CDISC Oncology
Information Session

John Owen, Kathleen Mellars, Melanie Paules, Erin Muhlbradt, Richann Watson, Paul Slagle
Agenda

• Oncology Standards Development Plan (John Owen)
• Status of Oncology Projects (John Owen)
  ▪ Breast Cancer
  ▪ Prostate Cancer
  ▪ Colorectal Cancer
  ▪ Lung Cancer
• Oncology Standards Updates
  ▪ CDASH (Kathy Mellars)
  ▪ SDS (SDTM and CT) (Melanie Paules)
  ▪ ADaM (Richann Watson/Paul Slagle)
• Review Opportunities (John Owen)
• Next Oncology Information Session (John Owen)
• Q & A
Oncology Standards Development Plan

John Owen
Oncology Standards Development Plan

• Focus development of new concepts within an indication

• Reuse/reference concepts developed in previous User Guides

• Re-use knowledge/trained resource across ONCO TA projects

• Use of SHARE Ecosystem Tools to streamline development

• Liaison with CDISC foundational groups
  - ONCO SDS group
  - ONCO CDASH team
  - ONCO ADaM team
Oncology Standards Development Plan

- **Oncology WIKI Site** – provides access to:
  - What’s new in Oncology
  - Links to TAUG WIKI Sites
  - Links to ONCO information sessions
  - Links to ONCO SME group
  - Links to ONCO Foundational Groups
    - SDS/ADaM/CDASH

BrCa  PrCa  CrCa  LuCa
Oncology Standards Development Plan
Status of Oncology Projects

John Owen
# CFAST Oncology Program Overview

## November 2016

<table>
<thead>
<tr>
<th>Project</th>
<th>Charter Approved</th>
<th>Internal Review</th>
<th>Public Review</th>
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*Italic dates indicates planned dates*
Current Status of the Breast Cancer Data Standards Project

- **BrCa TAUG**
  - Published on CDISC Website 16\(^{th}\) May 2016
  - [http://www.cdisc.org/standards/therapeutic-areas/breast-cancer](http://www.cdisc.org/standards/therapeutic-areas/breast-cancer)

- **Education Course**
  - Published to CDISC’s BlueCloud online learning management system on 8\(^{th}\) August 2016
  - 8-chapter module
  - 67 minutes long
  - 20-question assessment.
Current Status of the Prostate Cancer Data Standards Project

- **Stage 3b – Public Review**
  - Released for public review 9th November 2016
  - Initially released for 30-day public review (ending 8th December 2016)
  - Will be extended to 60-day review (pending grant approval)
  - Extension notification will be sent out once approval is granted

- **Feedback from PrCa Public Review**
  - Webinar was held on 19th October 2016
  - Please ask any questions during the Q&A session at the end of the presentations
Current Status of the Prostate Cancer Data Standards Project

- Some highlights of the SHARE/PrCa Collaboration

WIKI TAUG – SHARE Ecosystem tool

- Instructions for Reviewers
  - TAUG-PrCa
    - TAUG-PrCa compiled
    - TAUG-PrCa sections
    - PrCa figures
    - PrCa concept maps
    - PrCa examples
    - PrCa CDASH Metadata
    - PrCa Biomedical Concepts
    - PrCa TA Specification
Current Status of the Prostate Cancer Data Standards Project

- Some highlights of the SHARE/PrCa Collaboration

CDASH WIKI CRFs – developed as SHARE ecosystem tools

Migration of WIKI CDASH CRF’s to CRF Generator examples during public review

CRF Generator uses CDASH metadata to automatically render CRF templates within the WIKI
Current Status of the Prostate Cancer Data Standards Project

- Some highlights of the SHARE/PrCa Collaboration

Dataset Example Macros – developed as SHARE ecosystem tools
Current Status of the Prostate Cancer Data Standards Project

• Some highlights of the SHARE/PrCa Collaboration

Comment collection, review and resolution using JIRA
Current Status of the Prostate Cancer Data Standards Project

• Some highlights of the SHARE/PrCa Collaboration

TA Spec Generation
Current Status of the Colorectal Cancer Data Standards Project

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<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3a</th>
<th>Stage 3b</th>
<th>Stage 3c</th>
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- **Stage 3a – Internal Review**
  - Published for Internal Review 22\textsuperscript{nd} November 2016
  - Comment deadline 15\textsuperscript{th} December 2016
  - Link to TAUG-CrCa >> [http://wiki.cdisc.org/display/TAUGCrCa](http://wiki.cdisc.org/display/TAUGCrCa)
# Current Status of the Lung Cancer Data Standards Project

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- Scoping and Planning Stage to start January 2017
CDASH Model 1.0 and CDASHIG 2.0

Kathleen Mellars
Thanks to the CDASH Model and CDASHIG Team
CDASH – What’s new?

