

CDISC Pediatric User Network Minutes	
	<p>Date: 17th April 2024 Place: Zoom Time 2:00-3:00 BST / 3:00-4:00 GMT</p>
Attendees	<p>John Owen, John Ezzell, Avril Palmeri, Anando Sen, Thomas Luethy, Giorgio Reggiardo, Claudia Pansieri, James Webbe, Johan Vande Walle, Gabriele Ahne, Corinna Engel, Kasey Baker, Melissa Walsh, Rick Watts, Beth Potter, Breanne Stewart, James Wyncoll, Kimberly Pang, Molly Pursell</p>
Review of outstanding actions	<ul style="list-style-type: none"> • Volunteer to be part of the CPUG-LT (All) Ongoing – We need more volunteers from different backgrounds for the leadership group, especially from industry. This will be discussed on the next leadership call. • Arrange the first CPUG-LT meeting to work on CPUG charter/topics for next meeting (JO/AP) Complete. The first call took place on 23rd January. The next call is scheduled for 8th May. • Set up CPUG wiki and email distribution list (JO/CDISC) Complete – The CPUN Wiki site has been set up. It includes links to meeting materials, a calendar and a sign-up box to join the mailing list. Members of the CPUN have already been added to the mailing list. • Arrange comms activities to disseminate information to the community on the CPUG (JO/AP) Ongoing – this will be discussed on the May leadership call. • Set date(s) for next CPUG meeting (JO/AP) – Complete
CDISC pediatric training modules	<ul style="list-style-type: none"> • John Ezzell provided information about the CDISC education team, how CDISC education fits within the CDISC charter, how it operates and the tools that are used to develop and deliver training. • The different categories of education are available on the CDISC website. Q&A and discussion forums are available for trainees. Certificates and badges that can be included in email signatures are also available. Training is accessed on the Education page of the CDISC website with a free login. • Experts (SMEs) work with the CDISC education team to develop training. • JO asked if it is better to keep the introduction modules for people who are new to CDISC separate from the pediatric-specific training or whether it should be rolled into one curriculum. This is a question for this group to discuss and decide. The group also needs to decide on the right level and amount of detail for the introduction to CDISC standards. KB commented that the training for the Rare Disease TAUG is so specific that they did not have an extensive foundational overview. Having a training module that gives an overview of the CDISC journey to help those new to CDISC get started and follow the process would be beneficial. JE confirmed the curriculum can be designed to accommodate different learning needs. It can be very prescriptive for those new to CDISC and then become more flexible for advanced users. • JWV commented that particularly for rare diseases, data needs to be standardized from the start as there will only be a small number of patients

	<p>worldwide. The sooner researchers start their CDISC journey so they can standardize their data, the better.</p> <ul style="list-style-type: none"> • MP from the KD-CAAP study commented that they are not very familiar with CDISC, particularly at the data manager and trial manager level. Within the trials unit, they have a data management team who are trying to incorporate CDISC standards into their trial design. The user guide and training modules would be helpful as an introduction to CDISC for this group. Action: Are there any other groups like this within the c4c network that would be willing to provide feedback on information that would be useful for them as they are on their journey with CDISC standards and to provide feedback on the training. Form a pilot group to take this forward. MW commented that she might be able to find someone to volunteer for this too, based in the Irish NH for c4c that supports in the setup of their eCRFs. JE showed an example of post-training surveys that can be customized. • It will take approximately 3-5 months to develop the training for the Pediatrics User Guide. A lot of foundational training already exists but we would need input on the curriculum from the pilot group that would feedback to this group.
<p>Pediatric user network charter</p>	<ul style="list-style-type: none"> • JO showed the draft network charter. The charter will be finalized during the May leadership call. • Action: The group is asked to review the charter on the attached slides and provide feedback. • Action: AP will confirm if the c4c funding statement needs to be included.
<p>Next call</p>	<ul style="list-style-type: none"> • The next call is scheduled for 13th June but may need to be rescheduled based on changes to JO's availability. The draft agenda is included in the attached slides. Action: the group is asked to send ideas for the June agenda and future calls.



CDISC Pediatric Network Meeting

17th April 2024

John Owen, Head, PMO, CDISC

John Ezzell, Head of Education, CDISC

The CDISC logo consists of the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are three small circles in red, yellow, and light blue. Above the letter "c" is a small light blue circle.



