



The Show Must Go On: Best Practices for Submitting SDTM Data for Ongoing Studies

KRISTIN KELLY- Pinnacle 21 by Certara
PHUSE US Connect 2025 – SA06
MARCH 18, 2025

Agenda

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Introduction

- The CDISC SDTMIG guidance assumes study data from a completed study
- There have been an increasing number of submissions that include data from ongoing studies
- Because of limited guidance, the SDTM standards are implemented inconsistently across sponsors
 - Making it difficult for a reviewer to readily determine study status
- With the inclusion of the 'ONGOSIND/Ongoing Study Indicator' parameter in TS, this is a necessary first step in providing some standardization within the data for ongoing studies
 - This parameter first appeared in the FDA Study Data Technical Conformance Guide (sdTCG) in March 2024

Best Practices for SDTM Domains

- One approach to ensure transparency in the data that a study is ongoing would be to represent it in its current state rather than presenting it as a completed study
- Subjects that are still on-study should be readily discernable when looking at the SDTM data
- The following sections will discuss how this can be done in a few of the SDTM datasets themselves:
 - Demographics (DM)
 - Disposition (DS)
 - Trial Summary (TS)

Best Practices for SDTM Domains

Demographics (DM)

- When a sponsor chooses to populate all the reference date/time variables in DM as if all subjects have reached the milestones needed to complete the study, it is difficult for a reviewer to determine if the study is still ongoing

USUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	>>>	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
CWCW-645-0005	2023-07-15T08:32	2024-02-24T09:34	2023-07-15T08:32	2024-02-24T09:34	2023-06-30	2024-04-15		CWCW15	Drug CWCW645 15 mg	CWCW15	Drug CWCW645 15 mg	
CWCW-645-0006					2023-07-01	2023-08-15						SCREEN FAILURE
CWCW-645-1007	2023-06-10T10:30	2024-08-10T10:30	2023-06-10T10:30	2024-08-10T10:30	2023-05-17	2024-09-10		PLACEBO	Placebo	PLACEBO	Placebo	
CWCW-645-1008	2023-08-01T08:23	2024-09-15T11:34	2023-08-01T08:23	2024-09-15T11:34	2023-06-28	2024-09-24		CWCW10	Drug CWCW645 10 mg	CWCW10	Drug CWCW645 10 mg	
CWCW-645-1111	2023-07-12T15:00	2024-05-12T13:00	2023-07-12T15:00	2024-05-12T13:00	2023-06-29	2024-06-30		CWCW05	Drug CWCW645 5 mg	CWCW05	Drug CWCW645 5 mg	

Best Practices for SDTM Domains

Demographics (DM)

- In the define.xml, the following Methods for reference dates/times are provided

DM Variable	Method
RFSTDTC	Date/Time of First Dose
RFENDTC	Date/Time of Last Dose
RFXSTDTC	Date/Time of First Dose
RFXENDTC	Date/Time of Last Dose
RFPENDTC	Latest Date available for subject/Last Contact Date

Best Practices for SDTM Domains

Demographics (DM)

- Because USUBJID = 'CWCW-645-1007' and 'CWCW-645-1111' are still in the study and have received at least one dose, a better representation might be the following:

USUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	>>>	ARMCD	ARM	ACTARMCD	ACTARM	ARMNRS
CWCW-645-0005	2023-07-15T08:32	2024-02-24T09:34	2023-07-15T08:32	2024-02-24T09:34	2023-06-30	2024-04-15		CWCW15	Drug CWCW645 15 mg	CWCW15	Drug CWCW645 15 mg	
CWCW-645-0006					2023-07-01	2023-08-15						SCREEN FAILURE
CWCW-645-1007	2023-06-10T10:30		2023-06-10T10:30		2023-05-17			PLACEBO	Placebo	PLACEBO	Placebo	
CWCW-645-1008	2023-08-01T08:23	2024-09-15T11:34	2023-08-01T08:23	2024-09-15T11:34	2023-06-28	2024-09-24		CWCW10	Drug CWCW645 10 mg	CWCW10	Drug CWCW645 10 mg	
CWCW-645-1111	2023-07-12T15:00		2023-07-12T15:00		2023-06-29			CWCW05	Drug CWCW645 5 mg	CWCW05	Drug CWCW645 5 mg	

Best Practices for SDTM Domains

Disposition (DS)

- It is recommended to only represent data collected thus far for each subject (similar to DM):

