

# My Personal Experience: Self-creation of SEND Dataset

Eisai Co., Ltd.

August 4, 2016

Gen Sato, PhD, DABT

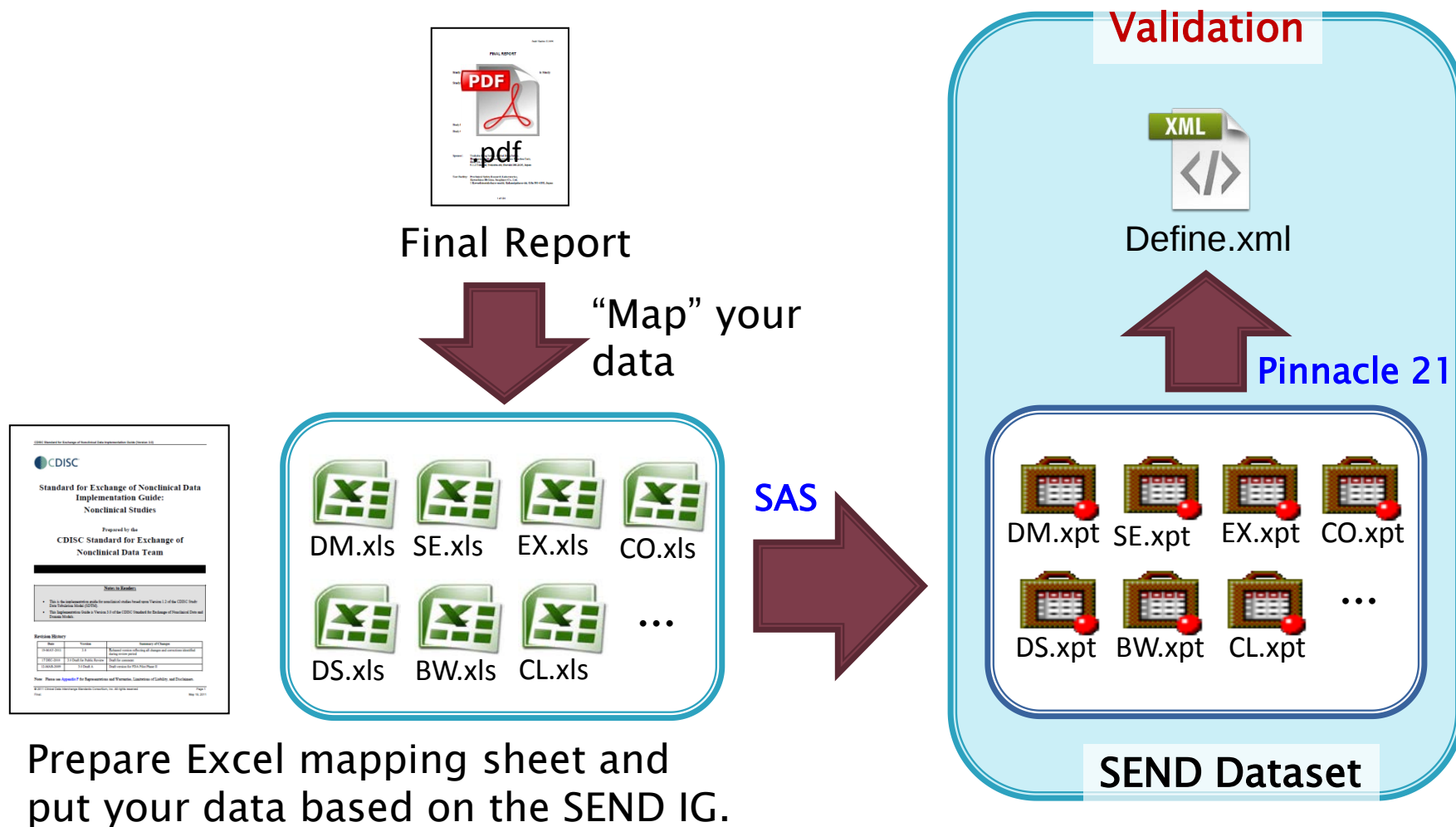
Global Regulatory, Nonclinical Japan



- **The comments made in this presentation are individual opinion of the presenter, and are not necessarily reflective of the positions of Eisai.**
- **The contents in this presentation are current understanding of the presenter and may further be updated.**
- **The presenter does not guarantee that the SEND Dataset created based on this presentation will be 100% accepted by the regulatory agency.**

- At the annual Japanese Society of Toxicology (J-SOT) meeting in June 2016, I briefly explained how to “manually” create SEND datasets
- I DO NOT recommend self-creation of SEND datasets for regulatory submission purpose (leave it to your SEND software or outsourcing!)
- However, it is good to experience such process by yourself so that you can understand the structure of SEND datasets in details
- You may be able to acquire knowledge to correct SEND datasets when necessary as a result

# Flowchart of SEND Dataset Creation



# **Creation of SEND Datasets (each domain)**

# Creation of SEND Dataset in Excel (1)

## 5.3.1 SUBJECT ELEMENTS – SE

se.xpt, Subject Elements - Special-Purpose Domains. One record per element experienced per subject, Tabulation.

| Variable Name | Variable Label             | Type | Controlled Terms, Codelist, or Format | Role              | CDISC Notes                                                                                                                                                                                                                                                                                                                                                                                                           | Core |
|---------------|----------------------------|------|---------------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| STUDYID       | Study Identifier           | Char |                                       | Identifier        | Unique identifier for a study.                                                                                                                                                                                                                                                                                                                                                                                        | Req  |
| DOMAIN        | Domain Abbreviation        | Char | SE                                    | Identifier        | Two-character abbreviation for the domain.                                                                                                                                                                                                                                                                                                                                                                            | Req  |
| USUBJID       | Unique Subject Identifier  | Char |                                       | Identifier        | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.                                                                                                                                                                                                                                                                                          | Req  |
| SESEQ         | Sequence Number            | Num  |                                       | Identifier        | Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number.                                                                                                                                                                                                                                                                                              | Req  |
| ETCD          | Element Code               | Char |                                       | Topic             | Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use UNPLAN as the value for ETCD to represent this Element. The value in ETCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). | Req  |
| ELEMENT       | Description of Element     | Char |                                       | Synonym Qualifier | The name of the Element. The same Element may occur more than once within an Arm. If ETCD has the value of UNPLAN, then ELEMENT should be blank.                                                                                                                                                                                                                                                                      | Perm |
| SESTDTC       | Start Date/Time of Element | Char | ISO 8601                              | Timing            | Start date/time for an Element for each subject.                                                                                                                                                                                                                                                                                                                                                                      | Req  |
| SEENDTC       | End Date/Time of Element   | Char | ISO 8601                              | Timing            | End date/time for an Element for each subject.                                                                                                                                                                                                                                                                                                                                                                        | Exp  |
| SEUPDES       |                            |      |                                       |                   |                                                                                                                                                                                                                                                                                                                                                                                                                       |      |

SE.xls [互換モード] - Microsoft Excel

ファイル ホーム 挿入 ページレイアウト 数式 データ 送受 表示 Acrobat BizLingo

MS Pゴシック 11 A A 折り返して全体を表示する 文字列 条件付き書式 テーブルとして書式設定 セルのスタイル 挿入 削除 書式 セル 並べ替えとフィルター 検索と選択 編集

I32 fx

1 STUDYID DOMAIN USUBJID SESEQ ETCD ELEMENT SESTDTC SEENDTC SEUPDES

2

3

4

5

6

# Creation of SEND Dataset in Excel (2)

## 5.3.1 SUBJECT ELEMENTS – SE

se.xpt, Subject Elements - Special-Purpose Domains. One record per element experienced per subject, Tabulation.

