Prostate Cancer
Therapeutic Area User Guide

Education Webinar Presentation
19th October 2016
10am CDT
AGENDA

• Introduction to Prostate Cancer
• Prostate Cancer Project Update
• SHARE Collaboration
• Biomedical Concepts
• PrCa TAUG Overview
  • Sections
  • Domains
  • Variables
  • Non-Standard Variables
• Controlled Terminology
• Q&A 1
• Analysis Data
• Public Review Information
• Q&A 2
Introduction to Prostate Cancer

• Prostate cancer is the most common cause of non-skin cancer in men.

• It is estimated that, in 2014, 233,000 men will be diagnosed with prostate cancer in the US, and nearly 29,500 men will die of the disease.

• Standard treatments include watchful waiting, surgery, radiation therapy, hormone therapy, chemotherapy therapy, biological therapy, and bisphosphonate therapy.

1 Source: http://www.cancer.gov/
There are often no early symptoms of the disease and the tumors often grow very slowly.

Symptoms of the disease may not become apparent until the cancer has reached an advanced stage.

Further reading suggestions can be found in Appendix 7.5.3.
Introduction to Prostate Cancer – cont.

• Scope of the TAUG is focused on castrate-resistant and/or metastatic setting (based on regulatory input and current industry research trends)

• Issues covered include (with examples):
  • Pathology Assessments
  • Collection and reporting of tumor assessments using RECIST 1.1 and the PCWG guidelines.
  • Collection and reporting of Skeletal Related Events
  • Trial and Subject Milestones.
  • QRS Instruments
  • Analysis endpoints and dataset example
Prostate Cancer Disease Stages

- Clinically Localized Disease
  - Early Intervention:Radical Prostatectomy, Radiation Therapy, Brachytherapy

- Non-castrate
  - Clinical Metastases Non-castrate
  - Rising PSA Non-castrate

- Chemo naïve/Castrate
  - Clinical Metastases Castrate
  - Rising PSA Castrate
  - Doca
  - Taxane

- Chemo- /Chemo-failed
  - Clinical Metastases: Chemo-failed

Prostate cancer clinical-states model, a framework for patient management and drug development (Scher et al: JCO 26:1148-1159, 2008)
• Final SRC review comments currently being addressed and TAUG being prepared for public review release

• Anticipated Public Review Release date week commencing 24th October 2016

• Public review period will be for 60 days (increased from 30 after regulatory and stakeholder feedback)

• Anticipated review comments closing date 16th December 2016
SHARE provides access to curated, machine-readable CDISC Standards to:

- Support reuse and management of standards
- Implement standards in real time or as packages
- Meaningfully exchange health research data
- Over time, reduce costs
- Maintain compliance of data submission to FDA, PMDA
SHARE Collaboration – cont.

SHARE ecosystem tools used in the development of TAUG-PrCa

- e-SHARE tools used as reference in development of content
- WIKI TAUG Development/collaboration site
- WIKI CDASH CRF development
  - CRF Generator tool implementation during PR
- SDTM and ADaM Dataset creation macros
- TA Specification Document
SHARE Collaboration – cont.

For information

Agenda
SHARE Deep Dive

Date/Time
Thursday 20th October 2016 10:00 AM CDT

Panelists
CDISC SHARE Team Members:
Dr. Lauren Becnel, Senior Director of Biomedical Informatics and Alliances
Anthony Chow, Sr. Manager, Technical Development

For more information on our webinars, please visit www.cdisc.org/webinars.
Biomedical Concepts

- Biomedical Concepts are high-level building blocks of clinical research information that encapsulate lower level implementation details like variables and terminologies.
- The Prostate Cancer Project collaborated with the SHARE team to develop Biomedical Concepts
  - Lab Tests, Pathology Tests and QRS Instruments were developed
- Biomedical concepts are provided in the WIKI TAUG-PrCa for review and comment.

