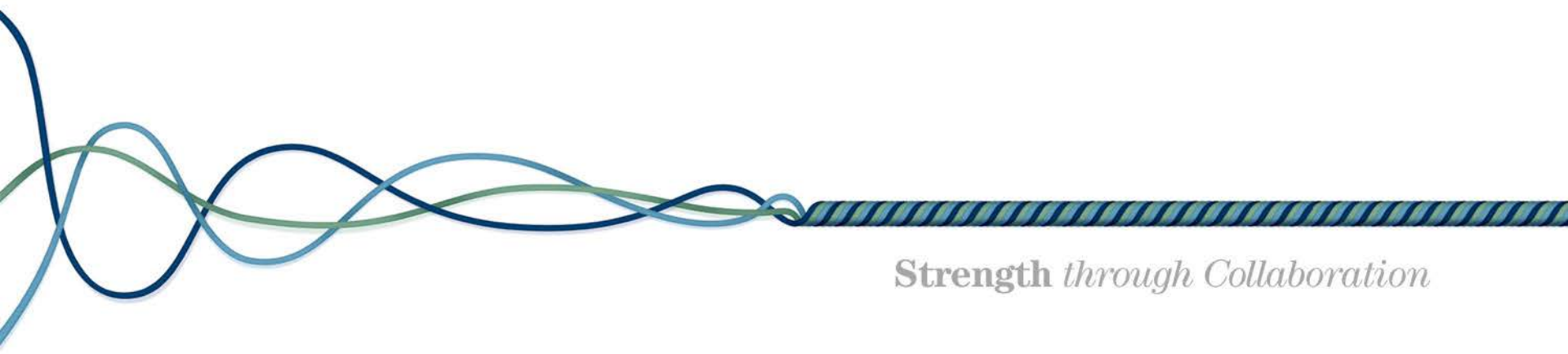
CDISC Public Webinar – Standards Updates and Additions

May 12 2016



Agenda

- RA TA Public Review
  - Mikenlette Avent, UCB
  - Trisha Simpson, UCB
  - Beth Seremula, Chiltern
  - Tatiana Sotingco, J&J
  - Kristin Kelly, Accenture
  - Dr. Benjamin Hsu, J&J
  - Erin Muhlbradt, NIH CVI
- CV Imaging TA Public Review
  - Amy Palmer, CDISC
  - Jordan Li, NIH
  - Rene Dahlheimer, CDISC
  - Abby Steen, NIH

Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

Mikenlette: Where are standards documents in the Wiki?

OR

RA Team: When can we start registering for the European Interchange?

Rheumatoid Arthritis Therapeutic Area User Guide

Public Review Education Webinar Presentation
May 12, 2016

Mikenlette Avent
Kristin Kelly
Erin Muhlbradt
Beth Seremula

Strength *through Collaboration*

CDISC

AGENDA

- *Introduction to Rheumatoid Arthritis*
- *TAUG Review Stage and Public Review Timeline*
- *Controlled Terminology*
- *Musculoskeletal System Findings (MK) Domain*
- *Analysis Data Model (ADaM)*

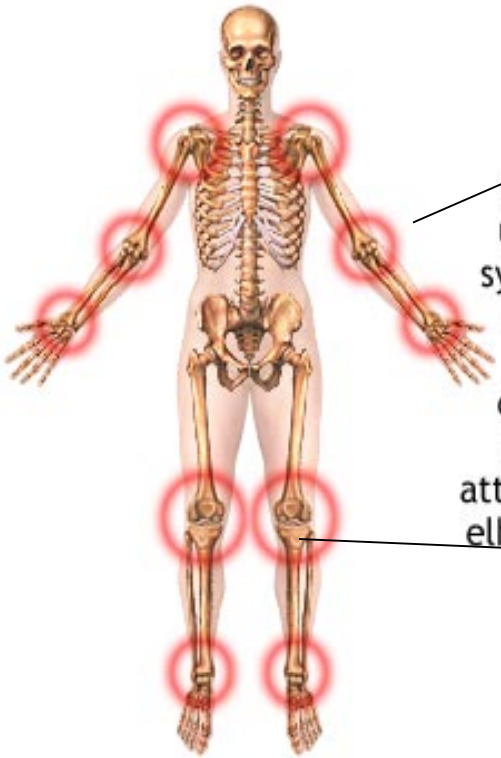
Introduction to Rheumatoid Arthritis

- Systemic, chronic, immune-mediated disease manifesting predominantly as arthritis
- Prevalence : ~1% of adult population
- Age of onset between 30 - 50 years
- 2- to 3-fold more common in women
- Higher mortality rates, shortens life span by 3 -18 years 50% disabled in 10 years
- 5% of ambulatory visits, >250,000 hospitalizations/year, Cost = $65 billion/year

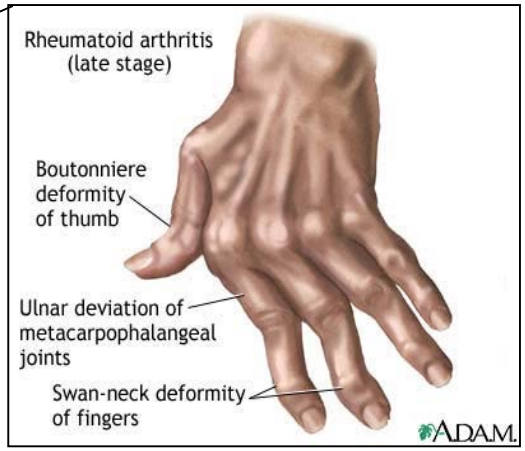
Koopman WJ, et. al. *Arthritis and Allied Conditions*. 1997; 13th ed.