| Variable Name | Variable Label             | Type | Controlled Terms, Codelist, or Format | Role              | CDISC Notes                                                                                                                                                                                                                                                                                                                                                                                                           | Core |
|---------------|----------------------------|------|---------------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| STUDYID       | Study Identifier           | Char |                                       | Identifier        | Unique identifier for a study.                                                                                                                                                                                                                                                                                                                                                                                        | Req  |
| DOMAIN        | Domain Abbreviation        | Char | SE                                    | Identifier        | Two-character abbreviation for the domain.                                                                                                                                                                                                                                                                                                                                                                            | Req  |
| USUBJID       | Unique Subject Identifier  | Char |                                       | Identifier        | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.                                                                                                                                                                                                                                                                                          | Req  |
| SESEQ         | Sequence Number            | Num  |                                       | Identifier        | Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number.                                                                                                                                                                                                                                                                                              | Req  |
| ETCD          | Element Code               | Char |                                       | Topic             | Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use UNPLAN as the value for ETCD to represent this Element. The value in ETCD cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST” is not valid). | Req  |
| ELEMENT       | Description of Element     | Char |                                       | Synonym Qualifier | The name of the Element. The same Element may occur more than once within an Arm. If ETCD has the value of UNPLAN, then ELEMENT should be blank.                                                                                                                                                                                                                                                                      | Perm |
| SESTDTC       | Start Date/Time of Element | Char | ISO 8601                              | Timing            | Start date/time for an Element for each subject.                                                                                                                                                                                                                                                                                                                                                                      | Req  |
| SEENDTC       | End Date/Time of           | Char | ISO 8601                              | Timing            | End date/time for an Element for each subject                                                                                                                                                                                                                                                                                                                                                                         | Exp  |
| SEUPDES       |                            |      |                                       |                   |                                                                                                                                                                                                                                                                                                                                                                                                                       |      |

|   | A       | B      | C        | D     | E     | F               | G                | H                | I       | J |
|---|---------|--------|----------|-------|-------|-----------------|------------------|------------------|---------|---|
| 1 | STUDYID | DOMAIN | USUBJID  | SESEQ | ETCD  | ELEMENT         | SESTDTC          | SEENDTC          | SEUPDES |   |
| 2 | ABC1    | SE     | ABC1-001 | 1     | SCRN  | Screen          | 2008-01-08       | 2008-01-14T07:00 |         |   |
| 3 | ABC1    | SE     | ABC1-001 | 2     | GP 01 | Vehicle Control | 2008-01-14T07:00 | 2008-01-27T09:00 |         |   |
| 4 |         |        |          |       |       |                 |                  |                  |         |   |
| 5 |         |        |          |       |       |                 |                  |                  |         |   |
| 6 |         |        |          |       |       |                 |                  |                  |         |   |

# Creation of SEND Dataset in Excel (3)

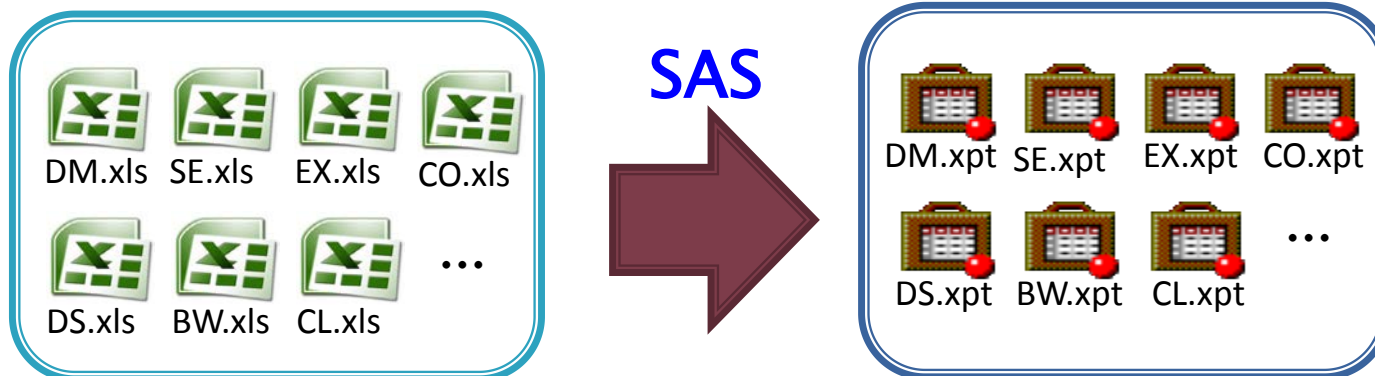
## 5.3.1 SUBJECT ELEMENTS – SE

se.xpt, Subject Elements – Special-Purpose Domains. One record per element experienced per subject, Tabulation.

| Variable Name | Variable Label             | Type | Controlled Terms, Codelist, or Format | Role              | CDISC Notes                                                                                                                                                                                                                                                                                                                                                                                                           | Core |
|---------------|----------------------------|------|---------------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| STUDYID       | Study Identifier           | Char |                                       | Identifier        | Unique identifier for a study.                                                                                                                                                                                                                                                                                                                                                                                        | Req  |
| DOMAIN        | Domain Abbreviation        | Char | SE                                    | Identifier        | Two-character abbreviation for the domain.                                                                                                                                                                                                                                                                                                                                                                            | Req  |
| USUBJID       | Unique Subject Identifier  | Char |                                       | Identifier        | Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.                                                                                                                                                                                                                                                                                          | Req  |
| SESEQ         | Sequence Number            | Num  |                                       | Identifier        | Sequence number given to ensure uniqueness of subject records within a USUBJID within a domain. May be any valid number.                                                                                                                                                                                                                                                                                              | Req  |
| ETCD          | Element Code               | Char |                                       | Topic             | Short name of the Element used for programming and sorting. The same Element may occur more than once within an Arm. If an encountered Element differs from the planned Element to the point that it is considered a new Element, then use UNPLAN as the value for ETCD to represent this Element. The value in ETCD cannot be longer than 8 characters, nor can it start with a number (e.g., “1TEST” is not valid). | Req  |
| ELEMENT       | Description of Element     | Char |                                       | Synonym Qualifier | The name of the Element. The same Element may occur more than once within an Arm. If ETCD has the value of UNPLAN, then ELEMENT should be blank.                                                                                                                                                                                                                                                                      | Perm |
| SESTDTC       | Start Date/Time of Element | Char | ISO 8601                              | Timing            | Start date/time for an Element for each subject.                                                                                                                                                                                                                                                                                                                                                                      | Req  |
| SEENDTC       | End Date/Time of           | Char | ISO 8601                              | Timing            | End date/time for an Element for each subject.                                                                                                                                                                                                                                                                                                                                                                        | Exp  |
| SEUPDES       |                            |      |                                       |                   |                                                                                                                                                                                                                                                                                                                                                                                                                       |      |

The screenshot shows an Excel spreadsheet with columns A through J. Row 1 contains headers: STUDYID, DOMAIN, USUBJID, SESEQ, ETCD, ELEMENT, SESTDTC, SEENDTC, SEUPDES. Row 2 contains data: ABC1, SE, ABC1-001, 1. Row 3 contains data: ABC1, SE, ABC1-001, 2. The SESEQ column is highlighted in yellow. The 'セルの書式設定' (Format Cells) dialog box is open, showing the 'Number' category with '1' selected in the 'Decimal places' field. An orange arrow points from the 'Num' type in the table above to the SESEQ cell in the spreadsheet.

