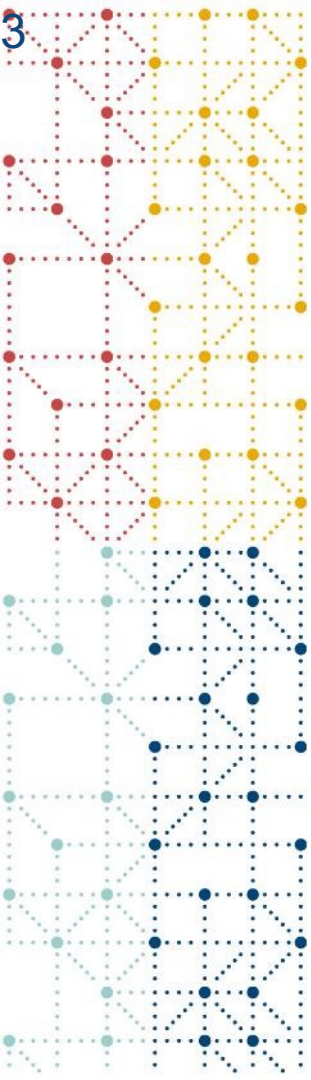
Pediatrics User Guide Public Review

Becca Leary, c4c Senior Project Manager, The John Walton Muscular Dystrophy Research Centre
Richard Marshall, Lead Developer, CDISC
John Owen, Head PMO, CDISC

Tuesday, 12 July
11:00AM – 12:30PM US ET

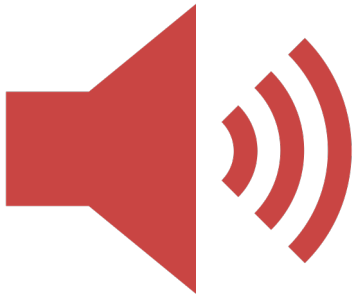
Today's Agenda

1. Housekeeping
2. Speaker Introduction
3. Feature Presentation
4. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping

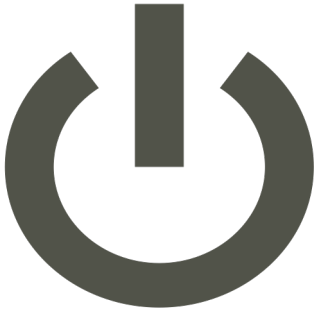


You will remain on **mute**

Housekeeping

Submit questions at any time via the Questions tool on your Zoom app

Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping

A recording of this webinar and the slides will be available in the **Public Webinar Archive.** Check under the “Events” tab on the CDISC homepage.

Our Presenters

Becca Leary c4c Senior Project Manager The John Walton Muscular Dystrophy Research Centre	**Richard Marshall** Lead Developer CDISC
John Owen Head PMO CDISC	

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Introduction to conect4children (c4c)

Becca Leary (UNEW)

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389.
The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

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Impact of challenges

- Poor feasibility
- Inexperienced staff
- Fragmented approach
- Poor study design
- Inefficient use of resources

Leading to poor quality, delayed, or even failed trails

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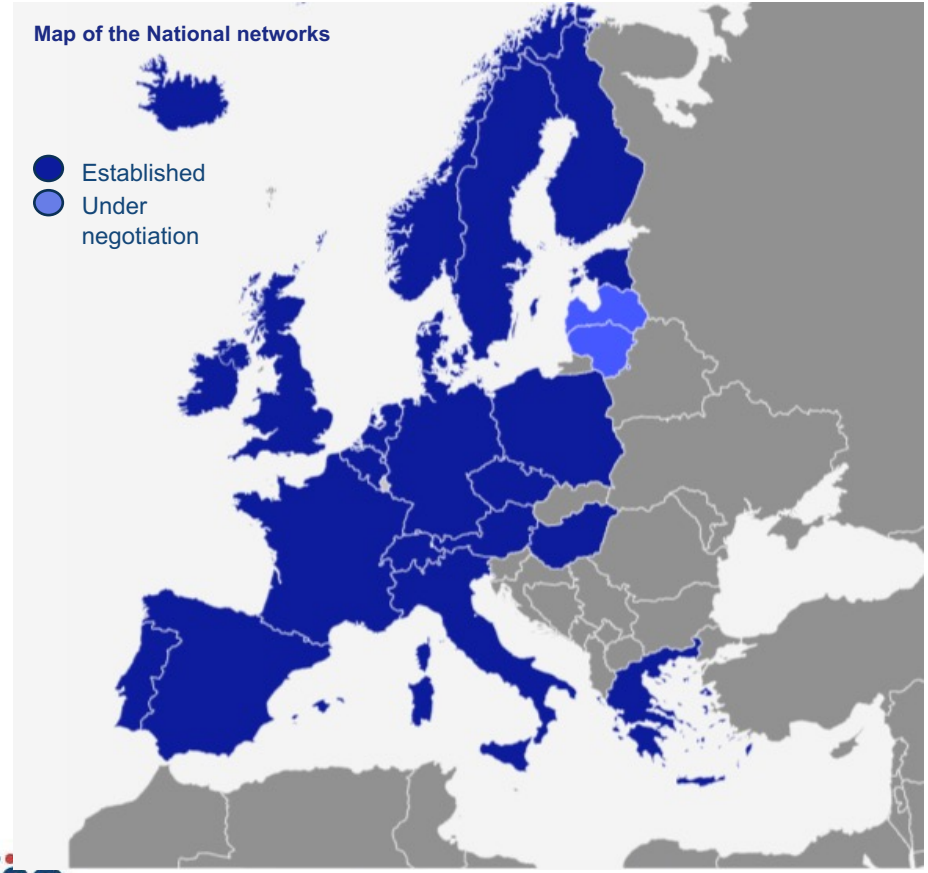
Vision

Better medicines for babies, children and young people through a pan-European clinical trial network

Private-public partnership between Academia and Pharma

The c4c Consortium members



- 10 EFPIA companies
- 20 paediatric national hubs established (Iceland & Finland are joined networks)
- 2 paediatric national networks under negotiation
- 2 large patient advocacy groups
- 8 EU multinational specialty networks
- 3 global research networks
- Total number of sites - 240

To know more about the c4c Consortium visit: www.conect4childen.org

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Version 2.0

Data standardization and Harmonization

- Scarce data
- Share-ability
- Potential future reuse

- Data standards
- Harmonization of terminology
- Data dictionary

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Paediatrics User Guide

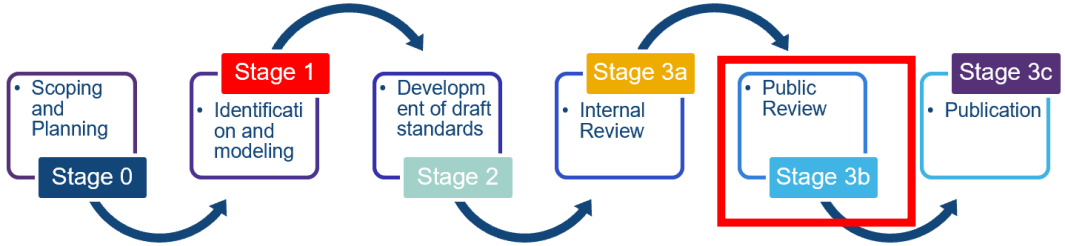
Collaboration

Pediatrics UG – Public Review Webinar

Presented by
John Owen, Head PMO, CDISC
Richard Marshall, Standards Lead, CDISC

12th July 2022

Timelines



CDISC Standards Development Process (COP-001)

2020	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG												

2021	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 0							Stage 1	W1	Stage 2		

2022	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 2			Stage 3a		W2		Stage 3b			Stage 3	W3

