Preparing for SEND

Presented by Roman Radelicki
Team Manager Data Programming, Life Sciences, SGS Belgium NV

04.12.2018

PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

PREPARING FOR SEND

Overview

- **Introduction**
- FDA Data Standards Catalog
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

INTRODUCTION

- Assign a coordinator to drive the process of evaluating
  - What is needed to implement SEND
  - How can we implement this in our organization

- Follow the CDISC SEND training as a starting point
- Create an implementation plan for organization

PREPARING FOR SEND

Overview

- Introduction
- **FDA Data Standards Catalog**
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v5.1 (08-2-2018) - Supported and Required Standards						
Data Exchange Standard	Supported Version	Supported Implementation Guide Version	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends
Standard for Exchange of Nonclinical Data (SEND)	1.2	3.0	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SEND	1.5	3.1	08/21/2017		3/15/2019 [1] 3/15/2020 [2]	
Notes:						
[1]	For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					
[2]	For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v5.1 (08-2-2018) - Supported and Required Standards						
Data Exchange Standard	Supported Version	Supported Implementation Guide Version	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends
Standard for Exchange of Nonclinical Data (SEND)	1.2	3.0	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SEND	1.5	3.1	08/21/2017		3/15/2019 [1] 3/15/2020 [2]	
Notes:						
[1]	For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					
[2]	For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v5.1 (08-2-2018) - Supported and Required Standards						
Data Exchange Standard	Supported Version	Supported Implementation Guide Version	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends
Standard for Exchange of Nonclinical Data (SEND)	1.2	3.0	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SEND	1.5	3.1	08/21/2017		3/15/2019 [1] 3/15/2020 [2]	
Notes:						
[1]	For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					
[2]	For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v5.1 (08-2-2018) - Supported and Required Standards						
Data Exchange Standard	Supported Version	Supported Implementation Guide Version	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends
Standard for Exchange of Nonclinical Data (SEND)	1.2	3.0	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SEND	1.5	3.1	08/21/2017		3/15/2019 [1] 3/15/2020 [2]	
Notes:						
[1]	For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					
[2]	For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					

FDA DATA STANDARDS CATALOG

FDA Data Standards Catalog v5.1 (08-2-2018) - Supported and Required Standards						
Data Exchange Standard	Supported Version	Supported Implementation Guide Version	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends
Standard for Exchange of Nonclinical Data (SEND)	1.2	3.0	06/13/2011	03/15/2019 [1] 03/15/2020 [2]	12/17/2016 [1] 12/17/2017 [2]	03/15/2019 [1] 03/15/2020 [2]
SEND	1.5	3.1	08/21/2017		3/15/2019 [1] 3/15/2020 [2]	
Notes:						
[1]	For NDAs, ANDAs, and certain BLAs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					
[2]	For certain INDs. See section II.A of the Providing Regulatory Submissions In Electronic Format — Standardized Study Data guidance document					

