30 November 2016
10:00-11:30am CST

CDISC Oncology Information Session

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

Strength *through Collaboration*

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

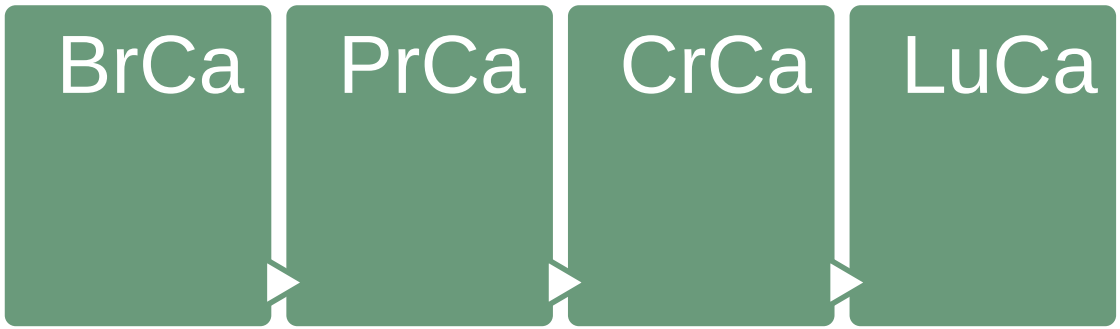
John Owen

Oncology Standards Development Plan

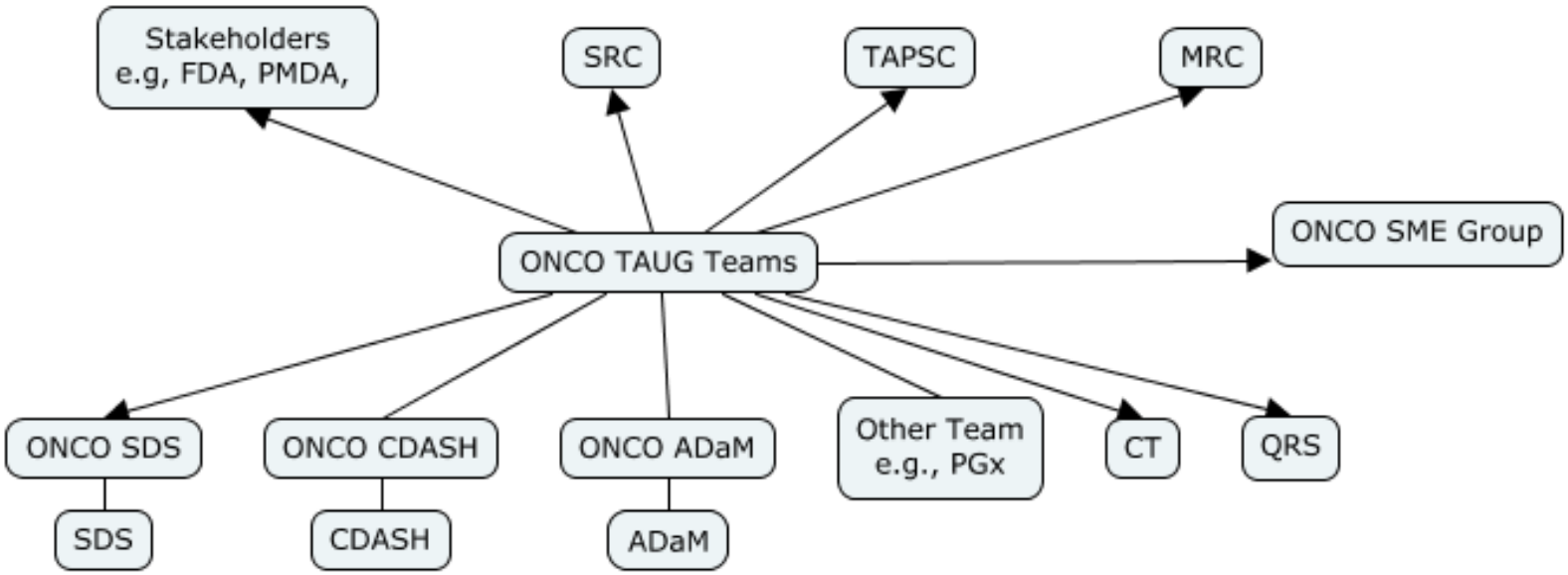
- Focus development of new concepts within an indication
- Reuse/reference concepts developed in previous User Guides
- Re-use knowledge/trained resource across ONCO TA projects
- Use of SHARE Ecosystem Tools to streamline development
- Liaison with CDISC foundational groups
  - ONCO SDS group
  - ONCO 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



Oncology Standards Development Plan



Status of Oncology Projects

John Owen

CFAST Oncology Program Overview November 2016

Project	Charter Approved	Internal Review	Public Review	Publication
Breast Cancer BrCa	**Oct 2014**	**Mar 2015**	**Nov 2015**	**May 2016**
Prostate Cancer PrCa	**Nov 2015**	**Jul 2016**	**Nov 2016**	*Mar 2017*
Colorectal Cancer CrCa	**May 2016**	**Nov 2017**	*Jan 2017*	*Mar 2017*
Lung Cancer LuCa	*Jan 2017*			

Italic dates indicates planned dates

Current Status of the Breast Cancer Data Standards Project

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance, Education & SHARE Finalization

- **BrCa TAUG**
  - Published on CDISC Website 16th May 2016
  - http://www.cdisc.org/standards/therapeutic-areas/breast-cancer
- **Education Course**
  - Published to CDISC's BlueCloud online learning management system on 8th August 2016
  - 8-chapter module
  - 67 minutes long
  - 20-question assessment.