- Instructions for Reviewers
  - TAUG-PrCa
    - TAUG-PrCa compiled
    - TAUG-PrCa sections
    - PrCa figures
    - PrCa concept maps
    - PrCa examples
  - PrCa CDASH Metadata
  - PrCa Biomedical Concepts
Overview of TAUG content

TAUG-PrCa sections
- Introduction
  - Overview of Prostate Cancer
  - Subject and Disease Characteristics
  - Disease Assessments
- Routine Data
- Analysis Data
- Appendices

Introduction
- How to Read this Document
- Organization of this Document
- Known Issues

Subject and Disease Characteristics
- Initial Diagnosis
- Staging
- Pathology

Disease Assessments
- Treatments
- Disease Assessments and Response for Metastatic Disease
- Disease Assessments for Progression From nmCRPC to mCRPC
- Skeletal-Related Events
- Questionnaires, Ratings, and Scales

Routine Data
- Concomitant Medications
- Treatment Side Effects
- Trial Milestones

See later slides
Pathology

- Representation of PCA3 mRNA and PSA mRNA using LB
- Gleason Grading represented using MI
- Perineural Invasion/Capsular Penetration represented using MI
  - Two approaches shown
    - What did you see?
    - Did you see?
- Prostate Tissue Cores represented using MI
Disease Assessments and Response for Metastatic Disease

- RECIST 1.1 examples covered in TAUG-BrCa
- TAUG-PrCa focus on Bone Lesion assessments and response
Bone Scintigraphy

- Nuclear scanning technique for detecting abnormalities in the bone
- Patient injected with nuclear material and then scanned with a gamma camera

https://commons.wikimedia.org/wiki/File:SPECT_CT.JPG
Bone scintigraphy – cont.

- The bone scan shows areas of unusual bone activity (radioactive material is taken up by bone building osteoblasts cells)

- Osteoblast activity is triggered by bone tumors and therefore bone scintigraphy is used in the evaluation of these tumors.

- mCRPC (Metastatis Castrate Resistant Prostate Cancer) Patients exhibit a high degree of bone involvement and are not measurable.

https://commons.wikimedia.org/wiki/File:Prostate-mets-102.jpg
Bone Flare Phenomenon in Prostate Cancer

• Changes can occur on post-baseline bone scans characterized by:
  ▪ An increase in size or uptake intensity (of nuclear material) of known lesions and/or
  ▪ Appearance of new lesions

• These changes may be due to a “healing” response (active osteoblastic activity) as opposed to actual tumor progression

• Thought to occur within 12 weeks (3 months) of therapy initiation – This is termed the “Flare Window”

• Can lead to “early” determination of progression/discontinuation of therapy before therapy has had a chance to take effect
PCWG2/3 Guidelines

• Prostate Cancer Working Group 2 and 3 Guidelines take into account bone flare when evaluating bone progression in Prostate Cancer

• It is highly recommended that the review community become familiar with these response guidelines before reviewing the examples

PCWG 2 Reference

PCWG 3 Reference
<table>
<thead>
<tr>
<th>Baseline</th>
<th>1st Scan</th>
<th>2nd Scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLARE WINDOW</td>
<td>POST-FLARE WINDOW</td>
<td></td>
</tr>
<tr>
<td>3 Bone Lesions</td>
<td>3 Bone Lesions</td>
<td>3 Bone Lesions</td>
</tr>
<tr>
<td></td>
<td>2 New Bone Lesions</td>
<td>2 New Bone Lesions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>persisting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 Additional Bone Lesions</td>
</tr>
<tr>
<td>Unconfirmed Progression</td>
<td></td>
<td>Progression confirmed (2+2 rule)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Date of Progression = 1st Scan Date</td>
</tr>
</tbody>
</table>

Protocols will define rPFS definitions (including scan frequency etc)
<table>
<thead>
<tr>
<th>Baseline</th>
<th>1st Scan</th>
<th>2nd Scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLARE WINDOW</td>
<td>POST-FLARE WINDOW</td>
<td></td>
</tr>
<tr>
<td>• 3 Bone Lesions</td>
<td>• 3 Bone Lesions</td>
<td>• 3 Bone Lesions</td>
</tr>
<tr>
<td></td>
<td>• 2 New Bone Lesions</td>
<td>• 2 New Bone Lesions persisting</td>
</tr>
<tr>
<td>Unconfirmed Progression</td>
<td></td>
<td>No Progression</td>
</tr>
</tbody>
</table>

Protocols will define rPFS definitions (including scan frequency etc)
Example 1, bone tumors are reported as total counts of lesions; the specific location of each of the bone tumors are not collected. This example also shows how to represent information on tumor markers (e.g., PSA) that may be followed as part of disease assessments and response and how to represent that a subject had no measurable disease at baseline.