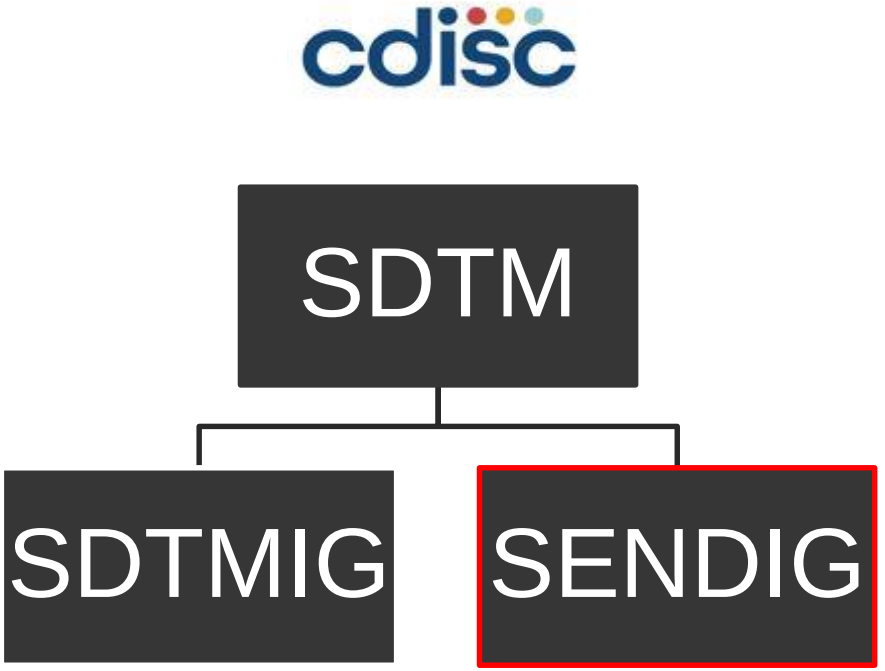
PREPARING FOR SEND

Overview

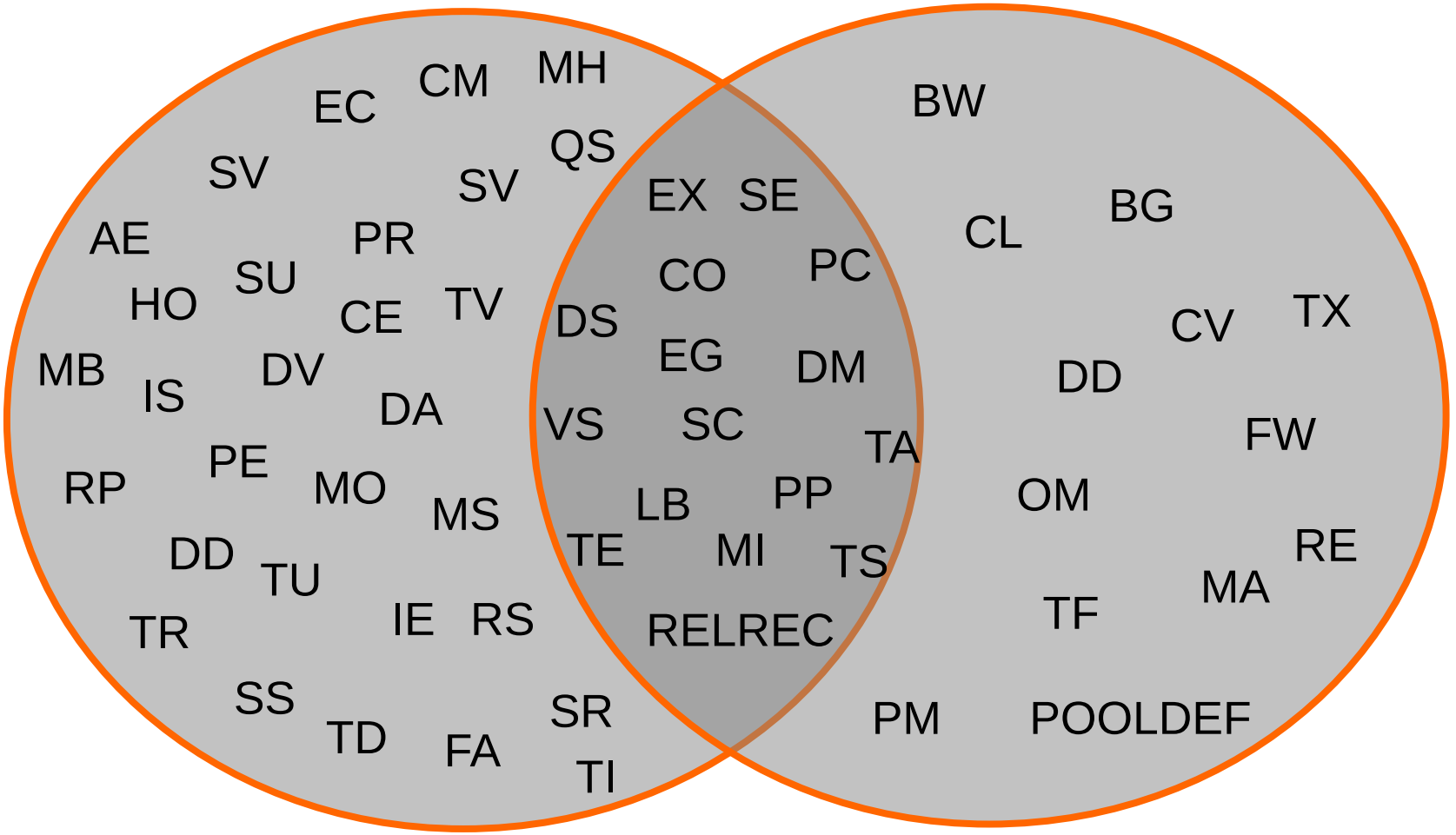
- Introduction
- FDA Data Standards Catalog
- **Origin of SEND**
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