Current Status of the Prostate Cancer Data Standards Project

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance, Educations & SHARE Finalization

- 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

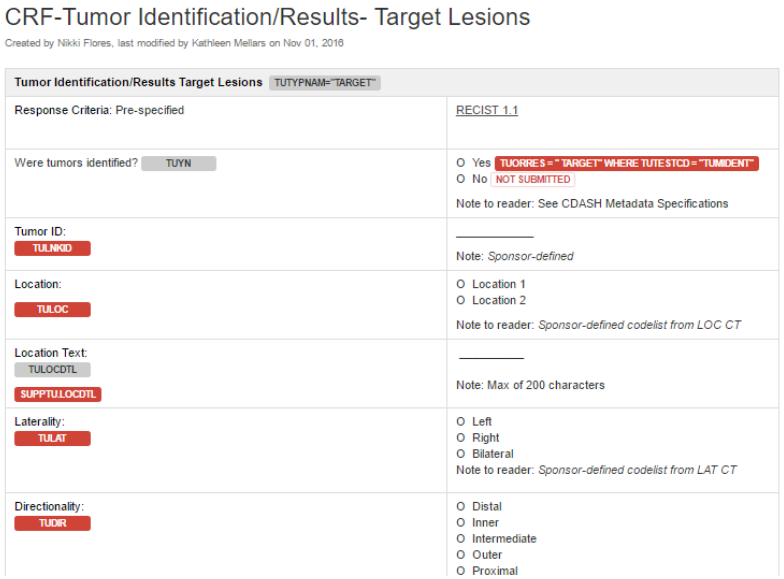
Current Status of the Prostate Cancer Data Standards Project

- 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



CRF-Tumor Identification/Results- Target Lesions

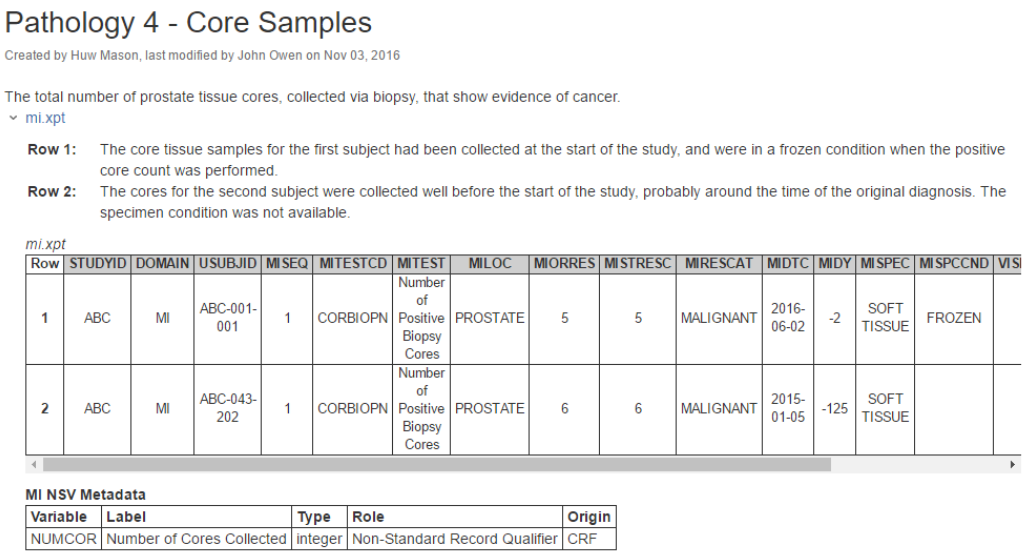
Created by Nikki Flores, last modified by Kathleen Mellars on Nov 01, 2016

Tumor Identification/Results Target Lesions TUTYPNAM="TARGET"	
Response Criteria: Pre-specified	RECIST 1.1
Were tumors identified? TUYN	O Yes TUORRES = "TARGET" WHERE TUTESTCD = "TUMIDENT" O No NOT SUBMITTED Note to reader: See CDASH Metadata Specifications
Tumor ID: TULNKID	_____ Note: *Sponsor-defined*
Location: TULOC	O Location 1 O Location 2 Note to reader: *Sponsor-defined codelist from LOC CT*
Location Text: TULOCDTL SUPPTU.LOCDTL	_____ Note: Max of 200 characters
Laterality: TULAT	O Left O Right O Bilateral Note to reader: *Sponsor-defined codelist from LAT CT*
Directionality: TUDIR	O Distal O Inner O Intermediate O Outer O Proximal

Current Status of the Prostate Cancer Data Standards Project

- Some highlights of the SHARE/PrCa Collaboration

Dataset Example Macros – developed as SHARE ecosystem tools



Pathology 4 - Core Samples

Created by Huw Mason, last modified by John Owen on Nov 03, 2016

The total number of prostate tissue cores, collected via biopsy, that show evidence of cancer.

mi.xpt

Row 1: The core tissue samples for the first subject had been collected at the start of the study, and were in a frozen condition when the positive core count was performed.