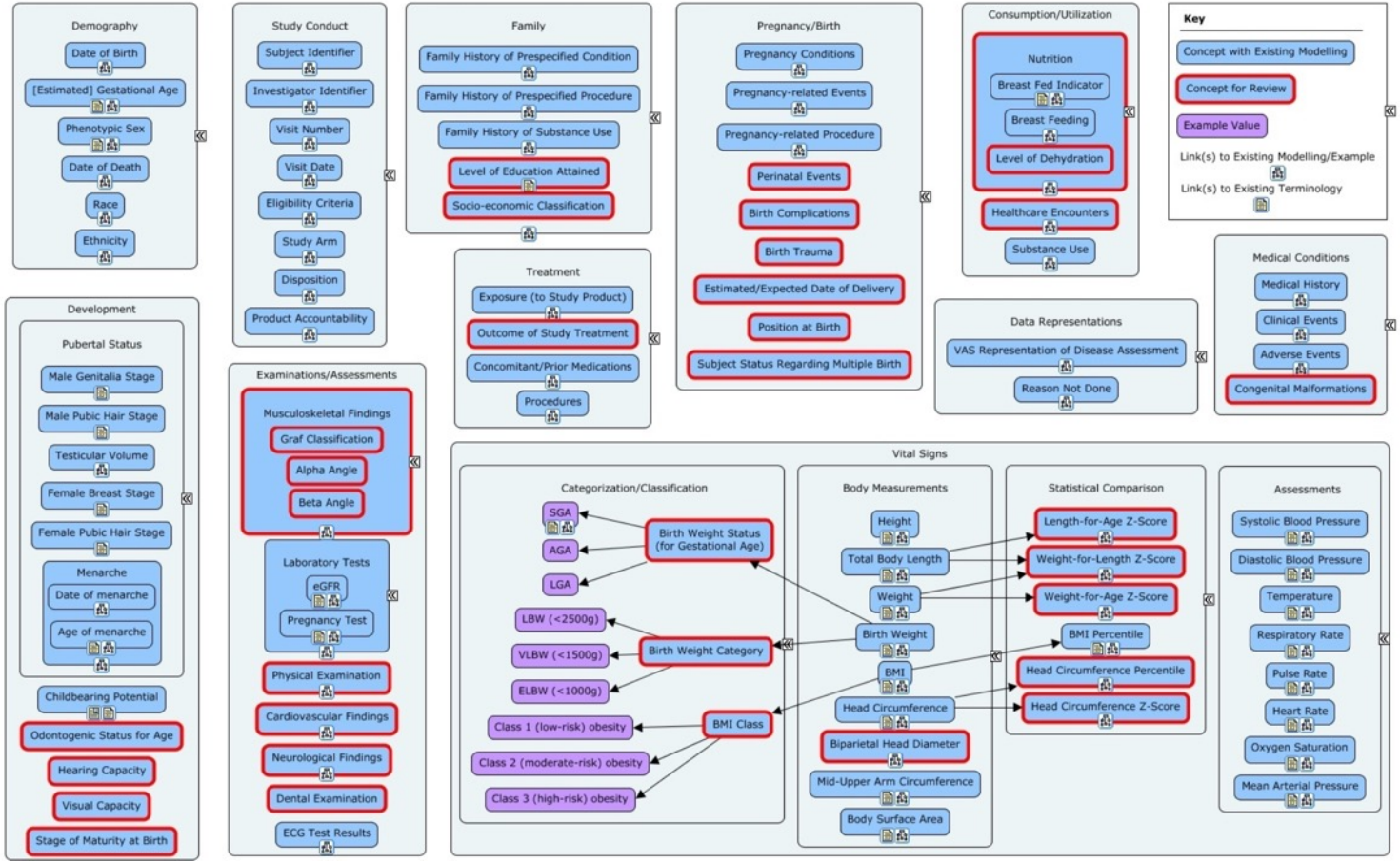
Stage 0	Scoping and Planning
Stage 1	Identification/Modeling of Concepts
Stage 2	Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

TAUG Deliverable Feb 2023 (M58)
Submission required April 2023 (M60)

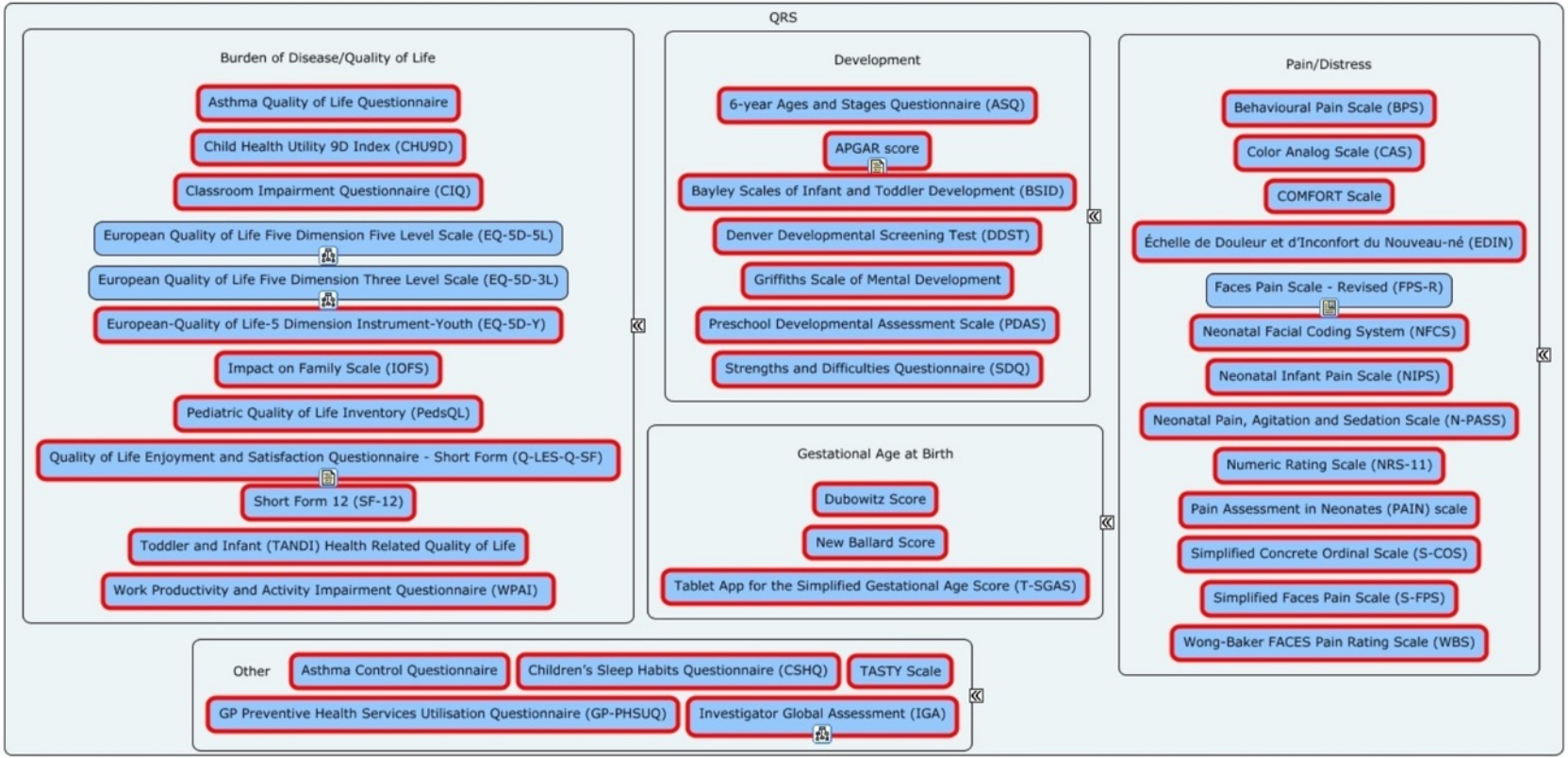
Scoping, Modeling and Standards Development

CDISC formed a cross-functional team with pediatric SMEs from the c4c consortium and CDISC volunteers

Identified pediatric cross-cutting concepts related to pediatric clinical trials



QRS Instruments



Standards Development

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Data Standards User Guide for Pediat

Version 1.0 (Draft)

Prepared by the
Pediatrics Standards Development Team

Notes to Readers

- This is the draft version 1.0 of the Data Standards User Guide for Pediatrics. It is intended for Internal R
- This document is based on CDASH Model v1.2, CDASH-IG v2.2, SDTM v2.0, SDTMIG v3.4, SDTMIG-AP v

Revision History

Date	Version
2022-03-01	Draft

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreemen
the European Union's Horizon 2020 research and innovation programme and EFPIA. CDISC would like to recogn
consortium in development of this user guide.