# Conversion of Excel to SAS EXPORT file



## How to convert Excel to .xpt?

- Import your Excel file (.xls) to SAS Work
- Export your dataset as SAS EXPORT file (.xpt)

## Issues you may be faced:

- Need manually put “Label” name for each Variable
- Variable length should be shortened

# **Creation of Define.xml file (SEND)**

# What is (Define).xml?



Comment `<!-- Dataset Definition (TE) -->`

```
<ItemGroupDef OID="IG.TE"
  Domain="TE"
  Name="TE"
  Repeating="No"
  IsReferenceData="Yes"
  SASDatasetName="TE"
  Purpose="Tabulation"
  def:Structure="One record per planned Element"
  def:Class="TRIAL DESIGN"
  def:ArchiveLocationID="LF.TE">
```

Element

```
<Description>
```

```
  <TranslatedText xml:lang="en">Trial Elements</TranslatedText>
```

```
</Description>
```

```
<ItemRef ItemOID="IT.STUDYID" OrderNumber="1" Mandatory="Yes" KeySequence="1"/>
<ItemRef ItemOID="IT.TE.DOMAIN" OrderNumber="2" Mandatory="Yes"/>
<ItemRef ItemOID="IT.TE.ETCD" OrderNumber="3" Mandatory="Yes" KeySequence="2"/>
<ItemRef ItemOID="IT.TE.ELEMENT" OrderNumber="4" Mandatory="Yes"/>
<ItemRef ItemOID="IT.TE.TESTRL" OrderNumber="5" Mandatory="Yes"/>
<ItemRef ItemOID="IT.TE.TEDUR" OrderNumber="6" Mandatory="No"/>
<def:leaf ID="LF.TE" xlink:href="te.xpt">
  <def:title>te.xpt</def:title>
</def:leaf>
</ItemGroupDef>
```

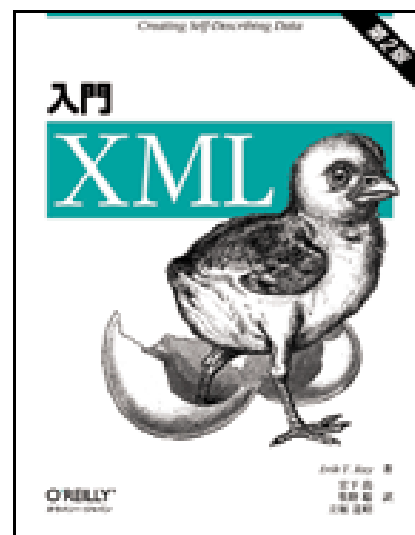
- ✓ XML: EXtensible Markup Language
- ✓ Describe data as elements using tag  
`<ABC> ~ </ABC>`
- ✓ FDA recommend to use Define.xml since 2005

# If you are interested in XML...

## (Examples)

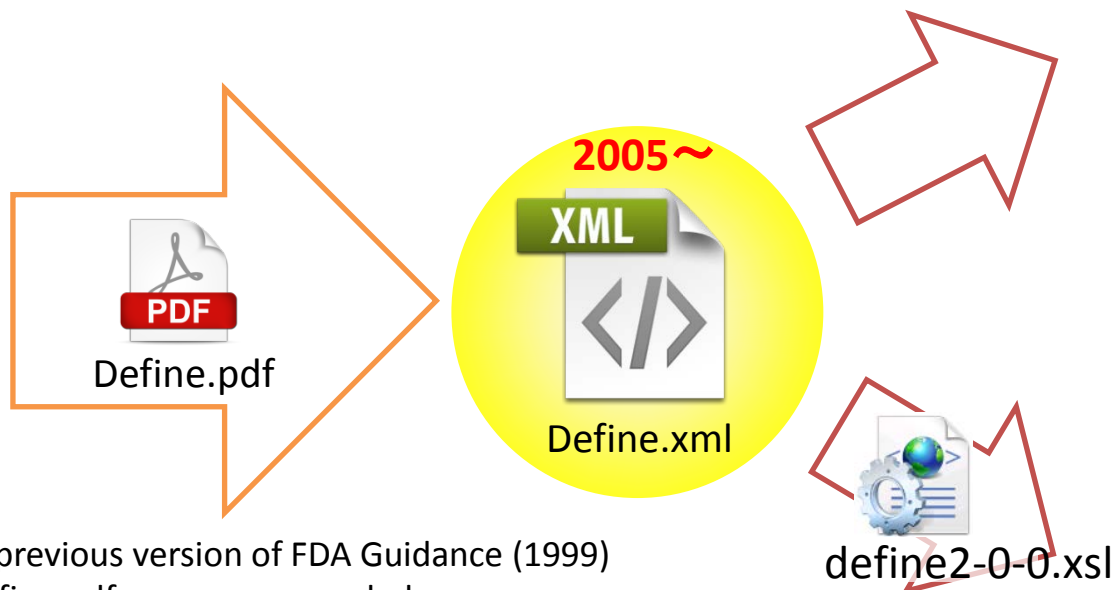


やさしいXML  
(高橋 真奈 著)



入門XML(オライリー)

# Making XML human-readable



In previous version of FDA Guidance (1999) Define.pdf was recommended.  
Even now, Define.pdf need to be attached in case of Define v1.0 due to printing issue.

```
<!-- Dataset Definition (TE) -->
<ItemGroupDef OID="IG.TE"
  Domain="TE"
  Name="TE"
  Repeating="No"
  IsReferenceData="Yes"
  SASDatasetName="TE"
  Purpose="Tabulation"
  def:Structure="One record per planned Element"
  def:Class="TRIAL DESIGN"
  def:ArchiveLocationId="LF.TE">
  <Description>
    <TranslatedText xml:lang="en">Trial Elements</TranslatedText>
  </Description>
  <ItemRef ItemOID="IT.STUDVID" OrderNumber="1" Mandatory="Yes" KeySequence="1"/>
  <ItemRef ItemOID="IT.TE.DOMAIN" OrderNumber="2" Mandatory="Yes"/>
  <ItemRef ItemOID="IT.TE.ECD" OrderNumber="3" Mandatory="Yes" KeySequence="2"/>
  <ItemRef ItemOID="IT.TE.ELEMENT" OrderNumber="4" Mandatory="Yes"/>
  <ItemRef ItemOID="IT.TE.TESTRL" OrderNumber="5" Mandatory="Yes"/>
  <ItemRef ItemOID="IT.TE.TEDUR" OrderNumber="6" Mandatory="No"/>
  <def:leaf ID="LF.TE" xlink:href="te.xps">
  </def:leaf>
</ItemGroupDef>
```

Machine readable

Same contents (some may not be shown)

| Item | Item Name  | Item Type     | Item Description                   | Item Value |
|------|------------|---------------|------------------------------------|------------|
| 1    | STUDVID    | Study ID      | One record per planned Element per | STUDVID    |
| 2    | TE.DOMAIN  | Domain        | One record per planned Element     | TE.DOMAIN  |
| 3    | TE.ECD     | Element Class | One record per planned Element per | TE.ECD     |
| 4    | TE.ELEMENT | Element       | One record per planned Element per | TE.ELEMENT |
| 5    | TE.TESTRL  | Test Result   | One record per planned Element per | TE.TESTRL  |
| 6    | TE.TEDUR   | Test Duration | One record per planned Element per | TE.TEDUR   |

Human readable

- **A Define-XML file includes the following key content components:**
  1. XML header, the ODM root element, Study and MetaDataVersion.
  2. Information about linked PDF documents such as annotated Case Report Forms and Supplemental Data Definitions.
  3. Dataset definitions.
  4. Variable definitions.
  5. Value definitions (including Where Clause definitions)
  6. Controlled Terminology definitions
  7. Computational Method definitions
  8. Comment definitions

# How to create Define.xml? (PhUSE Wiki)



## Preparation

[\[edit\]](#)

### Getting a Base File

[\[edit\]](#)

If you are using a vendor solution to create SEND files, it typically will come bundled with functionality to output a define.xml file.

If you need to create one yourself, then the [OpenCDISC Validator](#) tool can be used to generate the basis of a define.xml file off a set of SEND XPT files (select "Generate Define.xml" and then your SEND XPT files). This is a good starting point for your define.xml, as it will create all of the structural basics for you; however, it does not have the ability to populate the company-specific information such as comments, desired data types, custom controlled terminology, and so on.

Another option is to use an example define file provided from the [define-xml](#) site. These have more realistic examples, although not SEND-based.