Example 2 shows how to represent data on a subject that had both non-measurable and measurable extraskeletal disease and bone tumors where a complete response was achieved before progression was observed.

Example 3 highlights how one could follow bone tumor by region (e.g., skull, thorax) rather than using a single count of bone tumors.
Progression From nmCRPC to mCRPC

- Example 1, This example shows how to record tumor assessments used to determine when the first metastatic disease was identified.
Skeletal-Related Events

Sample CRFs
- Annotated CRF: Adverse Events including Skeletal-Related Events
- Annotated CRF: Radiation Procedures
- Annotated CRF: Surgery Procedures

• **Example 1**, Representing SREs using AE and PR Domains using a multi-form approach
Questionnaires/Ratings and Scales

• Shows commonly used QRS instrument related to PrCa and the status of the supplements

• Note: Development of new QRS supplements follows the standard QRS process and not developed within the TAUG itself

<table>
<thead>
<tr>
<th>Full Name and Abbreviation</th>
<th>Permission</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Expanded Prostate Cancer Index Composite Short Form (EPIC-26)</td>
<td>Granted</td>
</tr>
<tr>
<td>Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP)</td>
<td>Granted</td>
</tr>
<tr>
<td>EORTC QLQ-PR25</td>
<td>Denied</td>
</tr>
<tr>
<td>EORTC QLQ-C30</td>
<td>Denied</td>
</tr>
<tr>
<td>EORTC QLQ-C15-PAL</td>
<td>Denied</td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy - General (Version 4) (FACT-G)</td>
<td>Granted</td>
</tr>
<tr>
<td>Functional Assessment of Cancer Therapy - Prostate (Version 4) (FACT-P)</td>
<td>Granted</td>
</tr>
<tr>
<td>FACT/NCCN-Prostate Symptom Index (Version 2) (FACT/NCCN FPSI-17)</td>
<td>Granted</td>
</tr>
<tr>
<td>European Quality of Life Questionnaire (EQ-5D-3L)</td>
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</tr>
<tr>
<td>European Quality of Life Questionnaire (EQ-5D-5L)</td>
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<tr>
<td>Prostate Cancer Specific Quality of Life Instrument</td>
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<tr>
<td>Brief Fatigue Inventory (BFI)</td>
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<td>Brief Pain Inventory - Short Form (BPI-SF)</td>
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<tr>
<td>Brief Pain Inventory (BPI)</td>
<td>Granted</td>
</tr>
</tbody>
</table>
Trial Milestones

- **Example 1**, Illustrating the use of the Trial Milestones and Subject Milestones domain to collect protocol-specified milestones prior to study start

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>MIDSTYPE</th>
<th>TMDEF</th>
<th>TMRPT</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>PRC1222</td>
<td>TM</td>
<td>INITDX</td>
<td>Initial Prostate Cancer Dx</td>
<td>N</td>
</tr>
<tr>
<td>2</td>
<td>PRC1222</td>
<td>TM</td>
<td>DXMCRPC</td>
<td>Diagnosis of metastatic castration-resistant prostate cancer</td>
<td>N</td>
</tr>
<tr>
<td>3</td>
<td>PRC1222</td>
<td>TM</td>
<td>PDAFTDOX</td>
<td>Progression after docetaxel-based chemotherapy regimen</td>
<td>N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>SMSEQ</th>
<th>MIDSTYPE</th>
<th>MIDS</th>
<th>SMSTDTCT</th>
<th>SMENDTCT</th>
<th>SMSTDDY</th>
<th>SMENDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PRC1222</td>
<td>SM</td>
<td>9001</td>
<td>1</td>
<td>INITDX</td>
<td>INITDX</td>
<td>2007-01-23</td>
<td>-1441</td>
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<tr>
<td>2</td>
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<tr>
<td>3</td>
<td>PRC1222</td>
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<td>PDAFTDOX</td>
<td>PDAFTDOX</td>
<td>2010-12-03</td>
<td>-32</td>
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</table>
**Domains**

- No new domains were submitted for this version of the TAUG
- The following Domains are referenced in the TAUG

