



CDISC Pediatric Network Meeting

17th April 2024

John Owen, Head, PMO, CDISC

John Ezzell, Head of Education, CDISC

**cdisc**



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](#)



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[<](#)
[>](#)
April 2024
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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

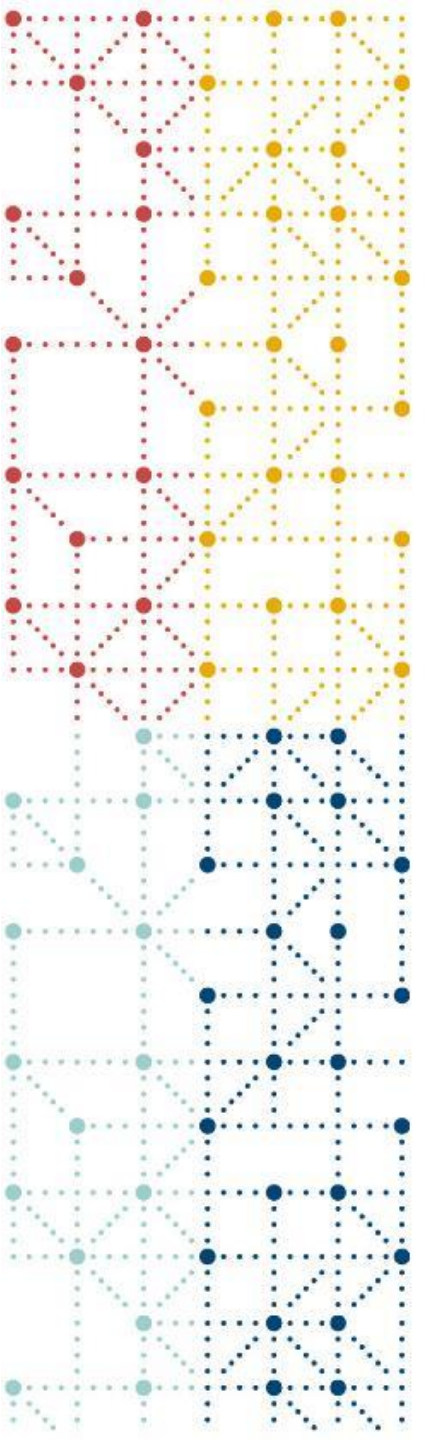


<https://wiki.cdisc.org/display/PEDUN/Pediatric+User+Network>

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



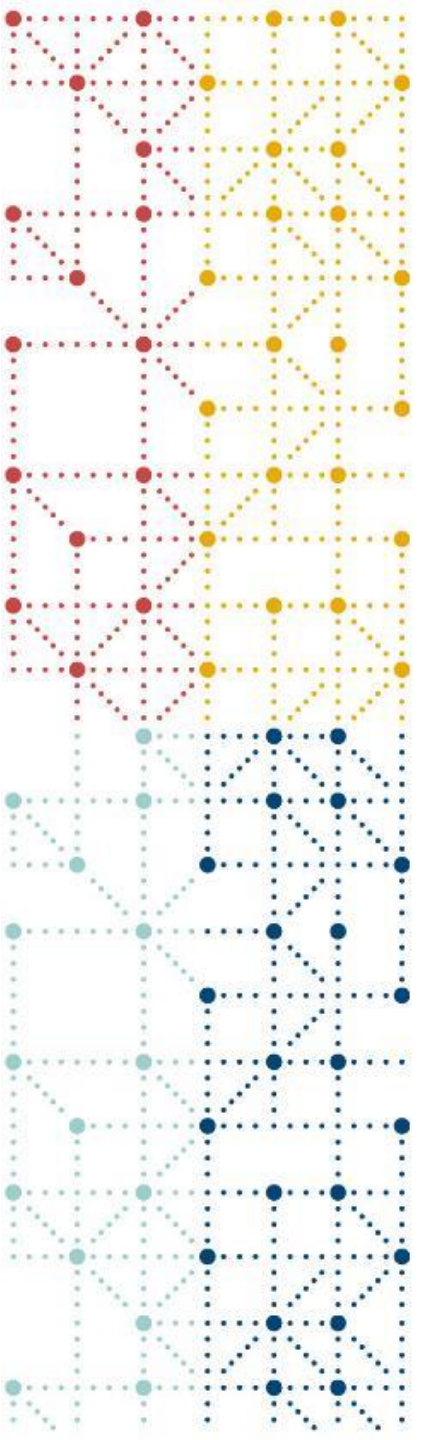
Introduction to Pediatrics Training Curriculum