### Refining

[\[edit\]](#)

The raw define file needs several additions and refinements.

- File/study metadata:
  - Creation datetime in the ODM element's CreationDateTime attribute
  - Study Name, Description, and Protocol Name in the Study element's GlobalVariables subelement (e.g., ABC123, 28-Day Oral Toxicology Study in Rats, and ABC123, respectively)
  - Name under the MetaDataVersion element's Name attribute (e.g., "Study ABC123, Data Definitions")
- Domain (ItemGroupDef) keys under the def:DomainKeys attribute
- Domain variable references' (ItemRef) attributes, including a review of the Mandatory and Role attributes for domain variables (can be incorrect in the templates)
- Variable definitions' (ItemDef) attributes, including:
  - Populating the Origin attribute
  - Populating the Comments attribute
  - Revising the Type and/or Length attributes
  - Added a CodeListRef subelement when CT applies to the variable
- CodeList elements for each CT list used (internal and external)
- Any value lists used (ValueList), including SUPP-- variable descriptions.

# Define.xml prep using Pinnacle 21 (1)



**P21**  
pinnacle21-community.exe

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an open source toolkit for the CDISC professional

Where would you like to begin?

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Check compliance with SDTM, SEND, ADaM, and Define.xml
- Define.xml Generator**  
Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets
- Data Converter**  
Convert data between SAS XPORT, Excel, CSV, and Dataset-XML
- ClinicalTrials.gov Miner**  
Aggregate clinical outcomes and site info across trials and therapeutic areas

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# Define.xml prep using Pinnacle 21 (2)



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## Define.xml Generator

create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets

### Create Excel Specification

#### Extract Metadata from SAS XPORT Datasets

Source Data

Drop files here to select them  
or



Browse...

Select your datasets

Configuration

SEND 3.0 (FDA)



Create

#### Import Define.xml

Define.xml

Browse...

Create

# Define.xml prep using Pinnacle 21 (3)



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## Define.xml Generator

*create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets*

Create Excel  
Extract Metadata  
Source Data  
Configuration  
Import Define.xml  
Define.xml

### Generating Define.xml Excel Spec

Complete!

Close Open Spec

F:\SEND\ Instem PDS VABBA SEND IDS.xpt  
14 files Add more files Remove all  
SEND 3.0 (FDA)  
Create  
Import Define.xml  
Define.xml Browse... Create

Excel Spec file is automatically saved at: pinnacle21-community > components > reports

# Define.xml prep using Pinnacle 21 (4)



define-2016-04-08T14-22.xlsx - Microsoft Excel

ファイル ホーム 挿入 ページレイアウト 数式 データ 校閲 表示 Acrobat BizLingo

Calibri 11 A<sup>+</sup> A<sup>-</sup> B I U 折り返して全体を表示する 標準 条件付き書式 テーブルとして書式設定 セルのスタイル 挿入 削除 書式 並べ替えとフィルター 検索と選択

|    | A                | B       | C | D | E | F | G |
|----|------------------|---------|---|---|---|---|---|
| 1  | Attribute        | Value   |   |   |   |   |   |
| 2  | StudyName        |         |   |   |   |   |   |
| 3  | StudyDescription | (blank) |   |   |   |   |   |
| 4  | ProtocolName     |         |   |   |   |   |   |
| 5  | StandardName     | SEND-IG |   |   |   |   |   |
| 6  | StandardVersion  | 3.0     |   |   |   |   |   |
| 7  | Language         | en      |   |   |   |   |   |
| 8  |                  |         |   |   |   |   |   |
| 9  |                  |         |   |   |   |   |   |
| 10 |                  |         |   |   |   |   |   |
| 11 |                  |         |   |   |   |   |   |
| 12 |                  |         |   |   |   |   |   |
| 13 |                  |         |   |   |   |   |   |
| 14 |                  |         |   |   |   |   |   |
| 15 |                  |         |   |   |   |   |   |
| 16 |                  |         |   |   |   |   |   |
| 17 |                  |         |   |   |   |   |   |
| 18 |                  |         |   |   |   |   |   |
| 19 |                  |         |   |   |   |   |   |
| 20 |                  |         |   |   |   |   |   |
| 21 |                  |         |   |   |   |   |   |
| 22 |                  |         |   |   |   |   |   |

Study Datasets Variables ValueLevel WhereClauses Codelists Dictionaries Methods Comments Document1

コマンド 125%

# Define.xml prep using Pinnacle 21 (5)



define-2016-04-08T14-22.xlsx - Microsoft Excel

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Calibri 11 A<sup>+</sup> A<sup>-</sup> 標準 条件付き書式 テーブルとして書式設定 セルのスタイル 挿入 削除 書式 並べ替えとフィルター 検索と選択

Order

|    | A     | B       | C        | D            | E         | F      | G                  | H      | I         | J        | K      |
|----|-------|---------|----------|--------------|-----------|--------|--------------------|--------|-----------|----------|--------|
| 1  | Order | Dataset | Variable | Where Clause | Data Type | Length | Significant Digits | Format | Mandatory | Codelist | Origin |
| 2  |       |         |          |              |           |        |                    |        |           |          |        |
| 3  |       |         |          |              |           |        |                    |        |           |          |        |
| 4  |       |         |          |              |           |        |                    |        |           |          |        |
| 5  |       |         |          |              |           |        |                    |        |           |          |        |
| 6  |       |         |          |              |           |        |                    |        |           |          |        |
| 7  |       |         |          |              |           |        |                    |        |           |          |        |
| 8  |       |         |          |              |           |        |                    |        |           |          |        |
| 9  |       |         |          |              |           |        |                    |        |           |          |        |
| 10 |       |         |          |              |           |        |                    |        |           |          |        |
| 11 |       |         |          |              |           |        |                    |        |           |          |        |
| 12 |       |         |          |              |           |        |                    |        |           |          |        |
| 13 |       |         |          |              |           |        |                    |        |           |          |        |
| 14 |       |         |          |              |           |        |                    |        |           |          |        |
| 15 |       |         |          |              |           |        |                    |        |           |          |        |
| 16 |       |         |          |              |           |        |                    |        |           |          |        |
| 17 |       |         |          |              |           |        |                    |        |           |          |        |
| 18 |       |         |          |              |           |        |                    |        |           |          |        |
| 19 |       |         |          |              |           |        |                    |        |           |          |        |
| 20 |       |         |          |              |           |        |                    |        |           |          |        |
| 21 |       |         |          |              |           |        |                    |        |           |          |        |
| 22 |       |         |          |              |           |        |                    |        |           |          |        |
| 23 |       |         |          |              |           |        |                    |        |           |          |        |
| 24 |       |         |          |              |           |        |                    |        |           |          |        |
| 25 |       |         |          |              |           |        |                    |        |           |          |        |
| 26 |       |         |          |              |           |        |                    |        |           |          |        |
| 27 |       |         |          |              |           |        |                    |        |           |          |        |
| 28 |       |         |          |              |           |        |                    |        |           |          |        |
| 29 |       |         |          |              |           |        |                    |        |           |          |        |
| 30 |       |         |          |              |           |        |                    |        |           |          |        |

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Study Datasets Variables ValueLevel WhereClauses Codelists Dictionaries Methods Comments Documents

コマンド 100%

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- ClinicalTrials.gov

## Define.xml Generator

create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets

Generate Define.xml

Excel Spec

Browse...

Generate

Choose your Excel Spec  
after “refining”

# Define.xml prep using Pinnacle 21 (8)



Pinnacle 21 Community

File View Help

- Home
- Validator
- Define.xml
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- Generate Define
- Converter
- ClinicalTrials.gov

## Define.xml Generator

create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets

Generate Define.xml

Excel Spec

### Generating Define.xml



Complete!

Close

Open Define.xml

ports\define-2016-04-08T14-22.xls

Browse...