conect 4children

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Appendix B: Glossary and Abbreviations
Appendix C: Non-Standard Variables (NSVs)
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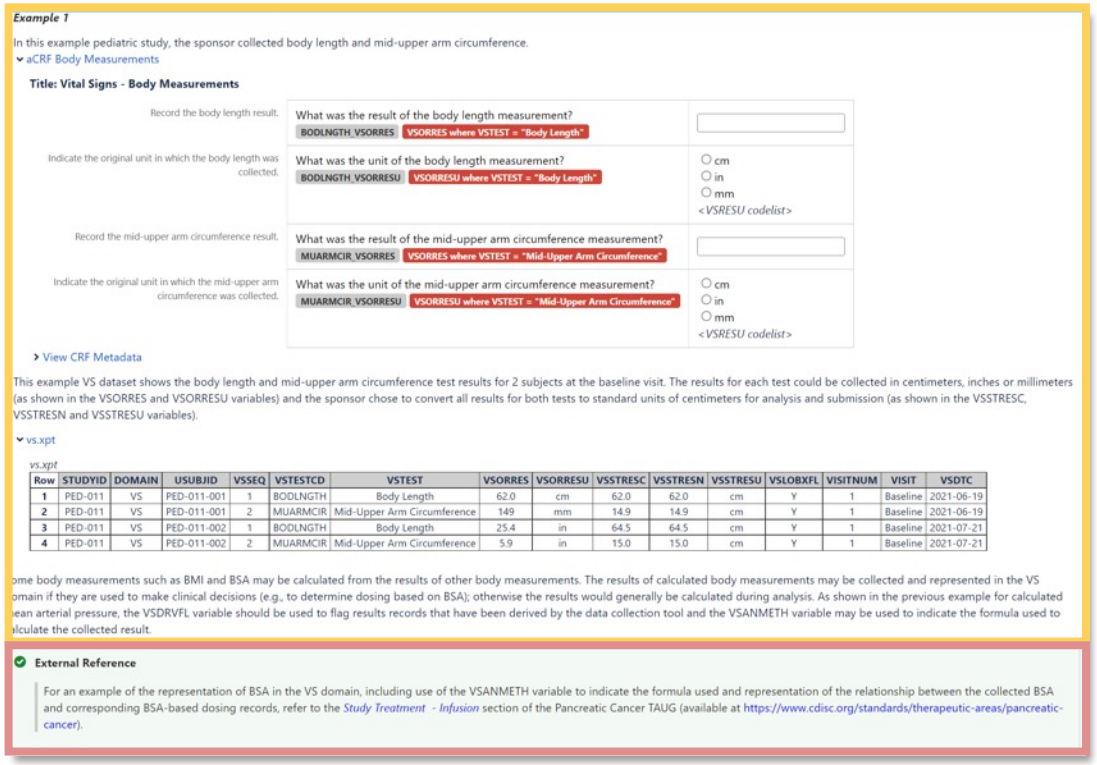
Appendix E: Representations and Warranties, Limitations of Liability, and Disclaimers

Standards Development

- Develop CDASH CRFs and SDTM Table examples for new concepts

- Links to existing examples of data collection (CDASH) and Data Tabulation (SDTM)



Example 1

In this example pediatric study, the sponsor collected body length and mid-upper arm circumference.

aCRF Body Measurements

Title: Vital Signs - Body Measurements

Record the body length result.	What was the result of the body length measurement? BODLNGTH_VSORRES VSORRES where VSTEST = "Body Length"	
Indicate the original unit in which the body length was collected.	What was the unit of the body length measurement? BODLNGTH_VSORRESU VSORRESU where VSTEST = "Body Length"	○ cm ○ in ○ mm <*VSRESU codelist*>
Record the mid-upper arm circumference result.	What was the result of the mid-upper arm circumference measurement? MUARMCIR_VSORRES VSORRES where VSTEST = "Mid-Upper Arm Circumference"	
Indicate the original unit in which the mid-upper arm circumference was collected.	What was the unit of the mid-upper arm circumference measurement? MUARMCIR_VSORRESU VSORRESU where VSTEST = "Mid-Upper Arm Circumference"	○ cm ○ in ○ mm <*VSRESU codelist*>

View CRF Metadata

This example VS dataset shows the body length and mid-upper arm circumference test results for 2 subjects at the baseline visit. The results for each test could be collected in centimeters, inches or millimeters (as shown in the VSORRES and VSORRESU variables) and the sponsor chose to convert all results for both tests to standard units of centimeters for analysis and submission (as shown in the VSSTRESC, VSSTRESN and VSSTRESU variables).

vs.xpt

vs.xpt

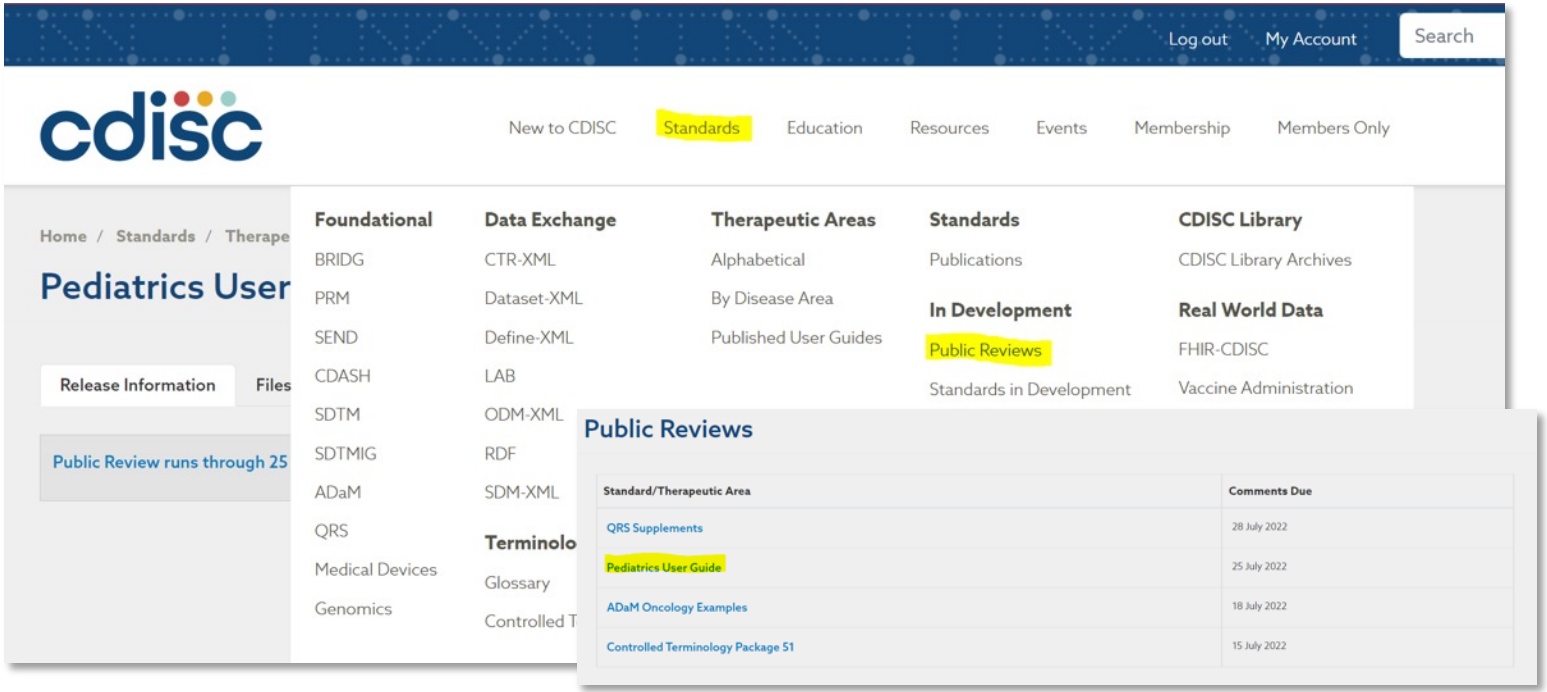
Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSLOBXFL	VISITNUM	VISIT	VSDTC
1	PED-011	VS	PED-011-001	1	BODLNGTH	Body Length	62.0	cm	62.0	62.0	cm	Y	1	Baseline	2021-06-19
2	PED-011	VS	PED-011-001	2	MUARMCIR	Mid-Upper Arm Circumference	149	mm	14.9	14.9	cm	Y	1	Baseline	2021-06-19
3	PED-011	VS	PED-011-002	1	BODLNGTH	Body Length	25.4	in	64.5	64.5	cm	Y	1	Baseline	2021-07-21
4	PED-011	VS	PED-011-002	2	MUARMCIR	Mid-Upper Arm Circumference	5.9	in	15.0	15.0	cm	Y	1	Baseline	2021-07-21

ome body measurements such as BMI and BSA may be calculated from the results of other body measurements. The results of calculated body measurements may be collected and represented in the VS omain if they are used to make clinical decisions (e.g., to determine dosing based on BSA); otherwise the results would generally be calculated during analysis. As shown in the previous example for calculated ean arterial pressure, the VSDRVFL variable should be used to flag results records that have been derived by the data collection tool and the VSANMETH variable may be used to indicate the formula used to lculate the collected result.

