SDTM new domains

Clinical classification CC

- Domain for named instruments whose output is an ordinal or categorical score
  - Surrogate for , ranking of , disease status or other physiological or biological status
  - Findings domain
  - CCCAT: name of the instrument
  - CCTEST/CCTESTCD: Name of the questions of the instrument

Clinical classification CC

- Domain for named instruments whose output is an ordinal or categorical score
  - Surrogate for , ranking of , disease status or other physiological or biological status
  - Based solely on objective data from clinical records, or may involved a clincial judgement or interpretation of directly observable signs, behaviors or other physical mainfestations related to the condition of the subject
  - Are often composite scores based on diverse inputs
  - Subject evaluator interactions are at most implied, but often altogether absent
  - Different from functional test, they are not task or performance based
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Clinical classification CC

- Findings domain
  - CCCAT: name of the instrument - req
  - CCTEST/CCTESTCD: Name of the questions of the instrument
  - CCRESCAT Result category
  - CCEVAL and CCEVALID (Evaluator and Evaluator Identifier)
  - CCEVINTX Evaluation Interval Text *ISO 8601*
    - *CDISC notes …where interval is not able to be presented in ISO 8601*

Clinical classification CC

- Assumptions:
  - According to general definition of findings domains
  - QS,FT and CC domains fall under the category of Clinical outcome assessment (COA).
    - CDISC publishes standard COA supplements to the SDTMIG along with controlled terminology
    - Governed by Controlled terminology COA Sub-Team

Clinical classification CC

- Assumptions:
  - Data that is used for input to the composite scores such as labs or clinical events are included in the CC domain – also inlcuded in its original domain and linked via RELREC
  - Example Child- Pugh/Apache. The points or score classification are mapped to the standard result variables (STRESC/STRESN)

Clinical classification CC

- Examples:
  - Child Pugh Classification
  - Apache Score
  - NYHA Classification
  - Killip Class for Subject
  - Canadian CV Society Grading Scale

- Questions: can that be used for Cancer classifications?

Ophthalmic Examinations OE

- Findings related to tests that measure a person's ocular health and visual status to detect abnormalities and to determine how well the person can see
  - Collected on CRF or received from central provider
  - Should not include morphological opthalmic examinations – only physiological opththalmic examinations
  - Not a domain to place all ophthalmic related data

Ophthalmic Examinations OE

- Findings domain
  - New variable FOCID Focus of Study-Specific Interest CTL: OEFOCUS
    - OD Oculus Dexter (Right Eye)
    - OS Oculus Sinister (Left Eye)
    - OU Oculus Uterque (Both Eyes)
    - Introduced in SDTM v.1.5
      - FOCID facilitate creating the cohesive OESingle Virtual View containing all records from OE, MO and other findings domains
    - Location can then be used for more specific location of the eye e.g. conjunctiva, eye lid etc.

Ophthalmic Examinations OE

- Findings domain
  - OETEST, OETSTDTL and OEMETHOD are expected to describe uniquely an opthalmic test
  - -CAT and –SCAT are variables for ophthalmic examinations
    - E.g. Visual acuity, Contrast Sensitivity, Color Vision, Visual Field
    - OEREPNUM Repetition number

Ophthalmic Examinations OE

- Examples
  - Visual acuity
  - Contrast sensitivity
  - Color Vision
  - Visual Field
  - Ocular Comfort

  Others?
  - Fundus Photography
  - Indirect ophthalmoscopy: posterior segment examination
  - Fluorescein angiography (FA