STUDYID	USUBJID	DSTERM	DSDECOD	DSCAT	EPOCH	DSSTDTC
CWCW-645	CWCW-645-0005	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2023-06-30
CWCW-645	CWCW-645-0005	COMPLETED	COMPLETED	DISPOSITION EVENT	TREATMENT	2024-02-24
CWCW-645	CWCW-645-0005	COMPLETED	COMPLETED	DISPOSITION EVENT	FOLLOW-UP	2024-04-15
CWCW-645	CWCW-645-0006	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2023-07-01
CWCW-645	CWCW-645-0006	SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVENT	SCREENING	2023-08-15
CWCW-645	CWCW-645-1007	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2023-05-17
CWCW-645	CWCW-645-1111	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2023-06-29

Best Practices for SDTM Domains

Trial Summary (TS)

- There are several parameters that can be leveraged in TS to indicate that the study is ongoing

FDA Desired - Clinical	TSPARMCD	TSPARM
Y	DCUTDESC	Data Cutoff Description
Y	DCUTDTC	Data Cutoff Date
Y	ONGOSIND	Ongoing Study Indicator
Y	SENDTC	Study End Date

- Listed in Appendix B in the FDA sdTCG and all should be included in TS (i.e., FDA Desired = 'Y')
 - TSPARMCD/TSPARM = 'ONGOSIND/Ongoing Study Indicator' was added in March 2024

Best Practices for SDTM Domains

Trial Summary (TS)

- For the same example study, these 4 parameters might be configured like this:

STUDYID	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD
CWCW-645	1	IA	DCUTDESC	Data Cutoff Description	INTERIM ANALYSIS		
CWCW-645	1	IA	DCUTDTC	Data Cutoff Date	2024-09-30		
CWCW-645	1		ONGOSIND	Ongoing Study Indicator	Y		C49488
CWCW-645	1		SENDTC	Study End Date		NAV	

- This makes it easy to determine that the study is ongoing when looking in TS

Updates to P21 Validation Rules

- Another component for submission of ongoing studies is running the CDISC and FDA validation rules against the data
- There are several rules that may surface for an ongoing study because the rule logic is based on checking standardized data from completed studies
- Sometimes these rules have been explained as 'false positives' in the cSDRG
 - This is not an accurate explanation as the rule is working as intended
- There has been a need to have a mechanism present in the data that can be leveraged in validation to 'turn off' some the rules that assume a complete study
 - 'ONGOSIND' in TS provides this mechanism

Updates to P21 Validation Rules

New Rule for 'ONGOSIND' in TS

- There is one new rule that checks for the presence of a record where TSPARMCD = 'ONGOSIND' because it is an 'FDA Desired' parameter

Rule ID	Message	Description	Message Type	Review Impact
SD2287	Missing ONGOSIND Trial Summary Parameter	Ongoing Study Indicator' (ONGOSIND) record must be populated in Trial Summary (TS) domain. It is an 'FDA Desired' parameter listed in the Technical Conformance Guide (TCG).	Error	High

- If this rule fires in validation, it's because the record is missing and should be added
- This rule should NOT be explained in the cSDRG
- It is a simple update to TS in order to fulfill FDA requirements so....JUST DO IT!

Updates to P21 Validation Rules

Rules that Check the Disposition (DS) Domain

- Subjects that are still on-study will typically not have a record where DSCAT = 'DISPOSITION EVENT' and will be flagged by these rules

Rule ID	Message	Description	Message Type	Review Impact
SD0069	No Disposition record found for subject	All Demographics (DM) subjects (USUBJID) should have at least one record in the Disposition (DS) domain. The only possible exceptions for SDTMIG v3.2 (and earlier) are Screen Failures (ARMCD=SCRNFAIL) and Not Assigned Treatment (ARMCD=NOTASSGN) subjects, or subjects with ARMCD=null. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	Medium
SD2288	No DISPOSITION EVENT record found for subject	All subjects (USUBJID) should have at least one record in the Disposition (DS) domain with Disposition Category (DSCAT) equal to DISPOSITION EVENT. Subjects with ARMCD='SCRNFAIL', ARMCD = null, or ARMCD='NOTASSGN' are excluded from this check. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	High

- These two rules will no longer be triggered in validation as long as DM, DS and TS are run together and ONGOSIND = 'Y'

Updates to P21 Validation Rules

Rules that Check the Disposition (DS) Domain

- Other rules that are triggered are due to not having the final DS record for a subject