External Reference

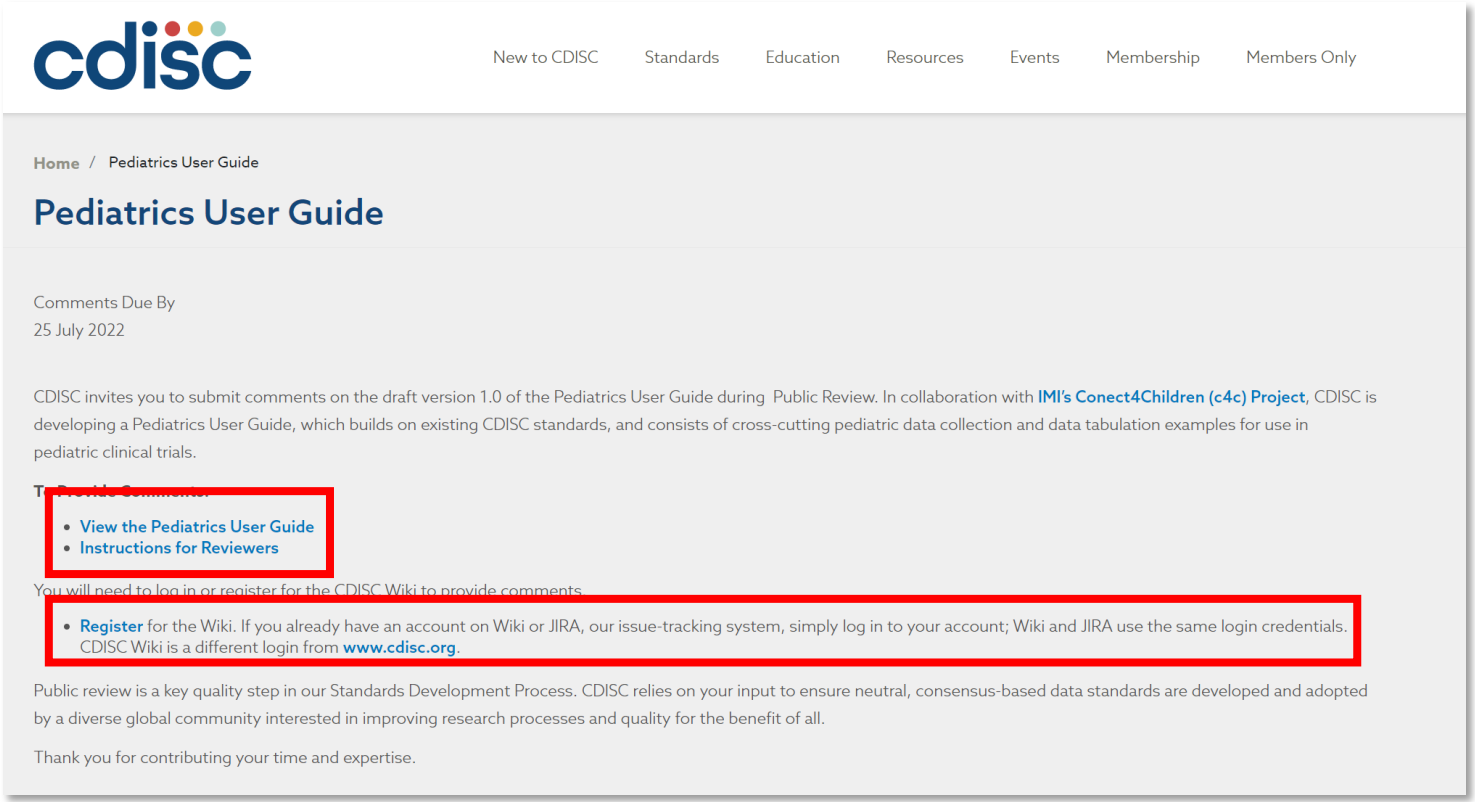
For an example of the representation of BSA in the VS domain, including use of the VSANMETH variable to indicate the formula used and representation of the relationship between the collected BSA and corresponding BSA-based dosing records, refer to the *Study Treatment - Infusion* section of the Pancreatic Cancer TAUG (available at https://www.cdisc.org/standards/therapeutic-areas/pancreatic-cancer).

Public review links



https://www.cdisc.org/

Public review links



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Home / Pediatrics User Guide

Pediatrics User Guide

Comments Due By
25 July 2022

CDISC invites you to submit comments on the draft version 1.0 of the Pediatrics User Guide during Public Review. In collaboration with **IMI's Conect4Children (c4c) Project**, CDISC is developing a Pediatrics User Guide, which builds on existing CDISC standards, and consists of cross-cutting pediatric data collection and data tabulation examples for use in pediatric clinical trials.

To Provide Comments:

- View the Pediatrics User Guide
- Instructions for Reviewers

You will need to log in or register for the CDISC Wiki to provide comments.

- **Register** for the Wiki. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account; Wiki and JIRA use the same login credentials. CDISC Wiki is a different login from **www.cdisc.org**.

Public review is a key quality step in our Standards Development Process. CDISC relies on your input to ensure neutral, consensus-based data standards are developed and adopted by a diverse global community interested in improving research processes and quality for the benefit of all.

Thank you for contributing your time and expertise.

https://www.cdisc.org/public-review/pediatrics-user-guide

Pediatrics User Guide Home

Pediatrics User Guide Home

Created by John Owen, last modified by Alana St. Clair on May 19, 2022

This is the landing page for the UG-Pediatrics. What would you like to do?

- **Read the UG-Pediatrics**
  There are two options, depending on your reading preference:
  - TAUG-Pediatrics compiled — This lets you view the entire document as a single web page, but is more prone to errors with the JIRA Connector. Please allow time for the whole document to load in your browser.
  - UG-Pediatrics sections — This displays each section on its own page, and comprises the source of the content displayed on the compiled view.
    › Jump to a specific section:
    - Draft Standards of Interest to UG-Pediatrics — These are CDISC standards-in-development that have influenced the development of the UG-Pediatrics, and are used in examples and/or modeling advice.

- **Look at examples**
  - UG-Pediatrics examples — This is where all examples used in the UG-Pediatrics live.

⚠ Note: Readers are recommended to use this directory only *after* reading the UG-Pediatrics in its entirety at least once.

- **Provide feedback**
  - Instructions for Reviewers — Detailed instructions for how to use JIRA to provide feedback on the UG-Pediatrics are given here.

Other resources you may find helpful:

- Introduction to Therapeutic Area Standards — This provides an overview of what to expect, and what *not* to expect, from a therapeutic area user guide such as the TAUG-__.
- TA001 - Overview of Therapeutic Area User Guides — This is a free introductory course on therapeutic area standards on the CDISC training campus.
- Reading on the Wiki — This page touches on some of the ways the Wiki edition of the UG-Pediatrics has been optimized for web use, with which a reader new to the CDISC Wiki may be unfamiliar.
- TA Specification — This is a spreadsheet that provides information, for newer and proposed domains and variables, on their relationships with versions of SDTM and the SDTMIG.

ⓘ TA Specifications were developed to assist FDA in their testing processes, but can also provide implementers with advice on how to adapt the representation of data shown in the TAUG to different versions of the standards. TA Specifications are provided as a resource to reviewers; we are not seeking comment on the TA Specification. However, we would appreciate being informed of inconsistencies in the content of the TA Specification and the TA User Guide.

ⓘ **Status**
This is a DRAFT standard, which means that it is still in development and not yet ready for provisional or general use.

✓ This document is best read online.

Comments on the UG-Pediatrics should be entered into JIRA at: https://jira.cdisc.org/projects/PEDIAC. For more detail, see the Instructions for Reviewers.

How to make comments

Instructions for Reviewers

Created by John Owen, last modified by Alana St. Clair on Mar 23, 2022

Reviewers are requested to provide comments via JIRA (Wiki and JIRA use the same credentials, so if you can see this page, then you can use JIRA).

