

SA06 - Submitting eCRT SDTM Data for ISS

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Aida has more than 22 years of experience in clinical trials. She has lead studies, compound and automation efforts and now is focused more on submission related activities across all Takeda therapeutic areas.

- This work was supported by Takeda and no additional funds or grants were received for this work
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- Presenter has no affiliation with vendors of any component of the described technology platforms

- Why Early Engagement Matters
- Pooled aCRF
- Pooled SDTM Data
- Specifications
- Reviewer's Guide Enhancements
- Challenges & Lessons Learned

Why Early Engagement Matters



Early Stakeholder Engagement

Engaging study teams and stakeholders early minimizes inconsistencies and promotes smooth data integration.

Proactive Issue Resolution

Early identification of data issues allows timely resolution, preventing complications during integration.

Setting Clear Integration Rules

Defining pooled origin and traceability rules from the start ensures consistency and regulatory compliance.

Improved Data Quality

Harmonized standards through early alignment improve the quality and reliability of ISS submissions.

1. Stack and combine all study-level aCRFs early to detect anomalies
2. Extract page information from the combined pdf
3. Compare P21E page metadata vs. Extracted page info

Frequency of the process

Every time an aCRF is updated

1. Stack SDTM data across studies
2. Manage updates while preserving original information
3. Keep only domains used in ADaM
4. Create pooled TS domain (ts.xpt) using Technical Conformance Guideline
 - harmonize the values of TSPARM/TSPARMCD across studies,
 - resolve TSVAL/TSVALCD inconsistencies and checks with SNOWMED registry sources.
 - TSPARMCD="SPREFID" - value should be "ISS".

Specifications



Page 1 of 22

ABC ISS - Value Remapping Report

Purpose: To display the consolidated list of variable values that have been remapped at the ISS level from their original mappings in individual studies

Date Generated: 02FEB2026

Domain: CM

Domain	Study	Subset Condition	Variable Name	Variable Value in Study	Value in ISS data
CM	ABC01		CMCAT	HISTORY OF BIOLOGIC THERAPY	PRIOR BIOLOGIC THERAPIES
	ABC02		CMCAT	HISTORY OF BIOLOGIC THERAPY	PRIOR BIOLOGIC THERAPIES

Page 1 of 107

ABC ISS - Variable Origin Report

Purpose: Displays the Variable origin from individual studies

Report Generated On: 02FEB2026

Domain: AE

Dataset	Variable	ABC001	ABC002	ABC003	ABC004	ABC005
AE	STUDYID	Protocol	Protocol	Protocol	Protocol	Protocol
AE	DOMAIN	Assigned	Assigned	Assigned	Assigned	Assigned
AE	USUBJID	Derived	Derived	Derived	Derived	Derived
AE	AESEQ	Derived	Derived	Derived	Derived	Derived
AE	AESPID	Collected	Assigned	eDT	Derived	Derived
AE	AETERM	Collected	Collected	Collected	Collected	Collected

Page 1 of 74

ABC ISS - Derivation methods Purpose - Description when Origin=DERIVED for Dataset: AE Report Generated On: 15JAN2026

