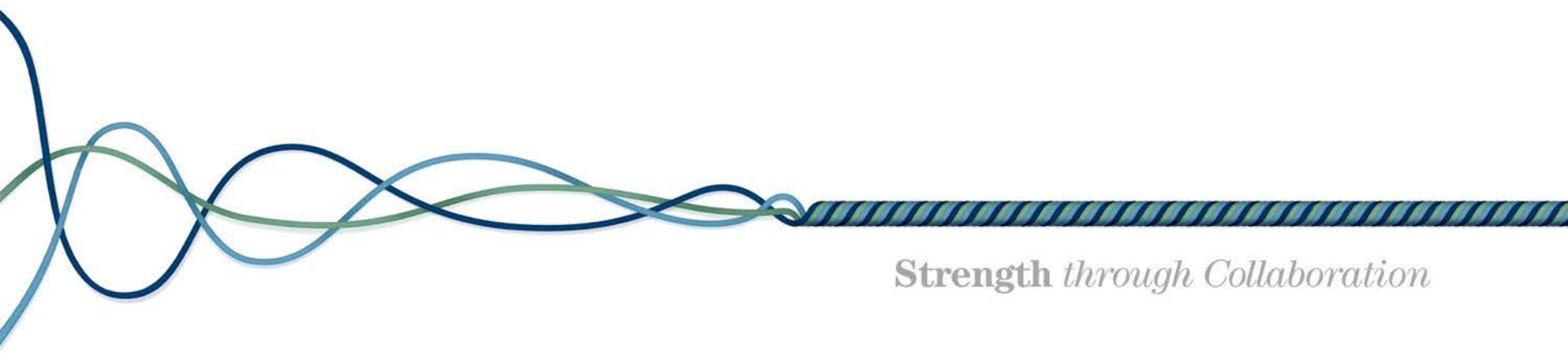
CDISC Public Webinar – Standards Updates and Additions

Oct 7 2015



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Agenda

- Breast Cancer TA Public Review
  - John Owen, CDISC
  - Erin Muhlbradt, NCI-NIH
  - Susan Kenny, Maximum Likelihood
  - Elizabeth Langevin, Takeda
  - Barrie Nelson, Onyx
  - Jeanne Schilder, Lilly

- CDISC Online Education & Event Updates
  - John Ezzell, CDISC

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Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

Amy: What are new updates in the Virology TAUG?

OR

CDISC: When can we start registering for the US Interchange?

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Breast Cancer
Therapeutic Area User Guide

Education Webinar Presentation

Wednesday 7th October 2015

10:00-11:30 CST

Strength *through Collaboration*

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AGENDA

- ***Introduction to Breast Cancer***
- ***Breast Cancer Therapeutic Area User Guide (TAUG)***
- ***Domains***
- ***Variables***
- ***Controlled Terminology***
- ***Analysis Data***
- ***Public Review Information***

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Introduction to Breast Cancer

- October 2015 is Breast Cancer Awareness Month
- Breast cancer is a solid tumor cancer arising in the epithelial cells of the breast (mainly in the milk ducts or glands)
- Breast cancer is the most frequently diagnosed cancer in women worldwide (including developed and developing countries)
- Breast Cancer is the leading cause of cancer death in women
  - 23% of total cancer cases [1]
  - 14% of cancer deaths [1]
- Breast cancer also occurs in men, but it is rare

1. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. *CA Cancer J Clin. 2011;61:69-90.*

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Introduction to Breast Cancer

- Risk factors for breast cancer include [2]
  - Sex
  - Age
  - Family history
  - Early menarche
  - Late menopause
  - Postmenopausal obesity
  - Use of combined estrogen and progestin menopausal hormones
  - Cigarette smoking
  - Alcohol consumption

- The etiology of breast cancer is influenced by diet as well as hormonal and reproductive factors [3]

- Treatment options may include combinations of surgery, radiation therapy, Chemotherapy and hormone therapy

- Breast Cancer background provided in Appendix E – Clinical Background

- Further reading suggestions can be found in Appendix F2

2. American Cancer Society. *Breast Cancer Facts & Figures 2013-2014. Atlanta, Ga: American Cancer Society; 2013.*
3. Fabbri A, Carcangiu ML, Carbone A. Histological Classification of Breast Cancer. In: Bombardieri E, Bonadonna G, Gianni L, eds. *Breast Cancer: Nuclear Medicine in Diagnosis and Therapeutic Options. New York: Springer; 2008.*

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Breast Cancer - TAUG

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

- Final SRC review comments currently being addressed
- Anticipated Public Review Release date 19th October 2015
- Anticipated review comments closing date 18th November 2015

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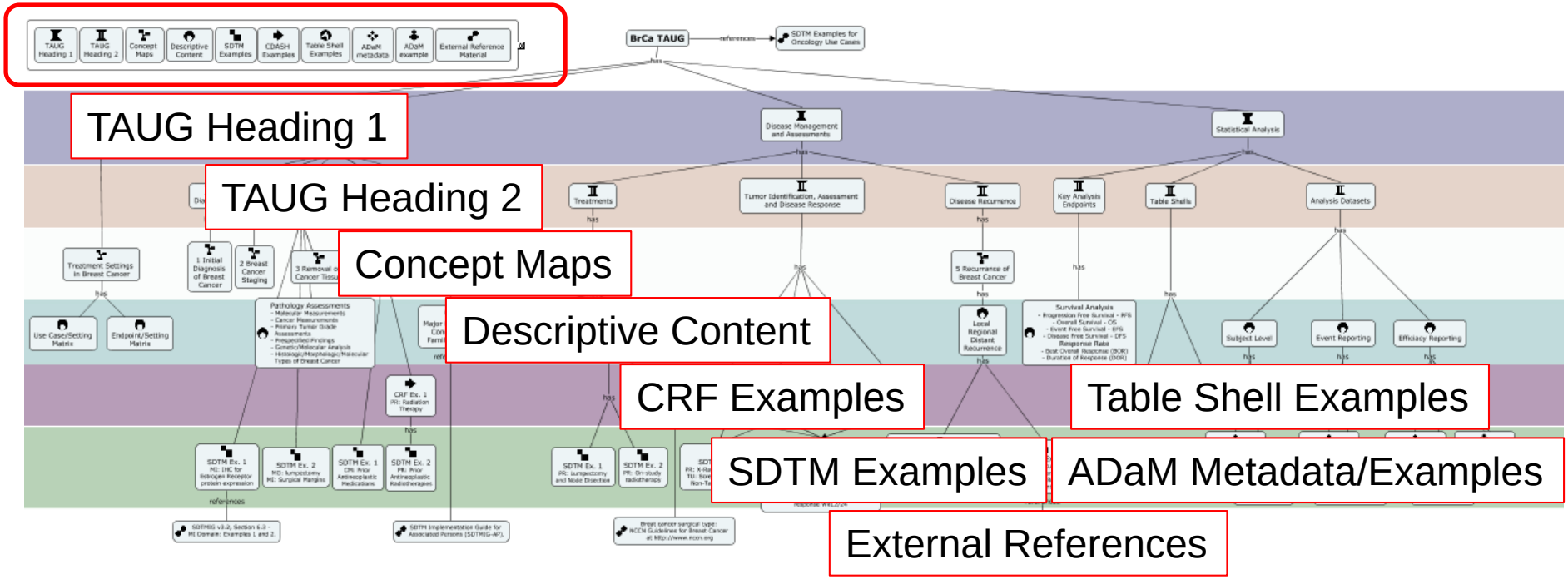
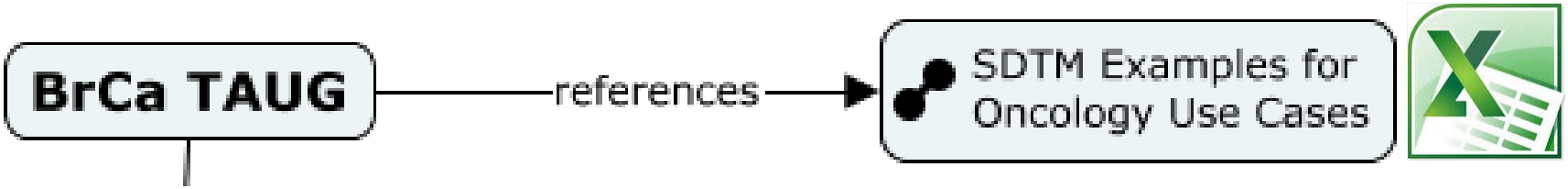
Breast Cancer - TAUG

