we evolve?
The CDISC 360 Project: Adding a conceptual layer to standards

• Create and store standards as concepts which create meaning between data
• Electronically publish data standards as linked metadata
• Add computer executable process metadata which enables end to end automation
• CDISC 360 will develop concept-based standard definitions, and test and demonstrate end-to-end automation of study specification, data processing, and analysis

➡ Test and demonstrate, but not building software
Biomedical Concept

Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mayHave Specimen Type (C70713)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mayHave Reference Range (C71474)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mayHave Planned Time Points (C2826271)

Unit (C71620) defaultCode % (C25613)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Collection Date/Time (C82515)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Laboratory Test Code (C83322)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mayHave Logical Observation Identifiers Names and Codes (LOINC) (C82502)
Laboratory Test Name (C67154) usesCode Hemoglobin A1C/Hemoglobin (C111207)

Laboratory Test Code (C65047) usesCode HBA1CHGB (C111207)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Baseline Flag (C82526)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mayHave Specimen Condition (C83024)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Laboratory Test Name (C117142)

Unit of Measure (C25709) usesNCICodelist Unit (C71620)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Unit of Measure (C25709)

Planned Time Points (C2826271) specify Time Points
Laboratory Test Result (C36292) mayBeUsedIn Reference Range Comparison (C122757)
Reference Range Indicator (C78736) usesCode ABNORMAL (C78802); HIGH (C78801); LOW (C78727)
Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) mustHave Laboratory Test Result (C36292)
Specimen Type (C78734) usesCode BLOOD (C12434)

Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207) belongsTo LB
Specimen Condition (C83024) usesNCICodelist Specimen Condition (C78733)

if LBLSTRESN eq to "" and LBLTESTCD = "HBA1CHGB"" and LBDTCD is

uses Laboratory Test Code (C83322)

Reference Range (C71474) mayBeUsedIn Reference Range Comparison (C122757)
Laboratory Test Code (C83322) Laboratory Test Code (C65047)
Laboratory Test Code (C83322) Laboratory Test Result (C36292)

if LBLSTRESN eq to "" and LBLTESTCD = "HBA1CHGB"" and LBDTCD is

usesCode % (C25613); mmol/mol (C111253); fraction of 1 (C105484)

Triple Store
Biomedical Concept

Attributes are linked to the element

<table>
<thead>
<tr>
<th>Class</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name</td>
<td>LBORRES</td>
</tr>
<tr>
<td>Variable Label</td>
<td>Result or Finding in Original Units</td>
</tr>
<tr>
<td>Type</td>
<td>Char</td>
</tr>
<tr>
<td>Core</td>
<td>Exp</td>
</tr>
<tr>
<td>Role</td>
<td>Result Qualifier</td>
</tr>
<tr>
<td>CDISC Notes</td>
<td>Result of the measurement or finding as originally received or collected.</td>
</tr>
<tr>
<td>Core</td>
<td>Exp</td>
</tr>
</tbody>
</table>

Sourced from SDTM 1.4 SDTMIG 3.2

**Laboratory Test Result (C36292)**

CDASH.LB–Local Processing.LBORRES
CDASH.LB–Local Processing.LBORRESU
SDTM.LB.LBORRES
SDTM.LB.LBST
SDTM.LB.LBSTRESN
BRIDG.PerformedObservationResult.value
Biomedical Concept

Linking controlled terminology to the variable

- Laboratory Test Code (C83322)
- Laboratory Test Code (C65047)
- HBA1CHGB (C111207)
- Laboratory Test Name (C117142)
- Laboratory Test Name (C67154)
- Hemoglobin A1C/Hemoglobin (C111207)
- Specimen Type (C70713)
- Specimen Type (C89134)
- BLOOD (C12434)
- Specimen Condition (C83024)
- Specimen Condition (C87833)
- Unit of Measure (C25709)
- Unit (C71620)
- % (C25613)
- % (C25613); mmol/mol (C111253); fraction of 1 (C105484)
- Reference Range (C71474)
- Reference Range Comparison (C122757)
- Normal Range Comparison Result (C122756)
- Reference Range Indicator (C78736)
- ABDNORMAL(C78902); HIGH (C78890); LOW (C78801); NORMAL (C78727)
Biomedical Concept

