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SDTM Modeling in Investigator-Initiated Clinical Trials for Solid Tumors: A Case Study by CJUG-SDTM

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Meet the Speaker

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September 2009: Joined EPS Corporation in the Data Management Department.

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September 2015: Left EPS Corporation.

October 2015: Joined the NPO Organization for Supporting Clinical Research.

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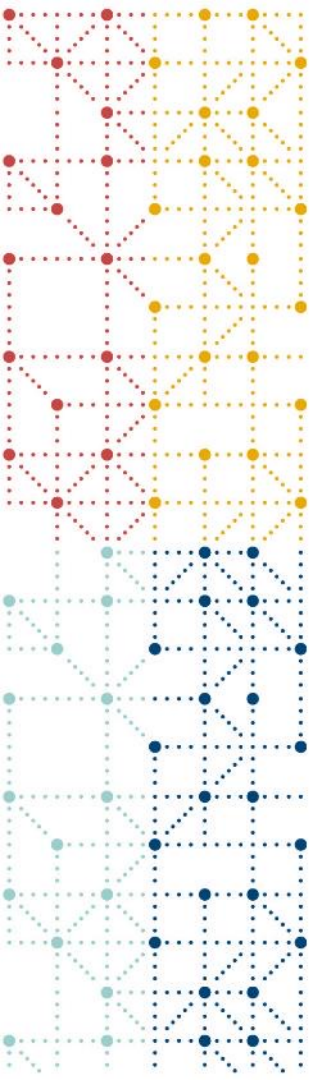
- The author(s) have no real or apparent conflicts of interest to report.



Agenda

1. Introduction
2. SDTM
3. Method
4. Results
5. Conclusion

1. Introduction

A. Background

B. Purpose

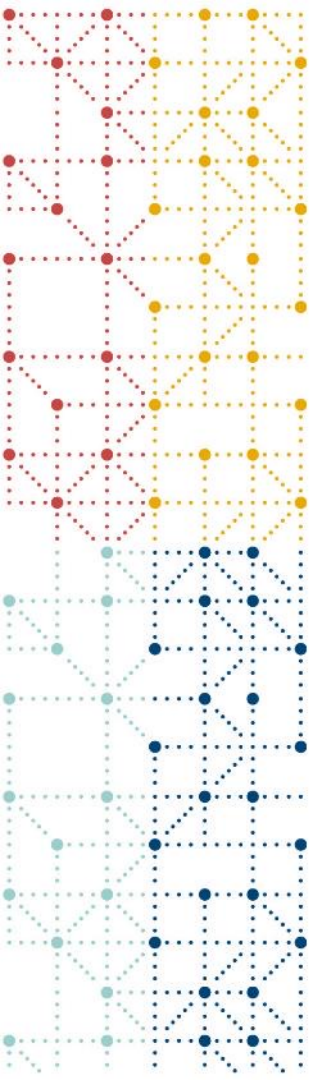
Background

CDISC Standards: Empowering Collaboration in the Pharmaceutical Ecosystem with Stakeholders and Resources

Purpose

Ensure accurate ecosystem functionality in the creation of SDTM for CDISC standards.

- SDTM IG 3.2 (Implementation Guide)
  - Comprehensive resource providing instructions and examples for SDTM implementation in clinical trials.
- TAS (Therapeutic Area Standards)
  - Supplements SDTM IG with therapeutic area-specific guidelines.
- Other CDISC standards-related papers
  - Offer insights into evolving best practices and updates.
- CJUG-SDTM community
  - Knowledge and experience gained from previous CJUG-SDTM activities.

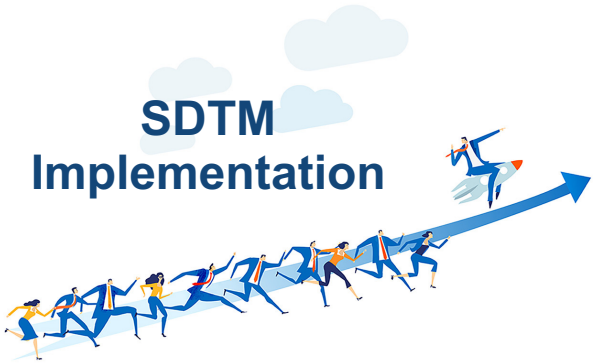


SDTM

A. Importance of SDTM in building the ecosystem

Importance of SDTM in building the ecosystem

Let's explore the importance of SDTM in building this ecosystem.