- An overview of the Breast Cancer TAUG is represented in the following document diagram



Breast Cancer - TAUG

- References to SDTM Examples for Oncology Use Cases



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Breast Cancer - TAUG

- Standard Section 1
  - PURPOSE
  - ORGANIZATION OF THIS DOCUMENT
  - CONCEPT MAP GENERAL INFORMATION
  - CONTROLLED TERMINOLOGY GENERAL INFORMATION
  - RELATIONSHIPS TO OTHER STANDARDS
  - KNOWN ISSUES

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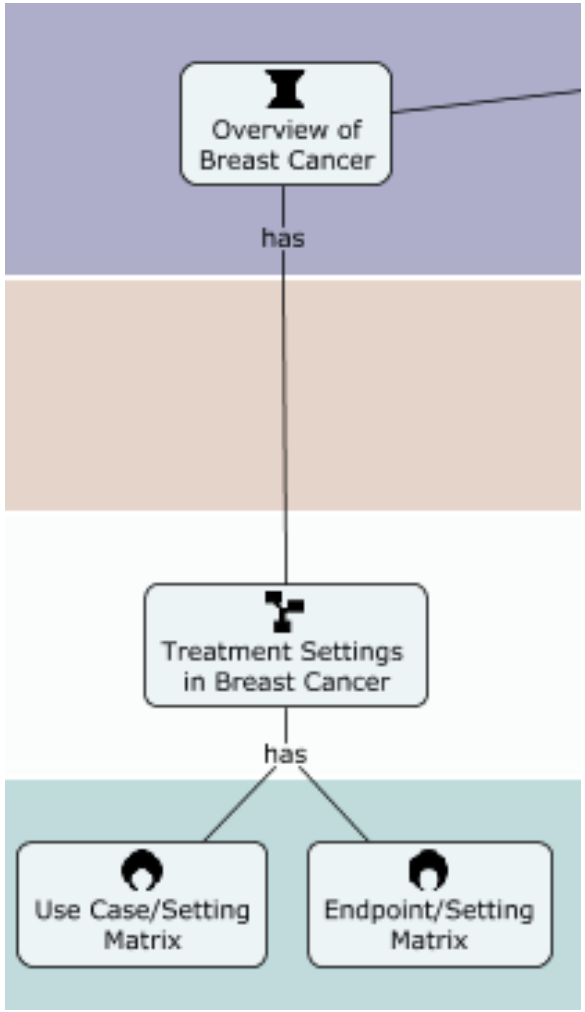
Breast Cancer - TAUG

- Section 2 – **New:** Overview of Breast Cancer



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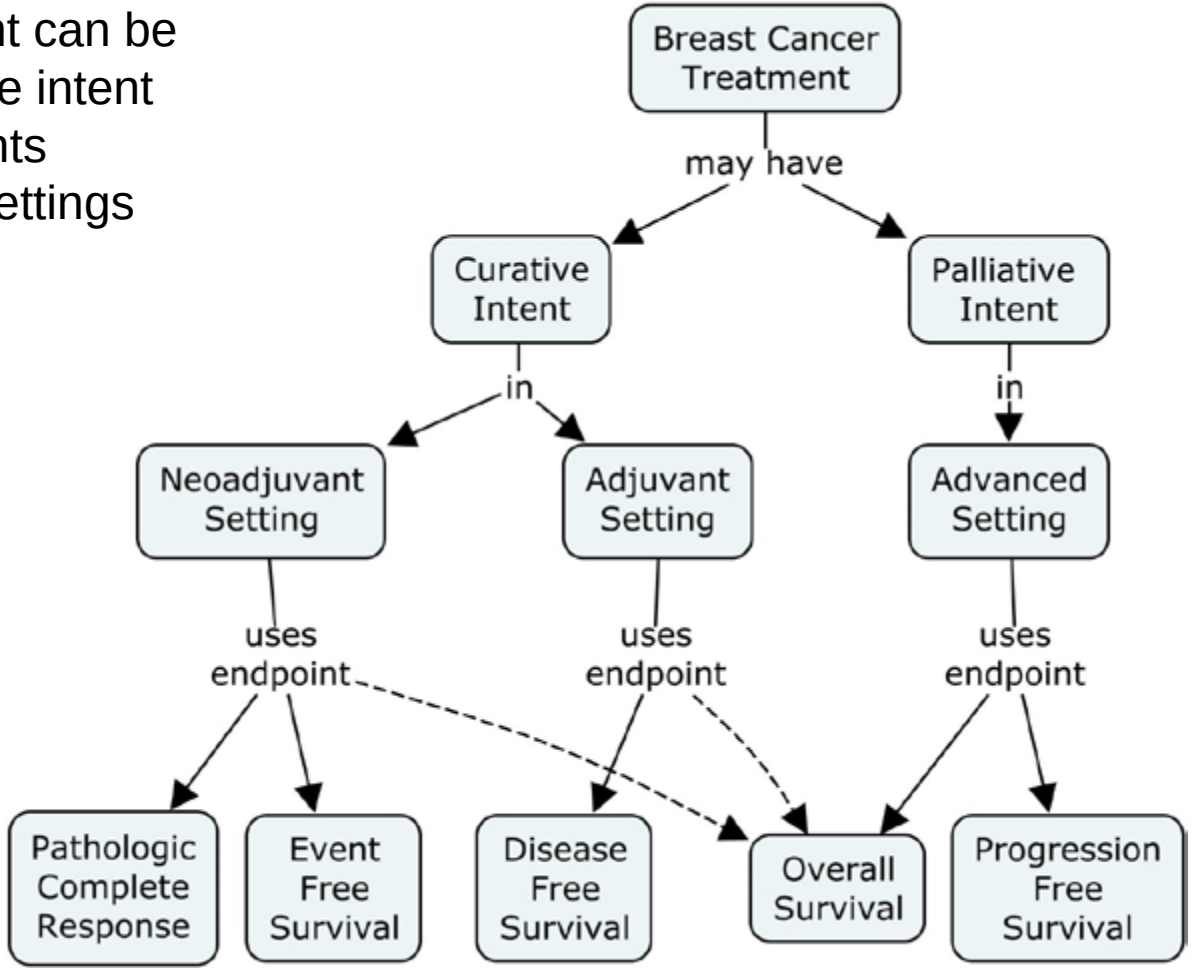
Breast Cancer - TAUG