Standardize value level metadata

Hemoglobin A1C to Hemoglobin Ratio Measurement (C111207)

Collection Date/Time (C82515)

Planned Time Points (C826271)

Logical Observation Identifiers Names and Codes (LOINC) (C82501)

Baseline Flag (C82526)

Reference Range (C71475)

Laboratory Test Code (C83322)

Laboratory Test Name (C717142)

Specimen Type (C70713)

Specimen Condition (C83024)

Unit of Measure (C25709)

Quantitation Range (C125010)

Reference Range Comparison (C122757)

Normal Range Comparison Result (C122756)

Laboratory Test Result (C362971)

Specimen Condition (C78713)

Unit (C71620)

defaultCode

usesCode

usesCodeList

% (C25613)

% (C25613); mmol/mo l (C111253); fraction of 1 (C105484)

usesCodeList

ABNORMAL(C78802); HIGH (C78800); LOW (C78801); NORMAL (C78727)

usesCode

usesCodeList

HBA1C/CHGB (C111207)

Hemoglobin A1C/Hemoglobin (C111207)

BLOOD (C124349)
Biomedical Concept

Machine Executable Algorithms
Analysis Concept

Mean change from baseline in glycosylated hemoglobin

- MustHave Parameter Code uses Terminology
  - Parameter uses Terminology
    - Derivation Type resultsIn
    - Analysis Value resultsIn
      - Change from Baseline resultsIn
        - Baseline Value resultsIn
          - Analysis Baseline Record Flag resultsIn
            - Planned Treatment uses
              - Intent-To-Treat Population Flag uses
                - Analysis Visit
                  - Set to "Y" when AVISIT = "Baseline"
          - AVAL-BASE
            - AVAL where ABLFL = "Y"
          - LB, LBTESTSN where LB.LBTESTCD = "HBA1CHGB"
          - Standardized Laboratory Test Result
          - Laboratory Test Code
    - Laboratory Test Code
    - Laboratory Test Name
    - Laboratory Unit
    - "LOCF" when AVAL is imputed using last observation carried forward (post-baseline only)

Key:
- Derivation
- Terminology
- Variable
- Variable Connector
- Analysis Concept

For all colors, dotted line indicates customizable
Analysis Result

**Statistical method**
- **Test of hypothesis comparing treatments**
  - uses
  - results in
  - includes one to many

**Analysis results**
- has

**Metadata**
- **Selection criterion**
  - WHERE ITTFL = "Y" and PARAMCD = "HBAIC" and CHG ne . and ANL01FL = "Y" and DTYPF = " ."
- **Primary outcome measure**
  - Change in HbA1c from baseline
- **Specified in SAP**

**Documentation**
- LS means and 95% CIs are based on repeated measures model adjusting for planned treatment, baseline HbA1c value, avist, avist*baseline and avist*treatment interaction.

**Programming statements**
- PROC MIXED DATA = ADHBAIC:
  - WHERE ITTFL = "Y" and PARAMCD = "HBAIC" and CHG ne . and ANL01FL = "Y" and DTYPF = " CLASS TRTP AVISIT;"
  - MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / DDFM=KR;LSMEANS TRTP / CL DIFF; REPEATED usubjbd / subject = USUBJ BD=UN;RUN ;

**Programming language**
- SAS has version is 9.2

**Mean change from baseline in glycosylated hemoglobin**
- Table 4.2.1/Figure 4.2.1
- Treatment difference results (LSMean, confidence interval, p-value)
The Biomedical Concept and Analysis Concept are **ONE MODEL**
The Power of a Conceptual Model for Data Standards

• Linking controlled terminology to the variable – standardize value level metadata