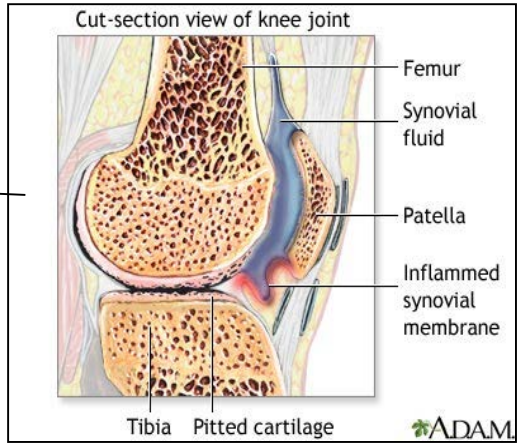
The Arthritis of RA

- Symmetric, erosive, joint inflammation [1]
- Often affects small joints in hands, wrist, feet
- Joint pain, stiffness, swelling, and limitations in physical functioning and motion [1]
- Disease progression → tissue damage, joint deformity, disability [2]



Rheumatoid arthritis usually affects joints symmetrically (on both sides equally), may initially begin in a couple of joints only, and most frequently attacks the wrists, hands, elbows, shoulders, knees and ankles





Sources: Images: http://www.nlm.nih.gov/MEDLINEPLUS/ency/imagepages/17130.htm
1) Decision Resources Rheumatoid Arthritis, June 2008, (2) NICE / NCCCC: Rheumatoid Arthritis: national clinical guideline for management and treatment in adults, Feb 2009

Introduction to Rheumatoid Arthritis

ACR 1987 Classification Criteria for Rheumatoid Arthritis

Patients must have four of seven criteria:

- Morning stiffness lasting at least 1 hour*
- Swelling in 3 or more joints*
- Swelling in hand joints*
- Symmetric joint swelling*
- Erosions or decalcification on X-ray of hand
- Rheumatoid nodules
- Abnormal serum rheumatoid factor (IgM anti-IgG)

*Must be present at least 6 Weeks

Introduction to Rheumatoid Arthritis

The Goals of RA Management- Modify the Course of Disease

- Eliminate pain/swelling
- Prevent or control joint damage
- Prevent loss of function
- Arrest disease progression= complete remission
- Maximize the quality of life for the patient

American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. *Arthritis Rheum.* 2002;46:328-346.

Public Review Information

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 addressed
- Anticipated Public Review Release date 13May2016
- Anticipated review comments closing date 12June 2016

Public Review

- Review Package Contents
  - Readme File
  - TAUG File
  - CDASH Metadata Excel File

- CDISC Public Comment Tracker
  - JIRA Account Creation => http://wiki.cdisc.org/signup.action
  - Location => http://wiki.cdisc.org/display/TARA/TAUG-RA
  - Instructions => http://wiki.cdisc.org/display/TARA/ReadMe+for+TAUG-RA

Controlled Terminology

Summary of Controlled Terminology Developed during the Rheumatoid Arthritis Project

Batch	Details	Status
1	•New codelist for MKTEST/MKTESTCD •New test values for MKTEST/MKTESTCD •New values for LOC •Changes to existing LOC terms	Public review. Will be published with P26 publication on 2016-06-24
2	•New test values for MKTEST/MKTESTCD	In development. Will be published with P27 publication on 2016-09-30

Controlled Terminology

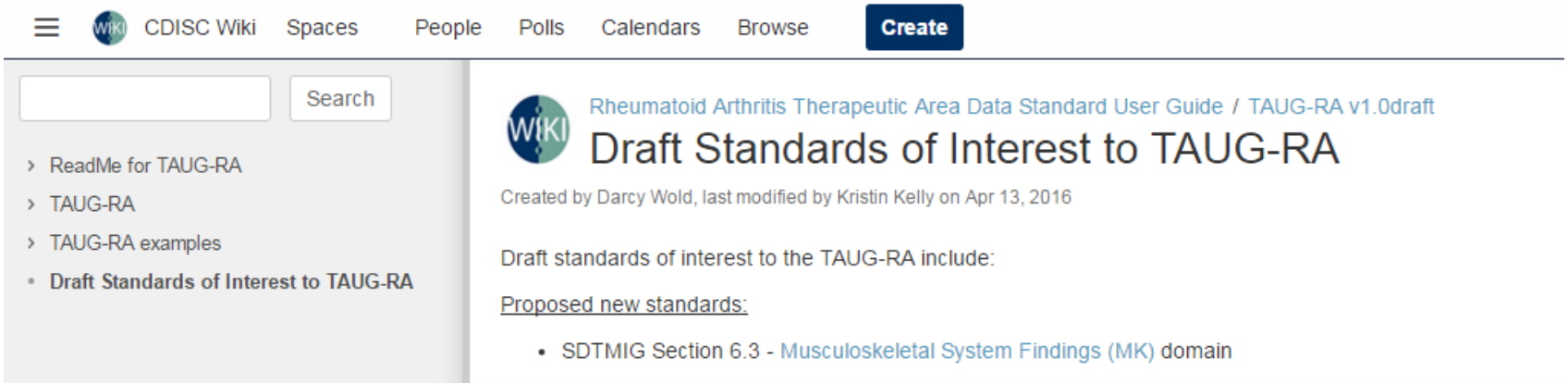
Summary of Questionnaires, Ratings, and Scales Controlled Terminology development status for the Rheumatoid Arthritis Project