- Breast Cancer treatment can be described in terms of the intent and setting and endpoints associated with these settings



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Breast Cancer - TAUG

- Therapeutic Area Users Guides are organised by kinds of data collected
- Section 2: Overview of Breast Cancer includes a matrix that links the different settings to the various use cases

Use Case	Example	Neoadjuvant	Adjuvant	Advanced
Estrogen receptor status	Section 3.3.1 Example 1	X	X	X
Gross pathology	Section 3.3.1 Example 2	X	X	
Prior anti-neoplastic therapy	Section 3.4.1 Example 1			X
Prior radiotherapy	Section 3.4.1 Example 2			X
	Example CRF 1			X
On-study surgeries	Section 4.1.1 Example 1	X		X
On-study radiotherapy	Section 4.1.1 Example 1	X	X	X
Tumor identification: target lesions	**Example CRF 2**	X		X
Tumor identification: non-target lesions	**Example CRF 3**	X		X
Tumor identification: new lesions	**Example CRF 4**	X	X	X
Disease Response	**Example CRF 5**	X		X
Tumor imaging and assessment	Section 4.2.1 Example 1			X
	Section 4.2.1 Example 1			X
	Section 4.2.1 Example 2			X
Disease Response	Section 4.3.1 Example 2	X		

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Breast Cancer - TAUG

- Section 2: Overview of Breast Cancer also includes links to the various endpoints described in the analysis section

Endpoint	Setting	TAUG Reference
Pathologic Complete Response (pCR)	Neoadjuvant	Not included*
Event Free Survival (EFS)	Neoadjuvant	Analysis Section 5.1.1.3
Disease Free Survival (DFS)	Adjuvant	Analysis Section 5.1.1.4
Overall Survival (OS)	Neoadjuvant, Adjuvant, Advanced	Analysis Section 5.1.1.2
Progression Free Survival (PFS)	Advanced	Analysis Section 5.1.1.1

- * NOTE: Pathologic Complete Survival (pCR) is not described in the analysis section because the final analysis of a binary endpoint is simple, and the derivation of the endpoint depends on the definition used, which will vary by study

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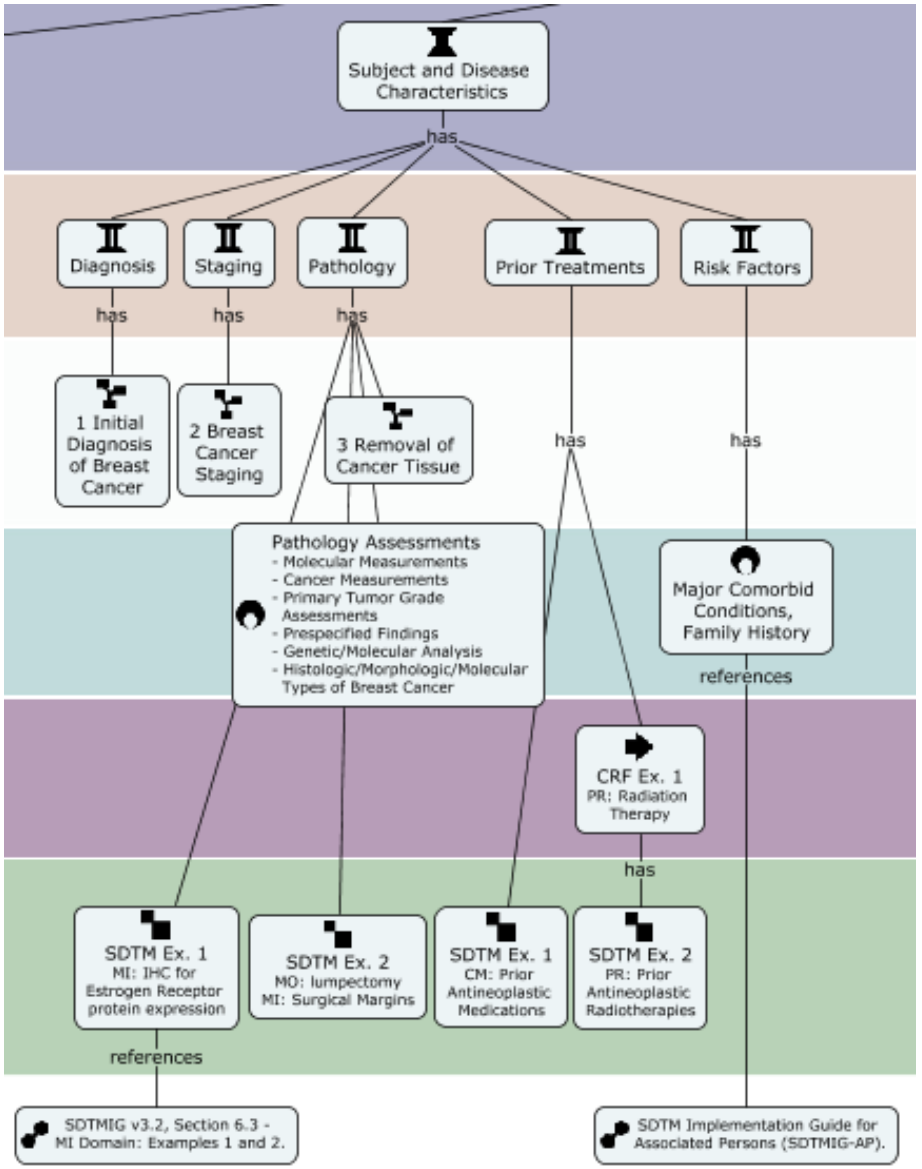
Breast Cancer - TAUG

