Using SDTM to address Frequently Asked Questions (FAQs) in DM Work

用SDTM解决DM常见问题

Presented by Yang Wu, Manager, Data Management, Pharmaron

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Meet the Speaker

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10 years of clinical clinical data management experience, with rich expertise in DCT (Data Collection Tools) design, data cleaning and external data management;

Including phase I-IV trials and RWS (Real World Studies);

Skilled in various therapeutic areas, particularly oncology;

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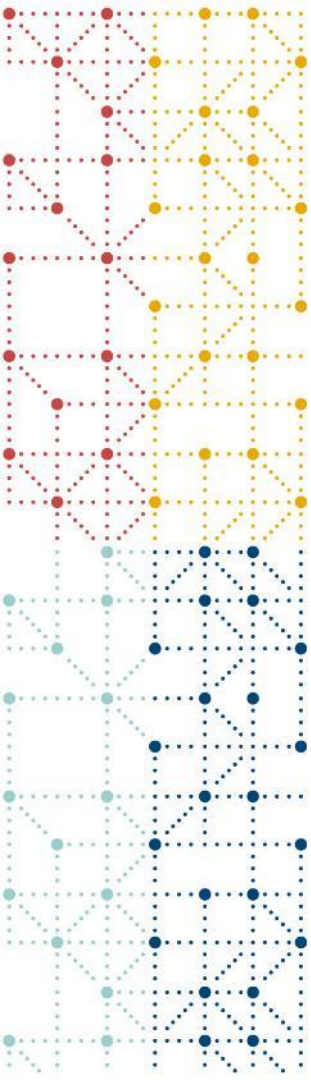
Agenda

1. Background
2. DM FAQs and Answers in SDTM
3. Summary



Background

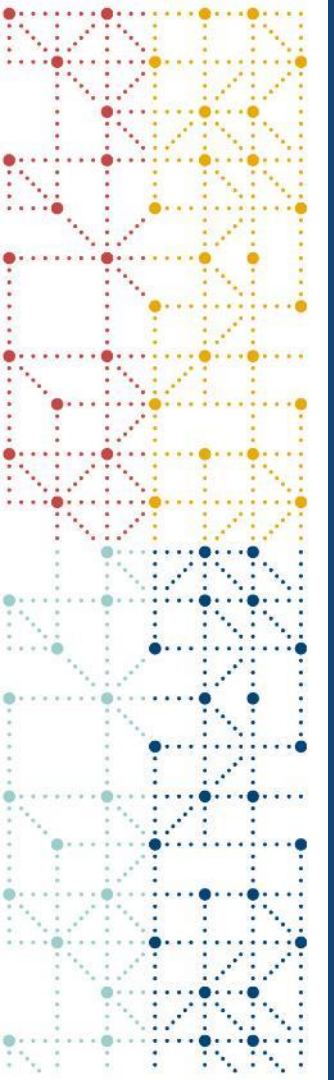
In DM work, some issues are *frequently* encountered …

Background

As a data manager, have you ever been asked these questions... :

- Issues recurrent across multiple projects
- Seems both options work
- Refer to the practices of previous projects?

Answer: SDTM provides clarity!



DM FAQs and Answers in SDTM

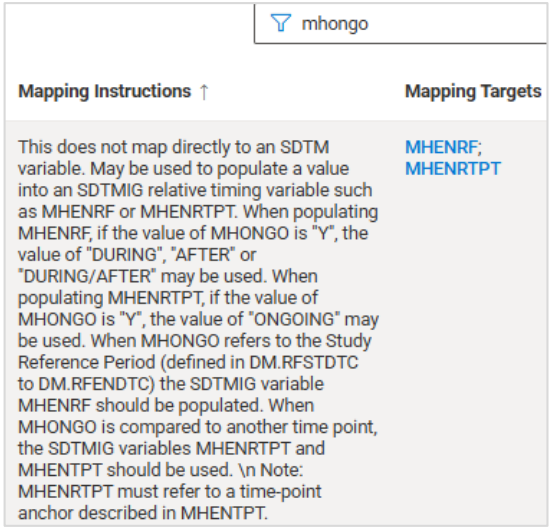
- Data entry rules
- CRF design

…

Medical History

Q: For a baseline medical history resolved post-treatment, should MHONGO and MHENDAT be updated?