Agenda

1. Updates and Review Outstanding Actions
2. Presentation: CDISC Pediatric Training Modules
3. Pediatric User Network Charter

CDISC and c4c



CDISC Pediatrics User Guide



CDISC Pediatric User Group/Network



CDISC Pediatric Training Curriculum

CPUN WIKI Site



Pediatric User Network

Created by Matthew Warren, last modified by John Owen on Mar 13, 2024

✔ Welcome!

Welcome to the CDISC Pediatric Network. To sign-up to the Network please submit your name and email below

Full Name:

Email:

- The network email is pedun@lists.cdisc.org
- **You must be a member of the list to send to it.**
- To unsubscribe, click the link in the footer of the email received from the list.

[› Pediatric User Network Charter](#)

[› Pediatric User Network Meetings](#)

[› Pediatric User Network Leadership Meetings](#)



Today



April 2024

Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17 📅 2:00 PM CPUN Meeting (UK Time)	18	19	20	21
22	23	24	25	26	27	28
29	30	1	2	3	4	5
6	7	8 📅 9:00 AM CPUN Leadership Meeting (UK Time)	9	10	11	12

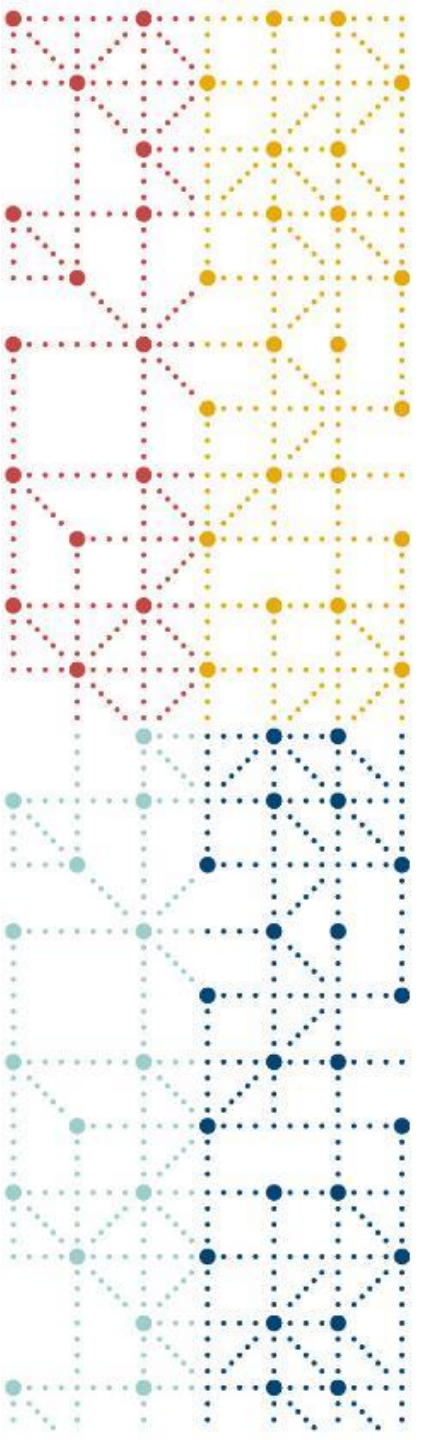


<https://wiki.cdisc.org/display/PEDUN/Pediatric+User+Network>

CPUN Meetings

- CPUN Kick off meeting 28th November 2023
- CPUN Leadership meeting 23 January 2024
- **CPUN Meeting 17 April 2024 – Training Presentation**
- CPUN Leadership meeting 8th May 2024
- CPUN Meeting 13th June 2024
 - Reschedule?