- Standardized Data Representation
- Facilitating Data Integration
- Enhancing Data Transparency
- Enabling Regulatory Compliance
- Supporting Interoperability
- Enabling Efficient Data Management
- Supporting Innovation and Collaboration

Method

A. Protocols used for SDTM modeling

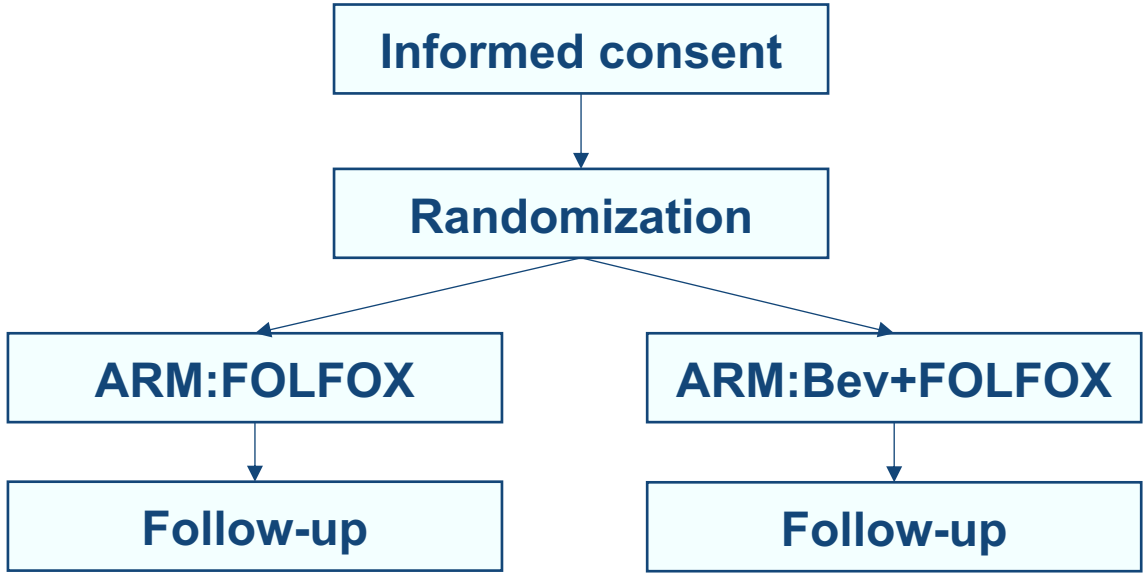
B. SDTM modeling process

C. Affiliations of the 3 team members

Protocols used for SDTM modeling

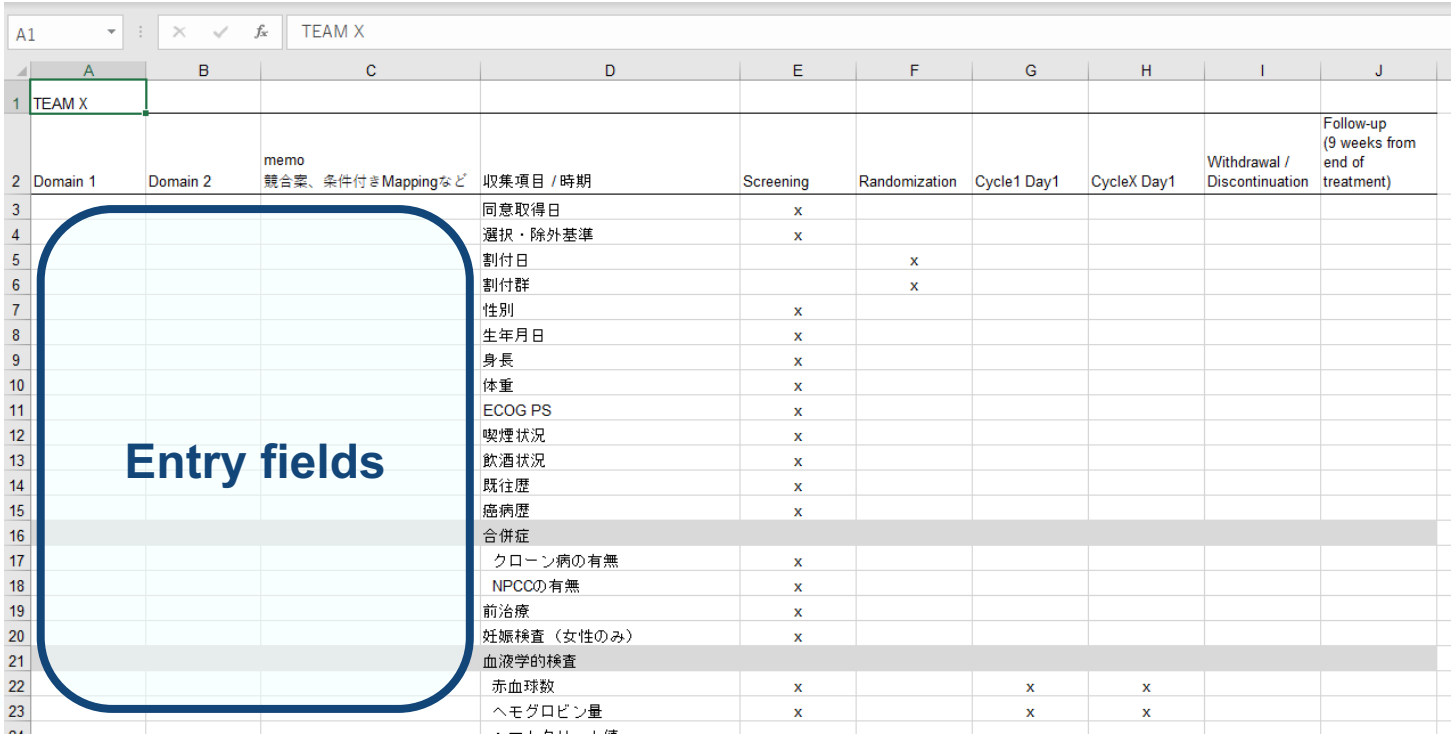
jRCT2031210656

Phase II multicenter, double-blind, randomized controlled trial of FOLFOX therapy with bevacizumab in patients with unresectable advanced / recurrent small bowel cancer (NHO-Bev-FOLFOX-SBC)



SDTM modeling process