Table 1 Identified QRS Measures of Interest to RA

Full Name and Abbreviation	Copyright Permission Status	Supplement Status
Patient Global Assessment of Disease Activity (PGA)	Public Domain	In progress
Physician Global Assessment of Disease Activity (PhysGA)	Public Domain	In progress
Patient Pain Assessment	Public Domain	In progress
Health Assessment Questionnaire-Disability Index (HAQ-DI)	Granted	In progress
SF-36 (Acute)	Denied	Will not be developed
FACIT-Fatigue Scale	Requested	
Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scale (BRAF-NRS)	Public Domain	In progress
Fatigue Severity Scale (FSS)	Granted	Done
MOS Sleep Scale-Revised (MOS Sleep-R) (v. 2010 Optum)	Requested from QRS Subteam	
EuroQOL EQ-5D	Granted	Done
Work Limitations Questionnaire	Denied	Will not be developed
Work Productivity and Activity Impairment (WPAI)	Public Domain	Done
Classification of Global Functional Status in Rheumatoid Arthritis	Granted	In progress

Domains

- New draft domain, MK (Musculoskeletal System Findings), proposed
  - Submitted to Standards Governance Committee (SGC) for approval to be published in a future version of the SDTMIG
  - Definition: A domain for morphological and physiological findings related to the system of muscles, tendons, ligaments, bones, joints and associated tissues.



Domain Examples

- Three aCRF and SDTM dataset examples in TAUG-RA v1.0

User Guide Section Number	Section Name	Examples	SDTM Domains used	Comments
3	Disease Assessments			
3.1	Swollen Joint Count/Tender Joint Count			
3.1.1	Swollen/Tender Joint Count Assessment	3.1 Example 1	MK	Example CRF 1
3.2	Radiographic and Other Imaging Assessments			
3.2.1	Joint Space Narrowing Assessment	3.2 Example 1	MK	Example CRF 1
3.2.2	Bone Erosion Assessment	3.2 Example 2	MK	Example CRF 2

* No new variables proposed for this TAUG

Swollen/Tender Joint Count

Swollen/Tender Joint Count Assessment

Complete assessment of each joint on one side/laterality before beginning assessment for the other side of the body.

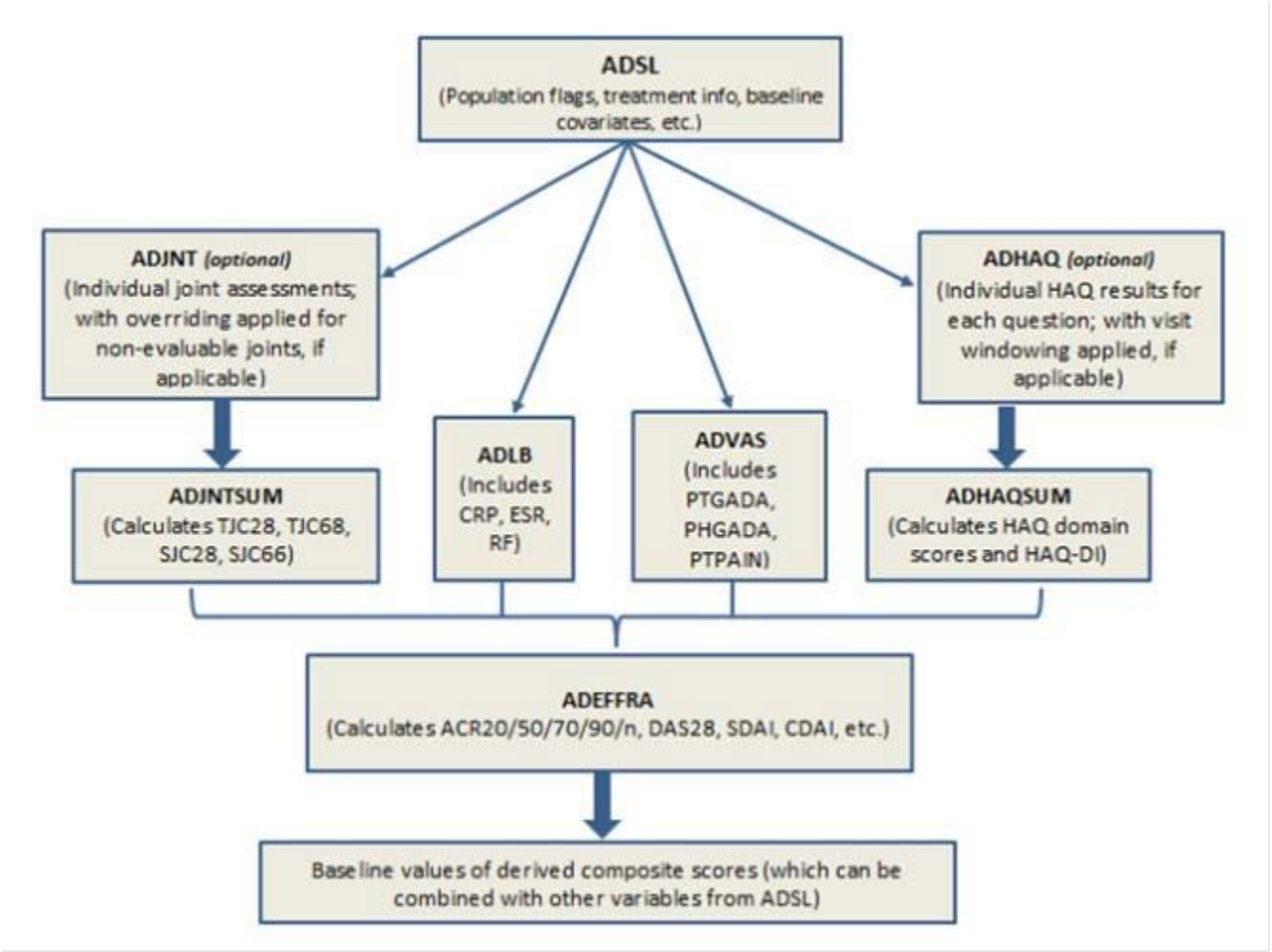
Date of Collection: (DD-MMM-YYYY) MKDTC MKDAT — _ _ / _ _ _ / _ _ _ _