- Review Outstanding Actions



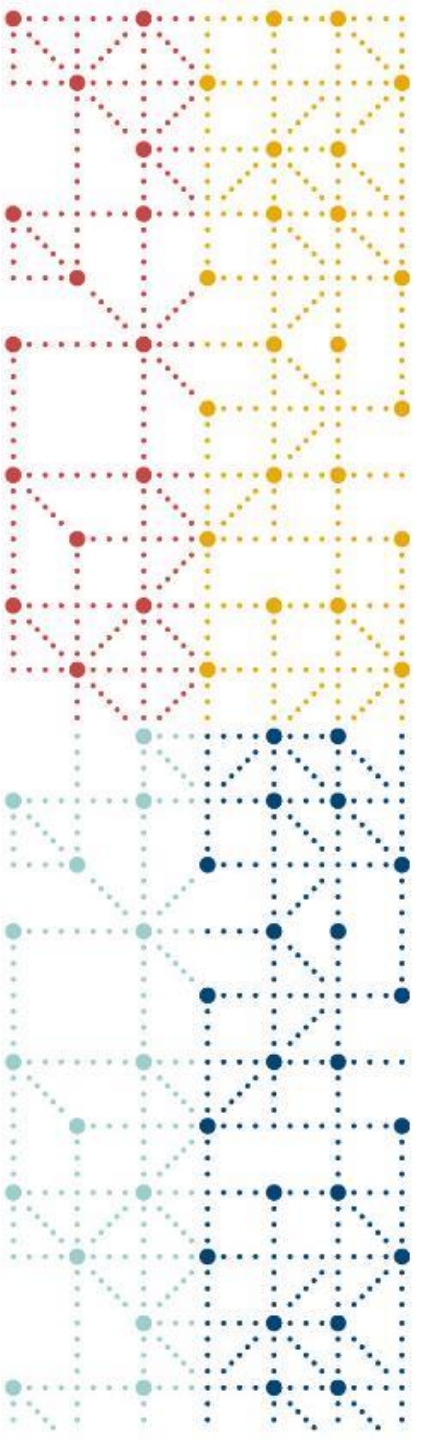
Introduction to Pediatrics Training Curriculum

John Ezzell, Head of Education CDISC



Agenda

1. Intro to CDISC Ed
2. Training Development
3. Pediatrics Community Feedback
4. Q&A



Intro to CDISC Ed

Ed Team Intro



John Ezzell
Head of Education

- Develops Overall Training Schedule and Strategy in Conjunction with VP of Partnerships and Development
- Oversees Training Development
- Manages Certifications and Vendors



Morgan Dancy
Senior Education Manager

- Oversees Public Training Schedule
- Manages Private Learning Stores
- Coordinates Instructor Authorization



Mackenzie Voots
Education Manager

- Oversees Private Training Schedule
- Manages Learning Management System (LMS)
- Leads publication of Trainings

CDISC Training Areas of Focus



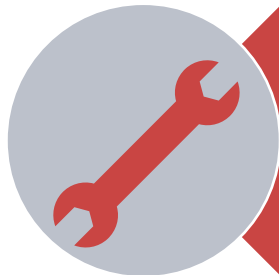
CDISC Standards & Publications

- Foundational Standards
- User Guides



Training by Audiences

- Experts and Newcomers
- Niche groups (e.g., Academics)



Tools

- CDISC Library, COSA tools, etc.
- Demos
- Instructions

CDISC LMS

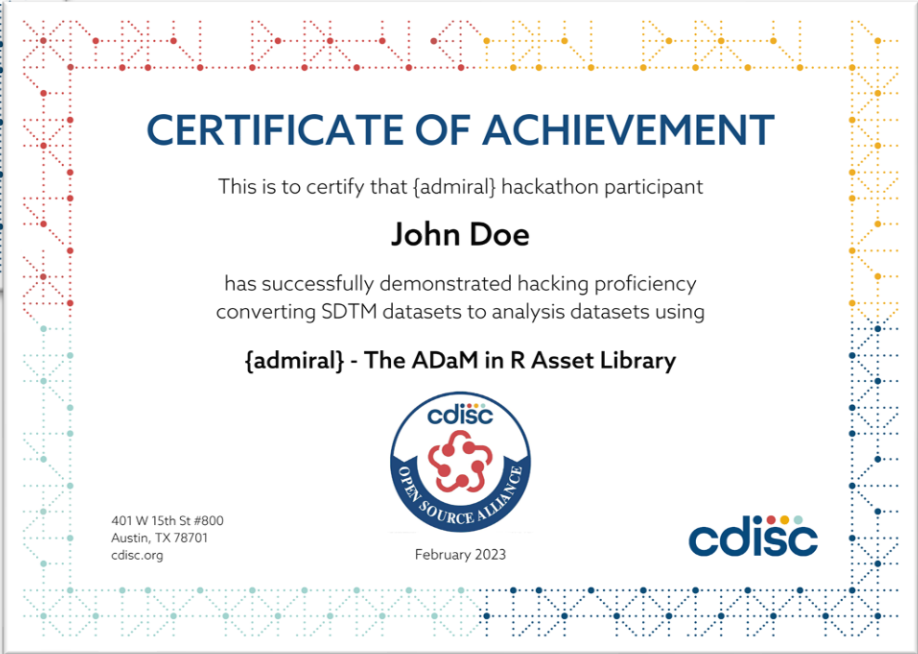
- Videos
- Interactive Activities
- Assessments
- CEUs