The 3 teams will be divided to input data into the modeling Excel template.



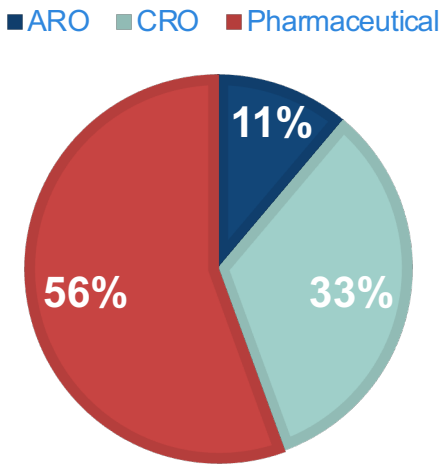
A1 | TEAM X

	A	B	C	D	E	F	G	H	I	J
1	TEAM X									
2	Domain 1	Domain 2	memo 競合案、条件付きMappingなど	収集項目 / 時期	Screening	Randomization	Cycle1 Day1	CycleX Day1	Withdrawal / Discontinuation	Follow-up (9 weeks from end of treatment)
3				同意取得日	x					
4				選択・除外基準	x					
5				割付日		x				
6				割付群		x				
7				性別	x					
8				生年月日	x					
9				身長	x					
10				体重	x					
11				ECOG PS	x					
12				喫煙状況	x					
13				飲酒状況	x					
14				既往歴	x					
15				癌病歴	x					
16				合併症						
17				クローン病の有無	x					
18				NPCCの有無	x					
19				前治療	x					
20				妊娠検査（女性のみ）	x					
21				血液学的検査						
22				赤血球数	x		x	x		
23				ヘモグロビン量	x		x	x		