- Section 3 – Subject and Disease Characteristics



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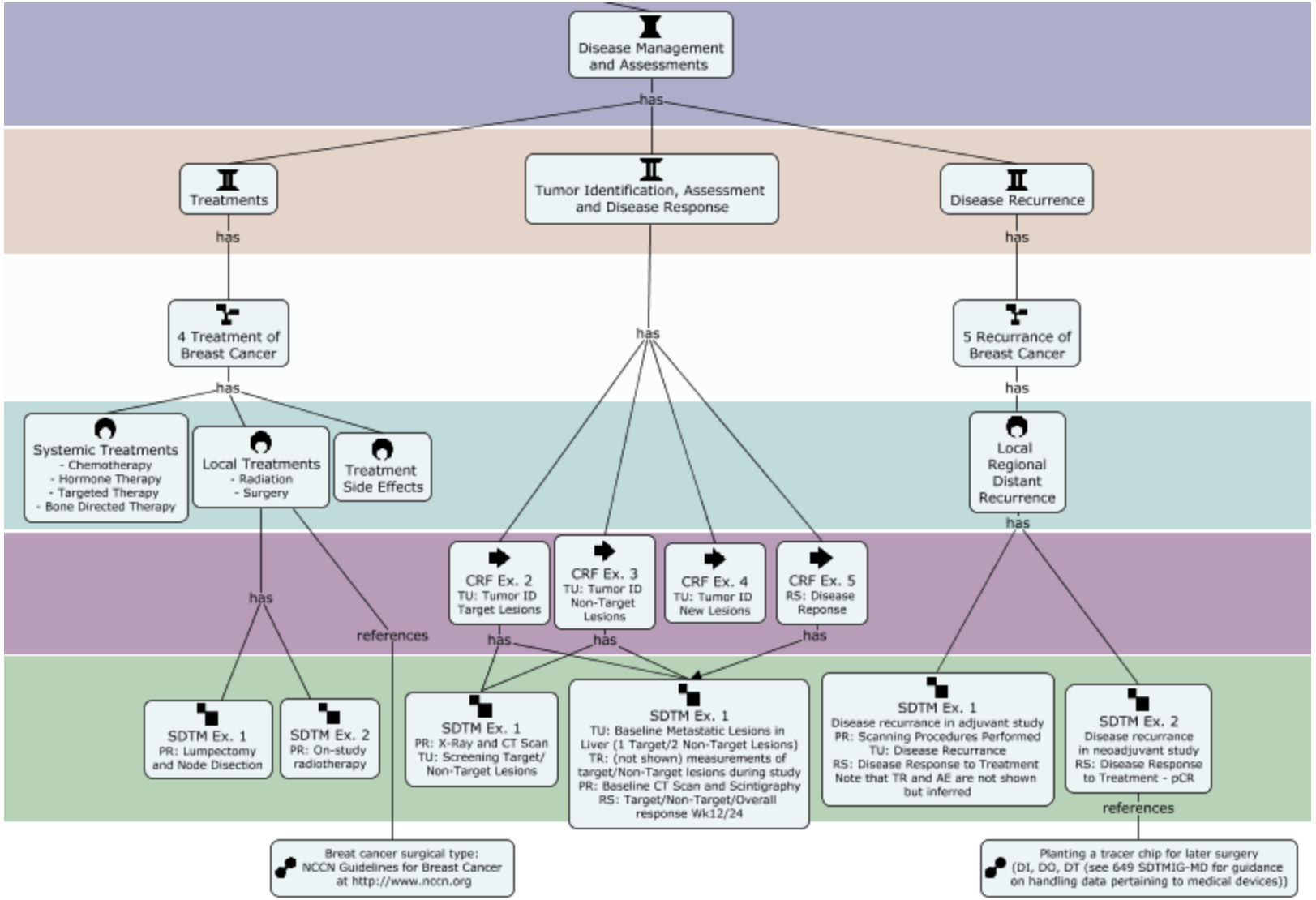
Breast Cancer - TAUG

- Section 4 – Disease Management and Assessments



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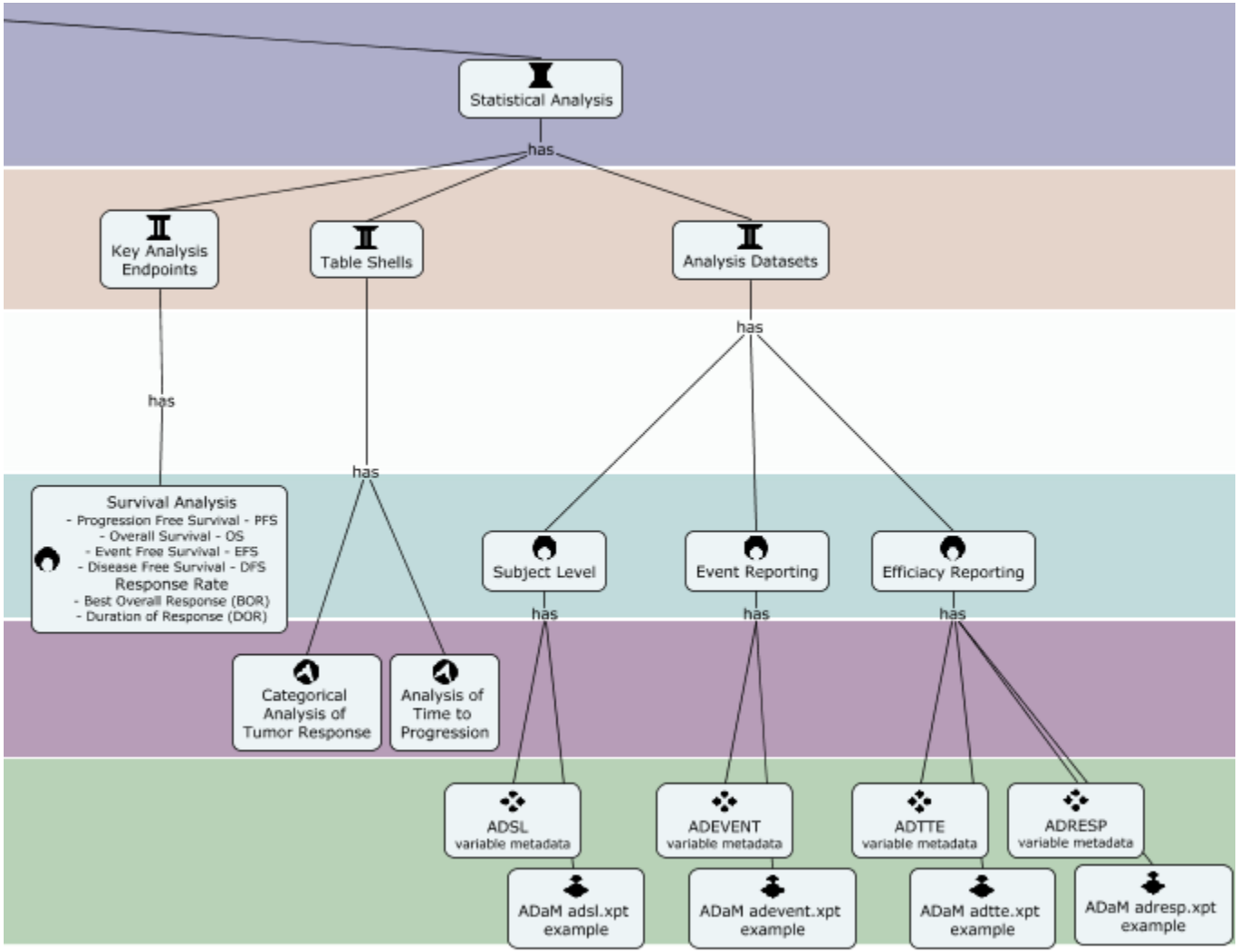
Breast Cancer - TAUG