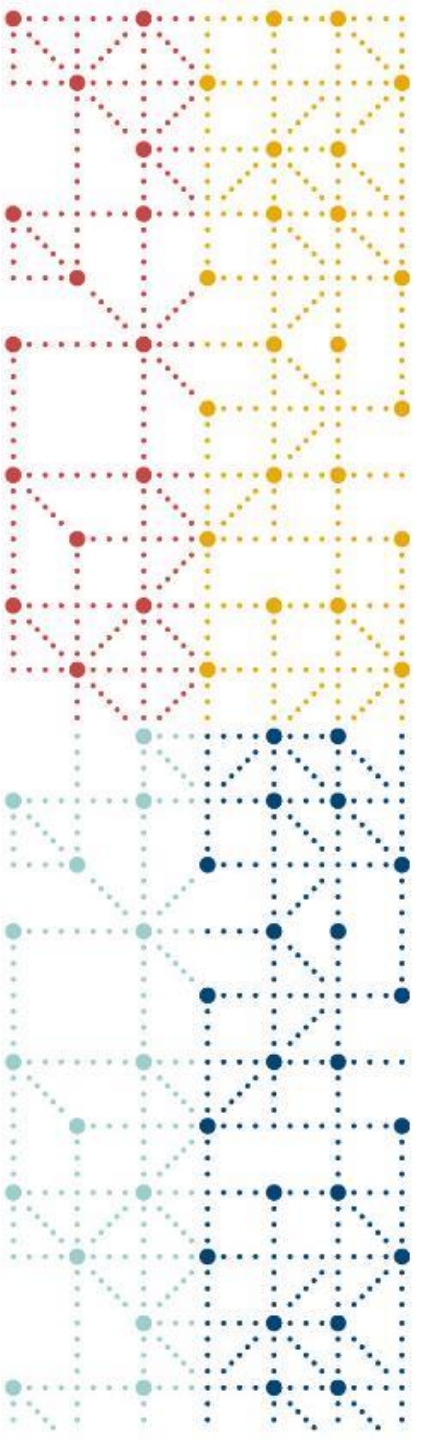


The screenshot shows the CDISC LMS interface. At the top is the CDISC logo and a navigation menu with items like Home, Access Learning, Browse Our Course Catalog, My Certificates, Tabulate Certification, Programs, Membership Benefits, Visit CDISC.org, Contact, and Reports. The user is logged in as John Ezzell. The main content area is for the course "CDISC for Academic Researchers". It includes a left sidebar with a course menu (Participants, Badges, Grades, General, Welcome, Chapter 1-8, CDASH Resources, ADaM Resources, Helpful Links) and an administration section (Course administration, Grades, Question bank, Switch role to..., Return to my normal role). The main content has a "Welcome" section with an "Intellectual Property Notice" and a "Chapter 1" section with video links. Below this is a video player for "ACAD001: CDISC for Academic Researchers" with a progress bar and a "Mark the video as complete" section with "Complete" and "Submit" buttons. On the right, there are sidebars for "SEARCH FORUMS", "LATEST NEWS", "UPCOMING EVENTS", and "RECENT ACTIVITY".

learn.cdisc.org

Certificates and Badges





UG Training Development

CDISC Training Development Tools

- Collaboration Tools

- Wiki
- SharePoint

- Authoring Tools

- Adobe Creative Suite
- HP5

- Delivery Tools

- iSpring
- Zoom
- Totara LMS

The screenshot displays the CDISC training development tools interface. The top section shows the course structure for 'ADAM MODULE 4: SUBJECT LEVEL ANALYSIS DATASET', including a navigation menu with options like 'Participants', 'Badges', 'Grades', 'Subject Level Analysis Dataset', 'Welcome', 'Course Overview', 'Chapter 1', 'Chapter 1 Activity', 'Chapter 2', 'Chapter 2 Activity', 'Helpful Links', 'Module 4 Final Assessment', 'Certificate of Achievement', and 'Survey'. Below this is an 'ADMINISTRATION' section with options for 'HSP' (Edit settings, Locally assigned roles, Permissions, Check permissions, Filters, Logs, Backup, Restore) and 'Course administration'.