Affiliations of the 3 team members

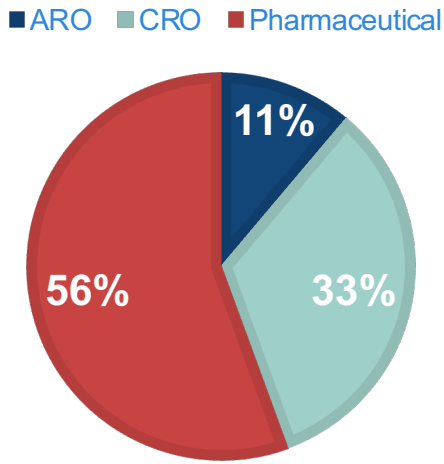
Team A

N=9



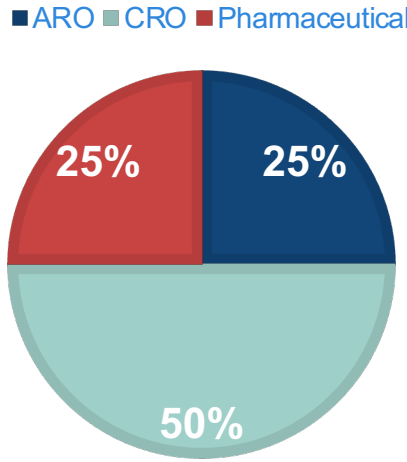
Team B

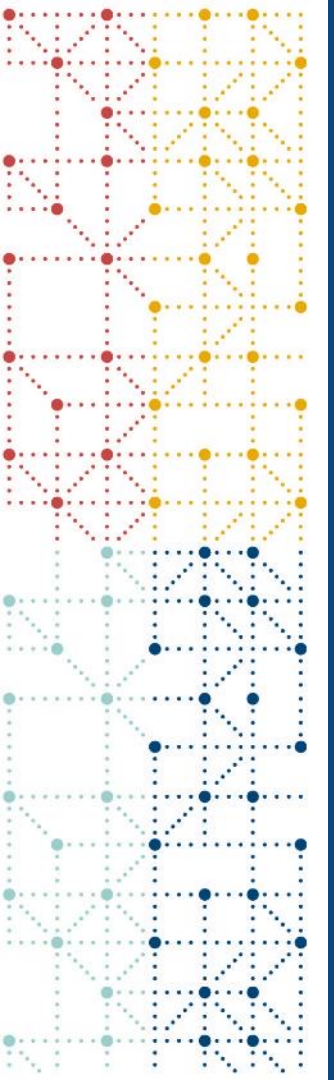
N=9



Team C

N=8



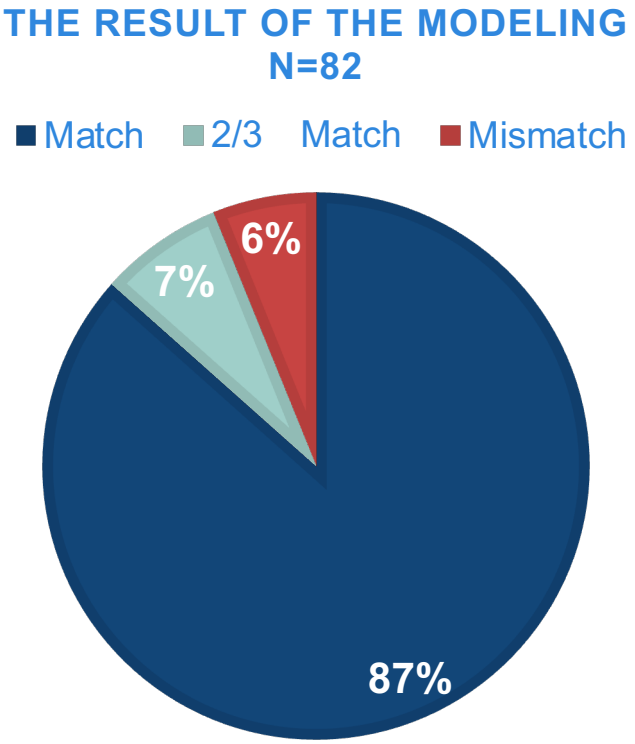


Results

A. Consistency and differences in SDTM modeling

B. Factors contributing to the differences

Consistency and differences in SDTM modeling



Factors contributing to the differences (1)