The JIRA project associated with the UG-Pediatrics is **Pediatrics (PEDIAC)** located at: https://jira.cdisc.org/projects/PEDIAC

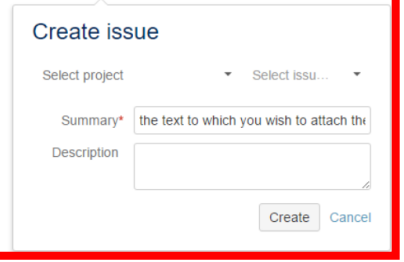
- If you have no edits or comments to a page
- To add comments to JIRA from within the Wiki
- To add comments from within JIRA

If you have no edits or comments to a page

1. Click 'Like' at the bottom of the page. This will help us determine who has read each page.

To add comments to JIRA from within the Wiki

1. Select the text (ideally, a short, unique phrase) to which you wish to attach the comment. After a moment, a small contextual menu should appear.
2. Within the contextual menu, click on the JIRA icon. This will trigger an abbreviated Create Issue form.
3. Choose the project associated with this document from the **Project** drop-down menu.
4. Choose "Review Comments" from the **Issue Type** drop-down menu.
5. Fill out the form.
    a. The **Summary** field will be pre-populated with the text that you selected. You can change this or leave it as it is.
    b. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
    c. In case of technical difficulties, please make sure to include a brief description of the context of your comment.
6. Click the "Create" button in the bottom left corner of the form to submit your comment as an issue.



Instructions for creating an issue from within Confluence (the Wiki) can be found here: https://confluence.atlassian.com/doc/use-jira-applications-and-confluence-together-427623543.html

To add comments from within JIRA

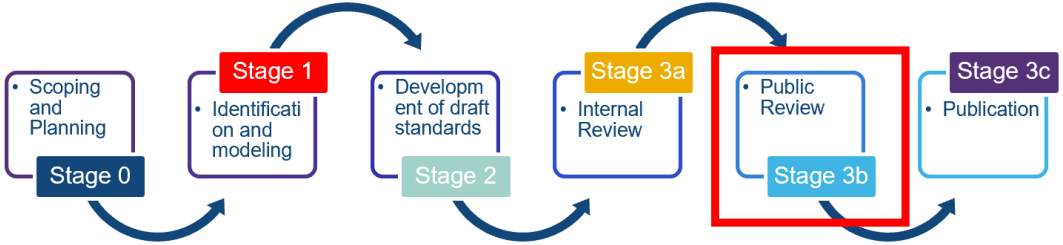
1. Go to the JIRA project associated with this document

> Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the Wiki and JIRA.

2. Click on the "Create" button in the top menu to bring up the Create Issue form.
3. Choose the project associated with this document from the **Project** drop-down menu, if it has not already been selected for you. (If a project has already been selected, make sure it's the right one!)
4. From the **Issue Type** drop-down menu, set the issue type to "Review Comments", if it is not already.
5. Fill out the form.
    a. In the **Summary** field, describe the content to which the comment applies.
    b. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
6. Click the "Create" button in the bottom right corner of the form to submit.

Instructions for creating an issue can be found here: https://confluence.atlassian.com/display/JIRA/Creating+an+Issue

Comment resolution process



CDISC Standards Development Process (COP-001)

2020	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG												

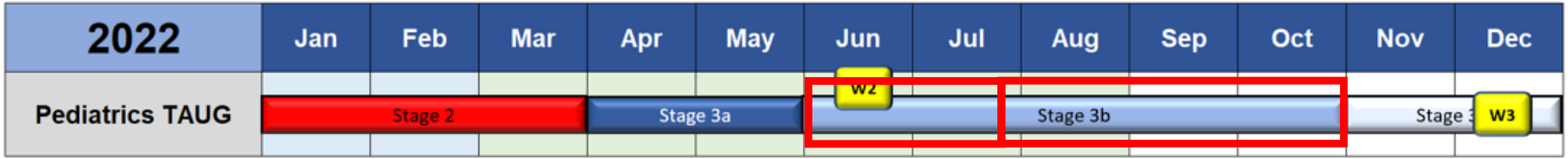
2021	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 0						Stage 1		W1	Stage 2		

2022	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 2			Stage 3a		W2	Stage 3b				Stage 3	W3

Stage 0	Scoping and Planning
Stage 1	Identification/Modeling of Concepts
Stage 2	Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

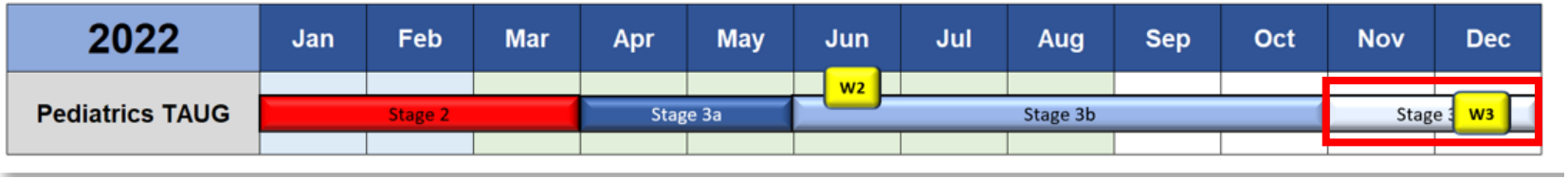
TAUG Deliverable Feb 2023 (M58)
Submission required April 2023 (M60)

Publication Process



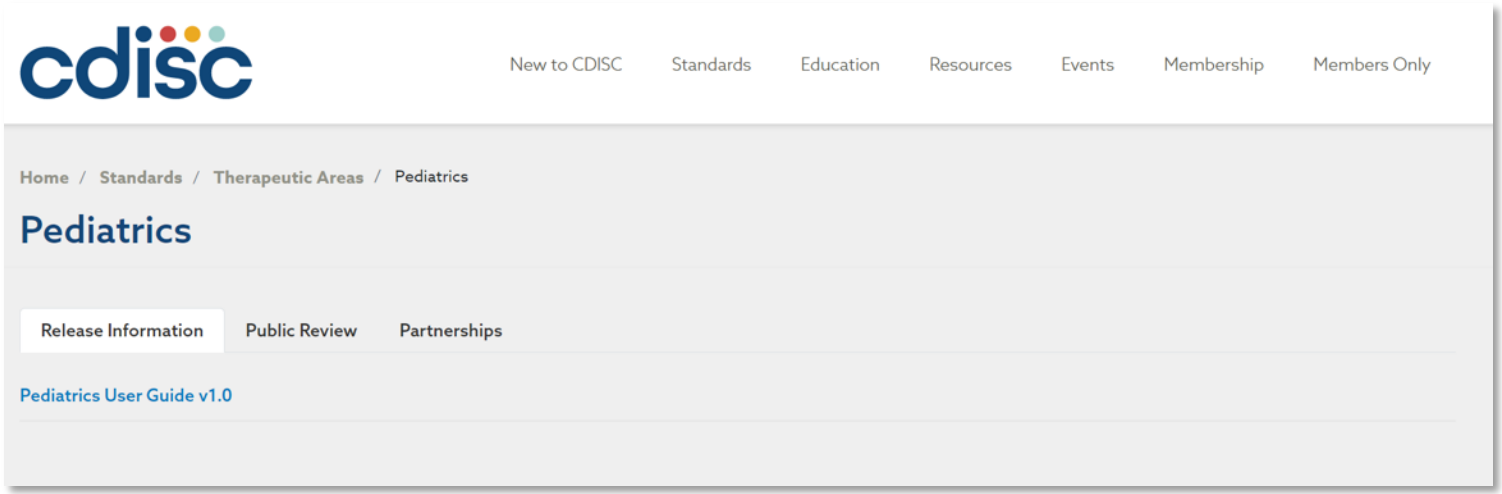
- 60-Day public review commenting ends 25th July 2022
  - We will look to extend this for a further 30-days if more time is required for commenting
- Team will then address all public review comments, using the assistance of the Pediatric SMEs if needed
- Some comments may be deferred to a future version of the User Guide if they are outside of the scope of the original version

Publication Process



- Approval from the CDISC Global Governance Group (GGG) for approval for publication
  - Review and approval of Public Review comments by GGG
  - Copy editing of the User Guide
  - Final approval from CDISC Head of Standards
- Hand-over to the publications team for publishing on www.cdisc.org
  - Public Review comments are also published