• Machine readable definition of validation rules

• Linking derivations and algorithms to variable(s)
  • Include process metadata (ETL instructions)

• Possibility to standardize Analysis outputs and Collection instruments
  • Combining layout, variables, process information together

• Link Analysis Concepts to Biomedical Concepts
  • Choose an analysis and automatically obtain all related end-to-end metadata

→ All of the above: enables automation, increase confidence in results, true analysis traceability
Use Case 1: Define

Selecting standards concepts and linked metadata needed for a study
Use Case 2: Build

Adding study design, concept configuration & generate artifacts

- Create Operational Database
- Operational Database
- Create Tabulation Datasets
- Tabulation Datasets
- Create ADaM Datasets
- ADaM Datasets
- Create Analysis Results structures & shells
- Analysis Datasets
- Clinical Study Reports
- TFL
- Study Build and configuration
- Configured study metadata
- Define Study artifacts
- Generate Study artifacts
- XML
- XML
- Metadata Selection
- Standards Metadata Selection
- PDF
- Clinical Study Reports
- CDASH
- SDTM
- Tabulation Datasets
- Define Study design, concept configuration & generate artifacts
- XML
- XML
Study Build

Configured study metadata

SDM / XML

Study builder tool

Standards Selection

Study design
- Visits
- Arm’s
- Epochs.....
- Study parameters (TS)
- Eligibility criteria
- Schedule of activities (SOA)
- Study workflow

Create artifacts (use case 2)

Study Build

Schedule of Activities (SoA)

Study Parameters (TS)

Study Design

Arm AB
- Run-in
  - A 5 mg, A 10 mg
- First Treatment Epoch
  - B 5 mg, B 10 mg
- Second Treatment Epoch
  - A 5 mg, A 10 mg
- Follow Up Epoch

Arm BA
- Run-in
  - B 5 mg, B 10 mg
- First Treatment Epoch
  - A 5 mg, A 10 mg
- Second Treatment Epoch
  - B 5 mg, B 10 mg
- Follow Up Epoch

Study Configuration
Use Case 3: Execute

Automatic population of data into artifacts
Expected Outcome

• Learn
  • What works and what doesn’t

• Assessment
  • Technology Gap Analysis
  • Standards Gap Analysis

• Building a base for the future
  • Inform and involve stakeholders
  • Effort calculation and Cost / Benefit Analysis
  • Scale up to deliver the standards metadata needed
  • Partnerships with vendors to ensure tools are made available
2. Project Approach
CDISC 360 Advisory Committee

**CDISC 360 Leadership Team**

- David Bobbitt  
  CDISC Chief Executive Officer
- Peter Van Reusel  
  CDISC Chief Standards Officer
- Sam Hume  
  CDISC Vice President Data Sciences
- Barry Cohen  
  CDISC 360 Project Manager

**CDISC 360 Board Representation**

- Chris Decker - dWise
- Dave Evans - Accenture
- Dave Hardison - Deloitte
- Pandu Kulkarni - Lilly
- Steve Rosenberg - Oracle
- Ulo Palm - * Transcelerate

**CDISC 360 Committee Members**

- Praveen Garg - Astra Zeneca
- Patrick Genyn - Johnson & Johnson
- Brooke Hinkson - Merck
- Ulo Palm - Allergan
- Mike Hamidi - CDISC
Collaboration Tools

- CDISC 360 Wiki
  - Collaborative content

- Jira
  - Issues management

- CMAP Cloud
  - Concept map development

- Slack
  - Instant messaging

- Cloud Collaboration Platform
  - Use case demo environment
Reason for this scope: the Diabetes TAUG provides standardized artifacts from analysis outputs to data collection. This allows the project team to focus on innovation and not on establishing a new data standard.
Project Standards Scope
FDA Use Case

- 2 safety endpoints:
  - MACE: Major Adverse Cardiac Event
  - AKI: Acute Kidney Injury
- Turn specifications into standard concepts
- Verify analysis outputs and endpoint data vs. specifications
- Explore traceability: analysis outputs to specifications