Row 2: The cores for the second subject were collected well before the start of the study, probably around the time of the original diagnosis. The specimen condition was not available.

mi.xpt

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MILOC	MIORRES	MISTRESC	MIRESCAT	MIDTC	MIDY	MISPEC	MISPCCND	VIS
1	ABC	MI	ABC-001-001	1	CORBIOPN	Number of Positive Biopsy Cores	PROSTATE	5	5	MALIGNANT	2016-06-02	-2	SOFT TISSUE	FROZEN	
2	ABC	MI	ABC-043-202	1	CORBIOPN	Number of Positive Biopsy Cores	PROSTATE	6	6	MALIGNANT	2015-01-05	-125	SOFT TISSUE		

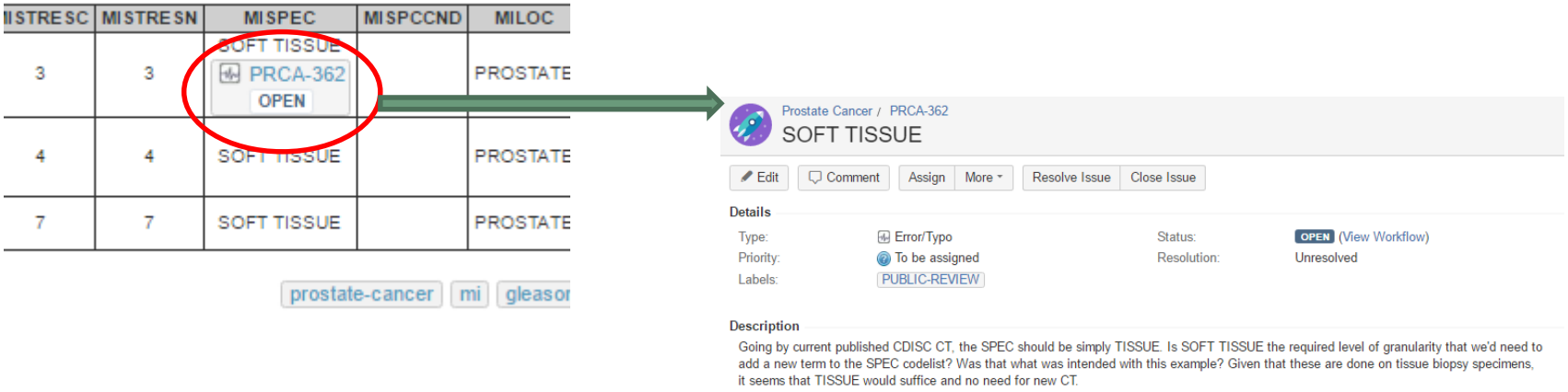
MI NSV Metadata

Variable	Label	Type	Role	Origin
NUMCOR	Number of Cores Collected	integer	Non-Standard Record Qualifier	CRF

Current Status of the Prostate Cancer Data Standards Project

- Some highlights of the SHARE/PrCa Collaboration

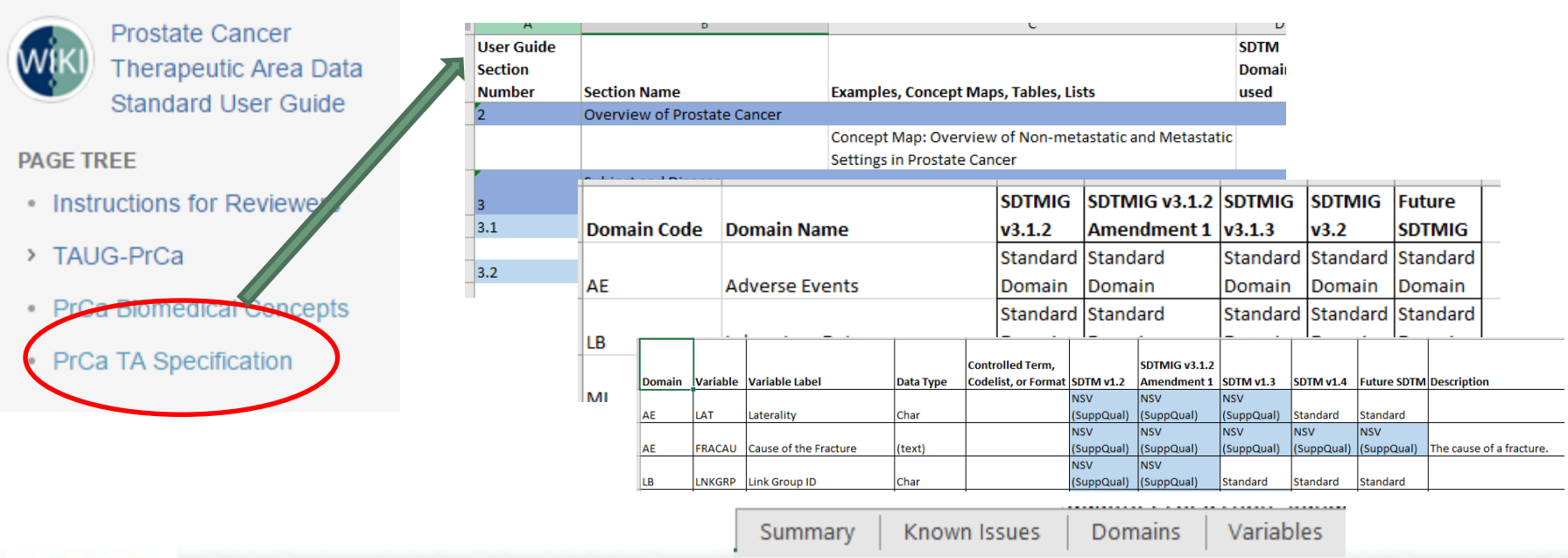
Comment collection, review and resolution using JIRA



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

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance, Education & SHARE Finalization

- Stage 3a – Internal Review
  - Published for Internal Review 22nd November 2016
  - Comment deadline 15th December 2016
  - Link to TAUG-CrCa >> http://wiki.cdisc.org/display/TAUGCrCa.