# **Validation of SEND Dataset**

# Pinnacle 21 Validation Rule



ID

Message

Description

Severity

|    | A              | B               | C                                                                                                 | D                                                                                                                                                                                                                                                                                                     | E           | F        |
|----|----------------|-----------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------|
| 1  | Pinnacle 21 ID | Publisher ID    | Message                                                                                           | Description                                                                                                                                                                                                                                                                                           | Category    | Severity |
| 2  | CT2001         | FDAN340         | -- value not found in '-- non-extensible codelist                                                 | Variable must be populated with terms from its CDISC controlled terminology codelist. New terms cannot be added into non-extensible codelists.                                                                                                                                                        | Terminology | Error    |
| 3  | CT2002         | FDAN341         | -- value not found in '-- extensible codelist                                                     | Variable should be populated with terms from its CDISC controlled terminology codelist. New terms can be added as long as they are not duplicates, synonyms or subsets of existing standard terms.                                                                                                    | Terminology | Warning  |
| 4  | CT2003         | FDAN342         | -- and -- values do not have the same Code in CDISC CT                                            | Paired variables such as TEST/TESTCD must be populated using terms with the same Codelist Code value in CDISC control terminology. There is one-to-one relationship between paired variable values defined in CDISC control terminology by Codelist Code value.                                       | Terminology | Error    |
| 5  | CT2004         | FDAN343         | -- value not found in '-- non-extensible codelist                                                 | Variable must be populated with terms from its CDISC controlled terminology codelist, when its value level condition is met. New terms cannot be added into non-extensible codelists.                                                                                                                 | Terminology | Error    |
| 6  | CT2005         | FDAN344         | -- value not found in '-- extensible codelist                                                     | Variable should be populated with terms from its CDISC controlled terminology codelist, when its value level condition is met. New terms can be added as long as they are not duplicates, synonyms or subsets of existing standard terms.                                                             | Terminology | Warning  |
| 7  | CT2006         | FDAN345         | -- and -- values do not have the same Code in CDISC CT                                            | Paired variables such as TEST/TESTCD must be populated using terms with the same Codelist Code value in CDISC control terminology. There is one-to-one relationship between paired variable values defined in CDISC control terminology by Codelist Code value within the same value level condition. | Terminology | Error    |
| 8  | SD0001         | FDAN014,FDAN015 | No records in data source                                                                         | Domain table should have at least one record.                                                                                                                                                                                                                                                         | Presence    | Warning  |
| 9  | SD0002         | FDAN018,FDAN019 | NULL value in -- variable marked as Required                                                      | Required variables (where Core attribute is 'Req') cannot be NULL for any records.                                                                                                                                                                                                                    | Presence    | Warning  |
| 10 | SD0003         | FDAN038         | Invalid ISO 8601 value for -- variable                                                            | Value of Dates/Time variables (*DTC) must conform to the ISO 8601 international standard.                                                                                                                                                                                                             | Format      | Error    |
| 11 | SD0004         | FDAN056         | Inconsistent value for DOMAIN                                                                     | Domain Abbreviation (DOMAIN) variable should be consistent with the name of the dataset.                                                                                                                                                                                                              | Consistency | Warning  |
| 12 | SD0005         | FDAN044         | Duplicate value for --SEQ variable                                                                | The value of Sequence Number (--SEQ) variable must be unique for each record within a domain and within each Unique Subject Identifier (USUBJID) or Pool Identifier (POOLID) variables value when they are present in the domain.                                                                     | Consistency | Error    |
| 13 | SD0007         | FDAN084         | Inconsistent value for Standard Units                                                             | Standard Units (--STRESU) must be consistent for all records with same Short Name of Measurement, Test or Examination (--TESTCD), Category (--CAT), Specimen Type (--SPEC) and Method of Test or Examination (--METHOD).                                                                              | Consistency | Warning  |
| 14 | SD0012         | FDAN106         | --STDY is after --ENDY                                                                            | Study Day of Start of Event, Exposure or Observation (--STDY) must be less or equal to Study Day of End of Event, Exposure or Observation (--ENDY).                                                                                                                                                   | Limit       | Warning  |
| 15 | SD0013         | FDAN107         | --STDTC is after --ENDTC                                                                          | Start Date/Time of Event, Exposure or Observation (--STDTC) must be less or equal to End Date/Time of Event, Exposure or Observation (--ENDTC).                                                                                                                                                       | Limit       | Warning  |
| 16 | SD0014         | FDAN081         | Negative value for --DOSE                                                                         | Non-missing Dose (--DOSE) value must be greater than or equal to 0.                                                                                                                                                                                                                                   | Limit       | Error    |
| 17 | SD0015         | FDAN082         | Negative value for --DUR                                                                          | 0.                                                                                                                                                                                                                                                                                                    | Limit       | Error    |
| 18 | SD0016         | FDAN114         | Character Result/Finding in Std Format (--STRESC) value should not be NULL, when Derived Flag (-- |                                                                                                                                                                                                                                                                                                       |             |          |



# FDA Specific SEND Validation Rules



← → ↺ ↻ 🏠 📄 [www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm](http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm) 🌟 ☰

1. The Agency can process, review, and archive electronic submissions that provide study data using the standards, formats, and terminologies specified in the **Data Standards Catalog** ([Click here](#)) For Centers other than CBER and CDER there may be additional supported standards, please check with the specific Center.

To submit standardized study data using a standards that is unsupported or retired, see the [guidelines for requesting a waiver to current supported clinical study data standard versions](#).

2. **For CDER and CBER: Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Standardized Study Data.** [Click here to access the full guidance document](#). The guidance describes how FDA plans to implement the requirements for the electronic submission of standardized study data.

3. **Study Data Technical Conformance Guide v3.0** [Click here to access the Guide](#). This Guide provides technical specifications, recommendations, and general considerations on how to submit standardized electronic study data.

3a. Recommendations for Preparing a Study Data Standardization Plan ([click here](#))

## 4. Study Data Validation Rules

### 4a. FDA Specific SEND Validation Rules

The following document outlines FDA's validation rules for SEND formatted non-clinical studies.

[Nonclinical Validator Specifications \(XLS\)](#)

### 4b. FDA Specific SDTM Validation Rules

The following document outlines FDA's validation rules for SDTM formatted clinical studies. [SDTM](#)

[Validator Specification \(XLS\)](#)

## Additional Center-specific information

- [CBER Study Data Standards](#) For additional information/support, please contact : [cber.cdsc@fda.hhs.gov](mailto:cber.cdsc@fda.hhs.gov)
- [CDER Study Data Standards](#) For additional information/support, please contact: [cdcr-edata@fda.hhs.gov](mailto:cdcr-edata@fda.hhs.gov)
- [CDRH Study Data Standards](#) For additional information/support, please contact: [CDRH.DataStandards@fda.hhs.gov](mailto:CDRH.DataStandards@fda.hhs.gov) Where indicated in the Data Standards Catalog, study data standards are recognized and supported by the Center, but are currently voluntary. See Center-specific page for further information.

<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>

## **Error:** SDRG Section 5.3

This section summarizes findings from validation. Insert errors from the SEND conformance report into the table provided.

- Annotate issues with a brief, non-technical explanation of the findings
- Do not include skipped validation checks or validation checks for which datasets do not exist.
- Explain why validation errors could not be corrected.
- If you are using a SEND conformance checker other than FDA rules, report only the diagnostic messages for validation rules that correspond with the FDA rules.

## **Warning :** SDRG Section 5.4

Describe any relevant validation warnings that could not be corrected similar to description of errors in section 5.3 above.

**Notice:** (No direct impact on data quality; usually informational)

# Validate Dataset using Pinnacle 21 (1)



**P21**  
pinnacle21-community.exe

**Pinnacle 21 Community**  
an open source toolkit for the CDISC professional

Where would you like to begin?