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

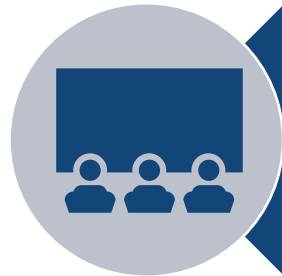
- Oversees Private Training Schedule
- Manages Learning Management System (LMS)
- Leads publication of Trainings

CDISC Training Areas of Focus



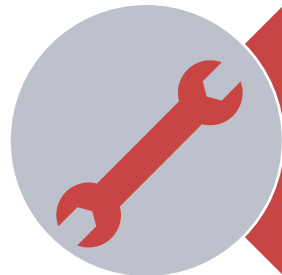
CDISC Standards & Publications

- Foundational Standards
- User Guides



Training by Audiences

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



Tools

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

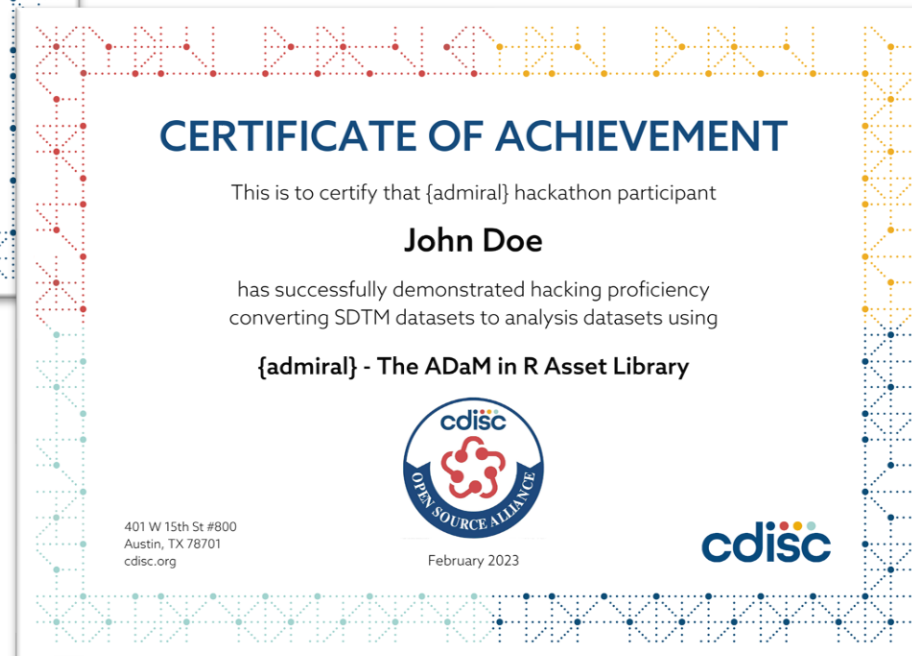
CDISC LMS

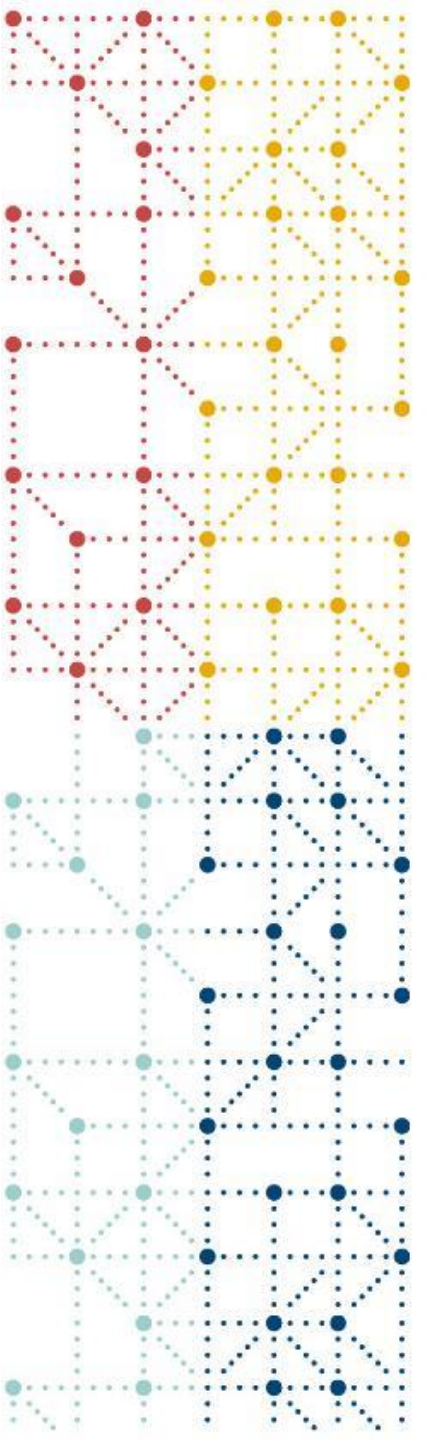
- Videos
- Interactive Activities
- Assessments
- CEUs



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 features a left sidebar with a table of contents including Participants, Badges, Grades, General, Welcome, and Chapters 1 through 8, along with CDASH, CDAM, and Helpful Links resources. Below this is an "ADMINISTRATION" section with options for Course administration, Grades, Question bank, and a role switcher. The main content area includes a "Welcome" section with an "Intellectual Property Notice" and a "Chapter 1" section with video and script links. A video player is embedded, showing a title card for "ACAD001: CDISC for Academic Researchers" and a CDISC logo. Below the video is a "Mark the video as complete:" section with radio buttons for "Complete" and a "Submit" button. On the right side, there are three widgets: "SEARCH FORUMS" with a search box and "Go" button; "LATEST NEWS" with a message that no announcements have been posted yet; and "UPCOMING EVENTS" with a message that there are no upcoming events. At the bottom right, a "RECENT ACTIVITY" widget shows activity since Tuesday, February 27, 2024, 9:31 AM. The bottom of the page shows "Interactive Content: 1 File: 1" and "Progress: 0 / 1".