ORIGIN OF SEND

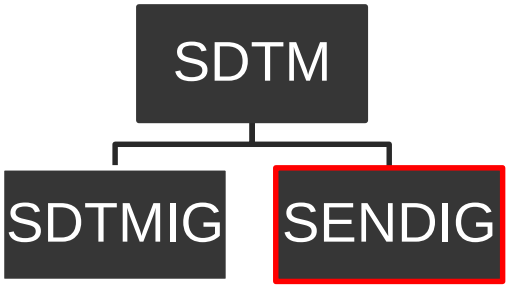
- SEND finds its foundations in the SDTM standard



SDTM & SEND DOMAINS



ORIGIN OF SEND



- Knowledge gained and some software tools built for SDTM can be used to a great extent
- You probably don’t need to start from scratch. With modifications, some existing processes may be re-used
- Create a new library for SEND like you would create a new library for
  - new/upgraded SDTM versions
  - Client specific implementation of SDTM

PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- **Origin of SEND**
  - **Process considirations**
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

PROCESS CONSIDIRATIONS

- Conversion process
  - Map, merge and convert source data (EDC, third party data, raw data files)
  - Scheduling/follow-up complete conversion process
  - Manage Metadata repository
- Transfer of datasets (draft, interim, final)
- Format of transferred datasets (XPT, SAS, Dataset-XML)
- Creation of define metadata
- Validation checks
- Trial design tables

PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- **Origin of SEND**
  - Process considirations
  - **High level differences SENDIG & SDTMIG**
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- Conclusion

HIGH LEVEL DIFFERENSES

Between SENDIG & SDTMIG

- Trial design
  - No TV, TI, TD
  - TX: trial sets
- Subject Pooling
  - POOLDEF: POOLID vs. USUBJID
- Tumor.xpt
- Example DM differences

HIGH LEVEL DIFFERENSES

Between SENDIG & SDTMIG

- Example DM differences
- List available of SDTM variable that do not fit the SEND model

SEND - Demographics		SDTM - Demographics	
•STUDYID	•AGETXT	•STUDYID	
•DOMAIN	•AGEU	•DOMAIN	•AGEU
•USUBJID	•SEX	•USUBJID	•SEX
•SUBJID	•SPECIES	•SUBJID	
•RFSTDTC	•STRAIN	•RFSTDTC	
•RFENDTC	•SBSTRAIN	•RFENDTC	
•RFXSTDTC		•RFXSTDTC	•RACE
•RFXENDTC		•RFXENDTC	•ETHNIC
	•ARMCD	•RFICDTC	•ARMCD
	•ARM	•RFPENDTC	•ARM
		•DTHDTC	•ACTARMCD
		•DTHFL	•ACTARM
•SITEID		•SITEID	•COUNTRY
		•INVID	
		•INVNAM	
•BRTHDTC	•SETCD	•BRTHDTC	
•AGE		•AGE	

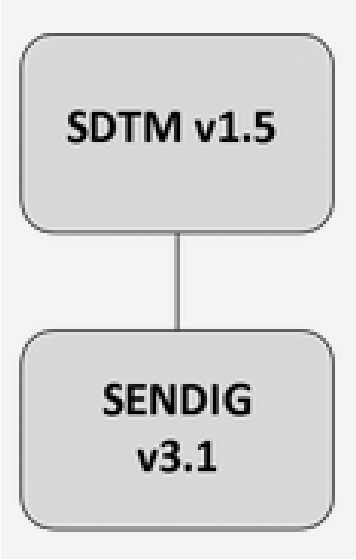
PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- **Origin of SEND**
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - **Changes in SENDIG v3.1**
- SEND validation
- Other regulators
- Conclusion

CHANGES IN SENDIG V3.1

- VISITDY = Permissible (not expected), use is not recommended, replaced by --NOMLBL, --NOMDY
- Two new domains for Safety Pharmacology studies have been added: Cardiovascular (CV) and Respiratory (RE)
- New FOCID variable added to several domains (EX, CL, MA, and MI)
- Use of SDTM v1.5
  contains new variables to support SEND that will not be used in human clinical trials



PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- **SEND validation**
- Other regulators
- Conclusion

SEND VALIDATION

- FDA has published business and validation rules which contains SDTM but also SEND specific rules
  update: in October 2018 FDA has published new validation rules including SEND v3.1

- PINNACLE 21 community version 2.2.0 only includes the FDA SEND v3.0 rules (depends on official rules published by CDISC, FDA or PMDA)

  P21 announced the release on P21 community version 3.0 in January 2019, which will include the newly release FDA validation rules

  P21 enterprise, all FDA Validator Rules are already available

PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- **Other regulators**
- Conclusion

OTHER REGULATORS

- At this moment SEND is an FDA requirement for certain submissions

- Clinical Trial Advisory Group on clinical trial data formats (CTAG2) is working on advising the EMA on clinical data formats, where it is leaning toward CDISC standards

- As of 2016, PMDA has put forward a schedule for requiring SDTM on the clinical side and plans to explore the nonclinical side as well

PREPARING FOR SEND

Overview

- Introduction
- FDA Data Standards Catalog
- Origin of SEND
  - Process considirations
  - High level differences SENDIG & SDTMIG
  - Changes in SENDIG v3.1
- SEND validation
- Other regulators
- **Conclusion**

CONCLUSION

- Although not always technically required for submission, SEND has advantages in operational use
  - Transfer/collaboration between organizations: CRO, client, providers, sites, regulatory authorities...
  - Client warehousing
  - Opportunities for harmonised and standardised software tools

BROAD CLINICAL RESEARCH SOLUTIONS

Roman Radelicki
Team Manager Data Programming

SGS
Life Sciences ,
Generaal De Wittelaan 19a bus 5
2800 Mechelen
Belgium

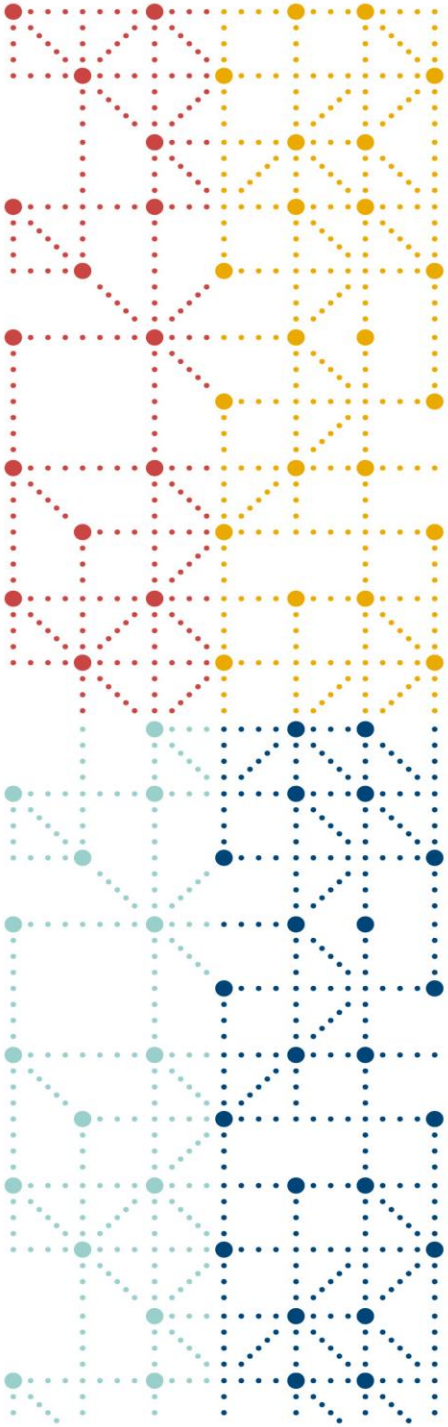
Phone: + 32 15 440 168
Fax: +32 15 29 93 02
E-mail : Roman.Radelicki@sgs.com

Web : www.sgs.com/lCRO

CONTACT US

clinicalresearch@sgs.com
EUROPE: +32 15 27 32 45
AMERICAS: + 877 677 2667
WWW.SGS.COM/CRO

JOIN THE SCIENTIFIC COMMUNITY
CONNECT ON LINKEDIN
www.sgs.com/LinkedIn-Life



Questions?

Thank You!

Roman Radelicki
Roman.Radelicki@sgs.com