Current Status of the lung Cancer Data Standards Project

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Biomedical Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance, Education & SHARE Finalization

- 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

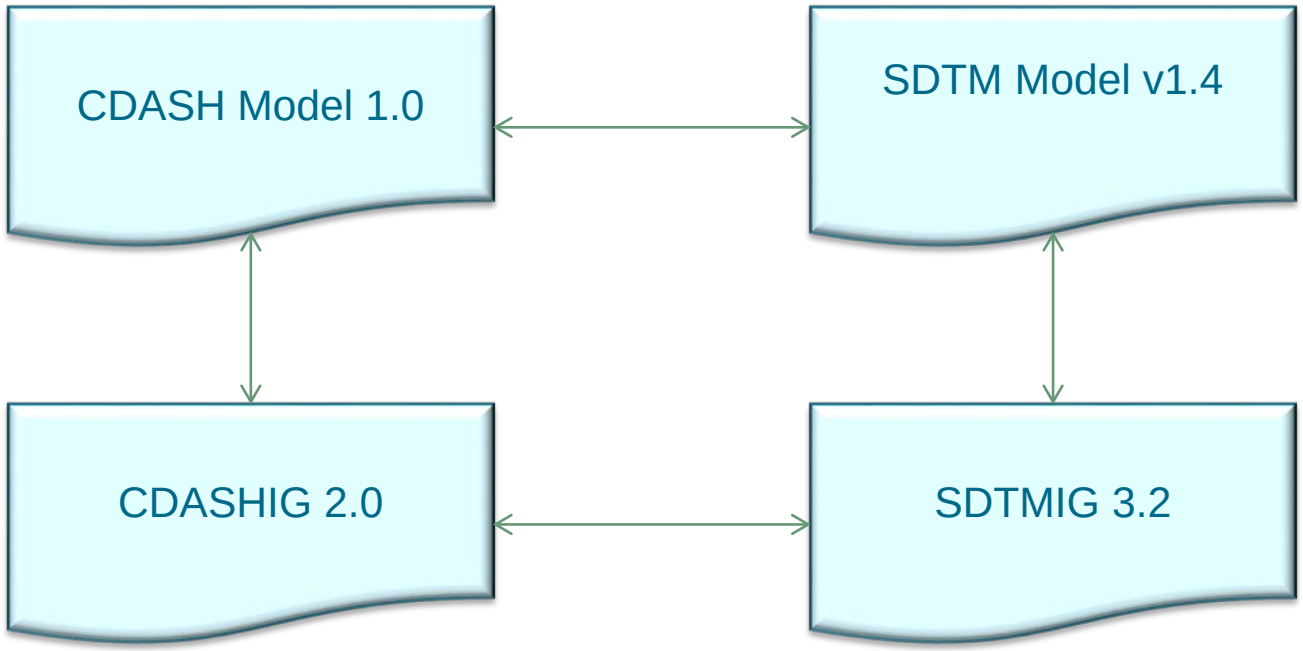
- Defines a framework for creating standard variables used in the collection of clinical trial data
- Provides variable naming conventions (e.g., root variable names)
- Includes metadata for
  - Identifier variables, and Timing variables
  - Special Purpose Domains (e.g., DM, CO)
  - SDTM General Observation 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