The main content area is titled 'Chapter 1 Activity' and contains a section for 'Required, Conditionally Required and Permissible ADSL Variables'. The instructions state: 'Instructions: Drag the ADSL variables into the correct category.' The variables are categorized into 'REQUIRED OR CONDITIONALLY REQUIRED VARIABLES' and 'PERMISSIBLE VARIABLES'. The variables shown are: RACE, SITEID: unique site identifier, RACEGRy: pooled race group, AGE and AGEU, STUDYID: study identifier, SITEGRy: pooled group of sites used for analysis, USUBJID: unique subject identifier, AGEGRy: pooled age group, REGIONy: pooled groups of sites into geographic regions, and SUBJID: subject identifier used within study.

The bottom section of the screenshot shows the CDISC website's 'Our Categories' section, featuring a grid of event cards for Raleigh, Berlin, Tokyo, Brussels, Ann Arbor, Shanghai, and Virtual Events in Japan, USA, and Europe. A 'CDISC Newcomers Virtual' event is also highlighted.

CDISC Training Development: Roles



Subject Matter Experts

- Focus: Content Development and Review



CDISC Ed Team

- Focus: Instructional Design, Presentation and Production



Training Development Strategy

Content:

- Overview of the Pediatrics UG
- Explanation of
 - datasets
 - concept maps
 - use cases

Process:

- CDISC Ed collaborates with SMEs on CDISC Overview content
- Pediatric UG SMEs content with support from CDISC Ed

Training Development Schedule



Possible Pediatrics UG Training Structure

Introduction to CDISC



Foundational Standards Overview

- CDASH model
- SDTM model
- ADaM model

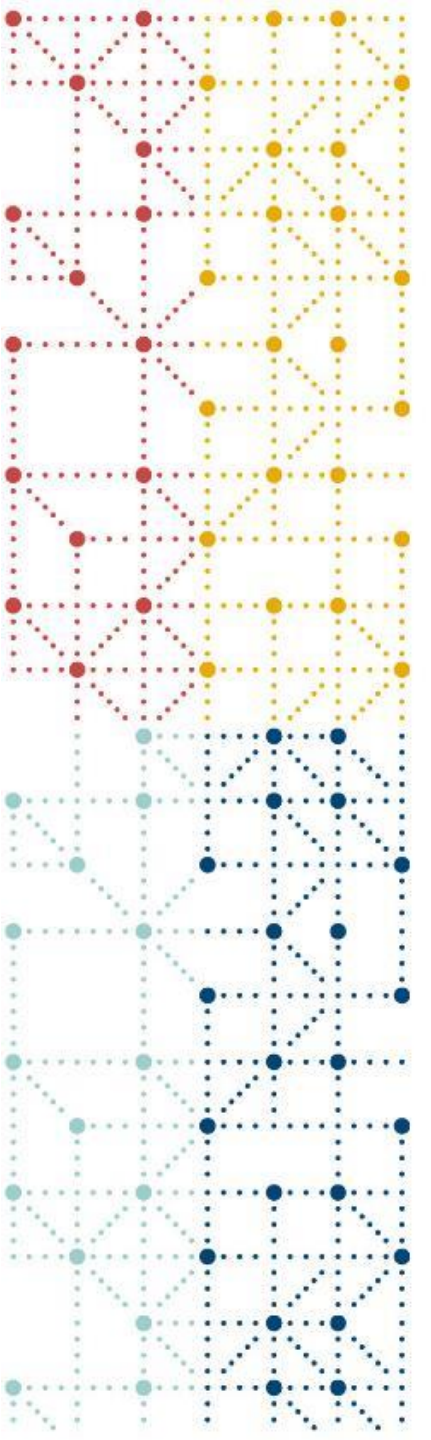
Pediatrics UG Content

CDISC UG Trainings

- Most CDISC UG trainings offered on-demand
- Available in CDISC Learn Store
- Free trainings available:
learnstore.cdisc.org
- Most trainings focused on drug development