- Validator**  
Check compliance with SDTM, SEND, ADaM, and Define.xml
- Define.xml Generator**  
Create compliant Define.xml 2.0 for SDTM, SEND, and ADaM datasets
- Data Converter**  
Convert data between SAS XPORT, Excel, CSV, and Dataset-XML
- ClinicalTrials.gov Miner**  
Aggregate clinical outcomes and site info across trials and therapeutic areas

**Recent Updates**

- Pinnacle 21 Community 2.1.1 is now available. [Download now.](#) 11 days ago
- PMDA Validation Rules webinar - recap and presentation slides are [now available.](#) 3 months ago
- Pinnacle 21 Community 2.1.0 is now available. [Download now.](#) 4 months ago
- OpenCDISC is now called Pinnacle 21. [Learn how this change affects Community.](#) 4 months ago
- OpenCDISC Community 2.0.1 is now available. [Download now](#) a year ago

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# Validate Dataset using Pinnacle 21 (2)



Pinnacle 21 Community

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Converter

ClinicalTrials.gov

Could not establish a connection

## Validator

check compliance with SDTM, SEND, ADaM, and Define.xml

Validate Data

Standard

SEND

Configuration

SEND 3.0 (FDA)

Source Format

SAS® Transport (XPORT)

Report Format

Excel

Source Data

Drop files here to select them  
or

①



Browse...

Select your datasets

Define.xml

②



Optional

Browse...

CDISC CT

2016-03-25

MedDRA

[Install now](#)

[More dictionaries](#)

③



Validate

# Validate Dataset using Pinnacle 21 (3)



|    | A                                                                                                    | B              | C            | D                                                                                               | E        | F     |
|----|------------------------------------------------------------------------------------------------------|----------------|--------------|-------------------------------------------------------------------------------------------------|----------|-------|
| 1  | Pinnacle 21 Validator Report                                                                         |                |              |                                                                                                 |          |       |
| 2  |                                                                                                      |                |              |                                                                                                 |          |       |
| 3  | Configuration: F:\SEND\OpenCDISC Validator\pinnacle21-community\components\config\SEND 3.0 (FDA).xml |                |              |                                                                                                 |          |       |
| 4  | Define.xml: F:\SEND\OpenCDISC Validator\pinnacle21-community                                         |                |              |                                                                                                 |          |       |
| 5  | Generated: 2016-01-29T08:15:00                                                                       |                |              |                                                                                                 |          |       |
| 6  | CDISC CT Version: 2015-09-25                                                                         |                |              |                                                                                                 |          |       |
| 7  | UNII Version: 2015-11-12                                                                             |                |              |                                                                                                 |          |       |
| 8  | NDF-RT Version: 2015-11-02                                                                           |                |              |                                                                                                 |          |       |
| 9  | Software Version: 2.1.0                                                                              |                |              |                                                                                                 |          |       |
| 10 |                                                                                                      |                |              |                                                                                                 |          |       |
| 11 | Issue Summary                                                                                        |                |              |                                                                                                 |          |       |
| 12 | Source                                                                                               | Pinnacle 21 ID | Publisher ID | Message                                                                                         | Severity | Found |
| 13 | GLOBAL                                                                                               |                |              |                                                                                                 |          |       |
| 14 |                                                                                                      | SD1020         | FDAN001      | Missing DM dataset                                                                              | Error    | 1     |
| 15 |                                                                                                      | SD1115         | FDAN002      | Missing TS dataset                                                                              | Error    | 1     |
| 16 |                                                                                                      | SE0007         | FDAN011      | Missing TX dataset                                                                              | Error    | 1     |
| 17 | BW                                                                                                   |                |              |                                                                                                 |          |       |
| 18 |                                                                                                      | SD1082         | FDAN036      | Variable length is too long for actual data                                                     | Error    | 11    |
| 19 |                                                                                                      | SE0063         | FDAN033      | SEND/dataset variable label mismatch                                                            | Warning  | 20    |
| 20 |                                                                                                      | SD1078         | FDAN055      | Permissible variable with missing value for all records                                         | Notice   | 5     |
| 21 |                                                                                                      | SKIP_SD0064    |              | DM is missing or lacks necessary variables and cannot be used for this cross-dataset validation | Notice   | 1     |
| 22 |                                                                                                      | SKIP_SD1005    |              | DM is missing or lacks necessary variables and cannot be used for this cross-dataset validation | Notice   | 1     |

①SD1082 (FDAN036): Variable length is too long for actual data



Error

②SE0063 (FDAN033): SEND/dataset variable label mismatch



Warning

③SD1078 (FDAN055): Permissible variable with missing value for all records



Notice

# Validate Dataset using Pinnacle 21 (4)

[SD1082/FDAN036](#)

**Before** Viewer - [BW.xpt]  
View Window Help

|    | Variable | Type | Len | DLen | Format | InFormat |
|----|----------|------|-----|------|--------|----------|
| 1  | STUDYID  | Char | 12  | 12   | \$12.  | \$12.    |
| 2  | DOMAIN   | Char | 4   | 4    | \$4.   | \$4.     |
| 3  | USUBJID  | Char | 24  | 15   | \$24.  | \$24.    |
| 4  | BWSEQ    | Num  | 8   | 12   | 12.    | .        |
| 5  | BWTESTCD | Char | 4   | 4    | \$4.   | \$4.     |
| 6  | BWTEST   | Char | 22  | 15   | \$22.  | \$22.    |
| 7  | BWORRES  | Char | 6   | 6    | \$6.   | \$6.     |
| 8  | BWORRESU | Char | 4   | 4    | \$4.   | \$4.     |
| 9  | BWSTRESC | Char | 6   | 6    | \$6.   | \$6.     |
| 10 | BWSTRESN | Num  | 8   | 12   | 12.    | .        |
| 11 | BWSTRESU | Char | 4   | 4    | \$4.   | \$4.     |
| 12 | BWSTAT   | Char | 2   | 2    | \$2.   | \$2.     |
| 13 | BWREASND | Char | 2   | 2    | \$2.   | \$2.     |
| 14 | BWBLFL   | Char | 2   | 2    | \$2.   | \$2.     |
| 15 | BWFAST   | Char | 2   | 2    | \$2.   | \$2.     |
| 16 | BWEXCLFL | Char | 2   | 2    | \$2.   | \$2.     |
| 17 | BWREASEX | Char | 2   | 2    | \$2.   | \$2.     |
| 18 | VISITDY  | Num  | 8   | 12   | 12.    | .        |
| 19 | BWDTC    | Char | 20  | 20   | \$20.  | \$20.    |
| 20 | BWDY     | Num  | 8   | 12   | 12.    | .        |



After

|  |  |  |  |  |  |  |  |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Len                                                                                 | DLen                                                                                | Format                                                                              | InFormat                                                                            |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 6                                                                                   | 12                                                                                  | \$12.                                                                               | \$12.                                                                               |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 2                                                                                   | 4                                                                                   | \$4.                                                                                | \$4.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 12                                                                                  | 15                                                                                  | \$24.                                                                               | \$24.                                                                               |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 8                                                                                   | 12                                                                                  | 12.                                                                                 | .                                                                                   |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 2                                                                                   | 4                                                                                   | \$4.                                                                                | \$4.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 11                                                                                  | 15                                                                                  | \$22.                                                                               | \$22.                                                                               |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 3                                                                                   | 6                                                                                   | \$6.                                                                                | \$6.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 2                                                                                   | 4                                                                                   | \$4.                                                                                | \$4.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 3                                                                                   | 6                                                                                   | \$6.                                                                                | \$6.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 8                                                                                   | 12                                                                                  | 12.                                                                                 | .                                                                                   |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 2                                                                                   | 4                                                                                   | \$4.                                                                                | \$4.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 1                                                                                   | 2                                                                                   | \$2.                                                                                | \$2.                                                                                |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 8                                                                                   | 12                                                                                  | 12.                                                                                 | .                                                                                   |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 10                                                                                  | 20                                                                                  | \$20.                                                                               | \$20.                                                                               |                                                                                     |                                                                                     |                                                                                     |                                                                                     |
| 8                                                                                   | 12                                                                                  | 12.                                                                                 | .                                                                                   |                                                                                     |                                                                                     |                                                                                     |                                                                                     |