- Specifications in CDASHIG v2.3 and SDTMIG v3.4



Name	Label	Description
MHENRF	End Relative to Reference Period	Describes the end of the event relative to the sponsor-defined reference period. The sponsor-defined reference period is a continuous period of time defined by a discrete starting point and a discrete ending point (represented by RFSTDTC and RFENDTC in Demographics). \n Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.
MHENRTPT	End Relative to Reference Time Point	Identifies the end of the event as being before or after the reference time point defined by variable MHENTPT. \n Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.

My suggestion is to update, for data accuracy purpose.

- From CDISC Data Standards Browser: https://library.cdisc.org/browser/#/mdr/sdtmig/3-4/classes/Events/datasets/MH

Adverse Event

- **Q:** Similar to last question, if the AE outcome is resolving, should the AE outcome date be entered?

59	AEENRTPT	End Relative to Reference Time Point	Identifies the end of the event as being before or after the reference time point defined by variable AEENTPT. \n Not all values of the codelist are allowable for this variable. See Section 4.4.7, Use of Relative Timing Variables.
60	AEENTPT	End Reference Time Point	Description of date/time in ISO 8601 character format of the reference point referred to by AEENRTPT. Examples: "2003-12-25", "VISIT 2".

- The answer is same to the last question.
- Pay attention to SAE reconciliation rules.

Baseline

Q：Should the retest data at baseline be recorded in the screening period /D1 visit or the unscheduled visit?

Name	Label	Data Type	Role	Qualifies ...	Described Value Domain	Notes	Usage Restrictions	Definition
--BLFL	Baseline Flag	Char	Record Qualifier			Result value is in --STRESC. Should be "Y" or null.		An indication that the record is the sponsor-defined baseline assessment, used in study data tabulation.

Name	Label	Description	Data Type	Role	Core
EGBLFL	Baseline Flag	Indicator used to identify a baseline value. Should be "Y" or null. Note that EGBLFL is retained for backward compatibility. The authoritative baseline for statistical analysis is in an ADaM dataset.	Char	Record Qualifier	Perm

- If you put the re-test data in unscheduled visit, it meets the common rules; If you put the re-test data in screening/baseline visit, it's convenient for data verification. I prefer to enter in screening visit.
- Pictures from CDISC Data Standards Browser: https://library.cdisc.org/browser/#/mdr/sdtmig/3-4/classes/Events/datasets/EG

Subject Visits (SV)

Q: When a visit spans multiple days, which date should be recorded?

- Earliest assessment date?
- Date of Exposure?
- The date the patient see the doctor?

Ordinal ↑	Name	Label	Description	Data Type	Role	Core
14	SVSTDY	Study Day of Start of Observation	Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Num	Timing	Perm
15	SVENDY	Study Day of End of Observation	Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.	Num	Timing	Perm

- Since there's always 1 visit date for 1 visit on CRF, I prefer to use the earliest date.
- From CDISC Data Standards Browser: https://library.cdisc.org/browser/#/mdr/sdtmig/3-4/classes/Events/datasets/SV

Demographics(RFPENDTC)

- Flow of the date.

受试者完成所有研究阶段以及末次访视或研究日程表上的最后一次计划程序即视为完成研究。

研究结束

受试者是否完成研究?	○是 ○否
完成或提前退出日期	_____
最主要的提前退出原因	○受试者主动退出，拒绝进一步随访 ○受试者失访 ○受试者死亡 ○申办方决定提前终止试验 ○研究过程中受试者发生妊娠事件 ○不良事件、实验室检查异

RFPENDTC，最好是在《研究总结页》采集，而不是在全部数据里找最大日期哟。

譬如2021-05-15，是该受试者的最后一次常规访视，但有一条AE如“腹泻”未愈。2021-05-22日进行了该AE的随访，仍未愈。2021-05-29、2021-06-05、2021-06-12尝试电话联系该受试者，均未联系上，失访 。

该受试者在研究中最晚日期(RFPENDTC)，正确的应该是2021-05-22。如果《研究结束页》[完成/退出日期]填写的是2021-05-15(最后一次常规访视日期)，那从数据中找出的最晚日期，就是2021-05-15(错误)。该AE的“仍持续”，正确的表达是2021-05-22时“仍持续”，但数据中是没有这个日期的。(当然后边这个仍持续的日期，也可以在AE页采集，请参看另一篇帖子“AE转归/结束日期”。

↑ From wechat official account: Data Science Express

D0?