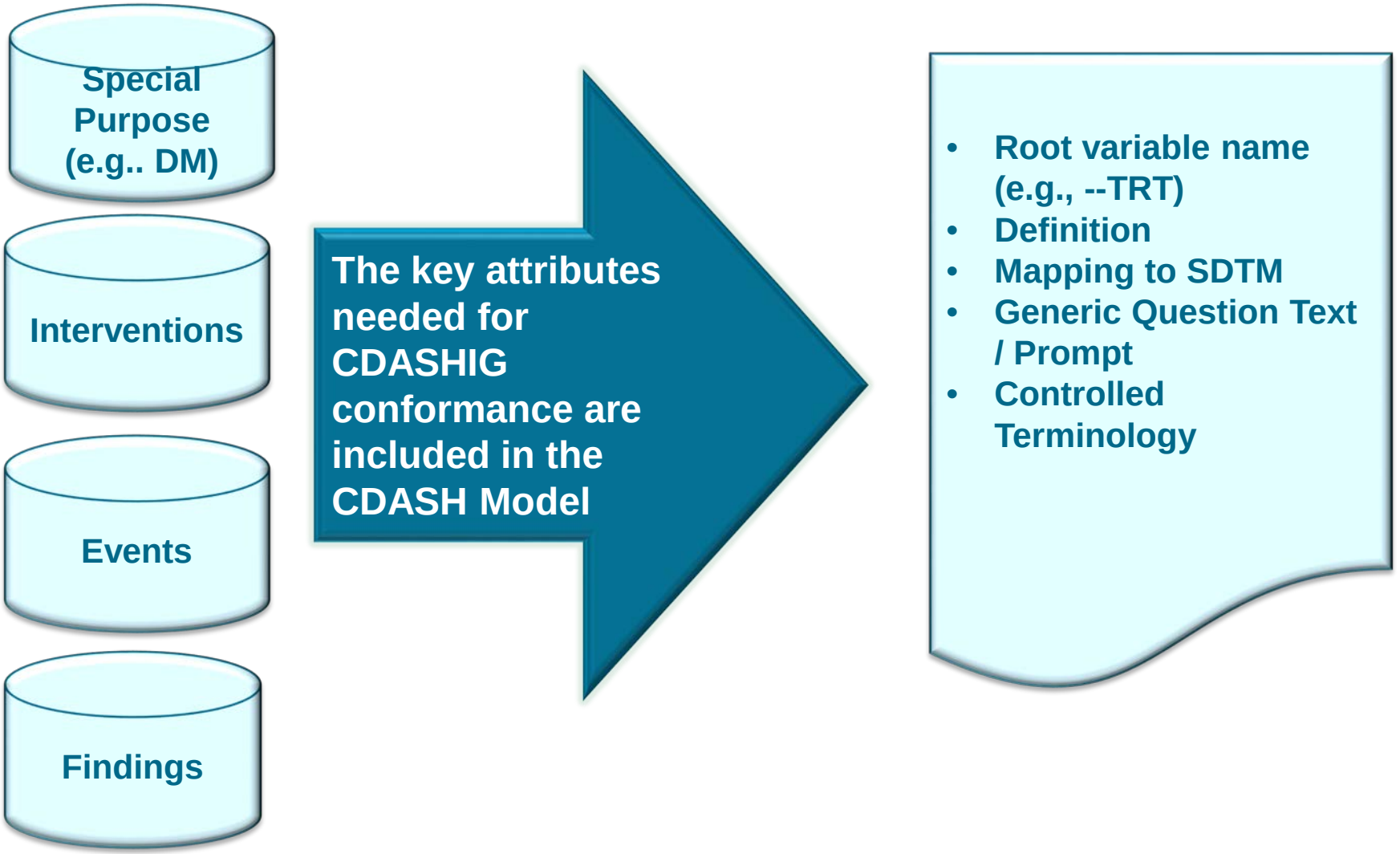
- Aligns with SDTMIG
  - Domains are organized by Class
  - General Assumptions per Class
  - General Assumptions per Domain
- Domain metadata for SDTMIG domains based on the CDASH Model
- aCRF examples for each domain, unless otherwise specified
  - Example which are not meant to imply that any particular 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



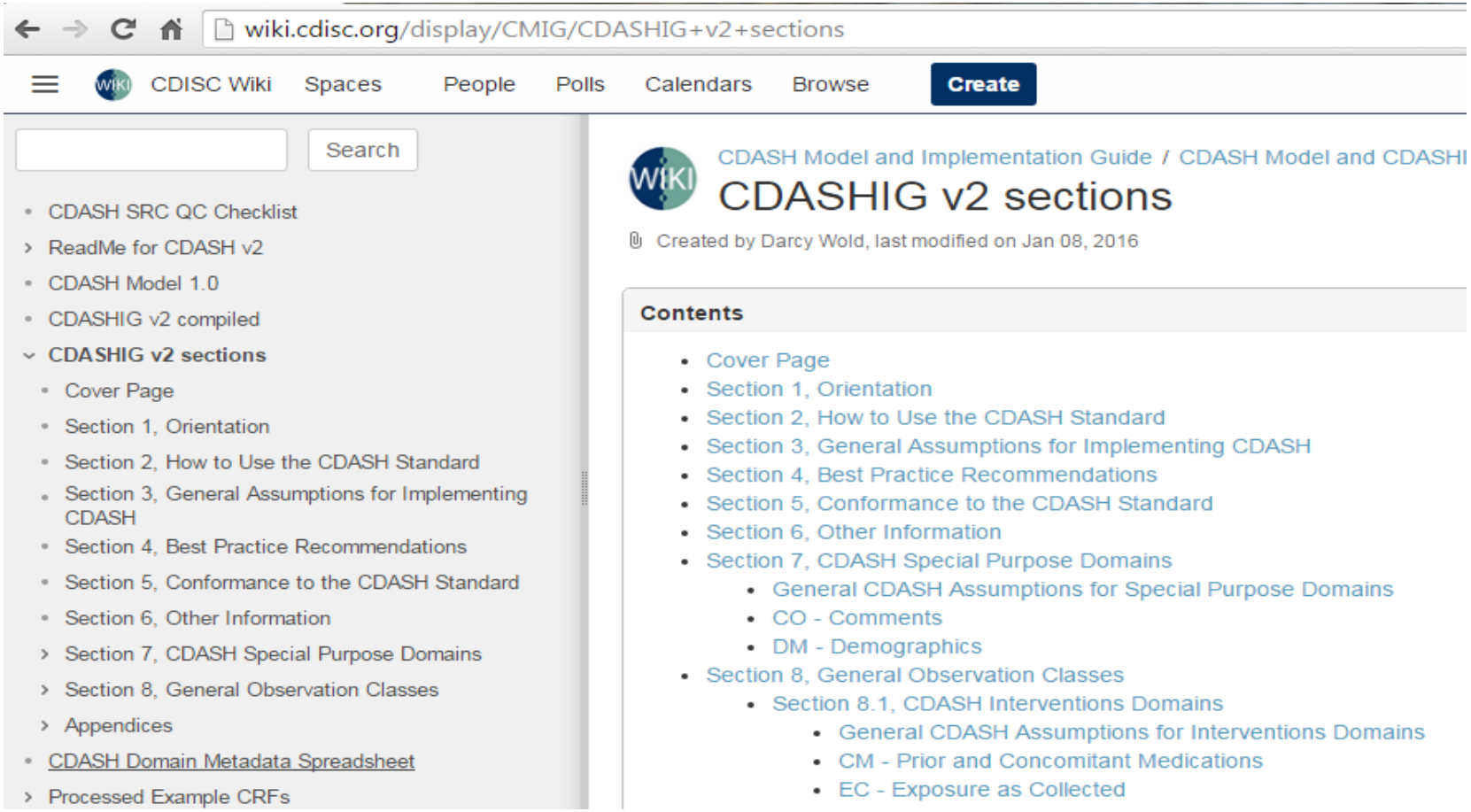
CDASH Model Metadata builds in traceability to SDTM Model and CDASHIG conformance