# Validate Dataset using Pinnacle 21 (5)



[SE0063/FDAN033](#)

SAS System Viewer - [BW.xpt]

File Edit View Window Help

|    | Variable | Type | Len | DLen | Format | InFormat | Label    |
|----|----------|------|-----|------|--------|----------|----------|
| 1  | STUDYID  | Char | 12  | 12   | \$12.  | \$12.    | STUDYID  |
| 2  | DOMAIN   | Char | 4   | 4    | \$4.   | \$4.     | DOMAIN   |
| 3  | USUBJID  | Char | 24  | 15   | \$24.  | \$24.    | USUBJID  |
| 4  | BWSEQ    | Num  | 8   | 12   | 12.    | .        | BWSEQ    |
| 5  | BWTESTCD | Char | 4   | 4    | \$4.   | \$4.     | BWTESTCD |
| 6  | BWTEST   | Char | 22  | 15   | \$22.  | \$22.    | BWTEST   |
| 7  | BWORRES  | Char | 6   | 6    | \$6.   | \$6.     | BWORRES  |
| 8  | BWORRESU | Char | 4   | 4    | \$4.   | \$4.     | BWORRESU |
| 9  | BWSTRESC | Char | 6   | 6    | \$6.   | \$6.     | BWSTRESC |
| 10 | BWSTRESN | Num  | 8   | 12   | 12.    | .        | BWSTRESN |
| 11 | BWSTRESU | Char | 4   | 4    | \$4.   | \$4.     | BWSTRESU |
| 12 | BWSTAT   | Char | 2   | 2    | \$2.   | \$2.     | BWSTAT   |
| 13 | BWREASND | Char | 2   | 2    | \$2.   | \$2.     | BWREASND |
| 14 | BWBLFL   | Char | 2   | 2    | \$2.   | \$2.     | BWBLFL   |
| 15 | BWFAST   | Char | 2   | 2    | \$2.   | \$2.     | BWFAST   |
| 16 | BWEXCLFL | Char | 2   | 2    | \$2.   | \$2.     | BWEXCLFL |
| 17 | BWREASEX | Char | 2   | 2    | \$2.   | \$2.     | BWREASEX |
| 18 | VISITDY  | Num  | 8   | 12   | 12.    | .        | VISITDY  |
| 19 | BWDTC    | Char | 20  | 20   | \$20.  | \$20.    | BWDTC    |
| 20 | BWDY     | Num  | 8   | 12   | 12.    | .        | BWDY     |

# Should “SEND IG3.0 Known Issues” be Corrected? (in terms of P21 validation)



| Domain | Description                                                                                                                 | Should be Corrected?          |
|--------|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| CO     | POOLID is missing from this domain description table.                                                                       | <b>No</b><br>(Warning-SD1076) |
| LB     | LBORNRLO and LBORNRHI should be type Char, not Num.                                                                         | <b>No</b><br>(Error-SE0055)   |
| PC     | The variable label for VISITDY should be "Planned Study Day of Collection", not "Visit Day", consistent with other domains. | <b>No</b><br>(Warning-SE0063) |
| TF     | The variable shown as TSTFNAM should be TFNAM.                                                                              | <b>Yes</b><br>(Error-SD0058)  |



# Reference Web Sites

# SEND IG v3.0 (May 2011)



← → ↺ 🏠 [www.cdisc.org/send](http://www.cdisc.org/send)

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Controlled Terminology  
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Questionnaires, Ratings and Scales  
RDF

## Standard for Exchange of Nonclinical Data (SEND)

### SEND Implementation Guide v3

The CDISC SEND Implementation Guide (IG) Version 3.0 is intended to guide the organization, structure, and format of standard nonclinical tabulation datasets for interchange between organizations such as sponsors and CROs and for submission to regulatory agencies (FDA). Version 3.0 of the SENDIG in the current production version is based upon and should be used in close concert with Version 2.0 of the SENDIG (SDTM).

The CDISC SEND Team is always interested in your comments. SEND can be submitted through the [CDISC Discussion forum](#).

**Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies**

Prepared by the  
**CDISC Standard for Exchange of Nonclinical Data Team**

**Notes to Readers**

- This is the implementation guide for nonclinical studies based upon Version 3.0 of the CDISC Study Data Tabulation Model (SDTM).
- This Implementation Guide is Version 3.0 of the CDISC Standard for Exchange of Nonclinical Data and Clinical Studies.

**Revisions History**

| Year       | Version | Number of Changes                                                                       |
|------------|---------|-----------------------------------------------------------------------------------------|
| 2009/01/01 | 1.0     | Initial release (including all changes and corrections identified during review period) |
| 2010/01/01 | 2.0     | Initial release (including all changes and corrections identified during review period) |
| 2010/01/01 | 3.0     | Initial release (including all changes and corrections identified during review period) |

Please see Appendix F for Representations and Variations, Limitations of Liability, and Disclaimers.

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May 10, 2011

**--Public Review--**  
Rheumatoid Arthritis TAUG  
Comments due 19 June 2016

**Volunteer for CDISC**

**SEND Team Charter**

**SEND Product Downloads**  
**SEND Implementation Guide (IG) Version 3.0**  
**Study Data Tabulation Model v1.2**

**CDISC Standards in RDF**  
RDF Reference Guide v1  
RDF User Guide v1

# SEND IG3.0 (Japanese Translation)

← → ↺ 🏠 [www.cdisc.org/j3c-cjug](http://www.cdisc.org/j3c-cjug)  

| Introduction of FDA Review Tools      |                                                                                                                                                                                              |      |                         |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------------------------|
| ADaM                                  |                                                                                                                                                                                              |      |                         |
| CJUG資料                                | 説明 (日本語 & 英語)                                                                                                                                                                                | 作成時期 | 備考                      |
| <a href="#">はじめてのADaM version 1.1</a> | ADaMとADaM IGの初心者向けの解説<br>This booklet titled "ADaM for Beginners in Japanese" (hereinafter called "this document") is a hand book on ADaM (Analysis Dataset Model) by Japan User Group ADaM. | 2013 | ADaM handbook_v.1.1.pdf |

SEND

| CJUG資料                                  | 説明 (日本語 & 英語)                                                                                                    | 作成時期 | 備考                                                                                                                                                                 |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <a href="#">SEND IG V3.0日本語訳(英語併記版)</a> | SEND IG V3.0の日本語訳(英語併記版)<br>Japanese translation of SEND IG V3.0(Japanese and English are described in parallel) | 2013 | SENDIG V3.0日本語訳(英語併記版)_Chapter 1-5.doc<br>SENDIG V3.0日本語訳(英語併記版)_Chapter 6_1.doc<br>SENDIG V3.0日本語訳(英語併記版)_Chapter 6_2.doc<br>SENDIG V3.0日本語訳(英語併記版)_Chapter 7.doc |
| <a href="#">SEND IG V3.0日本語訳</a>        | SEND IG V3.0の日本語訳<br>Japanese translation of SEND IG V3.0                                                        | 2013 | SENDIG V3.0日本語訳_Chapter 1-5.docx<br>SENDIG V3.0日本語訳_Chapter 6.docx<br>SENDIG V3.0日本語訳_Chapter 7-8.docx                                                             |

# SEND IG3.0 Known Issues



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## SEND Implementation Wiki - Known Issues

This page provides a list of key known issues.

[<< Go back to the SEND Implementation Wiki Landing Page](#)

**This page is under construction.**

See also:

- [FAQ](#)
- [Getting SEND-ready](#)
- [SEND Change Control Tracker \(CCT\)](#)

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- 1 Known Issues
- 1.1 SENDIG 3.0 Known Issues

### Known Issues

#### SENDIG 3.0 Known Issues

The following are known issues in the SEND 3.0 Implementation Guide that may affect the creation of a SEND dataset. These will be corrected in SEND 3.1.