Rule ID	Message	Description	Message Type	Review Impact
SD0080	AE start date is after the latest Disposition date	Start Date/Time of Adverse Event (AESTDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC). Investigator should provide a date of study discontinuation for each subject in Disposition (DS) domain. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	High
SD0082	Exposure end date is after the latest Disposition date	End Date/Time of Treatment (EXENDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC). Investigator should provide a date of study discontinuation for each subject in Disposition (DS) domain. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	High
SD1446	Exposure start date is after the latest Disposition date	Start Date/Time of Treatment (EXSTDTC) should be less than or equal to the Start Date/Time of the latest Disposition Event (DSSTDTC). Investigator should provide a date of study discontinuation for each subject in Disposition (DS) domain. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	High

- These rules will no longer be triggered in validation as long as TS is included and ONGOSIND = 'Y'

Updates to P21 Validation Rules

Rules that Check Against DM.RFPENDTC

- These rules will fire when RFPENDTC is before the date/time in a subject-level domain

Rule ID	Message	Description	Message Type	Review Impact
SD1202	--STDTC date is after RFPENDTC	Start Date/Time (--STDTC) variable value must be less than or equal to Date/Time of End of Participation (RFPENDTC). If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Error	Medium
SD1203	--DTC date is after RFPENDTC	Date/Time of Collection (--DTC) variable value must be less than or equal to Date/Time of End of Participation (RFPENDTC). If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Error	Medium
SD1204	--ENDTC date is after RFPENDTC	End Date/Time (--ENDTC) variable value must be less than or equal to Date/Time of End of Participation (RFPENDTC). If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Error	Medium

- These rules will no longer be triggered in validation as long as TS is included and ONGOSIND = 'Y'

Updates to P21 Validation Rules

Rules that Check Against DM.RFENDTC

- These rules will fire when RFENDTC is left null and the subject is randomized and/or treated

Rule ID	Message	Description	Message Type	Review Impact
SD0088	RFENDTC is not provided for a randomized subject	Subject Reference End Date/Time (RFENDTC) should be populated for all randomized subjects, those where Planned Arm Code (ARMCD) is not equal to 'SCRNFAIL' or 'NOTASSGN' or null. If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	High
SD1376	RFENDTC is not provided for a treated subject	Subject Reference End Date/Time (RFENDTC) should be populated for all treated subjects, those where Actual Arm Code (ACTARMCD) is not equal to 'SCRNFAIL', 'NOTASSGN' or 'NOTTRT' (or null). If the study is ongoing, Parameter Value (TSVAL) for the 'ONGOSIND/Ongoing Study Indicator' parameter should be set to 'Y' in the Trial Summary (TS) domain.	Warning	Medium

- These rules will no longer be triggered in validation as long as TS is included and ONGOSIND = 'Y'

Best Practices For Validation

- These methods should NOT be used for a completed, locked study to avoid having to provide explanations in the cSDRG!
- For ongoing studies, a preparer of the data may want to keep these rules 'turned on' for QC purposes and there are a few ways this can be done:
 1. TS is not included in the validation
 2. TS is included but the ONGOSIND parameter is not present
 3. TS is included and ONGOSIND = 'N'
 4. TS is included and ONGOSIND = NULL
- Please note that even when ONGOSIND = 'Y' and TS is included in the validation, if there are instances in the data that fail the rule criteria, the rules will still fire and will need to be explained

Best Practices For the cSDRG

- Don't forget to note whether the study is ongoing or not in Section 3.1 in the cSDRG:

3. Subject Data Description

3.1 Overview

Are the submitted data taken from an ongoing study? <Yes> <No>

If yes, describe the data cut or database status:

(Text here)

Conclusion

- Though there is little guidance from CDISC on what to do for ongoing studies, there are ways that the SDTM data and submission deliverables can be compiled to ensure transparency downstream to a reviewer.
- With the introduction of the ONGOSIND parameter in TS, there is finally a mechanism present in the data that indicates that the study is ongoing.
 - It can be leveraged in validation for rules that are based on the assumptions for a completed study.
- Also, the recommendations for structuring certain datasets in this case, are simply that. It is always a sponsor decision on how to implement the standards.
- Hopefully, these best practices will be adopted by industry in order to ensure speed of review in an effort to always get drugs and vaccines to patients faster.



Questions?

Kristin Kelly
Pinnacle 21 by Certara
kristin.kelly@certara.com