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

TAUG	CRF Name	CDASH Domain Metadata
Breast Cancer	Prior Treatments – Radiation Therapy	PR
	RECIST -Tumor Identification/Results: Target Lesions, Non-Target Lesions, New	TU,TR
	RECIST-Disease Response	RS
Prostate Cancer	PCWG- Tumor Identification/Results: Bone Lesions, New Bone Lesions	TU,TR
	PCWG-Disease Response	RS
	Skeletal Related Events-(AEs, Radiation, Surgery)	AE, PR
Colon Cancer	Prior Anti-cancer Treatment	CM, PR
	Pain Medications	CM
	IR-RC –Tumor Identification/Results: Index, Non-Index, New Lesions	TU,TR,
	IR-RC- Disease Response	RS

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.
    - 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).
  - 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)

Row	STUDYID	DOMAIN	USUBJID	TUREFID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TUMETHOD	VISITNUM	VISIT
1	PRCA123	TU	99006			TRGEXM	Targeted Examination	ABSENT	ABSENT			10	SCREEN
2	PRCA123	TU	99006			TRGEXM	Targeted Examination	ABSENT	ABSENT			10	SCREEN
3	PRCA123	TU	99006	IMG-B0002	R-BNEW01	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	30	WEEK 16
4	PRCA123	TU	99006	IMG-B0003	R-BNEW02	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	50	WEEK 32
5	PRCA123	TU	99006	IMG-00003	R-NEW01	TUMIDENT	Tumor Identification	NEW	NEW	LUNG	CT SCAN	50	WEEK 32
6	PRCA123	TU	99006	IMG-00003	R-NEW02	TUMIDENT	Tumor Identification	NEW	NEW	LIVER	CT SCAN	50	WEEK 32

RESTRG
MEASURABLE TUMORS
NON-MEASURABLE

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.

Row	STUDYID	DOMAIN	USUBJID	TRGRPID	TRREFID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRSTRESC	TRSTRESN	VISITNUM	VISIT	EVLREF
1	PRCA123	TR	99006	BONE TUMOR	IMG-B0001	A1	R-BT01	BONECNT	Bone Tumor Count	0	0	0	10	SCREEN	
2	PRCA123	TR	99006	NEW BONE TUMOR	IMG-B0002	A2	R-BNEW01	NBONECNT	New Bone Tumor Count	1	1	1	30	WEEK 16	SINCE SCREEN
3	PRCA123	TR	99006	NEW BONE TUMOR	IMG-B0003	A3	R-BNEW02	NBONECNT	New Bone Tumor Count	3	3	3	50	WEEK 32	SINCE LAST SCAN
4	PRCA123	TR	99006	NEW BONE TUMOR		A3		TBONCNT2	Two or More New Bone Tumors	Y	Y		50	WEEK 32	SINCE LAST SCAN
5	PRCA123	TR	99006	NEW	IMG-00002	A3	R-NEW01	TUMSTATE	Tumor State	UNEQUIVOCAL PROGRESSION	UNEQUIVOCAL PROGRESSION		50	WEEK 32	
6	PRCA123	TR	99006	NEW	IMG-00003	A3	R-NEW02	TUMSTATE	Tumor State	UNEQUIVOCAL PROGRESSION	UNEQUIVOCAL PROGRESSION		50	WEEK 32	

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

Row	STUDYID	DOMAIN	USUBJID	RSLNKID	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	VISITNUM	VISIT
1	PRCA123	RS	99006	A2	METSIND	Metastatic Indicator	PCWG SCHER PROSTATE CANCER 2016	Y	Y	30	WEEK 16
2	PRCA123	RS	99006	A2	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2016	PD	PD	30	WEEK 16
3	PRCA123	RS	99006	A3	METSIND	Metastatic Indicator	PCWG SCHER PROSTATE CANCER 2016	Y	Y	50	WEEK 32
4	PRCA123	RS	99006	A3	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2016	PD	PD	50	WEEK 32

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.