Laterality: MKLAT — O Right O Left

		Tender (MKTESTCD = TNDRIND and MKTEST = Tenderness Indicator)			Swollen (MKTESTCD = SWLLRIND and MKTEST = Swollen Indicator)		
JOINT LOCATION	**Joint Not Evaluable** (MKSTAT = NOT DONE WHEN MKTESTCD = TNDRIND AND MKTESTCD = SWLLIND; MKREASND = JOINT NOT EVALUABLE)	**YES** MKORRES	**NO** MKORRES	**Not Done** MKSTAT = NOT DONE	**YES** MKORRES	**NO** MKORRES	**Not Done** MKSTAT = NOT DONE
UPPER BODY							
Temporomandibular (MKLOC = TEMPOROMANDIBULAR JOINT)	O	O	O	O	O	O	O

MKTESTCD	MKTEST	MKORRES	MKSTRESC	MKSTRESN	MKSTAT	MKREASND	MKLOC	MKLAT	VISITNUM	MKDTC
TNDRIND	Tenderness Indicator	Y	Y				TEMPOROMANDIBULAR JOINT	RIGHT	1	2012-09-30
SWLLIND	Swollen Indicator	Y	Y				TEMPOROMANDIBULAR JOINT	RIGHT	1	2012-09-30
TNDRIND	Tenderness Indicator	N	N				TEMPOROMANDIBULAR JOINT	LEFT	1	2012-09-30
SWLLIND	Swollen Indicator	N	N				TEMPOROMANDIBULAR JOINT	LEFT	1	2012-09-30
TNDRIND	Tenderness Indicator				NOT DONE	NOT EVALUABLE	ACROMIOCLAVICULAR JOINT	RIGHT	1	2012-09-30
SWLLIND	Swollen Indicator				NOT DONE	NOT EVALUABLE	ACROMIOCLAVICULAR JOINT	RIGHT	1	2012-09-30

Analysis Dataset – Section Overview

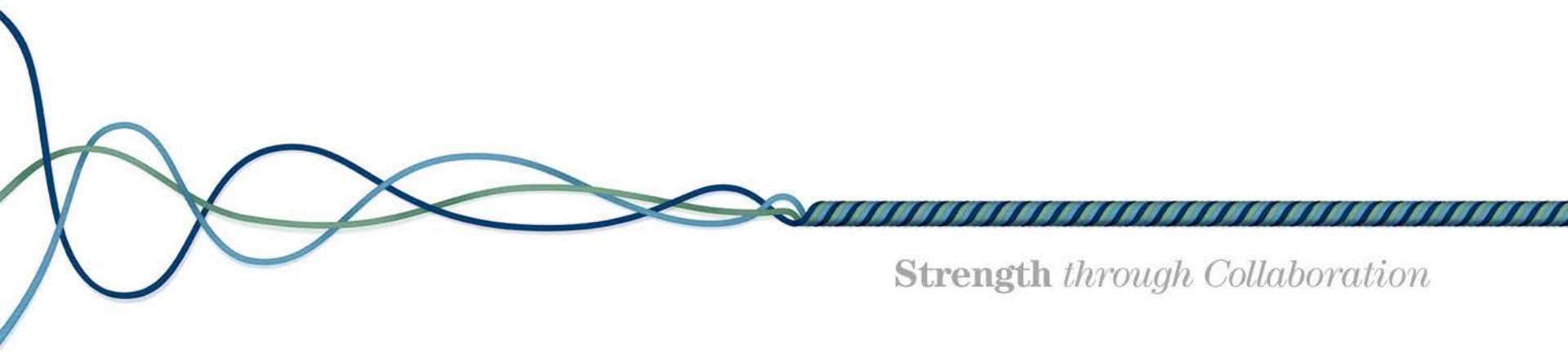


Analysis Data – Points of Note

- Important subject level variables that would typically appear in ADSL are shown.
- An approach of using BDS-based intermediate datasets is shown. These intermediate datasets assemble all information that is used for the derivation of composite efficacy endpoints.
- As with other TAUGs, these are examples of ADaM implementation and should not be interpreted as standard in and of themselves. Statistical methodology is not discussed.