The screenshot shows the CDISC website interface. At the top right, there are links for "Log In" and a shopping cart icon with "0". A search bar labeled "Search Courses" is also present. The CDISC logo is prominently displayed in the top left of the page content. Navigation links for "Return to CDISC.org" and "Education" are visible. The breadcrumb trail reads "Home / Catalog / TAUGs & Free Trainings". The main heading is "TAUGs & Free Trainings", accompanied by a circular icon containing an open book and the text "TAUGs & Free Trainings". Below this, a text block explains that users can access free on-demand trainings and will be prompted to create a cdiscID if they haven't. A large blue button labeled "Access Free Modules" with a cursor icon is the primary call to action. At the bottom, a list of free modules is provided, including topics like "Introduction to the Study Data Tabulation Model", "Introduction to the TMF Reference Model", and various TAUG modules for different medical conditions such as Asthma, Diabetes, Breast Cancer, Dyslipidemia, COPD, Prostate Cancer, Malaria, HIV, Lung Cancer, Type 1 Diabetes, Acute Kidney Injury, Heart Failure, Psoriasis, Crohn's Disease, and Pancreatic Cancer.



Pediatrics Community Feedback

Post-Training User Surveys

Home / Courses / SDTM Module 1: Introduction / Course Evaluation Survey / SDTM001 Survey / Complete a feedback

ADMINISTRATION

- Feedback administration
 - Edit settings
 - Locally assigned roles
 - Permissions
 - Check permissions
 - Filters
 - Logs
 - Backup
 - Restore
 - Questions
 - Analysis
 - Show responses
 - Feedback archive
- Course administration

SDTM001 Survey

Mode: Anonymous

The course materials contributed to learning the subject matter.*

(1) Strongly Disagree
 (2) Disagree
 (3) Neither Agree nor Disagree
 (4) Agree
 (5) Strongly Agree

As a result of taking this course, I have a greater understanding of the subject matter.*

(1) Strongly Disagree
 (2) Disagree
 (3) Neither Agree nor Disagree
 (4) Agree
 (5) Strongly Agree

Course materials were well organized and easy to follow.*

(1) Strongly Disagree
 (2) Disagree
 (3) Neither Agree nor Disagree
 (4) Agree
 (5) Strongly Agree

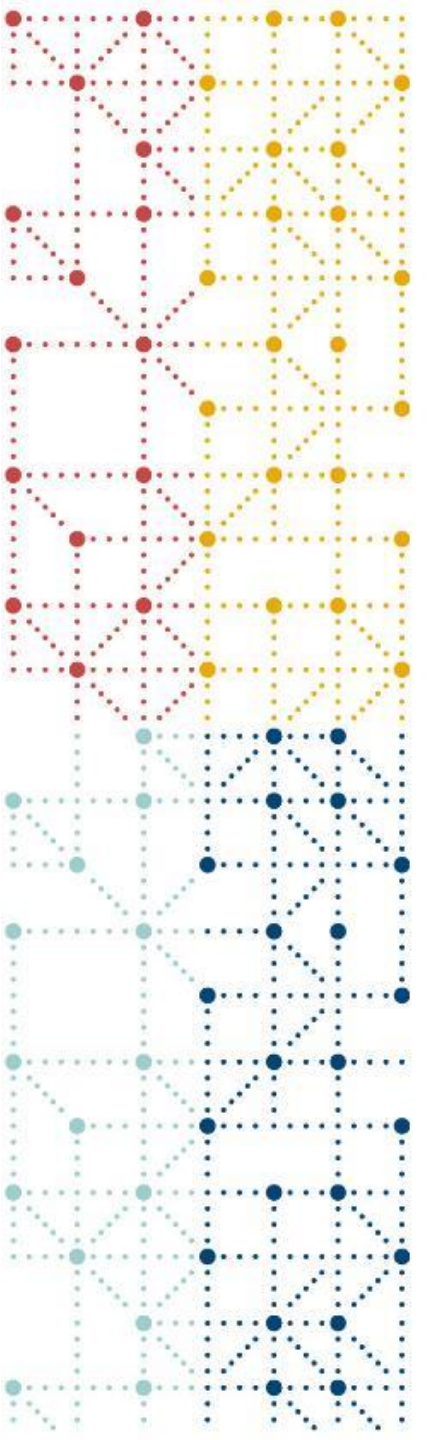
There was close agreement between the stated course outcomes and what was actually covered.*