Publication Process



https://www.cdisc.org/standards/therapeutic-areas/pediatrics

Content Review

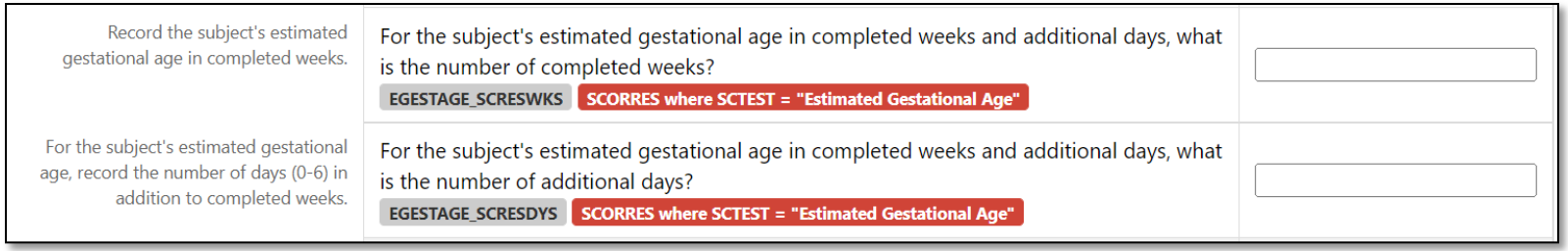
- Gestational Age
- Neurological Assessments: Reflexes
- Auricular Findings (AU) Domain
- Representation of Pregnancy and Birth Data
- Informed Consent / Assent

Gestational Age

- Use of the Subject Characteristics (SC) domain to record multiple assessments for the subject.
- Two terms for gestational age in SC test terminology:
  - EGESTAGE / Estimated Gestational Age
    - May be used for antenatal or postnatal assessments.
    - May be used for multiple assessments for a subject.
    - The date of estimation is recorded in SCDTC.
  - GSTABRTH / Gestational Age at Birth
    - May be used when gestational at birth is of specific interest.
    - SCDTC may contain date of estimation or date of collection.
    - May be useful when:
      - Subjects are enrolled after birth and only the subject's gestational age at the time of birth is of interest.
      - The exact date on which the estimation was made is either not available or not of interest.
      - Data privacy regulations prevent recording of a complete date that is identifiable as the subject's date of birth.

Gestational Age

- Collection format: weeks and days



Record the subject's estimated gestational age in completed weeks.	For the subject's estimated gestational age in completed weeks and additional days, what is the number of completed weeks? EGESTAGE_SCRESWKS SCORRES where SCTEST = "Estimated Gestational Age"	
For the subject's estimated gestational age, record the number of days (0-6) in addition to completed weeks.	For the subject's estimated gestational age in completed weeks and additional days, what is the number of additional days? EGESTAGE_SCRESDYS SCORRES where SCTEST = "Estimated Gestational Age"	

- SDTM does not support representation of results in mixed units.
- Gestational age is converted to a single unit (days or weeks) for representation in SDTM.
- SCORRES is used to represent the result in the original units and sponsors may convert the result to a standardized unit (represented in SCSTRESC/SCSTRESN/SCSTRESU) to support analysis.
- Sponsors may choose the appropriate unit to meet study needs.

Gestational Age

- Sponsors may also choose the format in which to represent gestational age results

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCORRESU	SCSTRESC	SCSTRESN	SCSTRESU
1	PED111	SC	PED111-01-103	1	GSTABRTH	Gestational Age at Birth	269	DAYS	269	269	DAYS
2	PED222	SC	PED222-01-103	1	GSTABRTH	Gestational Age at Birth	38 3/7	WEEKS	269	269	DAYS
3	PED444	SC	PED444-01-103	1	GSTABRTH	Gestational Age at Birth	38.43	WEEKS	269	269	DAYS
4	PED555	SC	PED555-01-103	1	GSTABRTH	Gestational Age at Birth	269	DAYS	38.43	38.43	WEEKS
5	PED666	SC	PED666-01-103	1	GSTABRTH	Gestational Age at Birth	38 3/7	WEEKS	38.43	38.43	WEEKS
6	PED888	SC	PED888-01-103	1	GSTABRTH	Gestational Age at Birth	38.43	WEEKS	38.43	38.43	WEEKS

- Points to consider when choosing a format:
  - The same standardized result unit (SCSTRESU) must be used for all records for a given test within a submission.
  - Gestational age should not be represented using a unit more precise than the collection unit (e.g. do not convert to days if only weeks were collected).
  - Representation format should be unambiguous (e.g., “38+3” may be misinterpreted as “41”)
  - When converting to weeks choose a precision that will not affect analysis.

Neurological Assessments: Reflexes

- Flexible modelling allows for representation of:
  - A single overall normal/abnormal response for each reflex
  - A normal/abnormal response for each evaluated anatomical location for each reflex
  - A normal/abnormal response for each evaluated anatomical location for each type for stimulus used to elicit each reflex (where applicable).

nv.xpt

Row	STUDYID	DOMAIN	USUBJID	NVSEQ	NVTESTCD	NVTEST	NVCAT	NVORRES	NVSTRESC	NVLOC	NVLAT	VISITNUM	VISIT	NVDTC	NVSTMDTL
1	PED025	NV	PED025-002	1	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	HEAD TURNED TO RIGHT
2	PED025	NV	PED025-002	2	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	HEAD TURNED TO RIGHT
3	PED025	NV	PED025-002	3	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	HEAD TURNED TO LEFT
4	PED025	NV	PED025-002	4	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	ABNORMAL	ABNORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	HEAD TURNED TO LEFT
5	PED025	NV	PED025-002	5	PLMGRRFX	Palmar Grasp Reflex	REFLEXES	NORMAL	NORMAL	HAND	LEFT	1	Screening	2020-08-05	
6	PED025	NV	PED025-002	6	PLMGRRFX	Palmar Grasp Reflex	REFLEXES	NORMAL	NORMAL	HAND	RIGHT	1	Screening	2020-08-05	
7	PED025	NV	PED025-002	7	PLTGRRFX	Plantar Grasp Reflex	REFLEXES	NORMAL	NORMAL	FOOT	LEFT	1	Screening	2020-08-05	
8	PED025	NV	PED025-002	8	PLTGRRFX	Plantar Grasp Reflex	REFLEXES	NORMAL	NORMAL	FOOT	RIGHT	1	Screening	2020-08-05	
9	PED025	NV	PED025-002	9	MORORFLX	Moro Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	
10	PED025	NV	PED025-002	10	MORORFLX	Moro Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	
11	PED025	NV	PED025-002	11	ROOTRFLX	Rooting Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	RIGHT CHEEK STROKED
12	PED025	NV	PED025-002	12	ROOTRFLX	Rooting Reflex	REFLEXES	ABNORMAL	ABNORMAL			1	Screening	2020-08-05	LEFT CHEEK STROKED
13	PED025	NV	PED025-002	13	STEPRFLX	Stepping Reflex	REFLEXES	NORMAL	NORMAL	LIMB, LOWER	LEFT	1	Screening	2020-08-05	
14	PED025	NV	PED025-002	14	STEPRFLX	Stepping Reflex	REFLEXES	NORMAL	NORMAL	LIMB, LOWER	RIGHT	1	Screening	2020-08-05	
15	PED025	NV	PED025-002	15	GLNTRFLX	Galant Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	RIGHT OF SPINE STROKED
16	PED025	NV	PED025-002	16	GLNTRFLX	Galant Reflex	REFLEXES	ABSENT	ABSENT			1	Screening	2020-08-05	LEFT OF SPINE STROKED
17	PED025	NV	PED025-002	17	SUCKRFLX	Sucking Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	

NV NSV Metadata

Variable	Label	Type	Role	Origin
NVSTMDTL	Stimulus Detail	text	Non-standard Variable Qualifier of --TESTCD	CRF

Auricular Findings (AU) Domain

- New Findings domain for the representation of findings relating to the structure and function of the auditory system.
- Examples include:
  - Weber and Rinne Tests

au.xpt

Row	STUDYID	DOMAIN	USUBJID	AUSEQ	AUTESTCD	AUTEST	AUORRES	AUSTRESC	AULOC	AULAT	AUMETHOD	VISITNUM	VISIT	AUDTC
1	PED028	AU	PED028-001	1	HEARLATN	Hearing Lateralization	MIDDLE	MIDDLE			WEBER TEST	1	Screening	2013-09-28
2	PED028	AU	PED028-001	2	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	RIGHT	RINNE TEST	1	Screening	2013-09-28
3	PED028	AU	PED028-001	3	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	LEFT	RINNE TEST	1	Screening	2013-09-28
4	PED028	AU	PED028-002	1	HEARLATN	Hearing Lateralization	RIGHT	RIGHT			WEBER TEST	1	Screening	2013-10-05
5	PED028	AU	PED028-002	2	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	RIGHT	RINNE TEST	1	Screening	2013-10-05
6	PED028	AU	PED028-002	3	AIRBNCND	Air to Bone Sound Conduction Comparison	NEGATIVE	NEGATIVE	EAR	LEFT	RINNE TEST	1	Screening	2013-10-05