• Almost everything!
  ▪ New CDASH Model v.1.0 introduced
  ▪ CDASH Standard v1.1 and CDASH User Guide v.1.0 were consolidated to create CDASHIG v2.0
  ▪ CDASH documents stored on the CDISC WIKI
  ▪ CDASH Model and Domain metadata can be downloaded as Excel spreadsheet
    • ability to include in SHARE
CDASH Model 1.0

- Defines a framework for creating standard variables used in the collection of clinical trial data
- Provides variable naming conventions (e.g., root variable names)
- Includes metadata for
  - Identifier variables, and Timing variables
  - Special Purpose Domains (e.g., DM, CO)
  - SDTM General Observation Classes (Events, Interventions, Findings)
  - Domain-specific variables
- Includes generic “parameterized” Question Text and Prompt- for flexible implementation (e.g., verb tense, sponsor defined time periods)
CDASH Implementation Guide (CDASHIG) 2.0

• Aligns with SDTMIG
  ▪ Domains are organized by Class
  ▪ General Assumptions per Class
  ▪ General Assumptions per Domain

• Domain metadata for SDTMIG domains based on the CDASH Model

• aCRF examples for each domain, unless otherwise specified
  ▪ Example which are not meant to imply that any particular layout is preferable over another
  ▪ Annotated to show SDTM mapping.
Relationships between SDTM and CDASH

- CDASH Model 1.0 aligns with SDTM Model 1.4
- CDASHIG 2.0 aligns with SDTMIG 3.2
CDASH Model Metadata builds in traceability to SDTM Model and CDASHIG conformance

- Root variable name (e.g., --TRT)
- Definition
- Mapping to SDTM
- Generic Question Text / Prompt
- Controlled Terminology

The key attributes needed for CDASHIG conformance are included in the CDASH Model

- Special Purpose (e.g., DM)
- Interventions
- Events
- Findings
Accessing the CDASH Guides

Available at CDASH Wiki:
http://wiki.cdisc.org/display/CMIG/CDASH+Model+and+CDASHIG
Oncology TAUGs – CDASH Components

• The Oncology TAUG provide:
  - Sample case report forms (CRFs) compliant with CDASH, and annotated with CDASH and SDTM variables
  - CDASH metadata for the sample CRFs (included in the CDASH Metadata)

Note:

1. Oncology TAUG CDASH components are currently not based on the new CDASH model. These components will be updated in future versions of the Oncology TAUGs - after the CDASH Model -1.0 and CDASHIG-2.0 have been published.

2. The CDASHIG v2.0 does not include the domain metadata for the TU,TR,RS domains. Metadata based on CDASH 1.0 are available in the Oncology TAUGs.
# Oncology TAUGs – CDASH CRF Examples

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<td>IR-RC- Disease Response</td>
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Oncology TAUGs-CDASH: Future

- Include Oncology SDTM domains into future version of the CDASHIG.
- Pilot using CDASH Domain Metadata to create CDASH CRF specific metadata.
- Auto-generating CDASH CRFs from the CRF metadata.
Oncology Standards Update: SDTM / Controlled Terminology

Melanie Paules / Erin Muhlbradt
Overview of SDTM and Controlled Terminology Development for Oncology

Overview on how Oncology SDS team and Oncology CFAST teams work together on SDTM and Controlled Terminology (CT):

• CFAST Oncology Teams
  ▪ Provide SMEs to SDS Oncology team.
  ▪ Develop concepts and create CRFs and SDTM examples within the TAUG.
  ▪ Perform gap analysis and propose new CT for CRFs and SDTM examples in the TAUG.

• Oncology SDS Team
  ▪ Provide SMEs to CFAST Oncology TA teams.
  ▪ Review and finalize the CT proposed by CFAST teams.
  ▪ Review Examples and CRFs from Oncology TAUGs.
  ▪ Independent development of SDTM examples for non-CFAST related tumor types, along with associated CT.
  ▪ The spreadsheet **SDTM Examples for Oncology Use Cases** is available at: [http://wiki.cdisc.org/x/5yuyAQ](http://wiki.cdisc.org/x/5yuyAQ).
    ▪ These example will eventually be moved into the CDISC Wiki along with the rest of the SDTM IG.
Oncology Domains and Controlled Terminology: TAUGs

- The TAUG-BrCa v1.0 and TAUG-PrCa (draft in public review) include advice and examples for SDTM and CT.
  - Guidance on which domain models and datasets from the SDTM IG to use in representing collected data.
  - Examples of SDTM datasets, with text describing the situational context and pointing out records of note.
  - Variable definition metadata for non-standard (Supplemental Qualifier) variables used in example SDTM datasets and/or CRF mapping annotations.
  - Note: TAUG-CrCa under development (internal review).
Oncology Domains and Controlled Terminology: TAUGs

• Controlled Terminology Status
  ▪ New CT covers both new codelists or new values to be added to existing codelists.
  ▪ New CT was developed to support Breast Cancer studies.
  ▪ New CT is under development for Prostate Cancer studies. The examples in the TAUG-PrCa are draft and likely to change based on public review and terminology development process.