(1) Strongly Disagree
 (2) Disagree
 (3) Neither Agree nor Disagree
 (4) Agree
 (5) Strongly Agree

The amount of interactive activities was

(1) Strongly Disagree

<https://learn.cdisc.org/mod/feedback/complete.php?id=1024&courseid>



Q&A

Q&A

- How much of the CDISC Standards spectrum should be included in the Pediatrics UG training?
- Who should be invited to participate in training evaluation surveys?
- Other questions?

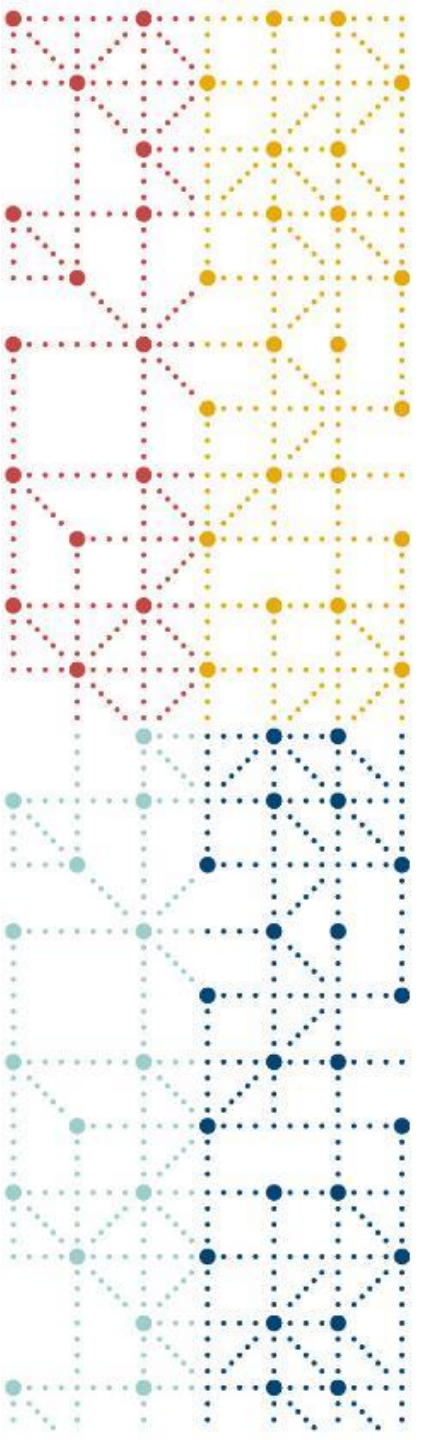


John Ezzell

Head of Education, CDISC

jezell@cdisc.org





Pediatric User Network Charter

John Owen, Head, PMO, CDISC

CPUN Charter



CPUN Charter

- **Name**

- CDISC Pediatric User Network (CPUN)

- **Mission**

- The mission of the CPUN is to develop a global volunteer-led pediatric user network composed of stakeholders actively meeting to discuss CDISC Standards and foster awareness of CDISC standards in the pediatric community.
- The CPUN will share experiences of implementing CDISC standards and collaborate to identify missing paediatric data items from the CDISC standards and channel these back into CDISC.
- The CPUN will be a cross functional membership group, providing a broad representation of roles across the pediatric research community with an interest in clinical data standards.
- CPUN members are welcome from all areas of research e.g., academia & industry and a range of roles e.g., Clinicians & Pediatricians, Clinical Data Managers, Biostatisticians, Clinical Data Standards Experts, CDISC experts (CDASH, SDTM, ADaM) in order to support this community in the adoption and implementation of CDISC standards.

CPUN Charter

• Budget and Resources

- Set-up of 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.
- The CPUN reflects input from its contributors and neither the IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained therein.
- Involvement in the CPUN is on a volunteer basis and is much appreciated in-order to build a global pediatric network forwarding CDISC clinical data standards in the area of pediatric research.