<table>
<thead>
<tr>
<th>Datasets</th>
<th>Description</th>
<th>Section in TA User Guide</th>
<th>Section Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LB</strong></td>
<td>Laboratory Test Results</td>
<td>3.3 Ex 1</td>
<td>Pathology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Ex 1</td>
<td>Disease Assessments and Response for Metastatic Disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Ex 2</td>
<td></td>
</tr>
<tr>
<td><strong>MI</strong></td>
<td>Microscopic Examination Findings</td>
<td>3.3 Ex 2</td>
<td>Pathology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.3 Ex 3</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td>3.3 Ex 4</td>
<td></td>
</tr>
<tr>
<td><strong>PR</strong></td>
<td>Procedures</td>
<td>4.2 Ex 1</td>
<td>Disease Assessments and Response for Metastatic Disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.4 Ex 1</td>
<td>Skeletal Related Events</td>
</tr>
<tr>
<td><strong>TU, TR, RS</strong></td>
<td>Tumor/Lesion Identification, Results, Response</td>
<td>4.2 Ex 1</td>
<td>Disease Assessments and Response for Metastatic Disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Ex 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 Ex 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.3 Ex 1</td>
<td>Disease Assessments and Response for nmPrCA to mPrCA</td>
</tr>
<tr>
<td><strong>AE</strong></td>
<td>Adverse Events</td>
<td>4.4 Ex 1</td>
<td>Skeletal Related Events</td>
</tr>
<tr>
<td><strong>TM, SM</strong></td>
<td>Trial /Subject Milestones</td>
<td>5.3 Ex 1</td>
<td>Trial Milestones</td>
</tr>
</tbody>
</table>
## Variables

- The following variables used in the TAUG-PrCa have been submitted to make standards SDTM variables

<table>
<thead>
<tr>
<th>Parent Domain</th>
<th>Variable</th>
<th>Label</th>
<th>SAS Data Type</th>
<th>XML Data Type</th>
<th>Role</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TR</td>
<td>EVLREF</td>
<td>Evaluation Reference</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Identifier Variable</td>
<td>An evaluation used to compare with the observation represented in this record. Example: comparison of an image with a baseline image, or the most recent prior image. The value would typically be a Visit Name (e.g., Baseline). The value could also be a reference to a specific measurement (e.g., 0-Hour, Last scan).</td>
<td>Request to make this a standard SDTM variable submitted.</td>
</tr>
<tr>
<td>MI</td>
<td>RESTRG</td>
<td>Pre-Specified Result Targeted by Test</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Variable Qualifier of --TESTCD</td>
<td>Describes the result targeted by the test identified in TESTCD. Used when the measurement, test, or examination indicates the presence or absence of a pre-specified result value.</td>
<td>Request to make this a standard SDTM variable submitted and undergoing public review.</td>
</tr>
</tbody>
</table>
# Non-Standard Variables

<table>
<thead>
<tr>
<th>Parent Domain</th>
<th>Variable</th>
<th>Label</th>
<th>SAS Data Type</th>
<th>XML Data Type</th>
<th>Codelist/Controlled Terms</th>
<th>Role</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>TR</td>
<td>EVLREF</td>
<td>Evaluation Reference</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Identifier Variable</td>
<td>An evaluation used to compare with the observation represented in this record. Example: comparison of an image with a baseline image, or the most recent prior image. The value would typically be a Visit Name (e.g., Baseline). The value could also be a reference to a specific measurement (e.g., 0-Hour, Last scan).</td>
<td>Request to make this a standard SDTM variable submitted.</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>RESTRG</td>
<td>Pre-Specified Result Targeted by Test</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Variable Qualifier of TESTCD</td>
<td>Describes the result targeted by the test identified in TESTCD. Used when the measurement, test, or examination indicates the presence or absence of a pre-specified result value.</td>
<td>Request to make this a standard SDTM variable submitted and undergoing public review.</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>NUMCOR</td>
<td>Number of Cores Collected</td>
<td>Num</td>
<td>Integer</td>
<td>Non-Standard Record Qualifier</td>
<td>The number of core samples taken in a biopsy procedure.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AE</td>
<td>FRACAU</td>
<td>Cause of the Fracture</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Record Qualifier</td>
<td>The cause of a fracture.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR</td>
<td>PRLOCn</td>
<td>Location of Procedure</td>
<td>Char</td>
<td>text</td>
<td>Non-Standard Variable Qualifier of PRLOC</td>
<td>The nth anatomical location of the procedure.</td>
<td>Used when PRLOC = MULTIPLE: n stands for an integer between 1 and the maximum number of locations needed. This is the mechanism for representing multiple locations described in SDTMIGv3.2 Section 4.1.2.8.3.</td>
<td></td>
</tr>
</tbody>
</table>
**Controlled Terminology**