➤ Reason for this scope: Document FDA standard safety analysis requirements that may be expressed in the analysis concept maps; ensure the enhanced standards meet reviewers’ needs
CDISC 360 Workstreams

Enhance Standards → Publish Standards

Define
Build
Execute

Study Library
CDISC 360 Workstreams

**Workstream 1 - ENHANCE STANDARDS**
Create concepts in knowledge graphs

**Workstream 2 - PUBLISH STANDARDS**
Load into library
Biomedical Concepts
Analysis Concepts
Foundational Standards

**Workstream 4 - DEFINE**
Identify and select standards specification (Use Case 1)

**Workstream 5 - BUILD**
Configure study specification and create artifacts (Use Case 2)

**Workstream 6 - EXECUTE**
Automatically process and transform data (Use Case 3)
3. Project Status
## Project Timeline

<table>
<thead>
<tr>
<th>#</th>
<th>Stage</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initiation, scoping, and internal staffing</td>
<td>Oct 2018</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>2</td>
<td>Planning, recruiting CDISC member participants</td>
<td>Dec 2019</td>
<td>Feb 2019</td>
</tr>
<tr>
<td>3</td>
<td>Align with Transcelerate Digital Data Flow Initiative</td>
<td>Oct 2018</td>
<td>Jan 2019</td>
</tr>
<tr>
<td>3</td>
<td>Onboarding CDISC member participants</td>
<td>Mar 2019</td>
<td>Apr 2019</td>
</tr>
<tr>
<td>5</td>
<td>Kickoff, workstreams briefing</td>
<td>Apr 2019</td>
<td>Apr 2019</td>
</tr>
<tr>
<td>6</td>
<td>Execution of agile sprints</td>
<td>Apr 2019</td>
<td>Oct 2019</td>
</tr>
<tr>
<td>8</td>
<td>Execution of agile sprints</td>
<td>Nov 2019</td>
<td>Mar 2020</td>
</tr>
<tr>
<td>9</td>
<td>Project evaluation – Stage 2 (CDISC EU Interchange)</td>
<td>Mar 2020</td>
<td>Mar 2020</td>
</tr>
<tr>
<td>10</td>
<td>Execution of agile sprints</td>
<td>Apr 2020</td>
<td>Nov 2020</td>
</tr>
</tbody>
</table>
Participation Summary

29 Organizations

67 Resources specified

Organization Types:
• Pharma-Biotech Sponsor: 18
• CRO: 4
• Technology Provider: 6
• Regulatory: 1
<table>
<thead>
<tr>
<th>Workstream</th>
<th>Lead</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WS 1</strong></td>
<td>Bess LeRoy</td>
<td>Manuel Anido, Joyce George, Swarupa Sudini, Jon Neville, Sally Cassells, Mikkel Traun, Chithra Subramaniam, Pei-Ling Chu, Sterling Hardy, Abnilash Chimbirithy, Venkata Maguluri, Yogesh Gupta, Carol Baker, Lauren Shinaberry</td>
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<tr>
<td><strong>WS 2</strong></td>
<td>Sam Hume</td>
<td>Francis Dsa, Stephen Pearce, Edward Altman, Haiping Yu, Jeanne Wagner, Erika Liu, Dave Iberson-Hurst, Nicolas de Saint Jorre, Roger Gagali Angoh</td>
</tr>
<tr>
<td><strong>WS 4</strong></td>
<td>Mikkel Traun</td>
<td>Trevor Mankus, Stephen Pearce, Rajesh Modi, Bharat Palakurthi, Lex Jansen, Sujit Khune, Roger Gagali Angoh</td>
</tr>
<tr>
<td><strong>WS 5</strong></td>
<td>Tianna Umann</td>
<td>Asavari Mehta, Ram Govindaraju, Devi Gohimukkula, Francis Dsa, Tobias Krøgholt, Smitha Karra, David Parkinson, Lauren Shinaberry, Jeanne Wagner</td>
</tr>
<tr>
<td><strong>WS 6</strong></td>
<td>Bhavin Busa</td>
<td>Binoy Varghese, Rick Rozinskas, Gina Selby, Naveen Kommuru, Jimmy Zhao, Anoop Ambika, Spandana Chelmilla, Lex Jansen, Prasanna Murugesan, Vinay S, Siva Tedla</td>
</tr>
</tbody>
</table>
360 Sprint Cycles for 2019