• Oncology SDTM Status
  ▪ No new domains have been added.
  ▪ New non-standard variables (NSV) have been added within the TAUGs.
  ▪ New NSV to assist in representing regimens in CM are being proposed as part of the development of the TAUG for Colorectal Cancer (CrCa).
Oncology Domains and Controlled Terminology: Oncology SDS Team

- SDTM Examples for Oncology Use Cases spreadsheet ([http://wiki.cdisc.org/x/5yuyAQ](http://wiki.cdisc.org/x/5yuyAQ)).
  - SDTM examples and CT are under development for the following criteria:
    - PCWG2/3 (to support PrCa TAUG)
    - Lugano
    - RANO
  - Includes examples to support Breast Cancer studies
    - The disease recurrence examples can be used as a reference for trials with disease recurrence endpoints in other tumor types.
  - Will be updated to include example(s) to support Prostate Cancer studies once public review of TAUG-PrCa is complete and the CT has been developed.
SDTM Examples for Pathology in Prostate Cancer

TAUG-PrCa contains 4 examples:

1. LB – laboratory findings of PCA3 mRNA and PSA mRNA on urine or blood specimens.

2. MI – microscopic findings of cellular differentiation in soft tissues in order to determine the Gleason primary and secondary scores along with the Gleason total sum.

3. MI - microscopic findings of infiltration of the membrane and extent of the cancer within the prostate gland lobes.
   - NSV: RESTRG=Pre-Specified Result Targeted by Test (CAPSULAR INVASION versus PERINEURAL INVASION)

4. MI - The total number of prostate tissue cores, collected via biopsy, that show evidence of cancer.
   - NSV: NUMCOR=Number of Cores Collected
Example 1: Progression to First Metastatic Disease in Prostate Cancer

- PCWG3 criteria to evaluate bone disease.
- RECIST 1.1 to evaluate soft tissue (extraskeletal) disease.
- Per PCWG3: "Any new unequivocal bone lesion, except if that lesion appears in the first post-treatment scan; in that case, document the event, continue treatment until 2 additional new lesions appear, and record both events".
- In the example to be presented:
  - At Week 16, First evidence of bone progression.
  - At Week 32, two or more additional bone tumors were identified, so progression was confirmed in bone. Two other non-bone sites of new tumors were also identified.
Example 1 for TU: Progression to First Metastatic Disease in Prostate Cancer

- Show identification of tumors including those identified as new metastatic disease in prostate cancer.
- CT is under development and will likely change from this example.
- RESTRG=Pre-Specified Result Targeted by Test is NSV (under discussion)

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### Example 1 for TR: Progression to First Metastatic Disease in Prostate Cancer

- **EVLREF**=Evaluation Reference is NSV.
- CT is under development and will likely change from this example.

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Example 1 for RS: Progression to First Metastatic Disease in Prostate Cancer

- Response evaluated using PCWG SCHER PROSTATE CANCER 2016 (aka PCWG3)
- MEDSIND = Metastatic Indicator

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Example 2: Disease Assessments in Prostate Cancer

• PCWG2 guidelines to evaluate the bone disease
• RECIST 1.1 to evaluate soft tissue (extraskeletal disease)
• PCWG2 guidelines to evaluate the tumor marker (later slides)
• In the following example to be presented:
  ▪ Tumor evaluations at screening visit were considered the baseline assessment.
  ▪ 12-week assessment was defined in the protocol as an assessment within the "flare" window.
  ▪ Sponsor elected not to report the anatomical location of each of the bone tumors.
• Other examples are available in the TAUG-PrCr.
### Example 2 for TU: Disease Assessments in Prostate Cancer

- Shows identification of tumors in prostate cancer.
- CT is under development and will likely change from this example.