  - Tympanometry

au.xpt

Row	STUDYID	DOMAIN	USUBJID	AUSEQ	AUTESTCD	AUTEST	AUORRES	AUORRESU	AUSTRESC	AUSTRESN	AUSTRESU	AULOC	AULAT	AUMETHOD	VISITNUM	VISIT	AUDTC
1	PED028	AU	PED028-001	1	PHCMPLNC	Physiological Compliance	0.8	mL	0.8	0.8	mL	TYMPANIC MEMBRANE	RIGHT	TYMPANOMETRY	1	Screening	2013-09-28
2	PED028	AU	PED028-001	2	VOLUME	Volume	0.9	mL	0.9	0.9	mL	EXTERNAL ACOUSTIC MEATUS	RIGHT	TYMPANOMETRY	1	Screening	2013-09-28
3	PED028	AU	PED028-001	3	AIRPRSSR	Air Pressure	-25	daPa	-25	-25	daPa	MIDDLE EAR	RIGHT	TYMPANOMETRY	1	Screening	2013-09-28
4	PED028	AU	PED028-001	4	TYMPGMTY	Tympanogram Type	A		A			EAR	RIGHT	TYMPANOMETRY	1	Screening	2013-09-28
5	PED028	AU	PED028-001	1	PHCMPLNC	Physiological Compliance	3.6	mL	3.6	3.6	mL	TYMPANIC MEMBRANE	LEFT	TYMPANOMETRY	1	Screening	2013-09-28
6	PED028	AU	PED028-001	2	VOLUME	Volume	1.6	mL	1.6	1.6	mL	EXTERNAL ACOUSTIC MEATUS	LEFT	TYMPANOMETRY	1	Screening	2013-09-28
7	PED028	AU	PED028-001	3	AIRPRSSR	Air Pressure	-15	daPa	-15	-15	daPa	MIDDLE EAR	LEFT	TYMPANOMETRY	1	Screening	2013-09-28
8	PED028	AU	PED028-001	4	TYMPGMTY	Tympanogram Type	Ad		Ad			EAR	LEFT	TYMPANOMETRY	1	Screening	2013-09-28

Representation of Pregnancy and Birth Data

- Representation of data relating to pregnancy and birth can be challenging because the data can include information:
  - Primarily about the mother, e.g.
    - Medical conditions experienced by the mother during pregnancy
    - Medications taken by the mother during pregnancy
  - Primarily about the fetus/infant, e.g.
    - Estimation of gestational age
    - Fetal measurements such as head circumference
  - About both mother and fetus/infant, e.g.
    - Events such as delivery and pregnancy outcome that are experienced by both mother and subject,
    - Delivery procedures such as cesarean delivery and assisted delivery that are performed on both the mother and the subject

Representation of Pregnancy and Birth Data

- Information primarily about the mother is represented in Associated Persons (AP) domains.

apsu.xpt

Row	STUDYID	DOMAIN	APID	SUSEQ	RSUBJID	SREL	SULNKID	SUTRT	SUPRESP	SUOCCUR	VISITNUM	VISIT	SUDTC	SUEVINTX
1	PED15	APSU	PED15-001-M	1	PED15-001	MOTHER, BIOLOGICAL		OPIOIDS	Y	N	1	Screening	2020-07-17	DURING PREGNANCY
2	PED15	APSU	PED15-002-M	1	PED15-002	MOTHER, BIOLOGICAL	NAS	OPIOIDS	Y	Y	1	Screening	2020-07-23	DURING PREGNANCY
3	PED15	APSU	PED15-003-M	1	PED15-003	MOTHER, BIOLOGICAL	NAS	OPIOIDS	Y	Y	1	Screening	2020-08-05	DURING PREGNANCY

- When the subject is uniquely identifiable, information primarily about the subject is represented in subject-related domains.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VSDTC
1	PED-678	VS	103	1	HDCIRC	Head Circumference	25	cm	25	25	cm	3	2016-04-16
2	PED-678	VS	104	1	HDCIRC	Head Circumference	28	cm	28	28	cm	3	2016-04-16

- When the subject is not uniquely identifiable, information primarily about subjects may be represented in AP domains as information about the mother.

apvs.xpt

Row	STUDYID	DOMAIN	APID	VSSEQ	RSUBJID	SREL	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VSDTC	VSFTINID
1	PED-789	APVS	103M	1	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference	25	cm	25	25	cm	3	2016-04-16	1
2	PED-789	APVS	103M	2	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference	28	cm	28	28	cm	3	2016-04-16	2

APVS NSV Metadata

Variable	Label	Type	Role	Origin
VSFTINID	Fetus/Infant Identifier	integer	Non-standard Identifier	CRF

Representation of Pregnancy and Birth Data

- When data relates both to the mother and the subject, sponsors may choose to represent the data in a subject-related domain, in an AP domain, or in both, depending on the needs of the study.
  - **Pregnancy-related Events, Example 1**:
    Procedures undergone by both subject and mother are represented in both subject-related and AP domains

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRLNKID	PRTRT	PRCAT	PRSTDTC	PRPURGNC
1	PED-456	PR	101	1	PRED-2	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	EMERGENCY
2	PED-456	PR	102	1	PRED-3	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	EMERGENCY
3	PED-456	PR	103	1	PRED-1	FORCEPS-ASSISTED DELIVERY	PREGNANCY-RELATED	2017-06-01	

appr.xpt

Row	STUDYID	DOMAIN	APID	PRSEQ	RSUBJID	SREL	PRLNKID	PRTRT	PRCAT	PRSTDTC	PRFTINID	PRPURGNC
1	PED-456	APPR	101M	1	MULTIPLE	MULTIPLE	PRED-2	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	2	EMERGENCY
2	PED-456	APPR	101M	2	MULTIPLE	MULTIPLE	PRED-3	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	3	EMERGENCY
3	PED-456	APPR	103M	1	103	MOTHER, BIOLOGICAL	PRED-1	FORCEPS-ASSISTED DELIVERY	PREGNANCY-RELATED	2017-06-01	1	
4	PED-456	APPR	104M	1	104	MOTHER, BIOLOGICAL	PRED-2	VACUUM-ASSISTED DELIVERY	PREGNANCY-RELATED	2018-11-10	2	

Representation of Pregnancy and Birth Data

- When data relates both to the mother and the subject, sponsors may choose to represent the data in a subject-related domain, in an AP domain, or in both, depending on the needs of the study.
  - **Pregnancy-related Events, Example 2**:
    Procedures undergone by both subject and mother are only represented in subject-related domains

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRLNKID	PRTRT	PRCAT	PRSTDTC	PRPURGNC
1	PED-567	PR	101	1	PRED-2	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	EMERGENCY
2	PED-567	PR	102	1	PRED-3	CESAREAN DELIVERY	PREGNANCY-RELATED	2017-10-25	EMERGENCY
3	PED-567	PR	103	1	PRED-1	FORCEPS-ASSISTED DELIVERY	PREGNANCY-RELATED	2017-06-01	

appr.xpt

Row	STUDYID	DOMAIN	APID	PRSEQ	RSUBJID	SREL	PRLNKID	PRTRT	PRCAT	PRSTDTC	PRFTINID	PRPURGNC
1	PED-567	APPR	104M	1	104	MOTHER, BIOLOGICAL	PRED-2	VACUUM-ASSISTED DELIVERY	PREGNANCY-RELATED	2018-11-10	2	

Informed Consent / Assent

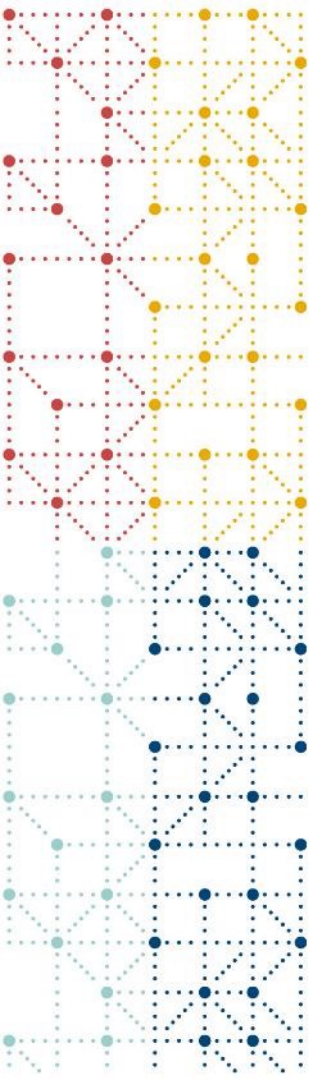
- Informed consent may be obtained from the subjects parent(s), legal guardian/custodian, or other legally authorized representative (LAR).
- Informed assent may be obtained from subjects old enough to understand the purpose of the study, but below the age of maturity.
- Subjects may need to provide informed consent on their own behalf on reaching the age of maturity.
- The obtaining of informed consent is represented in the DS domain, even if consent is obtained from a parent/guardian, because consent is for the subject.