- Summary of Controlled Terminology developed during the Prostate Cancer project

<table>
<thead>
<tr>
<th>Batch</th>
<th>Details</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>• New test terminology for TU, TR, RS</td>
<td>In development – Will be in public review with P29</td>
</tr>
<tr>
<td></td>
<td>• New response terminology for TU</td>
<td></td>
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<tr>
<td></td>
<td>• New terminology for RSCAT variable – PCWG3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Addition of synonyms to existing RSCAT values – PCWG1, PCWG2</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>• New test terminology for LB, MI</td>
<td>In development</td>
</tr>
<tr>
<td></td>
<td>• New terminology for MITSTDTL variable</td>
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</tr>
</tbody>
</table>
Oncology Information Session

• Introduction to the Oncology WIKI >>
  http://wiki.cdisc.org/display/ONCO/Oncology+Team

• Next Oncology information session planned
  • Date/time: 23rd November 2016 10:00-11:30 CDT
  • This will include a session on TAUG-PrCa Deep dive
  • Will allow reviewers time to review the content and raise any questions before the end of the public review period
Q&A Session 1
Overview of TAUG content

TAUG-PrCa sections
- Introduction
- Overview of Prostate Cancer
- Subject and Disease Characteristics
- Disease Assessments
- Routine Data
- Analysis Data
- Appendices

Analysis Data
- Analysis Endpoints
  - Time to Event
    - Progression-Free Survival – PFS
    - Overall Survival – OS
    - Event-Free Survival – EFS
    - Disease-Free Survival – DFS
    - Time to Second Progression – PFS2
    - Prostate-Specific Antigen (PSA)
  - Response Analysis
  - Table and Figure Shells
- Analysis Datasets
  - Subject-Level
  - Intermediate Event Dates Dataset
  - Efficacy Analysis Datasets
Table and Figure Shells

- Overall survival
- PSA Response Rate

- Kaplan-Meier plots for overall survival and Progression-free survival

- Forest plot

- Waterfall plot for PSA Change from Baseline
# Analysis Data Sets

<table>
<thead>
<tr>
<th>Datasets</th>
<th>Description</th>
<th>AdAM Type</th>
<th>Section in TA User Guide</th>
<th>Section Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADSL</td>
<td>Subject Level</td>
<td>Subject level</td>
<td>6.3.1</td>
<td>Subject Level</td>
</tr>
<tr>
<td>ADDATES</td>
<td>Event Dates</td>
<td>Other structure</td>
<td>6.3.2</td>
<td>Intermediate Events Data Sets</td>
</tr>
<tr>
<td>ADTTE</td>
<td>Time to Events</td>
<td>BDS structured</td>
<td>6.3.3</td>
<td>Efficacy Analysis Datasets</td>
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<tr>
<td>ADPSA</td>
<td>PSA Analysis</td>
<td>BDS structured</td>
<td>6.3.3</td>
<td>Efficacy Analysis Datasets</td>
</tr>
<tr>
<td>ADPFS2</td>
<td>2nd Progression</td>
<td>BDS structured</td>
<td>6.3.3</td>
<td>Efficacy Analysis Datasets</td>
</tr>
</tbody>
</table>
Analysis Data - Dataset Approach

- **ADSL** (subject-level)
  - (population flags, treatment info, baseline variables, etc.)

- **SDTM**
  - (domains tabulated based on CRF; such as DM, DS, TU, TR, RS, ...)

- **ADPSA**
  - (BDS structured contains PSA responses)

- **ADPFS2**
  - (BDS Structured contains second time PFS analysis endpoint)

- **ADDATES**
  - (Intermediate dataset contains efficacy analysis needed key censoring dates information)

- **ADTTE**
  - (BDS structured contains time to event analysis such as OS or PFS analysis endpoint)
### ADDATES Dataset Metadata

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Description</th>
<th>Class</th>
<th>Structure</th>
<th>Purpose</th>
<th>Keys</th>
<th>Location</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDATES Event Dates Dataset</td>
<td>Event Dates Analysis Dataset</td>
<td>ADAM OTHER</td>
<td>One record per subject per event</td>
<td>Analysis</td>
<td>STUDYID, USUBJID, ADTDESCD</td>
<td>ADDATES.xpt</td>
<td>ADDATES.SAS/SAP</td>
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</tbody>
</table>