A: Absence of matches with reference materials

Domain	Collected items
MH or SC or MI	Presence of RAS mutations

- Option 1: Stored in MH (Medical History)
  - MedDRA PT includes "10069755: K-ras mutation.“
- Option 2: Stored in SC (Subject Character)
  - RAS mutation is considered a covariate during analysis and was previously described in the Oncology section of the PhUSE Wiki. Please note that the PhUSE Wiki is no longer available.
- Option 3: Stored in MI (Microscopic Findings)
  - According to SDTM IG v3.2 (PR), histopathological findings are stored in the MI domain.

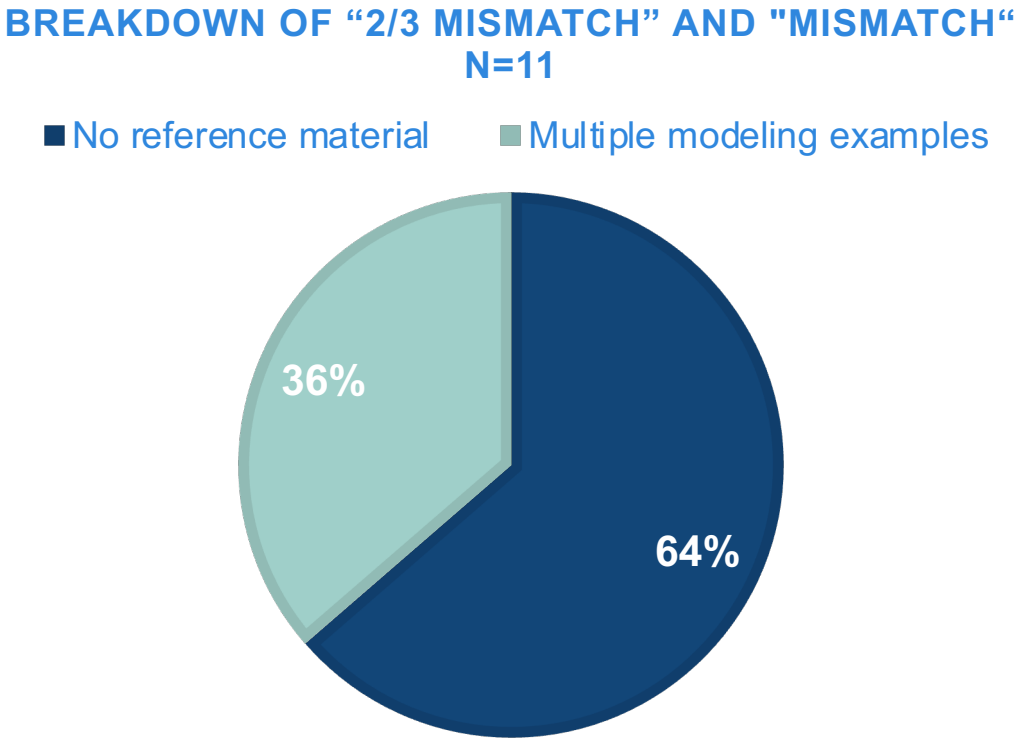
Factors contributing to the differences (2)