CPUN Charter

• Processes and Procedures

- The CPUN will be run according to CDISC's CDISC-COP-011 User Networks Operational Procedure which is available [here](#). The procedure is developed in the spirit of **supporting and encouraging User Groups** to be successful through a mutually beneficial relationship with CDISC.
- Involvement in the CPUN requires that rules set out in this procedure are followed by all members.
- A leadership team has been formed to assist in administering the CPUN and providing guidance for meeting topics and ideas for the activities of the CPUN
- The CPUN is free to set their own goals and agendas. Common goals are:
 - Sharing CDISC implementation experiences periodically
 - Discussing draft standards and providing comments to CDISC
 - Discussing mature standards and feeding back to CDISC on usefulness
 - Discussing new ideas to be channelled into CDISC
 - Networking among colleagues
 - Sharing recent conference participation and learning
 - Supporting CDISC utilization across languages, across cultures, and across user communities
- The CPUN is a fully independent body, whose legal and operational structure is at the discretion of it's members.
- The support that CDISC provides to recognized user groups is only meant to foster awareness and adoption of CDISC standards, and does not imply any sort of control, legal or otherwise, over these organizations.

CPUN Charter

• Communication

- The CPUN can take advantage of CDISC's communication channels to assist in promotion of CPUN activities (including e-blasts, social media, WIKI sites).

• Collaboration

- The CPUN will utilize a [public WIKI space](#) open to all.
- CPUN meetings will take place every 2 months
- CPUN Leadership meetings will take place every 2 months (alternate months to the CPUN meetings)
- Agendas, recordings and notes will be made available on the [CPUN WIKI](#)
- All CPUN meetings will be added to the [CPUN WIKI calendar](#)

Comments on the CPUN Charter



Next Meeting

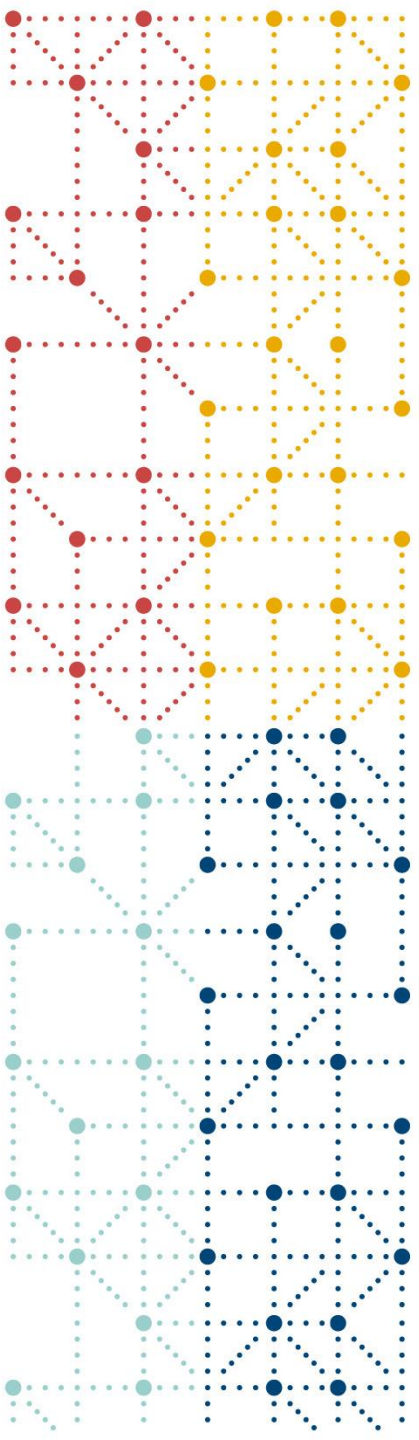


CPUN Meeting 13th June 2024

ACTION

Send any ideas for meetings topics by 9th May 2024

- Sharing CDISC implementation experiences
- Discussing draft/new standards and providing comments to CDISC
- Discussing mature standards and feeding back to CDISC
- Discussing new ideas to be channelled into CDISC
- Networking ideas
- Sharing recent conference participation and learning
- Supporting CDISC utilization across languages, across cultures, and across user communities



Thank you for being part of the CPUN