Row	STUDYID	DOMAIN	USUBJID	TUREFID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TUMETHOD	VISITNUM	VISIT
1	PRCA123	TU	99001	IMG-00002		TRGEXM	Targeted Examination	ABSENT	ABSENT		CT SCAN	10	SCREEN
2	PRCA123	TU	99001	IMG-0002	R-NT01	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	LUNG	CT SCAN	10	SCREEN
3	PRCA123	TU	99001	IMG-0002	R-NT02	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	LIVER	CT SCAN	10	SCREEN
4	PRCA123	TU	99001	IMG-B04002	R-BT01	TUMIDENT	Tumor Identification	BONE TUMOR	BONE TUMOR	BONE	SCINTIGRAPHY	10	SCREEN
5	PRCA123	TU	99001	IMG-B04012	R-BNEW01	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	20	WEEK 12
6	PRCA123	TU	99001	IMG-B04013	R-BNEW02	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	40	WEEK 24
7	PRCA123	TU	99001	IMG-B04014	R-BNEW03	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	50	WEEK 30
8	PRCA123	TU	99001	IMG-B04015	R-BNEW04	TUMIDENT	Tumor Identification	NEW BONE TUMOR	NEW BONE TUMOR	BONE	SCINTIGRAPHY	50	WEEK 38

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

Row	STUDYID	DOMAIN	USUBJID	TRGRPID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRSTRESC	VISITNUM	VISIT		EVLREF
3	PRCA123	TR	99001	BONE TUMOR	B1	R-BT01	BONECNT	Bone Tumor Count	3	3	10	SCREEN		
6	PRCA123	TR	99001	NEW BONE TUMOR	B2		TBONCNT2	Two or More New Bone Tumors	N	N	20	WEEK 12		SINCE BASELINE
7	PRCA123	TR	99001	NEW BONE TUMOR	B2	R-BNEW01	NBONECNT	New Bone Tumor Count	1	1	20	WEEK 12		SINCE BASELINE
10	PRCA123	TR	99001	NEW BONE TUMOR	B3		TBONCNT2	Two or More New Bone Tumors	N	N	30	WEEK 18		SINCE FLARE
11	PRCA123	TR	99001	NEW BONE TUMOR	B3		NBONECNT	New Bone Tumor Count	0	0	30	WEEK 18		SINCE FLARE
14	PRCA123	TR	99001	NEW BONE TUMOR	B4		TBONCNT2	Two or More New Bone Tumors	N	N	40	WEEK 24		SINCE FLARE
15	PRCA123	TR	99001	NEW BONE TUMOR	B4		NBONECNT	New Bone Tumor Count	0	0	40	WEEK 24		SINCE FLARE
18	PRCA123	TR	99001	NEW BONE TUMOR	B5		TBONCNT2	Two or More New Bone Tumors	Y	Y	50	WEEK 30		SINCE FLARE
19	PRCA123	TR	99001	NEW BONE TUMOR	B5	R-BNEW03	NBONECNT	New Bone Tumor Count	3	3	50	WEEK 30		SINCE FLARE
20	PRCA123	TR	99001	NEW BONE TUMOR	B6		PEBNCNT2	Two or More Persisting New Bone Tumors	Y	Y	60	WEEK 38		SINCE LAST SCAN
21	PRCA123	TR	99001	NEW BONE TUMOR	B6	R-BNEW04	NBONECNT	New Bone	4	4	60	WEEK 38		SINCE LAST SCAN

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

Row	STUDYID	DOMAIN	USUBJID	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	VISITNUM	VISIT
1	PRCA123	RS	99001		NTRGRESP	Non-target Response	RECIST 1.1	CR	CR	20	WEEK 12
2	PRCA123	RS	99001	A2	SFTSLRESP	Soft Tissue Response	RECIST 1.1	CR	CR	20	WEEK 12
3	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	20	WEEK 12
5	PRCA123	RS	99001	B2	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	20	WEEK 12
6	PRCA123	RS	99001		NTRGRESP	Non-target Response	RECIST 1.1	CR	CR	30	WEEK 18
7	PRCA123	RS	99001	A3	SFTSLRESP	Soft Tissue Response	RECIST 1.1	CR	CR	30	WEEK 18
8	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	30	WEEK 18
10	PRCA123	RS	99001	B3	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	30	WEEK 18
11	PRCA123	RS	99001		NTRGRESP	Non-target Response	RECIST 1.1	CR	CR	40	WEEK 24
12	PRCA123	RS	99001	A4	SFTSLRESP	Soft Tissue Response	RECIST 1.1	CR	CR	40	WEEK 24
13	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	40	WEEK 24
15	PRCA123	RS	99001	B4	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	40	WEEK 24
16	PRCA123	RS	99001		NTRGRESP	Non-target Response	RECIST 1.1	CR	CR	50	WEEK 30
17	PRCA123	RS	99001	A5	SFTSLRESP	Soft Tissue Response	RECIST 1.1	CR	CR	50	WEEK 30
19	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	PD	PD	50	WEEK 30
20	PRCA123	RS	99001	B5	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	PD	PD	50	WEEK 30
22	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	PD	PD	60	WEEK 38
23	PRCA123	RS	99001	B6	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	PD	PD	60	WEEK 38

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

Row	STUDYID	DOMAIN	USUBJID	LBLNKGRP	LBTESTCD	LBTEST	LBSCAT	LBORRES	LBORRESU	LBRESCAT	LBBLFL	VISITNUM	VISIT
1	PRCA123	LB	99001	LB1	PSA	Prostate Specific Antigen	TUMOR MARKER	30	ng/ml	ELEVATED	Y	10	SCREEN
2	PRCA123	LB	99001	LB2	PSA	Prostate Specific Antigen	TUMOR MARKER	14.5	ng/ml			20	WEEK 12
3	PRCA123	LB	99001	LB3	PSA	Prostate Specific Antigen	TUMOR MARKER	4,7	ng/ml			30	WEEK 18
4	PRCA123	LB	99001	LB4	PSA	Prostate Specific Antigen	TUMOR MARKER	6	ng/ml			40	WEEK 24
5	PRCA123	LB	99001	LB5	PSA	Prostate Specific Antigen	TUMOR MARKER	30	ng/ml			50	WEEK 30
6	PRCA123	LB	99001	LB6	PSA	Prostate Specific Antigen	TUMOR MARKER	45	ng/ml			60	WEEK 38