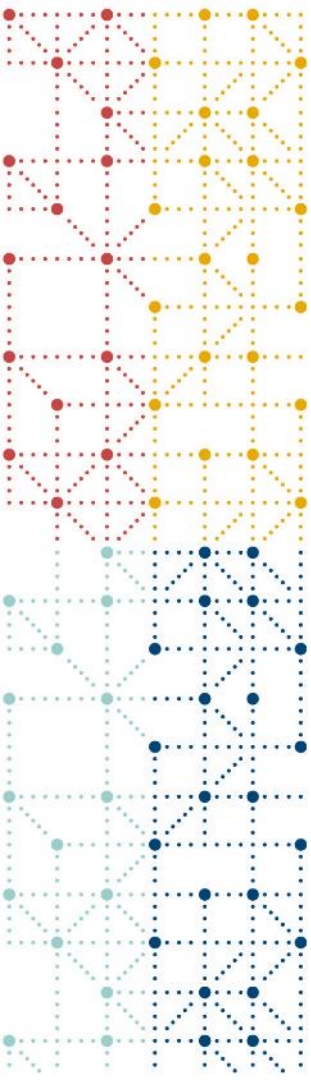
B: Presence of multiple modeling cases for the same item

Domain	Collected items
LB or IS	Virus testing results (HBs antigen, HBs antibody, HBc antibody, HCV antibody)

- Option 1: Stored in LB (Laboratory Test Results)
  - There is an example of storing in LB domain on TURG (CHCV) as shown in the release on 05/08/2015.
- Option 2: Stored in IS (Immunogenicity Specimen Assessments)
  - There is an example of HCAB being stored in IS according to SDTM-IG v3.2 released on 11/26/2013.

Factors contributing to the differences (3)





Conclusion

A. Need for continuous expansion of CDISC standards

B. Maintain compatibility with existing standards

Need for continuous expansion of CDISC standards

Pharmaceutical and medical device development is evolving rapidly.

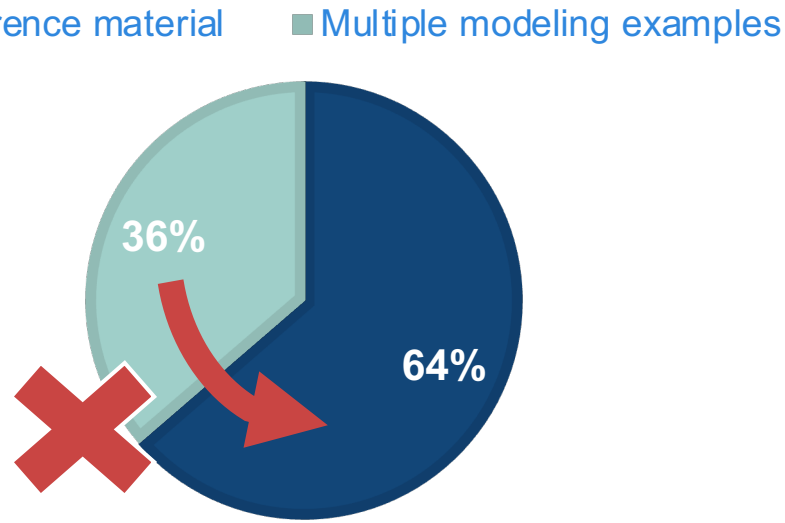
- Incorporating new data sources
  - Real-World Data (RWD)
  - Registry Data
- Incorporating new study types
  - Observational Studies
- Enhancing data integration
- Enhancing data analysis
- Enhancing collaboration
- Contributing to global harmonization efforts

Ultimately leading to improved patient outcomes.