- **Sprint 1**: 8 April Kick Off, 11 April WS Briefing
- **Sprint 2**: 2 May, 28 days
- **Sprint 3**: 30 May, 29 days
- **Sprint 4**: 27 June, 43 days
- **Sprint 5**: 8 August, 22 days
- **Sprint 6**: 29 August, 22 days
- **Sprint 7**: 26 September, 29 days
- **Sprint 8**: 24 October, 29 days
- **Sprint 9**: 21 November, 29 days
- **Sprint 10**: 12 December, 29 days

Today is 12 December.
4. Achievements so far
First Stable Concept Maps

Blood Pressure (C0005823)

- Vital Signs Test Code (C83466)
  - usesNClCodeList
  - usesCodes

- Vital Signs Test Code (C66741)
  - usesNClCodeList
  - usesCodes

Unit of Measure (C23709)

- mmHg (C49670)
  - usesNClCodeList
  - defaultCode

- cmHg (C147129)
  - usesNClCodeList
  - defaultCode

Laboratory Test Result (C36592)

- mustHave

Unit (C71620)

- usesNClCodeList
  - mmHg (C49670)
  - usesCodes

- defaultCode

Procedure Location (C117525)

- usesNClCodeList

Procedure Laterality (C117526)

- Latency (C99072)
  - usesCodes

Anatomical Location (C74456)

- commonUsedCodes
  - defaultCode

- ARM (C32141)
  - LEG (C32974)
  - CALF (C32972)
  - FINGER (C32608)

- LEFT (C25229)

- RIGHT (C25228)

Body position (C62161)

- usesNClCodeList
  - Position (C25146)
    - defaultCode

- SITTING (C62122)

- SITTING (C62122); SUPINE (C62167); STANDING (C62166); DECUBITUS (C77532); FOWLERS (C62173); LATERAL DECUBITUS (C100758); LEFT LATERAL DECUBITUS (C62172); PRONE (C52165); REVERSE TRENDELENBURG (C52169); RIGHT LATERAL DECUBITUS (C52171); SEMI-FOWLERS (C62174); SEMI-RECUMBENT (C113130); SLING (C52804); TRENDELENBURG (C52168); UNCONSTRAINED (C99804)

Collection date/time (C82515)

- mayHave

Planned Time Points (C2826271)

- specify

- Time Points

#CDISCUS | #ClearDataClearImpact
Transforming Biomedical Concepts into JSON

"designation": "Height",
"conceptId": "X25347",
"label": "Height Biomedical Concept",
"definition": "The vertical measurement or distance from the base…",
"testCode": "HEIGHT",
"testConceptId": "C25347",
"testName": "Height",
"loincCode": "8302-2",
"resultType": "Numeric",
"unitList": ["cm (C49668)", "in (C48500)", "mm (C28251)"],
"standardUnit": "cm (C49668)"
User Experience to demonstrate use cases
Standards and Biomedical Concepts Work Together

