The CDISC vision is to inform patient care & safety through higher quality medical research.
CFAST and SHARE
Bringing it All Together

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• Overview
• Understanding data by starting at the clinic
• Concept maps and BRIDG as modeling tools
• From models to metadata
• Using metadata
CFAST TA Standards Process

1. Understand Clinical Source of Data
   - then if necessary
   - then
2. Model Source Process
3. Model Data
   - then
   - using
   - BRIDG-based style sheet
4. Create Research Concept Metadata
   - using
   - BRIDG-based template
5. Includes
   - SDTM Domain
   - Test name/code (if applicable)
   - Variables
   - Value lists drawn from controlled terminology
   - Other research concepts which must or may be linked
6. then, as necessary
7. Create CDASH metadata and examples
8. Create SDTMIG-style data examples
9. Create example ADaM datasets and metadata
Understanding data by starting at the clinic

• CFAST Therapeutic Area User Guides (TAUG) work is based on the assumption that we need to understand what is happening in the clinic
• TAUGs include introductory material about the disease under study, and about the processes involved in collecting specialized data
• Why? This is different from standards like the SDTMIG.
Clinical settings from which data arise

• Familiarity with the “core” SDTMIG domains comes from our experience as patients, not just from dealing with clinical trial data

• Almost everyone here has
  ▪ Had vital signs taken
  ▪ Been asked about their medical history
  ▪ Had a physical exam
  ▪ Been asked about their medical problems (AEs)
  ▪ Given samples for lab tests
  ▪ Taken medications
  ▪ Had an ECG, an X-Ray, or some other imaging procedure
Understanding therapeutic area data

• For specialized TA data, those who handle data may not have any familiarity, either through their work or as patients

• TA teams develop and describe the clinical context of specialized data through
  ▪ Clinical expert team members’ contributions
  ▪ Research into clinical and regulatory references
  ▪ In some cases, team members’ experience as patients
Turning Understanding Into Models

• Clinical trial data doesn’t include, or need to include, all the details of what happens in the clinic.
• Modeling is the process of selecting and organizing the details that are needed for a particular purpose.
• There are many ways to describe models, many of them visual, with varying levels of formality.
Modeling Methodologies Used for TAs and SHARE

• Unified Modeling Language (UML) is a formal methodology used by software developers.

• The BRIDG model is expressed in UML
  ▪ It’s in the background for most users
  ▪ TA models are checked for consistency with BRIDG

• The TAUGs use diagrams called concept maps
  ▪ Visual representations
  ▪ Accessible without much user training
  ▪ Similar to, but slightly more formal than, mind maps
Concept Mapping Process for TAUGs

• Free software (c-map)
• Concept modelers use a style sheet with re-usable modules to build concept maps
  ▪ Modules based on BRIDG
  ▪ Keeps connection to BRIDG, but in the background
• Color coding conventions
  ▪ For activities such as observations, substance administrations
  ▪ For objects such as specimens, results, products
• Judgment needed to choose level of detail – informative, but not too busy
Concept Map Color Coding

Color coding in concept maps indicates relevant BRIDG classes.
CFAST TA Standards Process
Use of Concept Maps

**Note:** This diagram is a concept map!
Concept map to metadata

• Transition from concept maps to metadata facilitated by use of BRIDG-based tools
  ▪ Concept map style sheet
  ▪ Metadata creation templates
• Provides standards at a more granular level
  ▪ For each research concept, E.g., each test
• Detailed metadata, including
  ▪ Mappings to current standards (e.g., SDTM variables)
  ▪ Value lists drawn from controlled terminology
  ▪ Metadata about required or optional links to other research concepts
Preliminary metadata developed in spreadsheets included in Asthma TAUG. Full metadata to be housed in SHARE environment.
SHARE Metadata
Examples for Tests (Findings)

- Domain, TEST, TESTCD, relevant SDTM variables
- Value lists for attributes of a test and its results provide value-level metadata, such as
  - Value lists for results
  - Relevant values from the unit codelist
  - Relevant values from the method codelist
- Relevant links to other research concepts, such as
  - Specimen(s) on which the test is performed
  - Device(s) used in the test
  - Relevant assessors (e.g., whether a questionnaire is for completion by patient, caregiver, or clinician)
Uses of SHARE Metadata

• Study data collection specification
  ▪ Select research concepts, complete with terminology and links, rather than assembling individual variables

• Detailed specification of research concepts facilitates validation of data

• Define-xml
  ▪ Domain metadata built from concepts up
  ▪ Value level metadata comes with the concepts
  ▪ Potential to include much more metadata, easily
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• Questions?