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 tool interface. On the left, a navigation menu shows the course structure: ADAM MODULE 4: SUBJECT LEVEL ANALYSIS DATASET, with sub-items for 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 the navigation menu is the CDISC logo and a section titled "Our Categories" featuring event cards for Raleigh (8-12 April 2024), Berlin (22-23 & 26 April 2024), Tokyo (10-11 June 2024), Brussels (17-2), Ann Arbor, Shanghai (28-29 August 2024), a Virtual Event in Japan (February and March), a Virtual Training Event in May, and a Virtual Training Event in September. The main content area shows "Chapter 1 Activity" with instructions: "Required, Conditionally Required and Permissible ADSL Variables. Instructions: Drag the ADSL variables into the correct category." Below the instructions are two large boxes labeled "REQUIRED OR CONDITIONALLY REQUIRED VARIABLES" and "PERMISSIBLE VARIABLES". A list of ADSL variables is provided: SITEGRy (pooled group of sites used for analysis), USUBJID (unique subject identifier), AGEGRy (pooled age group), REGIONy (pooled groups of sites into geographic regions), SUBJID (subject identifier used within study), RACE, SITEID (unique site identifier), RACEGRy (pooled race group), AGE and AGEU, and STUDYID (study identifier). A "Check" button is located at the bottom of the activity page.