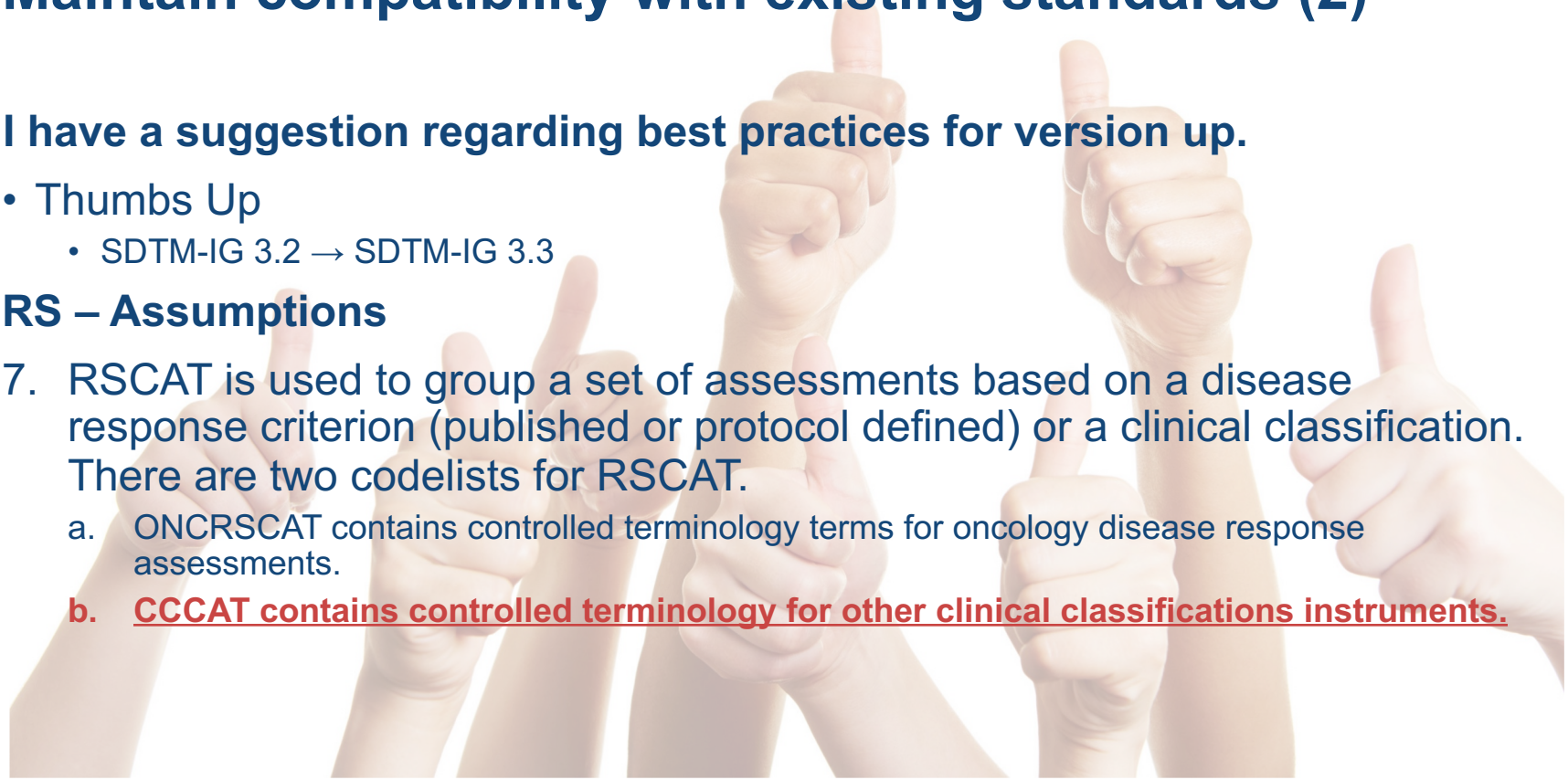
Maintain compatibility with existing standards (1)

Be cautious about upgrading to subdivide data!

Integrate similar data items into a single domain.



Maintain compatibility with existing standards (2)



I have a suggestion regarding best practices for version up.

- Thumbs Up
  - SDTM-IG 3.2 → SDTM-IG 3.3

RS – Assumptions

7. RSCAT is used to group a set of assessments based on a disease response criterion (published or protocol defined) or a clinical classification. There are two codelists for RSCAT.
   a. ONCRSCAT contains controlled terminology terms for oncology disease response assessments.
   b. CCCAT contains controlled terminology for other clinical classifications instruments.

Maintain compatibility with existing standards (3)

I have a suggestion regarding best practices for version up.

- Easy to overlook
  - SDTM Terminology 2021-9-24→SDTM Terminology 2021-12-17

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C118971		Yes	Category of Clinical Classification	CCCAT	Category of Clinical Classification	A grouping of observations within the Disease Response and Clin Classification domain.
C102116	C118971		Category of Clinical Classification	ECOG	ECOG1	Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, Carbone PP. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55). CDISC believes this instrument to be in the public domain, but you should perform your own assessment.

Thank You!

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