筛选期 -2w~0w		导入期 0~2w
-D14~0		D1~14
V1	V2	V3
D-14~-1	D0	D14±2d

The subject reference start date (RFSTDTC) is designated as study day 1. The study day value is incremented by 1 for each date following RFSTDTC. Dates prior to RFSTDTC are decreased by 1, with the date preceding RFSTDTC designated as study day -1 (there is no study day 0). This algorithm for determining Study Day is consistent with how people typically describe sequential days relative to a fixed reference point, but creates problems if used for mathematical calculations because it does not allow for a day 0. As such, Study Day is not suited for use in subsequent numerical computations, such as calculating duration. The raw date values should be used rather than Study Day in those calculations.

- As D0 is not allowed in data, suggest to avoid to set D0 visit from protocol.

CT

- **Q**: CRF lists “intravenous injection” but source data shows “intravenous drip”. Is it necessary to distinguish?

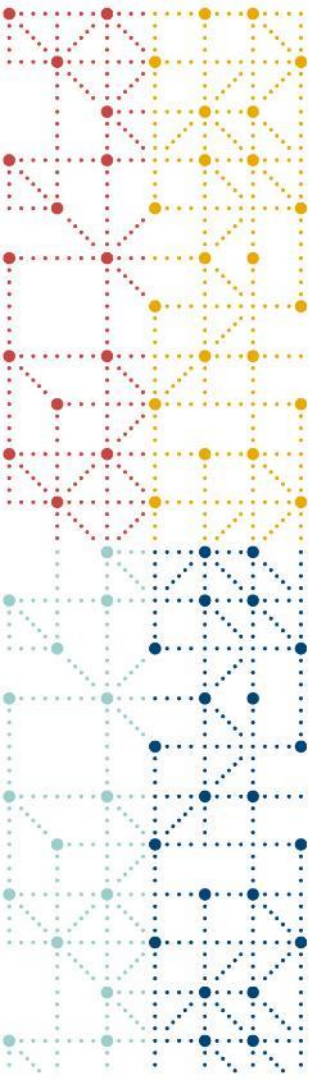
Term	Submission Value	Synonyms	Definition	NCI Preferred Term
C38274	INTRAVENOUS BOLUS		Administration within or into a vein or veins all at once. (FDA)	Intravenous Bolus
C38279	INTRAVENOUS DRIP		Administration within or into a vein or veins over a sustained period of time. (FDA)	Intravenous Drip
C38276	INTRAVENOUS		Administration within or into a vein or veins. (FDA)	Intravenous Route of Administration

- Since the ivgt is common used in clinical, I prefer to design on CRF, for more accurate data and convenient data cleaning procedures.
- Check the full edition CT.

Primary SOC

- If the reviewer comment to change coding result to another SOC, not the primary SOC?
- A：Primary SOC is required. You can report both SOCs, and suggest to turn to MedDRA official.

22	AEBODSYS	Body System or Organ Class	Dictionary derived. Body system or organ class used by the sponsor from the coding dictionary (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables, which may not necessarily be the primary SOC.
24	AESOC	Primary System Organ Class	Dictionary-derived text description of the primary SOC. Will be the same as AEBODSYS if the primary SOC was used for analysis.



Summary

Some tips

Summary

1. Clarity Over Ambiguity:

- Avoid vague answers; Maintain our professionalism.

2. Flexibility in Application:

- Balance compliance with usability (e.g., adapt to local workflows).

- **3.Global Perspective**:
- Master SDTM to drive automation/intelligence in data management.

Thank You!

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