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

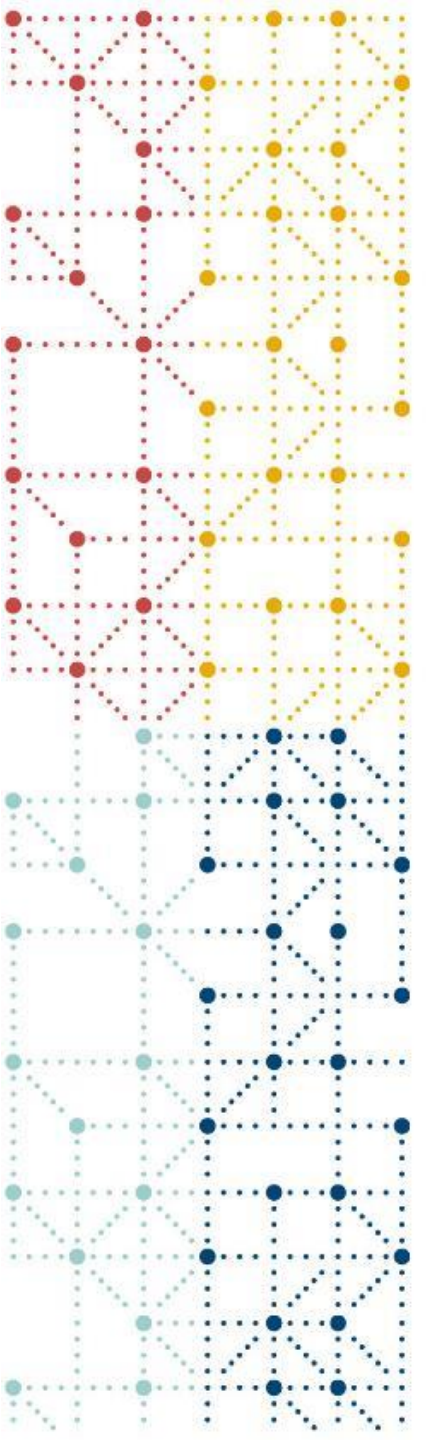
Pediatrics UG Content

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 white cursor icon is centered on the page. 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

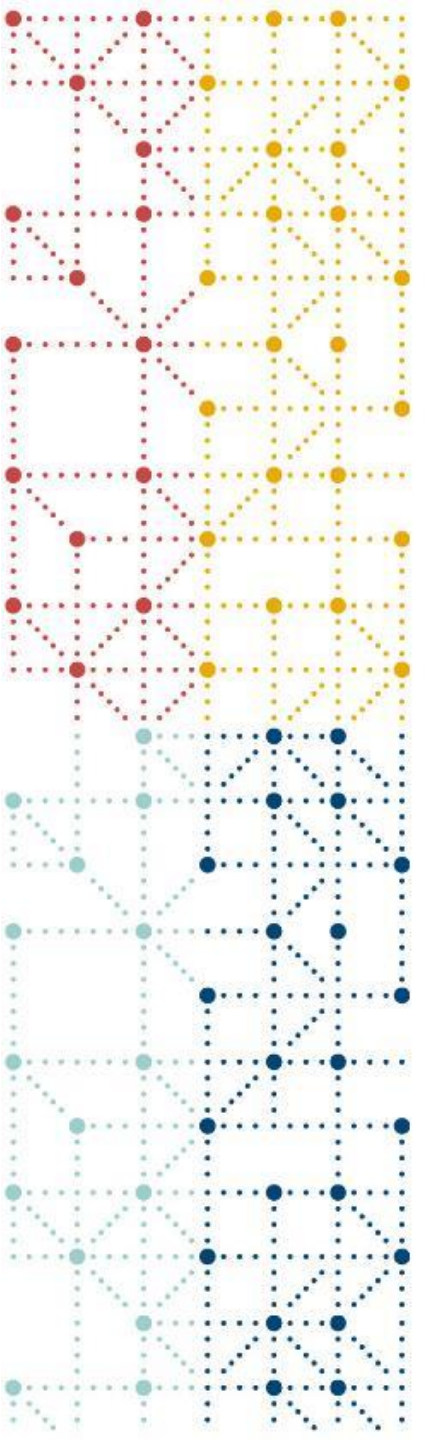
There was close agreement between the stated course outcomes and what was actually covered.*

(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?