**CO (Comments) Domain**  
POOLID is missing from this domain description table. If comments associated with a pool need to be reported in a SEND dataset, using POOLID in the CO domain is permitted.

**EX (Exposure) Domain**  
The CDISC notes in the domain description table for EXDOSU should indicate that these are units for both EXDOSE and EXDOSTXT, not just EXDOSE.

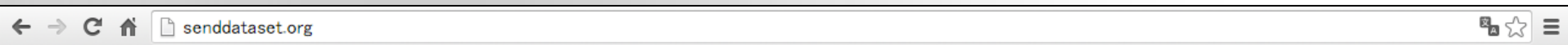
**CL (Clinical Observations) Domain**  
The variable label for CLDTC should be "Date/Time of Observation" not "Start Date/Time of Observation"

**EG (ECG Test Results) Domain**  
The variable label for EGLEAD should be "Lead Used Measurement" not "Location Used for Measurement".  
The variable label for EGDTC should be "Date/Time of ECG Collection" not "Date/Time of ECG".

**FW (Food and Water Consumption) Domain**

[http://www.phusewiki.org/wiki/index.php?title=SEND\\_Implementation\\_Wiki\\_-\\_Known\\_Issues](http://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_Wiki_-_Known_Issues)

# SEND Sample Dataset



## Welcome to SENDDataset.Org

This website has been set up as a simple repository for the storage and easy downloading of publically available SEND data sets.

| Data Set | Released By      | Original Release Date | Latest Update | SENDIG Version | Click button to download          |
|----------|------------------|-----------------------|---------------|----------------|-----------------------------------|
| PDS2014  | PDS Lifesciences | 19 May 2014           | 19 May 2014   | 3.0            | <a href="#">DOWNLOAD Data Set</a> |



### Useful Links

[PhUSE](#)

[CDISC](#)

[SEND Implementation Guide](#)

**SEND is the Standard for Exchange of Nonclinical Data**

For info contact [info@senddataset.org](mailto:info@senddataset.org)

Created by [PDS Lifesciences](#)

<http://senddataset.org/>

# SAS Universal Viewer



https://support.sas.com/downloads/package.htm?pid=712



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### All Downloads

### Downloads

### SAS Universal Viewer

Release 9.3 - JUL 2011

The SAS Universal Viewer is a replacement for the SAS System Viewer and is an application for the Windows environment to view SAS data sets and other simple text-based files. You cannot edit SAS data sets with the SAS Universal Viewer, but you can sort and filter data sets. The SAS Universal Viewer enables you to view the contents of SAS data sets without invoking SAS and without installing SAS on your machine.

To begin the download process, select the item in the table below which best meets your needs.

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| Microsoft® Windows®         | SAS Universal Viewer - All Localizations | <a href="#">sasuniviewer__93120__win__xx__web__1.zip</a> | 395MB | 407MB        | 2011-07      | <a href="#">pdf</a>   <a href="#">txt</a> |
| Microsoft® Windows® for x64 | SAS Universal Viewer                     | <a href="#">sasuniviewer__93120__wx6__en__web__1.zip</a> | 349MB | 358MB        | 2011-07      | <a href="#">pdf</a>   <a href="#">txt</a> |
| Microsoft® Windows® for x64 | SAS Universal Viewer - All Localizations | <a href="#">sasuniviewer__93120__wx6__xx__web__1.zip</a> | 349MB | 359MB        | 2011-07      | <a href="#">pdf</a>   <a href="#">txt</a> |



https://support.sas.com/downloads/package.htm?pid=712

## Download

### Downloads

The following is latest release of Pinnacle 21 Community, which includes Validator, Define.xml Generator, Data Converter, and ClinicalTrials.gov Miner. The download also contains the latest set of standard validation configurations.



PINNACLE 21 COMMUNITY 2.1.1  
DOWNLOAD FOR WINDOWS



PINNACLE 21 COMMUNITY 2.1.1  
DOWNLOAD FOR MAC OS X

[Release Notes](#)

### Installation and Usage

The following are basic installation and usage instructions. For additional information, please refer to [documentation](#).

[Installing Pinnacle 21 Community](#)

[Using Pinnacle 21 Community](#)

[Configuring Pinnacle 21 Validator for MedDRA](#)

### License

# Define-XML v2 (related documents)



← → ↺ 🏠 [www.cdisc.org/define-xml](http://www.cdisc.org/define-xml)

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ODM-XML  
Define-XML  
DataSet-XML  
Controlled Terminology  
Pharmacogenomics / Genetics  
Questionnaires, Ratings and Scales  
RDF

## Define-XML

### Public Review

#### New Draft CTR-XML Version 1.0 Friday 18 December 2015

The CTR-XML Standard Version 1.0 is now available for public comment. This specification describes the CTR-XML (Clinical Trial Registry) model, a model based on the CDISC Operational Data Model (ODM), and how it can be used by the World Health Organization (WHO), the European Union's ClinicalTrials.gov clinical trials results. The CTR-XML standard is focused on submissions of the study data directly to the all registries. Rather, it is to each of the 3 agencies mentioned here.

Please access the **document package** and provide comments through the CDISC Public Comment Tracker tool.

You will need to **login or register** for a CDISC portal account to use the tool. Help is also available

**Define.xml Specification**  
Define-XML-2-0-Specification.pdf

**Stylesheet**  
define2-0-0.xsl

etc.

--Public Review--

**Tuberculosis v2 TA User Guide** - Comments due 30 November 2015

**COPD v1 TA User Guide** - Comments due 7 December 2015

**Breast Cancer TA User Guide** - Comments due 9 December 2015

**CTR-XML Version 1.0** - Comments due 18 December 2015

**XML Team Charter**

**Define-XML and Related Downloads**

**Define-XML v2 (zip)**

**Define-XML v1 (zip)**

Define-XML Schema Validation

<http://www.cdisc.org/define-xml>



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SEND Implementation Wiki

Welcome to the SEND Implementation Wiki!

The SEND Implementation Wiki is a knowledge base on implementing SEND - a series of articles designed to help you understand and implement SEND, including modeling basics, useful links, FAQs, and more.

In addition to the wiki, the companion [SEND Implementation Forum](#) is a place for active discussion and to ask questions not already answered in the wiki.

What Is SEND?

SEND, or the **S**tandard for **E**xchange of **N**onclinical **D**ata, is an implementation of the CDISC Standard Data Tabulation Model (SDTM) which specifies a way to present nonclinical data in a consistent format.

By having a common model to which the industry can conform, many benefits can be realized, such as inter-company exchange that is consistent in format regardless of the parties involved, the ability for vendors to develop tools, and many others.

A SEND package consists of a few parts, but the main focus is on individual endpoint data. Endpoints typically map to domains (essentially, datasets), with a number of variables (a.k.a., columns or fields).

Pages

News

Keep up to date with SEND developments!

- [SEND Implementation News](#)

Fundamentals

New to SEND? These pages will introduce you to the model:

- [SEND Fundamentals](#) - Basics on SEND, such as what it is, where to find the implementation guide, and how to use it
- [CT Fundamentals](#) - Basics on Controlled Terminology, such as what it is and where to find it
- [Define.xml Fundamentals](#) - Basics on the define.xml, such as what it is and key links and preparation information

Implementation

Ok, so you need to implement SEND. Here are some pages that will help:

Contents [hide]

1 What Is SEND?

2 Pages

3 Links

[http://www.phusewiki.org/wiki/index.php?title=SEND\\_Implementation\\_Wiki](http://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_Wiki)

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***Thank you for your attention!***

Contact information:

Gen Sato ([g-sato@hhc.eisai.co.jp](mailto:g-sato@hhc.eisai.co.jp))