- Section 5 – Analysis Data (detail covered later)



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Breast Cancer - TAUG

- Appendices
  - PROJECT PROPOSAL
  - CFAST BRCA TEAM
  - GLOSSARY AND ABBREVIATIONS
  - NON-STANDARD VARIABLES
  - CLINICAL BACKGROUND
  - REFERENCES
  - REPRESENTATIONS AND WARRANTIES, LIMITATIONS OF LIABILITY, AND DISCLAIMERS

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Domains

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

Datasets	Description	Section in TA User Guide	Link*	Section Description
MI	Microscopic Findings	3.3.1 Ex 1		Pathology - Estrogen Receptor
		3.3.1 Ex 2	1	Pathology – Surgical Margin Status
MO	Morphology	3.3.1 Ex 2	1	Pathology – Lumpectomy Measurements
CM	Concomitant Medications	3.4.1 Ex 1		Prior Treatments - Prior Antineoplastic Therapies
PR	Procedures	3.4.1 Ex 2		Prior Treatments - Prior Antineoplastic Radiotherapy
		4.1.1 Ex 1		Treatments – Lumpectomy/Lymph Node Dissection
		4.1.1 Ex 2		Treatments – Radiation with Different Schedules
		4.2.1 Ex 1	2	Tumor ID/Assessments/Response – Screening CT Scan/Scintigraphy
		4.2.1 Ex 2	3	Tumor ID/Assessments/Response – Screening/Post-Screening CT Scan/Scintigraphy
		4.3.1 Ex 1	4	Disease Recurrence - Screening/Post-Screening CT Scan/MRI
TU	Tumor Identification	4.2.1 Ex 1	2	Tumor ID/Assessments/Response – Screening Tumor Identification
		4.2.1 Ex 2	3	Tumor ID/Assessments/Response – Screening Tumor Identification
		4.3.1 Ex 1	4	Tumor ID/Assessments/Response – Post-Screening Tumor Identification
RS	Disease Response	4.2.1 Ex 2	3	Tumor ID/Assessments/Response – Post-Screening Response
		4.3.1 Ex 1	4	Disease Recurrence – Post-Screening Response
		4.3.1 Ex 2		Disease Recurrence – Pathologic Complete Response (pCR)

* Link identifies those domains that are used within the same example

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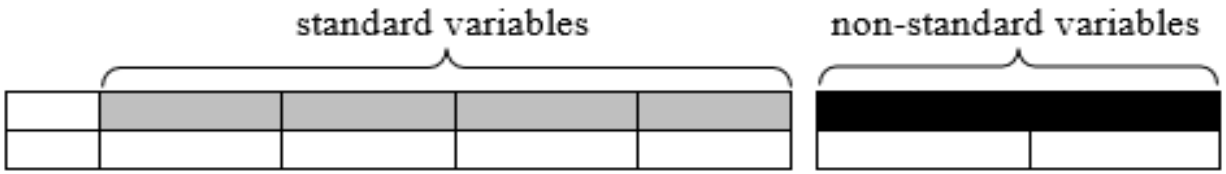
Variables

- No new standard variables were submitted for this version of the TAUG

- Non-Standard Variables
  - This document has adopted the practices outlined in the proposed SDTMIG Section 8.4.4, Alternative Representation of Non-Standard Variables (also called the NSV Proposal; circulated for public review as part of SDTMIG v3.3 Batch 2).
  - SDTM examples containing sample data requiring the use of a variable outside the standard set of variables included in SDTM v1.4 are represented not with supplemental qualifier records but with non-standard variables (NSVs) appended to the end of the parent domain
  - Sample value-level metadata for NSVs are given in tabulated form following each dataset in which they are used, and also in Appendix D. NSVs have been rendered visually distinct with white text on black in the header row, and separated from the standard variables by a small space.



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Variables

- Example NSV format in Prior Radiation Therapy Use Case

Row 1: Subject 123-1234 had a prior radiotherapy treatment given to the supraclavicular lymph nodes in an adjuvant setting.
Rows 2-3: Subject 123-2345 had two prior radiotherapy treatments: one given to the breast in a neoadjuvant setting, and the other given to the lumbar vertebrae in a metastatic setting.
Row 4: Subject 123-2346 had a prior radiotherapy treatment given to the axillary lymph nodes in an adjuvant setting.

