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 clinical judgement or interpretation of directly observable signs, behaviors or other physical manifestations 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
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 included 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 ophthalmic examinations – only physiological ophthalmic examinations
  - Not a domain to place all ophthalmic related data
Ophthalmic Examinations OE

• Findings domain
  – New variable FOCID  Focus of Study-Specific Interest
  CTL: OEOFOCUS
    • 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, OETSTDTDL and OEMETHOD are expected to describe uniquely an ophthalmic 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