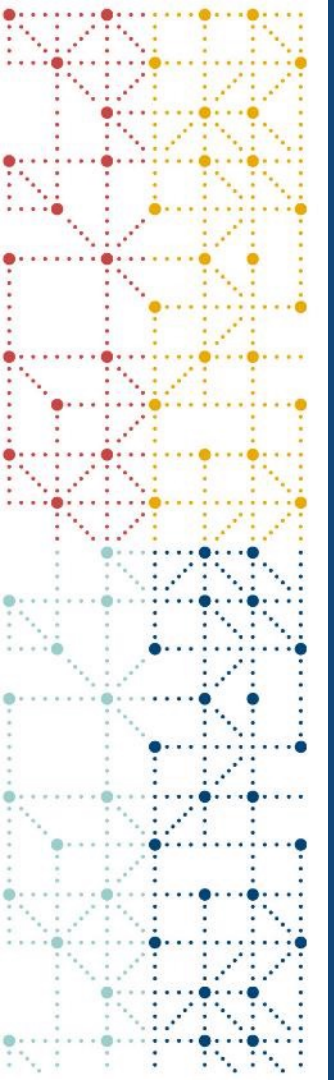
Row 1: Shows the first informed consent obtained for subject PED767-001.
Rows 2, 5: Show the obtaining of informed assent.
Row 3: Shows the second informed consent obtained for subject PED767-001, which was obtained when the subject reached the age of legal consent.
Row 4: Shows informed consent obtained for subject PED767-002.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	DSSTDTC
1	PED767	DS	PED767-001	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	2016-02-22
2	PED767	DS	PED767-001	2	INFORMED ASSENT OBTAINED	INFORMED ASSENT OBTAINED	PROTOCOL MILESTONE	2016-02-22
3	PED767	DS	PED767-001	3	RECONSENT AT AGE OF LEGAL CONSENT	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	2017-04-12
4	PED767	DS	PED767-002	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	2016-06-08
5	PED767	DS	PED767-002	2	INFORMED ASSENT OBTAINED	INFORMED ASSENT OBTAINED	PROTOCOL MILESTONE	2016-06-08

THANK YOU!





Questions & Answers

Audience Questions

Since this is an EU based project, are the pediatric data standards just relevant for the EU?

Audience Questions

Are there any plans to include disease specific pediatric data standards?

Audience Questions

Are there any plans to add ADaM examples into the user guide?

Audience Questions

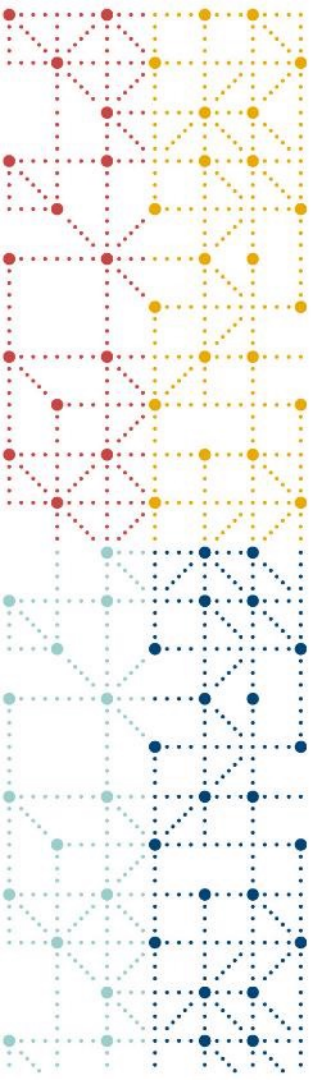
Can I comment further once my original comment has been actioned?

Audience Questions

How would you know who provided informed consent?

Audience Questions

Several similar projects are run by other organisations such as "Kinderformularium" etc. Do you work together with them?



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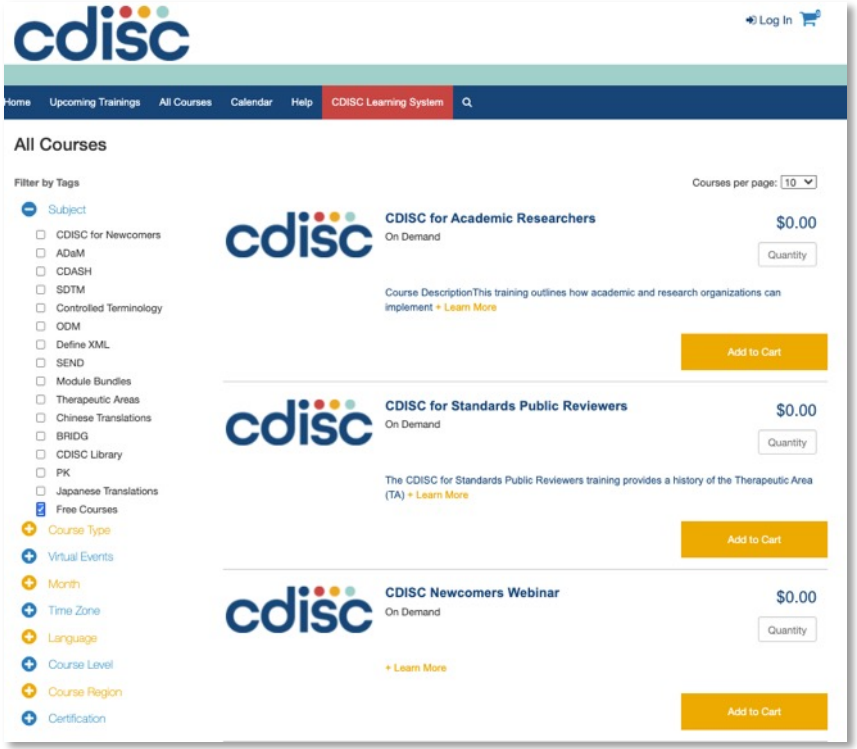

Http://learnstore.cdisc.org

Upcoming Webinars

Date	Title
8 SEP	QRS Office Hours
15 SEP	Genomics Findings Office Hours
29 SEP	COSA Spotlight Q3 (registration coming soon!)
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public review

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https://www.cdisc.org/form/webinartopicreq

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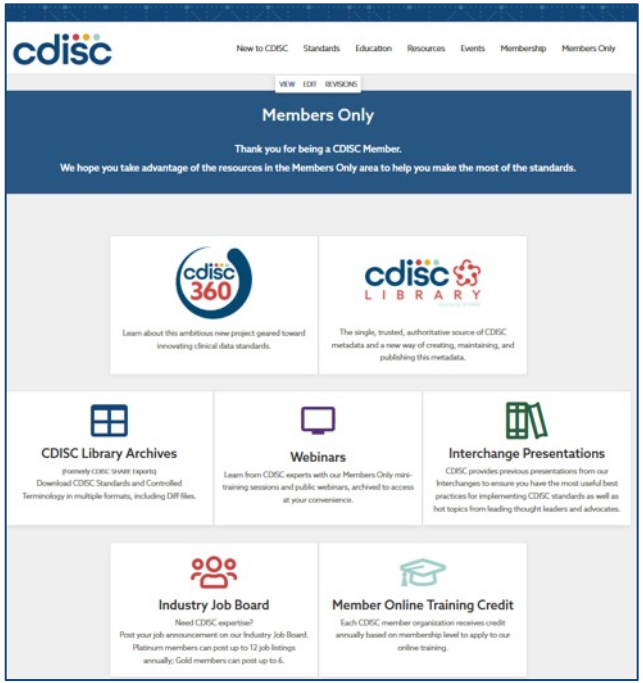

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