VS Domain from CDISC Library

```json
{
  "ordinal": "16",
  "name": "VSORRES",
  "label": "Vital Signs Result",
  "definition": "Result of the vital signs measurement as originally received or collected.",
  "questionText": "What was the result of the measurement?",
  "prompt": "Result",
  "completionInstructions": "Record the vital sign result.",
  "implementationNotes": "N/A",
  "simpleDatatype": "Char",
  "mappingInstructions": "Maps directly to the SDMIG variable listed in the column with the core": "HR",
  "_links": {
    "self": {
      "href": "/mdr/cdashig/2-0/domains/VS/fields/VSORRES",
      "title": "Vital Signs Result",
      "type": "Data Collection Field"
    },
    "parentProduct": {
      "href": "/mdr/cdashig/2-0",
      "title": "Clinical Data Acquisition Standards Harmonization Implementation Guide fo",
      "type": "Implementation Guide"
    },
    "parentDomain": {
      "href": "/mdr/cdashig/2-0/domains/VS",
      "title": "Vital Signs",
      "type": "CDAH Domain"
    },
    "rootItem": {
      "href": "/mdr/root/cdashig/domains/VS/fields/VSORRES",
      "title": "Version-agnostic anchor element for field VS.VSORRES",
      "type": "Root Data Element"
    }
  }
}
```

Height BC from CDISC 360

```json
{
  "designation": "Height",
  "conceptId": "X25347",
  "label": "Height Biomedical Concept",
  "definition": "The vertical measurement or distance from the base to the top of an object,
  "testCode": "HEIGHT",
  "testConceptId": "C25347",
  "sexName": "Height",
  "joinCode": "8302-2",
  "resultType": "Numeric",
  "unitList": [
    "on (C49668)", "in (C48500)", "mm (C28251)"
  ],
  "standardUnit": "on (C49668)",
  "_links": {
    "self": {
      "href": "/mdr/bc/1-0/VS/X25347",
      "title": "Height Biomedical Concept",
      "type": "Biomedical Concept"
    },
    "parentConcept": {
      "href": "/mdr/bc/1-0/VS",
      "title": "Vital Signs Biomedical Concepts",
      "type": "VS Biomedical Concept"
    },
    "rootItem": {
      "href": "/mdr/root/bc/domains/VS/concepts/Height",
      "title": "Version-agnostic anchor element for Biomedical Concept Height",
      "type": "Root Data Element"
    }
  }
}
```
Generate a Vital Signs CRF based on ODM

<table>
<thead>
<tr>
<th>Vital Signs (Timepoint)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the date of the vital signs measurement? (DD-MM-YYYY)</td>
<td></td>
</tr>
<tr>
<td>What was the time of the vital signs measurement? (24 hour clock)</td>
<td></td>
</tr>
<tr>
<td>Were vital signs performed?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Reason Not Performed</td>
</tr>
<tr>
<td>What was the result of the weight measurement?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>kg</td>
</tr>
<tr>
<td></td>
<td>LB</td>
</tr>
<tr>
<td>What was the result of the height measurement?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cm</td>
</tr>
<tr>
<td></td>
<td>in</td>
</tr>
<tr>
<td>What was the result of the temperature measurement?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>°C</td>
</tr>
<tr>
<td></td>
<td>°F</td>
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</table>

<table>
<thead>
<tr>
<th>Vital Signs (Timepoint)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the planned time point for this vital signs measurement?</td>
<td></td>
</tr>
<tr>
<td>What was the position of the subject during the measurement?</td>
<td></td>
</tr>
<tr>
<td>What was the result of the systolic blood pressure measurement?</td>
<td></td>
</tr>
<tr>
<td>What was the result of the diastolic blood pressure measurement?</td>
<td></td>
</tr>
<tr>
<td>What was the result of the heart rate measurement?</td>
<td></td>
</tr>
<tr>
<td>5 min pre-dose</td>
<td>Sitting</td>
</tr>
<tr>
<td>30 min post-dose</td>
<td>Sitting</td>
</tr>
<tr>
<td>Variable</td>
<td>Where Condition</td>
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<tr>
<td>------------</td>
<td>-----------------</td>
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<td>USUBJID</td>
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<td>VSSEQ</td>
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<tr>
<td>VTESTSCD</td>
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<tr>
<td>VSRESCD</td>
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</tr>
<tr>
<td>VSRRES</td>
<td></td>
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<tr>
<td>VSRRESU</td>
<td></td>
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Thank You!
Peter Van Reusel
KEEP CALM AND VOLUNTEER NOW!