CV Imaging Therapeutic Area User Guide v1.0, Public Review

Presented by Amy Palmer, CDISC, Jordan Li, NCI EVS, and Rene Dahlheimer, CDISC



Project Background

- The purpose of the CV Imaging Therapeutic Area User Guide is to describe how to use CDISC standards to represent data pertaining to cardiovascular (CV) imaging.
- This first version (v1.0) focuses on the representation of CV data from transthoracic echocardiography (TTE); it uses the Study Data Tabulation Model (SDTM).
- CDASH and ADaM were not in scope for this version of the CV Imaging TA User Guide.

Transthoracic Echocardiography

- The most commonly performed type of echocardiogram is a transthoracic echocardiogram (TTE), which is an ultrasound based method of detecting cardiovascular diseases or other abnormalities of the heart and its supporting structures. Using sound waves, TTE produces images that reveal both the structure and active functioning of the heart and cardiac vessels.
- The User Guide includes both patient-centered and researcher-oriented references in lieu of extensive clinical language.

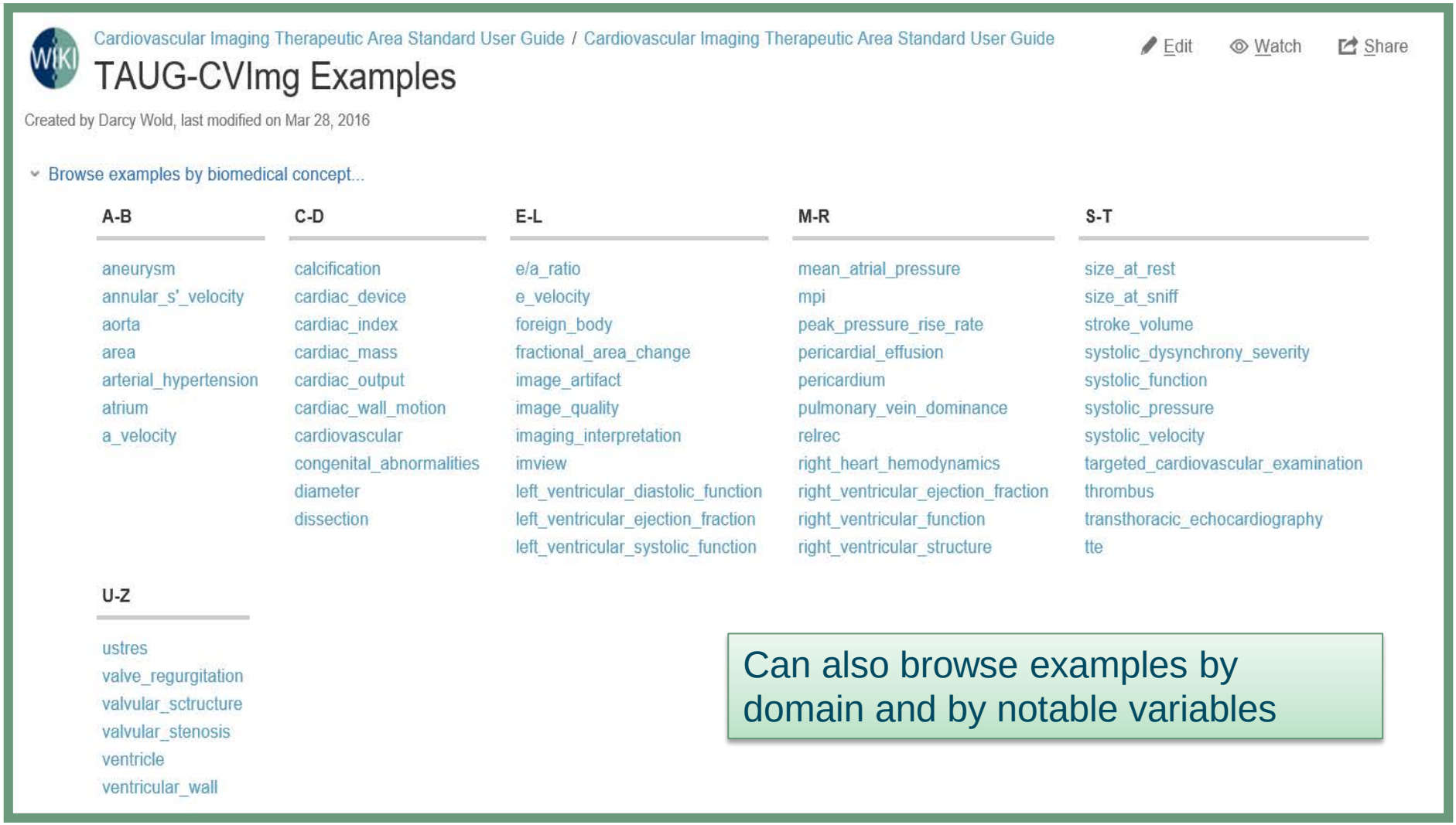
Link to the Resource Page:

- http://wiki.cdisc.org/display/TACVI/Transthoracic+Echocardiography

Concepts Covered

- Transthoracic Echocardiography Procedure
- Assessments
  - Atrial and Ventricular Structure and Function
  - Right Heart Hemodynamics
  - Pericardium and Arteries
  - Valvular Structure and Function
    - Valvular Structure
    - Valvular Regurgitation
    - Valvular Stenosis
  - Cardiac Mass and Thrombus
  - Congenital Abnormalities
  - Observed Cardiac Devices and Foreign Bodies

Concepts Covered



Cardiovascular Imaging Therapeutic Area Standard User Guide / Cardiovascular Imaging Therapeutic Area Standard User Guide

Edit Watch Share

TAUG-CVImg Examples

Created by Darcy Wold, last modified on Mar 28, 2016

Browse examples by biomedical concept...

