SDTM Underlying Principles, FAQS

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Setting the
Global Standard
for Clinical Data

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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Topicality (1)

- Topicality defines domain
  - What are you collecting data about?
    - Medication use, Interventions
    - Illness, Events
  - Regardless of how much data you collect
    - Just because you choose to collect less data does not change the topicality
  - Regardless of importance to your study
    - Just because you do not care about the details, only Y/N, does not change the topicality

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Topicality (2)

- It is <u>not</u> just about your study/application

- SDTM designed to facilitate:
  - Standard data transfer to FDA
  - Loading data to JANUS
  - Mining

- Data should not be different because of specific study/application needs

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Topicality (3)

- How to determine topicality
  - Pre-defined Domains

    (SDS v3.1 section 10.3.1)

  - Questionnaires

  - If it does not match an existing event or intervention, it is probably a finding

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Topicality (4)

- Do you smoke?   Y / N
  - Topicality = substance use, intervention

    DOMAIN   = SU

    SUTRT   = TOBACCO

    SUDECOD   = NICOTINE

    SUOCCUR   = Y

    You might have thought this is a finding
    (SDS v3.1 sections 6.1.3, 9.2.3)

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Topicality (5)

- Highest Tox Grade, by Visit/Cycle

  Nausea   1 ② 3   4   5

  Headache   1   2   3   4   5

  – Topicality = adverse events, events

DOMAIN	= AE	AEOCCUR	= Y
AECAT	= TOXICITY	AETOXGR	= 2
AETERM	= NAUSEA		

  You might have thought this is a finding

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Domains vs. CRF (1)

- CRF does not equal SDTM domain
- CRF domain can be split into SDTM:
  - Multiple domains
  - Comments
  - SUPPQUAL
  - RELREC
- CRF domains can be collapsed into SDTM domains

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Domains vs. CRF (2)

- Some CRF variables can be excluded from SDTM

    – Page not done? ☐

    – Does the subject have any past major conditions other than disease studied?

    ☐ Yes, list the condition(s) below

    1 _____

    2 _____

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Content (1)

- SDTM specifies structure, does not direct content

- SDTM provides vehicle for representing content

- Science & Regulation determine content

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Content (2)

- COMMENTS
  - Only submit if you have comments
  - Comments on a separate comments page

    DOMAIN   = CO

    RDOMAIN   =

    COVAL   = comment text

  - Comment variable in original domain

    DOMAIN   = CO

    RDOMAIN   = AE (for AE comments)

    COVAL   = comment text

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Content (3)

- SUPPQUAL
  - Only include variables that cannot be included in existing model
    - AETRTEM, Treatment Emergent
  - Usually needs to be submitted
    - If only for ITT, SAFETY, PPROT, COMPLT
  - Can now be one SUPPQUAL / Domain
    - xx_supp
    - New in SDS v3.1.1

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Content (4)

- RELREC
  - Only include if you need/want to identify relationships between records

    (Science and/or Regulation)

    - Discontinuation due to AE?   AE SEQ #: ___
      - If not submitting, annotate "not entered in database"
      - But why did you collect it?

    - SAE forms, Labs, Con Meds

  - Complicated, but simplest to handle all cases

    - Resolves many-many-many relationships

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FAQs – Core Variables (1)

- Required
  - Data is <u>useless</u> without
  - STUDYID, USUBJID, topic variable

- Permissible
  - Optional
  - Include only if you collected the data
    - Can vary study-by-study

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FAQs – Core Variables (2)

- Expected
  - Variable must be in dataset
  - Varies depending on domain
    - AESTDTC, expected
    - MHSTDTC, permissible
  - Can have Nulls, but not usually all Nulls…

    …But need to consider context
    - AESTDTC = Null for all AECAT = TOXICITY

    (example used on slide 6)

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FAQs – Inclusion/Exclusion

- List of all I/E questions defined in TI

- IE only includes exceptions
  - At trial start
  - During trial
    - Include in IE with appropriate IECAT and timing variables

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FAQs – Text >= 200 Chars

- Comments
  - COVAL – first 200 chars
  - COVAL1 – second 200 chars
  - COVAL2 – third 200 chars, and so on…

- Domains
  - Domain variable – first 200 chars
  - SUPPQUAL, QVAR = x1 – second 200 chars
  - SUPPQUAL, QVAR = x2 – third 200 chars, …

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FAQs – Misc

- RACEOTH – SC

- AETRTEM – SUPPQUAL

- Should not have nulls in QVAL
  - But deleting Null value records is a leap of faith

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