### ADDATES Variable Metadata

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Codelist/Controlled Terms</th>
<th>Source/Derivation/Comment</th>
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<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Text</td>
<td></td>
<td>SDTM.DM.STUDYID</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Text</td>
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<td>SDTM.DM.USUBJID</td>
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<tr>
<td>ASEQ</td>
<td>Analysis Sequence</td>
<td>Integer</td>
<td></td>
<td>Sequential number for associating a record number in the ADDATES dataset.</td>
</tr>
<tr>
<td>ADT</td>
<td>Analysis Date</td>
<td>Integer</td>
<td></td>
<td>This is the date that the event occurred.</td>
</tr>
<tr>
<td>ADTDESC</td>
<td>Description of Analysis</td>
<td>Text</td>
<td>Change in Anti-Cancer Therapy;</td>
<td>This is a text description of the event of interest that occurred on ADT and at study day.</td>
</tr>
</tbody>
</table>

#### addates.xpt

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
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<th>ASEQ</th>
<th>ADT</th>
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<td>ABC-123-001</td>
<td>1</td>
<td>03MAR2014</td>
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<td>RANDDT</td>
<td>1</td>
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<tr>
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<td>ABC-123-001</td>
<td>2</td>
<td>15OCT2014</td>
<td>Change in Anti-Cancer Therapy</td>
<td>RXCHGDT</td>
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<td>ABC-123</td>
<td>ABC-123-001</td>
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<td>15SEP2014</td>
<td>Date of Last Tumor Assessment with No PD</td>
<td>LNOPDDT</td>
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</tbody>
</table>
Important subject level variables that would typically appear in ADSL are shown.

An approach of using an intermediate dataset is shown. This intermediate dataset assembles all candidate dates used for the derivation of analysis variables related to time to event and response analyses.

- The Intermediate dataset is different in structure than what was presented in the Breast Cancer Therapeutic Area User Guide (TAUG-BrCa). In the TAUG-BrCa, a BDS dataset 'ADEVENT' was defined with parameters of 'Disposition', 'Assessment', 'Event', with AVALC describing the type of event and an optional variable SRCDESC providing additional information. The approach illustrated in TAUG-BrCa is reasonable yet upon reflection, it was considered not as easily extensible as the approach illustrated in this TAUG. Additionally, creating a transposed dataset from the BrCa ADEVENT dataset is not possible. For these reasons, a different approach is being considered.

Other BDS datasets are derived from the intermediate dataset for analysis of time to event and best response rates.

As with other TAUGs, these are examples of ADaM implementation and should not be interpreted as standards in and of themselves. Statistical methodology is not discussed.
Public Review

• Review Package Contents (will be made available only on the CDISC WIKI)
  • Links/Instructions will be provided in the Public Review announcement email

• Reviewers are requested to make any comments directly via JIRA
  • Detailed instructions are provided on the PrCA TAUG WIKI page.
  • Wiki and JIRA use the same credentials, so if you can see the TAUG-PrCa page in the WIKI, then you can use JIRA.
Public Review: Document Format

TAUG-PrCa compiled

- Allows review of entire document as a single document
- View is more prone to errors when entering comment into JIRA.

TAUG-PrCa sections

- Allows review of each section separately
- Easy navigation between sections using navigation label at the bottom of the page
- Reviews can also jump back and forth between sections
- Tables, and tables representing datasets (including any attendant row captions or footnotes), are inside expandable sections. Clicking on an indented line “ > “reveal the content within.
Public Review: Document Format

PrCa Examples and Concept Maps

- Allows all the CRFs, SDTM examples and concept maps used in the TAUG-PrCa to be viewed.
Public Review-Recommendations

• Reading the TAUG-PrCa in its entirety at least once before jumping to specific sections or examples

• Always check the Known Issues Section prior to review of the TAUG

• Keep the JIRA PrCA page and the WIKI PrCA Therapeutic User guide open in separate window
  • Comments can be entered without navigating back and forth between the Wiki and JIRA.
  • Always check to make sure the project selected in JIRA is Prostate Cancer.

• Add scope suggestions for future versions

• If you have no edits or comments to a page, click 'Like' at the bottom of the page. This will help us determine who has read each page.
Q&A Session 2