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)

Row	STUDYID	DOMAIN	USUBJID	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSEVALID	VISITNUM	VISIT
1	PRCA123	RS	99001		NTRGRESP	Non-target Response	RECIST 1.1	CR	CR	RADIOLOGIST	20	WEEK 12
2	PRCA123	RS	99001	A2	SFTSLRESP	Soft Tissue Response	RECIST 1.1	CR	CR	RADIOLOGIST	20	WEEK 12
3	PRCA123	RS	99001		BONERESP	Bone Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	RADIOLOGIST	20	WEEK 12
4	PRCA123	RS	99001	LB2	TMRESP	Tumor Marker Response	PCWG SCHER PROSTATE CANCER 2008	PR	PR	RADIOLOGIST	20	WEEK 12
5	PRCA123	RS	99001	B2	OVRLRESP	Overall Response	PCWG SCHER PROSTATE CANCER 2008	NON-PD	NON-PD	RADIOLOGIST	20	WEEK 12

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.

DOMAIN	USUBJID	AESEQ	AESPID	AETERM	...	AECAT	AESCAT	AELOC	AELAT	AESEV	AESER
AE	1001	1	101	Spinal Cord Compression	...	BONE RELATED	SPINAL CORD COMPRESSION			SEVERE	Y
AE	1002	2	102	Femoral Head Fracture	...	BONE RELATED	PATHOLOGICAL FRACTURE	HIP	RIGHT	SEVERE	Y
AE	1003	3	201	Shoulder Pain	...	BONE RELATED	OTHER BONE RELATED EVENT			MODERATE	N
AE	1003	4	202	Headache	...	GENERAL				MILD	N
AE	1004	5	203	Lumbar Spinal Stenosis	...	BONE RELATED	OTHER BONE RELATED EVENT			MILD	N
AE	1004	6	204	Wrist Fracture	...	BONE RELATED	NON-PATHOLOGICAL FRACTURE	WRIST	LEFT	MODERATE	N

FRACAU
BONE METASTASIS
OSTEOPOROSIS
TRAUMA

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

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRLNKID	PRTRT	PRCAT	PRINDC	PRDOSE	PRDOSU	PRLOC	PRLAT
1	PRC7777	PR	1001	1	101	MRI	GENERAL	Spinal Cord Compression				
2	PRC7777	PR	1001	2	101	External Beam Radiotherapy	RADIATION TO BONE	Spinal Cord Compression	8	Gy		
3	PRC7777	PR	1001	3	101	Vertebroplasty	SURGERY TO BONE	Spinal Cord Compression				
4	PRC7777	PR	1002	4	102	Hemiarthroplasty or Reconstruction Intramedullary Device	SURGERY TO BONE	Femoral Head Fracture			HIP	RIGHT
6	PRC7777	PR	1003	5	201	External Beam Radiotherapy	RADIATION To BONE	Shoulder Pain				
7	PRC777	PR	1004	6	204	Casting	GENERAL	Wrist Fracture			WRIST	LEFT

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

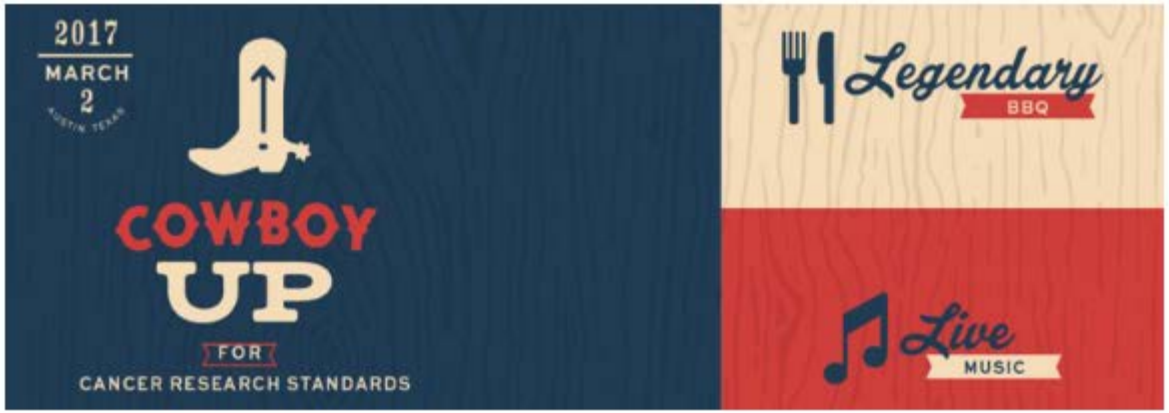
- Doers (minimum 4-8 hours/week)
- Reviewers (minimum 2-4 hours/week)
- PrCa
  - Public Reviewers (December 2016 – January 2017)
- CrCa
  - Internal Reviewers (December 2016)
  - Public Reviewers (January-March 2017)
- LuCa
  - Clinical Experts
  - SME Reviewers
- ONCO SDS – Contact Melanie Paules
- 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

- Cowboy Up! to Raise Funds for Cancer Research Standards. Enjoy live music from local artists, great local Bar-B-Q by Stubbs & presentations on cutting-edge Cancer Research.



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

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research

Strength *through Collaboration*