A-B

aneurysm
annular_s'_velocity
aorta
area
arterial_hypertension
atrium
a_velocity

C-D

calcification
cardiac_device
cardiac_index
cardiac_mass
cardiac_output
cardiac_wall_motion
cardiovascular
congenital_abnormalities
diameter
dissection

E-L

e/a_ratio
e_velocity
foreign_body
fractional_area_change
image_artifact
image_quality
imaging_interpretation
imview
left_ventricular_diastolic_function
left_ventricular_ejection_fraction
left_ventricular_systolic_function

M-R

mean_atrial_pressure
mpi
peak_pressure_rise_rate
pericardial_effusion
pericardium
pulmonary_vein_dominance
relrec
right_heart_hemodynamics
right_ventricular_ejection_fraction
right_ventricular_function
right_ventricular_structure

S-T

size_at_rest
size_at_sniff
stroke_volume
systolic_dysynchrony_severity
systolic_function
systolic_pressure
systolic_velocity
targeted_cardiovascular_examination
thrombus
transthoracic_echocardiography
tte

U-Z

ustres
valve_regurgitation
valvular_sctructure
valvular_stenosis
ventricle
ventricular_wall

Can also browse examples by domain and by notable variables

Draft Standards of Interest

Draft standards of interest to the TAUG-CVImg include:

- SDTMIG Section 6.1 - Procedure Agents (AG) domain
  - First used in the Diabetes TA
- SDTMIG Section 6.3 - Cardiovascular System Findings (CV) domain
  - Part of Batch 3 for SDTMIG v3.3; it will be posted for Public Review shortly.
- SDTMIG Section 8.4.4, Alternative Representation of Non-Standard Variables

Example – Heart Chamber Measurements – use of Device Domains to Represent Ultrasound Mode

DOMAIN	USUBJID	SPDEVID	CVSEQ	CVLNKID	CVTESTCD	CVTEST	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVLOC
CV	001-1002	ABC001	1		SIZE	Size	NORMAL		NORMAL			HEART, RIGHT ATRIUM
CV	001-1002	ABC001	2		MNDIAEVS	Minor Axis Cross-sec. Diameter, EVS	4.0	cm	4.0	4.0	cm	HEART, RIGHT ATRIUM
CV	001-1002	ABC001	3		AREAEVS	Area, End Ventricular Systole	17	cm2	17	17	cm2	HEART, RIGHT ATRIUM
CV	001-1002	ABC001	4	1	VOLEVS	Volume, End Ventricular Systole	40	mL	40	40	mL	HEART, LEFT VENTRICLE
CV	001-1002	ABC001	5		MNDIAEVS	Minor Axis Cross-sec. Diameter, EVS	4.0	cm	4.0	4.0	cm	HEART, LEFT VENTRICLE
CV	001-1002	ABC001	6		MNDIAEVD	Minor Axis Cross-sec. Diameter, EVD	5.0	cm	5.0	5.0	cm	HEART, LEFT VENTRICLE

Example – Heart Chamber Measurements – use of Device Domains to Represent Ultrasound Mode

A typical echocardiography machine has numerous modes, each of which has its own specific use and purpose. The DU domain example demonstrates that for this specific echocardiography machine, M-mode (Motion-mode) is selected. This DU record is linked to the CV example record in Row 4 via CVLNKID, which indicates that the volume of the left ventricle is determined by selecting the M-mode on the echocardiography machine.

The different mode choices for echocardiography include, but are not limited to, the following: M-mode, 2-Dimentional Mode, 3-Dimentional Mode, Biplane Area Length Mode, Tissue Doppler Mode, and Pulsed-wave Doppler Mode. A controlled terminology codelist may be developed for the various ultrasound modes.

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DULNKID	DUTESTCD	DUTEST	DUORRES	DUORRESU	DUSTRESC	DUMETHOD
1	ABC123	DU	001-1002	ABC001	1	1	ULTRMODE	ULTRASOUND MODE	M-Mode		M-Mode	TRANSTHORACIC ECHOCARDIOGRAPHY

Example – Cardiac Mass and Thrombus – use of --RESTRG

Variable Name	Variable Label	Type	Role	Description
--RESTRG	Prespecified Result Targeted by Test	Char	Variable Qualifier	Describes the result targeted by the test identified in TESTCD. Used when the measurement, test, or examination indicates the presence or absence of a prespecified result value. The value of --ORRES should indicate whether the prespecified result value was found to be present, not present, or not determined.