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• Shows identification of tumors in prostate cancer.
• CT is under development and will likely change from this example.
Example 2 for TR: Disease Assessments in Prostate Cancer

- Non-target assessments of lung and liver not shown
- CT is under development and will likely change from this example
- 1 new tumor in flare window. Subsequent assessments use the flare as the reference

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### Example 2 for RS: Disease Assessments in Prostate Cancer

- Tumor marker response not shown (later slide)
- CT is under development and will likely change from this example

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Example 2: Tumor Marker Response

- Tumor Marker: PSA
- PSA response was defined in the protocol following PCWG2 guidelines as:
  - Complete Response defined as PSA < 5 ng/mL
  - Partial Response defined as 50% decrease from baseline but PSA > 5 ng/mL
  - Progression defined as a 25% or greater increase and an absolute increase of 2 ng/mL or more from the baseline or the nadir.
## Example 2 for LB: Tumor Marker - PSA

- Take note of LBLNKGRP

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Example 2 for RS: Tumor Marker Response at Week 12

- Tumor Marker Response is a component of the overall response using PCWG SCHER PROSTATE CANCER 2008 (aka PCWG2)

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Skeletal-related events (SREs) of interest in Prostate Cancer

• The definition of bone-related adverse events and the types of bone-related adverse events were pre-defined in the protocol.
  ▪ Collected as AEs, categorized as bone-related or general, if bone-related, type of bone-related event occurred.
  ▪ "Spinal Cord Compression" and "Pathological Fracture" were protocol-defined SREs, while "Other Bone-Related Event" was a potential SRE.
  ▪ Any procedures related to the protocol-defined SREs are reported in the PR domain.
Skeletal-related events (SREs) of interest in Prostate Cancer

- Spinal Cord Compression" and "Pathological Fracture" were protocol-defined SREs, while "Other Bone-Related Event" was a potential SRE.
- Collected as AEs, categorized as bone-related or general, and if bone-related, the cause of the Fracture.

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Any procedures related to the protocol-defined SREs are reported in the PR domain.

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Oncology Standards Update – ADaM

Richann Watson/Paul Slagle
Introduction

• ADaM Oncology Team

• Original Proposed Topics for Discussion

• Status of Topics

• Next Steps
ADaM Oncology Team

- Richann Watson (co-lead)
- Amy Adyanthaya
- Andrew Noller
- Angelo Tinazzi
- Beth Seremula
- Cathy Bezek
- Heather Howell
- John Troxell
- Michael Willis

- Paul Slagle (co-lead)
- Monica Filimon
- Nate Freimark
- Priya Saradha
- Srinivas Veeragoni
- Susan Kenny
- Stephanie Qiu
- Tara Erb
- Wendy Zhang
Original Proposed Topics

- ADCYCLE – capture of cycles/visits *
- Linking prior treatments to represent a regimen *
- Type of data for ADEX and how it should be structured
- Lab Toxicity grading that for parameter that have hypo- and hyper- definition
- Dealing with local labs †
- Intermediate data set with all event dates for TTE data
- Different approaches between FDA and EU for PFS censoring *
- Controlled terminology for response in solid tumor and hematologic malignance *
- Determining PARAMCD/PARAM for lesions and locations *
- ADaM data set to derive Best Overall Response *

* Oncology specific
† Topic closed
Topic Status

• ADCYCLE: Proposal was put together using an interim dataset

• Lab Toxicity Grading: Proposal was put together and sent to ADaM team for review. Since this affected more than oncology proposal was taken to ADaM IG 1.2 team to incorporate concepts into ADaM IG

• Best Overall Response: Subteam made significant progress on putting together a proposal
Next Steps

• Revitalize the team

• Agree on a standard document format

• Start incorporating details on topics and examples into one document

• Discussions with CFAST Oncology teams
Volunteer / Review Opportunities

John Owen
Volunteer / Review Opportunities

• Doers (minimum 4-8 hours/week)
• Reviewers (minimum 2-4 hours/week)
• PrCa
  ▪ Public Reviewers (December 2016 – January 2017)
• CrCa
  ▪ Internal Reviewers (December 2016)
  ▪ Public Reviewers (January-March 2017)
• LuCa
  ▪ Clinical Experts
  ▪ SME Reviewers
• ONCO SDS – Contact Melanie Paules
• ONCO CDASH – Contact Lorraine Spencer
• ONCO ADaM – Contact Paul Slagle/Richann Watson
Next Oncology Information Session

• Q2 2017 – Date to be confirmed
2017 Cowboy Up! for Cancer Research Standards


Date & Location:
Thursday, 02 March, 2017
6:00 - 9:00pm
Stubbs Bar-B-Q
801 Red River St, Austin, TX 78701

http://www.cdisc.org/events/fundraiser/2017/cowboy-cancer-research-standards
Thank you!

Questions?

or

email john.owen@cdisc.org
The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research