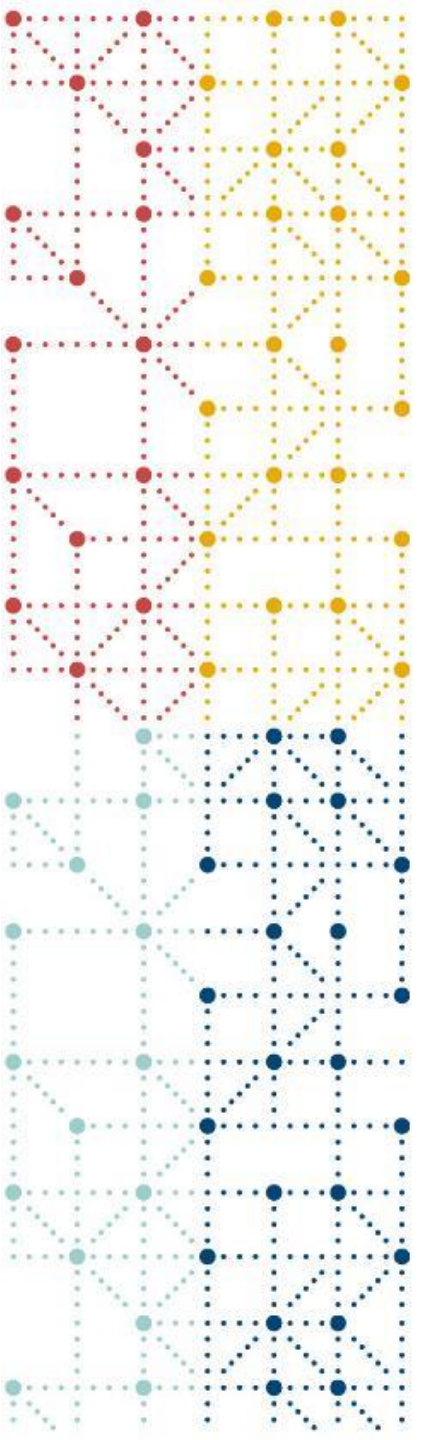


John Ezzell

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

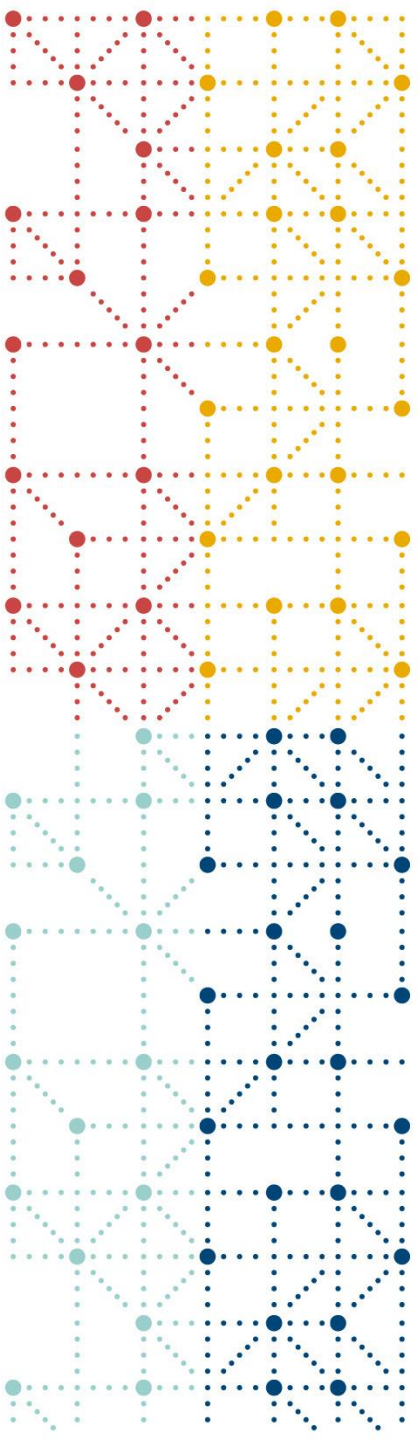
CPUN Meeting 13th June 2024

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