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVCAT	CVRESTRG	CVORRES	CVSTRESC	CVLOC
1	ABC123	CV	001-1002	1	TGCVEXAM	Targeted Cardiovascular Examination	CARDIAC MASS OR THROMBUS	Thrombus	PRESENT	PRESENT	HEART, RIGHT VENTRICLE
2	ABC123	CV	001-1002	2	TGCVEXAM	Targeted Cardiovascular Examination	CARDIAC MASS OR THROMBUS	Thrombus	PRESENT	PRESENT	HEART, LEFT ATRIUM
3	ABC123	CV	001-1002	3	TGCVEXAM	Targeted Cardiovascular Examination	CARDIAC MASS OR THROMBUS	Mass	ABSENT	ABSENT	INFERIOR VENA CAVA
4	ABC123	CV	002-2004	1	CVEXAM	Cardiovascular Examination	CARDIAC MASS OR THROMBUS		THROMBUS	THROMBUS	AORTA
5	ABC123	CV	002-2004	2	CVEXAM	Cardiovascular Examination	CARDIAC MASS OR THROMBUS		MASS	MASS	HEART, LEFT ATRIAL APPENDAGE

Example – Valvular Stenosis – use of Device Domains for Prosthetic Valve

cv.xpt

Row 1: Shows the measurement of effective orifice area (EOA) for the aortic valve.
Row 2: Shows the measurement of effective orifice area index which is calculated by dividing the effective orifice area (Row 1) by the Body Surface Area.
Row 3: Shows the measurement of performance index of the prosthetic valve which is calculated by dividing the effective orifice area (Row 1) by the internal orifice area (Device Properties (DO) domain Row 2) of the manufactured prosthesis. The --LNKID variable shows the relationship of the CV tests to the prosthetic valve in the DO domain.

D	CVSEQ	CVLNKID	CVTESTCD	CVTEST	CVSCAT	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVLOC	CVMETHOD
	1		EOA	Effective Orifice Area	VALVULAR STENOSIS	2.3	cm^2	2.3	2.3	cm^2	AORTIC VALVE	TRANSTHORACIC ECHOCARDIOGRAPHY
	2		EOAINDEX	Effective Orifice Area Index	VALVULAR STENOSIS	1.43	cm^2/m^2	1.43	1.43	cm^2/m^2	AORTIC VALVE	TRANSTHORACIC ECHOCARDIOGRAPHY
99	3	1	PERINDEX	Performance Index	VALVULAR STENOSIS	0.575		0.575	0.575		AORTIC VALVE	TRANSTHORACIC ECHOCARDIOGRAPHY

Example – Valvular Stenosis – use of Device Domains for Prosthetic Valve

The DI domain example demonstrates that the device found is a prosthetic valve.

di.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	ABC123	DI	VALVE999	1	DEVTYPE	Device Type	PROSTHETIC VALVE

The DO records below show the type and the internal office area of the prosthetic cardiac valve found at the aortic valve. Both records provide a link to the result shown in the CV domain example above.

do.xpt

Row 1: Shows the type of the prosthetic cardiac valve found in the aortic valve is mechanical.

Row 2: Shows the internal office area of the said prosthetic cardiac valve. The result of this measurement is used to calculate 'performance index' in CV domain Row 3; this DO record is linked via the --LIKID variable to the CV domain record.

DOMAIN	USUBJID	SPDEVID	DOSEQ	DOLNKID	DOTESTCD	DOTEST	DOORRES	DOORRESU	DOSTRESC	DOSTRESN	DOSTRESU	DOLOC	VISIT
DO	001-1002	VALVE999	1		PRCAVATY	Prosthetic Cardiac Valve Type	PROSTHETIC MECHANICAL		PROSTHETIC MECHANICAL			AORTIC VALVE	
DO	001-1002	VALVE999	2	1	INTEROA	Internal Orifice Area	400	mm^2	4	4	cm^2	AORTIC VALVE	

Controlled Terminology

- Summary of Controlled Terminology Developed during the CV Imaging Project

Batch	Details	# of Terminology	Status
1-3	▪ New TEST terminology for CV ▪ New values for LOC, METHOD	▪ CVTEST-CD: 71 ▪ LOC: 48 ▪ METHOD: 5	▪ Will be released with P26 publication on 2016-06-24
4	▪ New TEST terminology for CV and DU ▪ New response terminology for DU ▪ New values for LOC	▪ CVTEST-CD:43 ▪ DUTEST-CD: 1 ▪ DU response terms: 10 ▪ LOC: 4	▪ Will be submitted to CV terminology team for review ▪ Scheduled for P27 public review and official release on 2016-09-30

Controlled Terminology Philosophy

- In general, for best terminology practice, as well as to encourage reusability of a TEST value, TESTs are created *without* specifying an anatomical location within the TEST name. This enables a TEST to *post-coordinate* and be used with different anatomical structures captured by the --LOC variable.