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRCAT	PRINDC	PRLOC
1	ABC123	PR	ABC123-1234	1	BRACHYTHERAPY	RADIATION THERAPY	BREAST CANCER	SUPRACLAVICULAR LYMPH NODE
2	ABC123	PR	ABC123-2345	1	EXTERNAL BEAM RADIOTHERAPY	RADIATION THERAPY	BREAST CANCER	BREAST
3	ABC123	PR	ABC123-2345	2	BRACHYTHERAPY	RADIATION THERAPY	BREAST CANCER	LUMBAR VERTEBRA
4	ABC123	PR	ABC123-2346	1	BRACHYTHERAPY	RADIATION THERAPY	BREAST CANCER	AXILLARY LYMPH NODE

Row	VISITNUM	VISIT	PRSTDTC	PRENDTC	STT
1 (cont)	1	SCREENING	1990-04-15	1990-04-22	ADJUVANT
2 (cont)	1	SCREENING	1998-01-22	1998-02-10	NEOADJUVANT
3 (cont)	1	SCREENING	2007-04-30	2007-05-10	METASTATIC
4 (cont)	1	SCREENING	1998-05-30	1998-06-20	ADJUVANT

PR NSV Metadata

OID	Name	Label	Type	Controlled Terms	Role	Origin
IT.PR.SUPP.STT	STT	Setting	text	Adjuvant, Neo-Adjuvant, Metastatic, Unknown	Non-Standard Qualifier	CRF

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Variables

- The following NSV's were proposed for version 1 of the Breast Cancer TAUG

Parent Domain	Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role
CM	RSDISC	Reason for Discontinuation	text		Non-Standard Record Qualifier
CM, PR	STT	Setting	text	Treatment Setting (TRTMSTT)*	Non-Standard Record Qualifier
CM, PR	TRTINT	Treatment Intent	text	Treatment Intent (TRTINTNT)*	Non-Standard Record Qualifier
MI	PTSCL	Point Scale	text		Non-Standard Variable Qualifier of MITSTDTL
PR	CMLDOS	Cumulative Dose	float		Non-Standard Record Qualifier
PR	OUTTRT	Treatment Outcome		**	
PR	PRLOCn	Procedure Location n	text	Anatomical Location (C74456)	Non-Standard Record Qualifier
PR	RTTLFR	Total Fractions Count	integer		Non-Standard Record Qualifier
PR	TRTDTL	Treatment Detail	text	**	Non-Standard Variable Qualifier of PRTRT
PR	TRTLOC	Treatment-Relative Location	text	**	Non-Standard Record Qualifier
TU	LOCTXT	Location Text	text		Non-Standard Variable Qualifier of TULOC

Name	Description/Comments
RSDISC	The reason for ceasing (prior/concomitant) treatment.
STT	The setting as characterized by the purpose of the study treatment in relation to the primary treatment.
TRTINT	The therapeutic intent of the treatment.
PTSCL	When the score is determined by a multi-point scale, how many points are on the scale.
CMLDOS	For treatments with a cumulative effect, the total dose administered over the time period defined by --STDTC and --ENDTC. Used instead of --DOSE.
OUTTRT	The best outcome of the (prior) treatment.
PRLOC*n*	Used when PRLOC = MULTIPLE; *n* stands for an integer between 1 and the maximum number of locations needed.
RTTLFR	How many fractions of the intended total dose were administered.
TRTDTL	Further description of --TRT. In this document, this variable is used to hold the modality of the treatment.
TRTLOC	The location of the treatment's target, relative to the primary site of disease.
LOCTXT	Specifies the exact location of the identified tumor or lesion for identification purposes; used when --LOC, --LAT, and --DIR are not enough to distinguish it from another tumor/lesion in the same anatomical location.

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Controlled Terminology

Summary of Controlled Terminology Developed during the Breast Cancer Project

Batch	Details	Status
1	•New test terminology for MI, TU, RS •New response terminology for TU •New values for LOC, METHOD	Published with P23 publication on 2015-09-25
2	•New test terminology for TR, RS, SS •New response terminology for SS •New response codelists for suppquals ➢Treatment Intent ➢Treatment Setting •New response terminology for TU •New values for METHOD, PROCEDUR	Out for public review. Will be published with P24 publication on 2015-12-18
3	•New codelist for MITSTDTL variable •New response terminology for TR	Will go out for public review with P25 in December 2015

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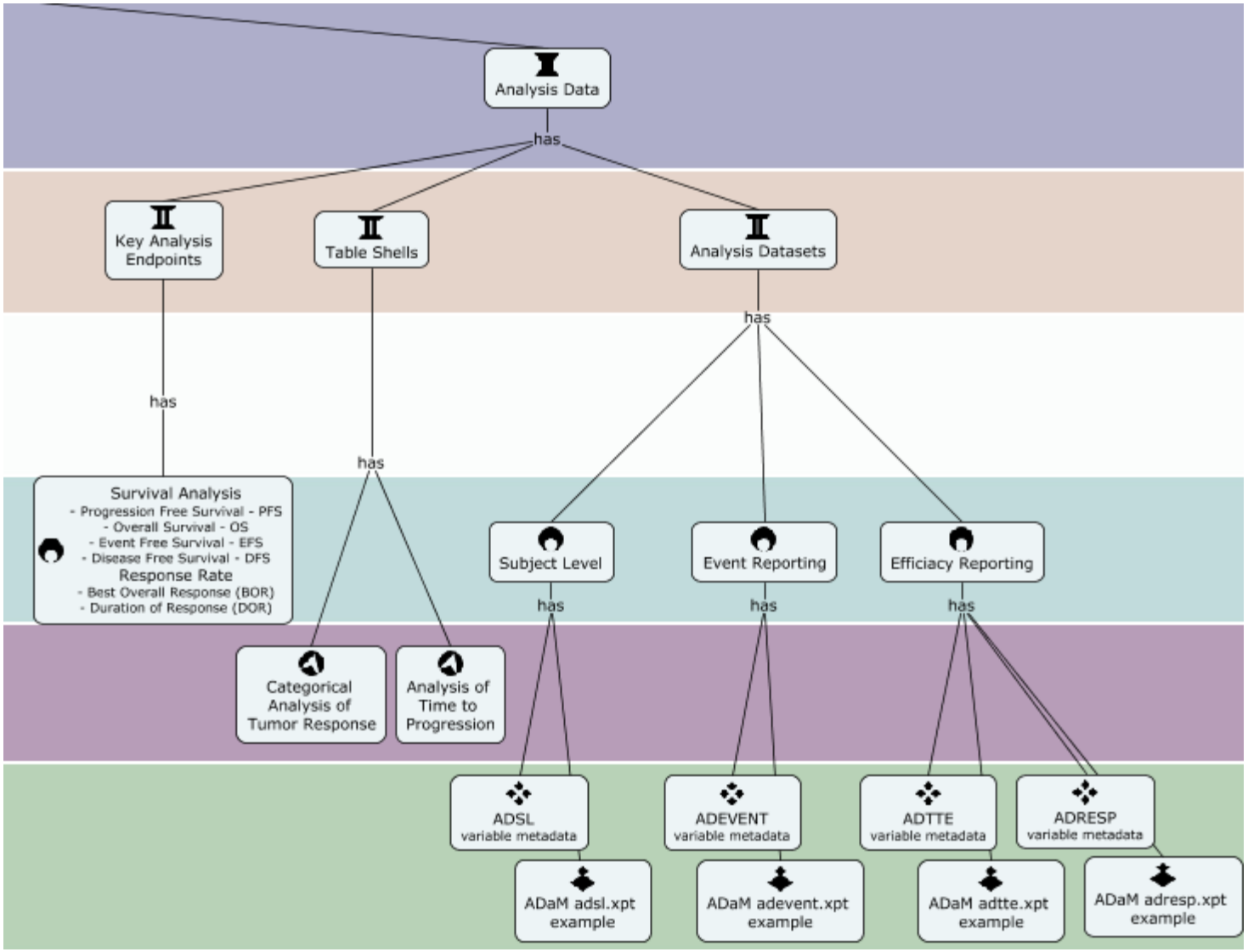
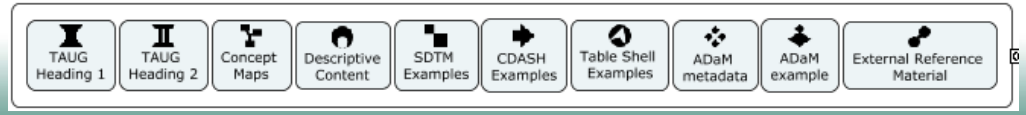
Analysis Data – Section Overview