Dataset	Variable Name	Where Clause	ABCR01	ABCR02	ABCR03	ABCR04	ABCR05
AE	AESDTC		If --ENDTC = RFSTUTC then --ENDTC = (ENDTC - RFSTUTC) + 1. Else if --ENDTC = RFSTUTC then --ENDTC = (ENDTC - RFSTUTC). Do not populate for partial dates.	Calculation of day of study based on AE end date compared to study start date.	If AESDTC is before RFSTUTC then populate with (AESDTC - DM.RFSTUTC); If AESDTC is on or after DM.RFSTUTC then populate with (AESDTC - DM.RFSTUTC + 1). Do not populate for partial dates.	If AESDTC is before RFSTUTC then populate with (AESDTC - RFSTUTC). Otherwise, if AESDTC is on or after RFSTUTC then (AESDTC - RFSTUTC + 1).	If AESDTC is before DM.RFSTUTC then populate with (AESDTC - DM.RFSTUTC); If AESDTC is on or after DM.RFSTUTC then populate with (AESDTC - DM.RFSTUTC + 1). Do not populate for partial dates.
AE	AESDTC		If RFSTUTC is not missing and RFSTUTC is not missing, then do the following: Set to 'ONGOING', if AESDTC is missing and AESDTC not missing; else set to 'REFUSE', if AESDTC is earlier than or same as RFSTUTC; else set to 'DURING', if AESDTC is later than or same as RFSTUTC and earlier than or same as RFSTUTC; else set to 'AFTER' if AESDTC is later than RFSTUTC.		If RFSTUTC not missing and RFSTUTC not missing, then do the following: Set to 'ONGOING', if AESDTC is missing and AESDTC not missing; else set to 'REFUSE', if AESDTC is earlier than or same as RFSTUTC; else set to 'DURING', if AESDTC is later than or same as RFSTUTC and earlier than or same as RFSTUTC; else set to 'AFTER' if AESDTC is later than RFSTUTC.		If DM.RFSTUTC not missing and DM.RFSTUTC not missing then do: Set to 'ONGOING', if AESDTC is missing and AESDTC not missing; else set to 'REFUSE', if AESDTC is earlier than or same as RFSTUTC; else set to 'DURING', if AESDTC is later than or same as RFSTUTC and earlier than or same as RFSTUTC; else set to 'AFTER' if AESDTC is later than RFSTUTC.
AE	AESEQ		Sorted by domain key variables and consecutively numbered each record within USUBJID starting with 1 using whole numbers.	Sequential number identifying records within each USUBJID and generated using the key sequence of the domain.	Sequence Number is derived after all domain records are created by first sorting all domain records by the given sort order (unique key). Set Sequence Number to 1 for the first record for a given USUBJID. Increment the Sequence Number by 1 for each subsequent record for the same USUBJID. Reset the Sequence Number back to 1 for the first record for the next USUBJID.	Sort data by domain keys and consecutively number each record within USUBJID starting with 1 using whole numbers.	Sequence Number given to ensure uniqueness of subject records within a domain.
AE	AESPID				Set to record number. Format to a three character sequence number padded with zeros.	Set to RECORDPOSITION. Format to a three character sequence number padded with zeros.	
AE	AESTDTC		If --ENDTC = RFSTUTC then --ENDTC = (ENDTC - RFSTUTC) + 1. Else if --ENDTC = RFSTUTC then --ENDTC = (ENDTC - RFSTUTC). Do not populate for partial dates.	Calculation of day of study based on AE start date compared to study start date.	If AESTDTC is before RFSTUTC then populate with (AESTDTC - DM.RFSTUTC); If AESTDTC is on or after DM.RFSTUTC then populate with (AESTDTC - DM.RFSTUTC + 1). Do not populate for partial dates.	If AESTDTC is before RFSTUTC then populate with (AESTDTC - RFSTUTC). Otherwise, if AESTDTC is on or after RFSTUTC then (AESTDTC - RFSTUTC + 1).	If AESTDTC is before DM.RFSTUTC then populate with (AESTDTC - DM.RFSTUTC); If AESTDTC is on or after DM.RFSTUTC then populate with (AESTDTC - DM.RFSTUTC + 1). Do not populate for partial dates.

Documents

ID ↕	Title ↕	Href ↕
ct_report	Terminology Report	ABC_ISS_CT_Values.pdf
methods_comments	Report	ABC_ISS_derivation_comments.pdf
origin_report	Origin and VLM Report	ABC_ISS_variable_origin.pdf
remapping	Remapping Report	ABC_ISS_Value_Remapping_Report.pdf

Specifications – Rules



Origin from any study	In Combination with origins from all other studies	ISS Origin	Other Origin
Same origin across all studies		Original	
Derived	Assigned and Collected	Derived	Collected, Assigned
Derived	Collected	Derived	Collected
Derived	Assigned	Derived	Assigned
Derived	Collected and eDT	Derived	Collected, eDT
Derived	Assigned and eDT	Derived	Assigned, eDT
Derived	Assigned and Protocol	Derived	Assigned, Protocol
Derived	Collected and Assigned and Protocol	Derived	Collected, Assigned, Protocol
Derived	Collected and Assigned and eDT	Derived	Collected, Assigned, eDT
Derived	eDT	Derived	eDT
Assigned	Protocol	Assigned	Protocol
Assigned	eDT	Assigned	eDT
Assigned	eDT and Protocol	Assigned	eDT, Protocol
Collected	Assigned	Collected	Assigned
Collected	Assigned, eDT	Collected	Assigned, eDT
Collected	Assigned, Protocol	Collected	Assigned, Protocol
Collected	eDT	Collected	eDT

AESPID	Sponsor-Defined Identifier	text	Identifier	3	Derived (Source: Sponsor) Annotated Case Report Form [169] Derivations Report [1] Comments Report [2]
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Role of Reviewer's Guide

The Reviewer's Guide offers essential context and guidance to facilitate regulatory review of submissions.

Template Updates

Updating templates with study status tables and data source documentation clarifies the integration process for reviewers.

Focused Issue Inclusion

Including only ISS integration-related P21E issues streamlines review and highlights key challenges effectively.

Flow Charts & Customization

Flow charts illustrate rollover processes and P21E alignment, enhancing clarity and navigation in the customized template.

1. Variability across studies creates early integration burden
2. Ongoing studies require iterative reconciliation
3. Tool limitations require creative workflows – automate!!!
4. Traceability requires purpose-built reporting – automate!!!
5. Validation findings must be interpreted carefully

Overall, these challenges underscore a central lesson: **successful ISS-level SDTM integration relies as much on process, governance, and judgment as on tools.**

Any questions?



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