CVTESTCD	CVTEST	CVCAT	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVLOC	CVMETHOD
ANNAVEL	Annular a' Velocity	LEFT VENTRICULAR DIASTOLIC FUNCTION	10.7	cm/s	10.7	10.7	cm/s	MITRAL VALVE, ANTERIOR ANNULUS	TRANSTHORACIC ECHOCARDIOGRAPHY
ANNAVEL	Annular a' Velocity	LEFT VENTRICULAR DIASTOLIC FUNCTION	11	cm/s	11	11	cm/s	MITRAL VALVE ANNULUS	TRANSTHORACIC ECHOCARDIOGRAPHY
ANNEVEL	Annular e' Velocity	LEFT VENTRICULAR DIASTOLIC FUNCTION	7.5	cm/s	7.5	7.5	cm/s	MITRAL VALVE, ANTERIOR ANNULUS	TRANSTHORACIC ECHOCARDIOGRAPHY
ANNEVEL	Annular e' Velocity	LEFT VENTRICULAR DIASTOLIC FUNCTION	11.5	cm/s	11.5	11.5	cm/s	MITRAL VALVE ANNULUS	TRANSTHORACIC ECHOCARDIOGRAPHY

Controlled Terminology Philosophy

However, sometimes the CVLOC variable is not populated, requiring a *pre-coordinated*, anatomical location-specific CVTEST to be created. This occurs when at least one of the following conditions is met:

- The CVTEST is a measurement that involves multiple, continuous, or undistinguishable anatomical locations;
- The CVLOC variable is unable to support the mathematical locational relationship presented by the corresponding CVTEST concept.

CVTESTCD	CVTEST	CVCAT	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVLOC
LVEFEST	Left Ventricular Ejection Fraction, Est	LEFT VENTRICULAR SYSTOLIC FUNCTION, OVERALL	55	%	55	55	%	
LVEFCALC	Left Ventricular Ejection Fraction, Cal	LEFT VENTRICULAR SYSTOLIC FUNCTION, OVERALL	48	%	48	48	%	
LVOTPVEL	LVOT Peak Velocity	LEFT VENTRICULAR SYSTOLIC FUNCTION, OVERALL	80	m/sec	80	80	m/sec	
MITRALEE	Mitral E/e´ Ratio	LEFT VENTRICULAR DIASTOLIC FUNCTION	7.5		7.5	7.5		

For More Controlled Terminology Information

- Please see Section 3.7 in the CV Imaging TAUG

http://wiki.cdisc.org/display/TACVI/Cardiovascular+Imaging+Controlled+Terminology

CV Imaging TA User Guide Public Review

- 30-day Public Review planned to start soon!
- Public Review will be in the CDISC WIKI, and comments should be entered in JIRA.
- Any questions during the review should be directed to Amy Palmer at apalmer@cdisc.org

How to Provide Comments Using the WIKI and JIRA (slide 1)

- Comments regarding ~~the~~ content, either present or missing, on a page should be captured in JIRA.
- Click on the following link: http://jira.cdisc.org/projects/CVIMAG to enter any issues.
  - Note: Keeping JIRA open in a separate window to capture comments is easier than navigating between the Wiki and JIRA.

How to Provide Comments Using the WIKI and JIRA (slide 2)

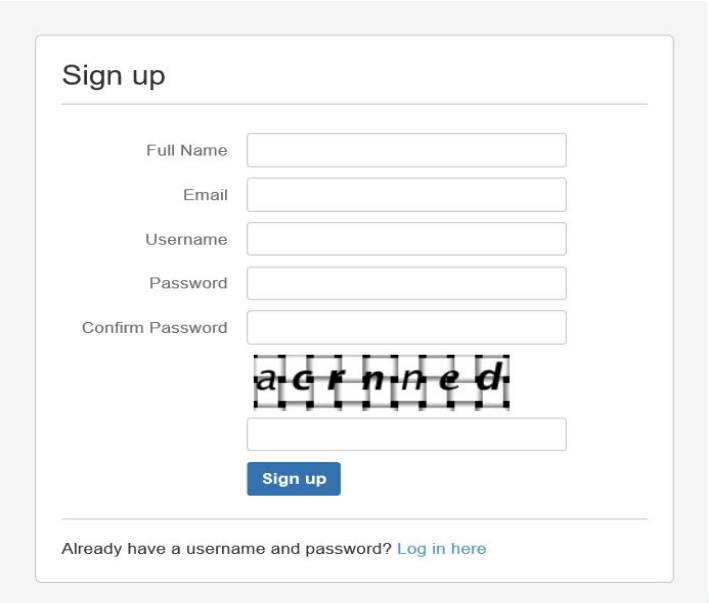
- Click on the "Create" button in the top menu to open the Create Issue form.
- Make sure the issue type is set to "Review Comments".
- Complete the form.
  - Provide a short summary of your comment in the "Summary" field.
  - Enter your comment and any additional details in the "Description". Please be thorough in your explanation, as this helps the team address your comment properly.
- To submit, Click the "Create" button in the bottom right corner of the form.

How to Provide Comments Using the WIKI and JIRA (slide 3)

- To add a JIRA issue directly from the page, select the text to which you wish to attach the comment. After a moment, a small contextual menu should appear.
  - Within the contextual menu, click on the icon that looks like an X (as shown to right). This will trigger a dialogue box containing the JIRA Issue Creation Form.
  - Complete the form and click "Create" to create your comment as an issue.
    - The page should automatically update with your comment inserted in place.
    - In case of technical difficulties, please make sure to provide a brief description of the context of your comment, so that the team can address it properly.

Signing up for the WIKI and JIRA

- Sign Up for WIKI/JIRA (or login if you already have an account) to get access to documents undergoing Public Review in CDISC WIKI and to comment in CDISC JIRA. Instructions for providing feedback are provided on the landing page for each document. **You only need one account to access both WIKI and JIRA.**
- http://wiki.cdisc.org/signup.action



Q&A

Any more questions?

Thank you for attending this webinar.

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