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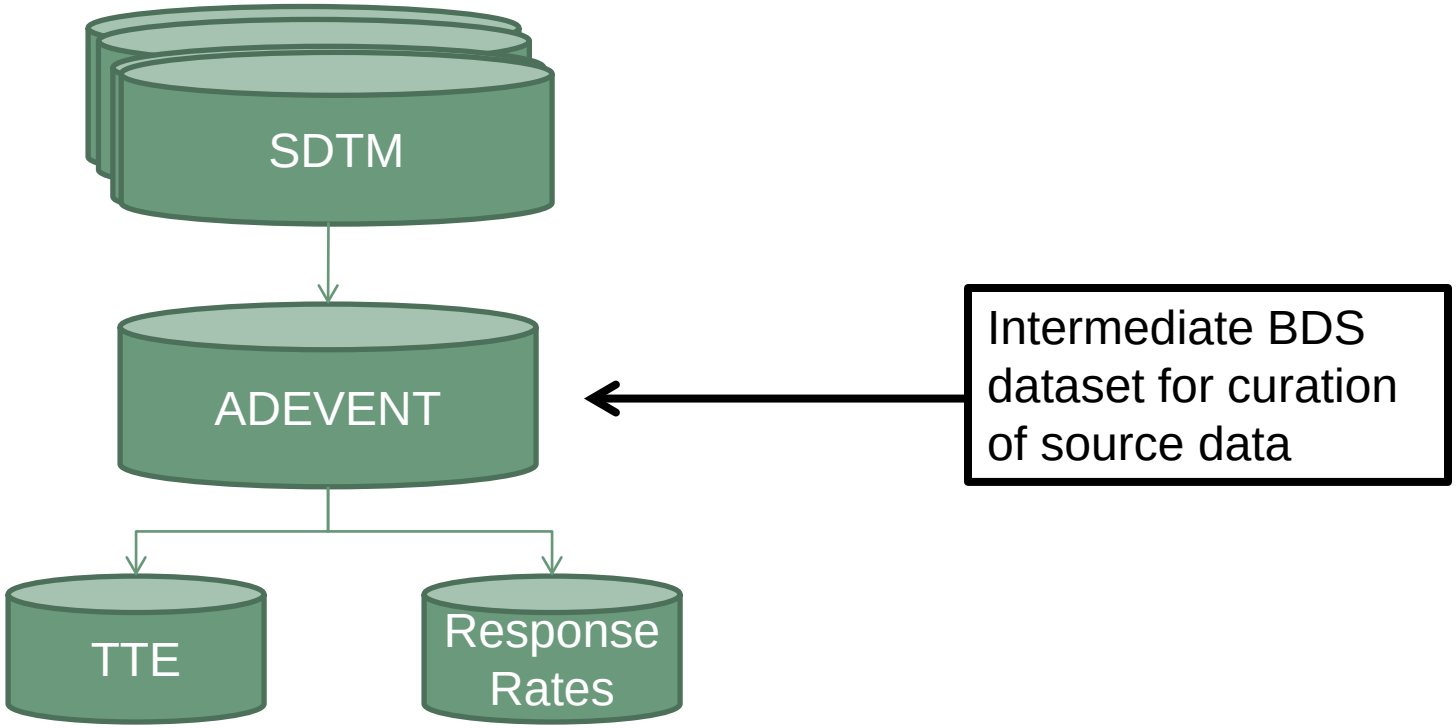
Analysis Data

Approach for the Creation of Analysis Datasets



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Analysis Data – Points of Note

- Important subject level variables that would typically appear in ADSL are shown
- An approach of using a BDS based intermediate dataset is shown. This intermediate dataset assembles all information that is used for the derivation of analysis variables related to time to event and response analyses.
- 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

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Public Review

- Review Package Contents (will be made available on the CDSIC Portal)
  - TAUG File in PDF format
  - Readme file
  - CDASH Metadata Excel File
  - Document Reference Map

  - Link to Oncology Use Cases Excel Sheet on CDISC Website

- CDISC Public Comment Tracker
  - Portal Account Creation => http://portal.cdisc.org/CT/pages/membershiprequest.aspx?Source=/CT
  - Location => http://portal.cdisc.org/CT/default.aspx
  - Instructions => http://portal.cdisc.org/CT/Pages/CCTT-Help.aspx

- Recommend to check the Known Issues Section 1.6 prior to review of the TAUG

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Public Review

- Anticipated Review Period (pending resolution of SRC comments)

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Breast Cancer
Therapeutic Area User Guide

Education Webinar Presentation

Wednesday 7th October 2015

10:00-11:30 CST

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Thank you!

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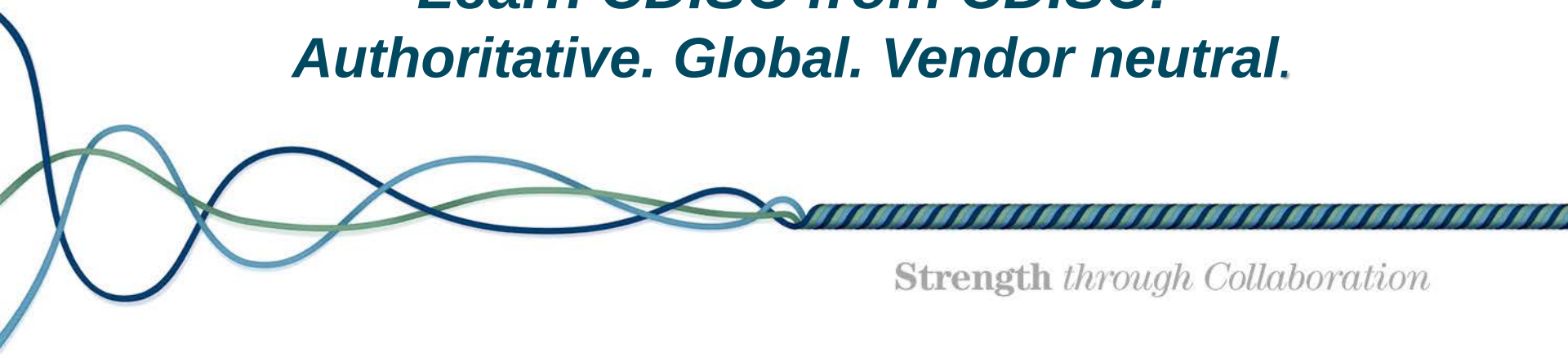

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Standard currently out for review

- Controlled Terminology P24
  - Visit http://cdisc.org/terminology for more information
  - Comments due 9 October 2015

Click here to submit your comments.

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Upcoming North America Public Courses and Events

Location	Dates	Courses Offered	Host
Cambridge, MA	12-16 Oct 2015	SDTM-PK, SDTM, ADaM, Define-XML	ALEXION
Chicago, IL (International Interchange)	9, 12-13 Nov	See website	CDISC
Morrisville, NC	9-12 Feb 2016	SDTM, CDASH, ADaM	SynteractHCR
Audubon, PA	2-11 Mar 2016	Courses corresponding to standards listed in Data Standards Catalog. See web.	BIOCLINICA
Visit cdisc.org/public-courses for information on other CDISC Public Training events.			

Check CDISC website for up-to-date information on Public Courses

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Upcoming Europe Public Courses and Events

Location	Dates	Courses Offered	Host
Copenhagen, Denmark	28 Oct - 3 Nov 2015	SDTM, ADaM, SEND	
Berkshire, UK	26-29 Jan 2016	SDTM, ADaM, Define-XML	
Paris, France	8-11 Mar 2016		
Europe Interchange in Vienna, Austra	25-29 Apr 2016		

Registration deadline indicates online deadline. Onsite registration is available before each event begins. Additional 2015 public training events can be found @ http://cdisc.org/public-courses.

Full 2016 Public Training Schedule is online
Check CDISC website for up-to-date information on Public Courses

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Upcoming Asia Public Courses and Events

Location	Dates	Courses Offered	Register by:	Early Registration Discounts	Host
Beijing, China	20-23 Oct 2015	SDTM, CDASH, ADaM, ODM, Define-XML	20 Sep 2015	*Expired*	PPD®
Shanghai, China	26-29 Oct 2015	SDTM, CDASH, ADaM, ODM, Define-XML	20 Sep 2015	*Expired*	gsk GlaxoSmithKline 葛兰素史克
Tokyo, Japan	14-18 Dec 2015	SDTM, CDASH, ADaM, ODM, Define-XML	13 Nov 2015	*13 Nov 2015*	EXICARE CAC EXICARE Corporation

Visit http://cdisc.org/public-courses for information on other CDISC Public Training events in Asia.

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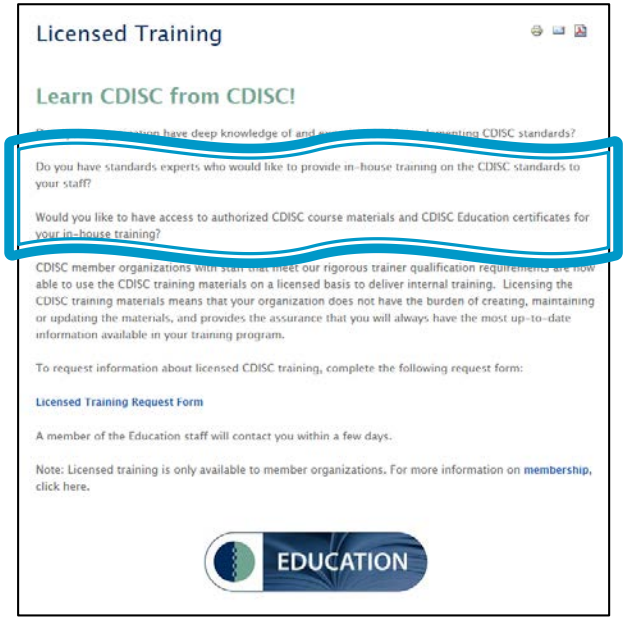
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EDUCATION

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- Online training created with support from CDISC standards development teams
- New CDISC trainings developed in tandem with standards development
- Online courses benefits:
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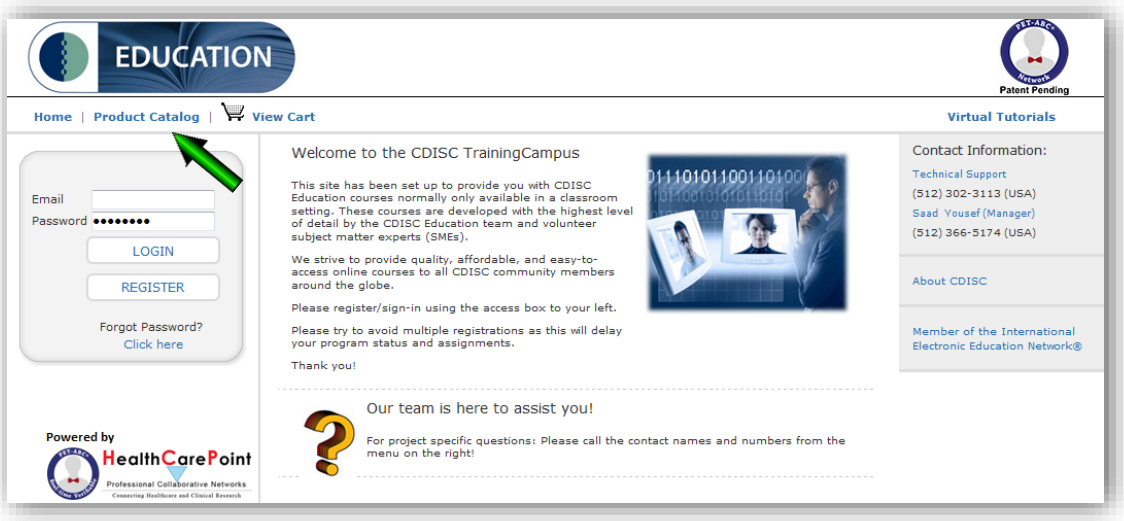
  - more content
  - greater depth
  - updated frequently



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Next Members Only Webinar

- **Agenda:**
  - EPOCH Variable
- **Date**: 22 Oct 2015, 11:00-12:30 PM EST
- **Speakers:**
  - Diane Wold, CDISC
- Register here.

Webinar details also at www.cdisc.org/webinars

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