CDISC Pediatric Network Meeting

17th April 2024

John Owen, Head, PMO, CDISC

John Ezzell, Head of Education, CDISC

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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: [_____]

[Submit]

- 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

cdisc — Pediatric User Network

Today	‹ ›	April 2024			Subscribe	Add Event

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

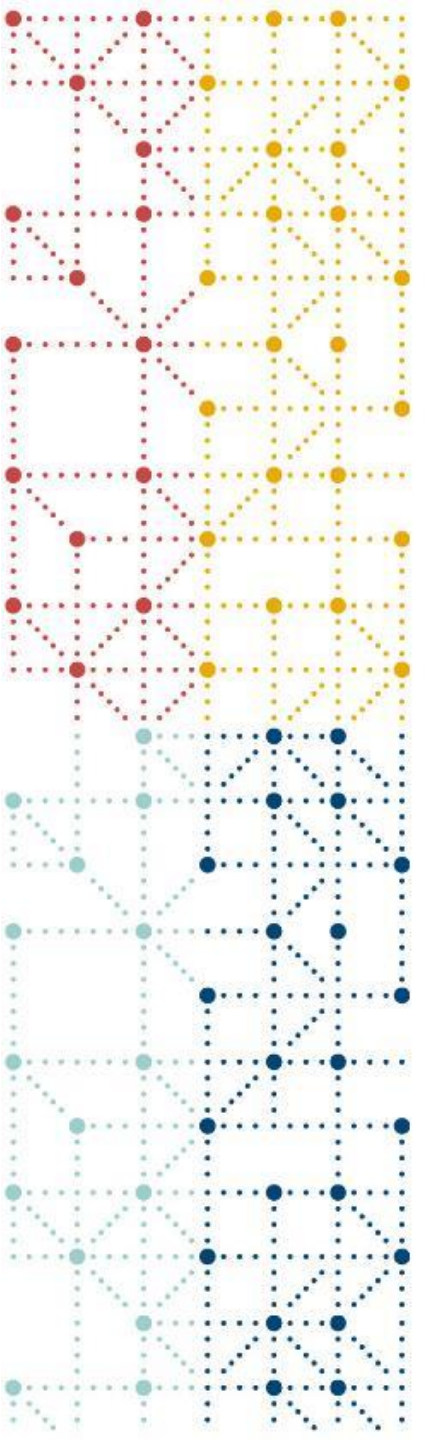https://wiki.cdisc.org/display/PEDUN/Pediatric+User+Network

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
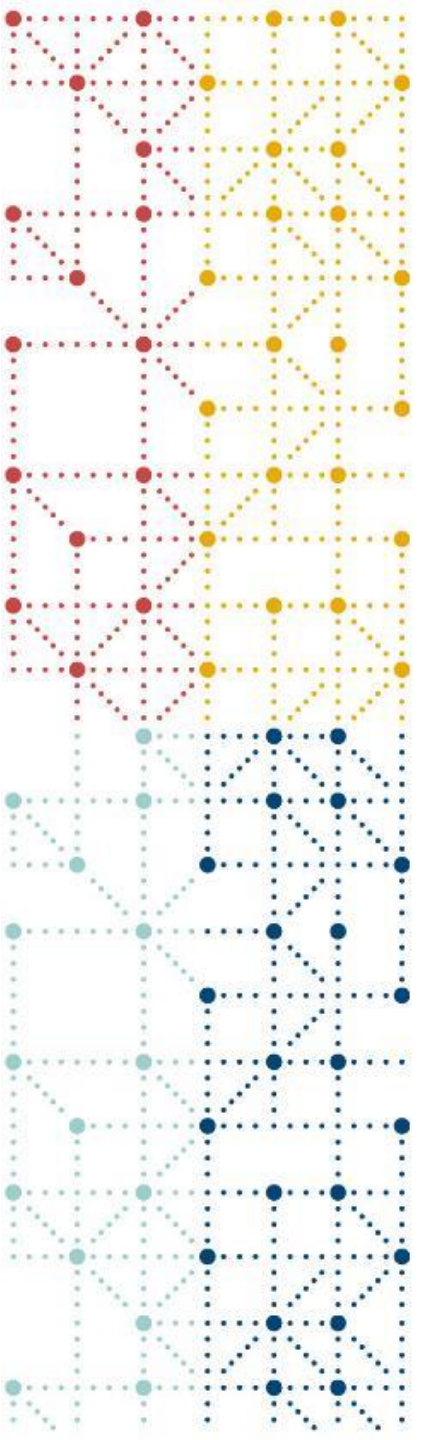 - Reschedule?

- 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
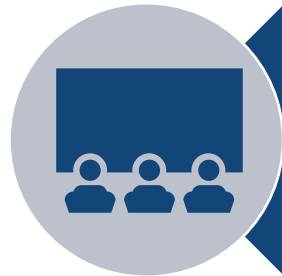
Training by Audiences

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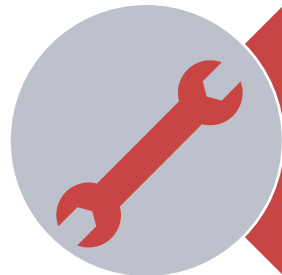
Tools

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

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CDISC LMS

- Videos
- Interactive Activities
- Assessments
- CEUs

learn.cdisc.org

Certificates and Badges
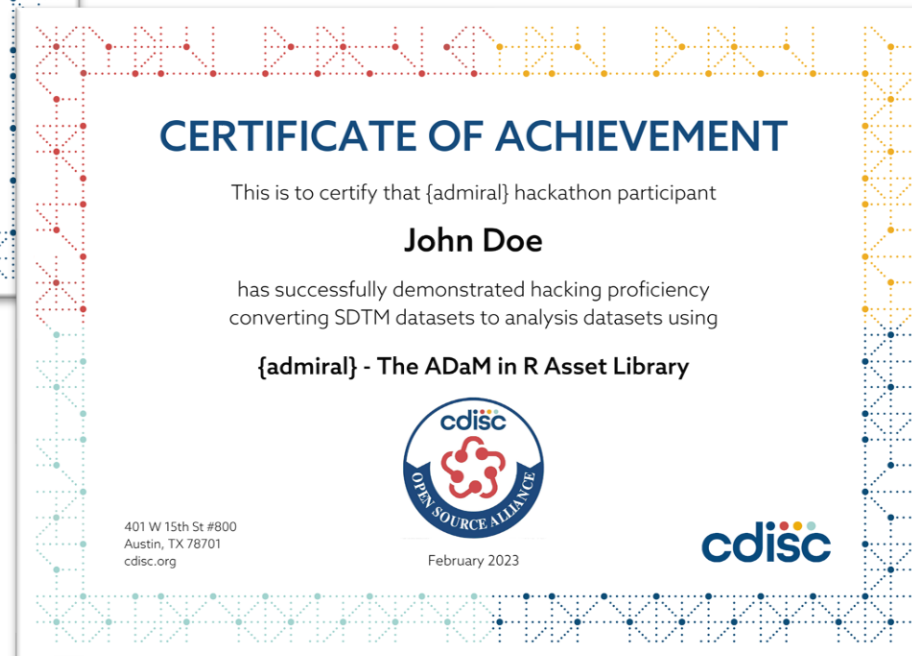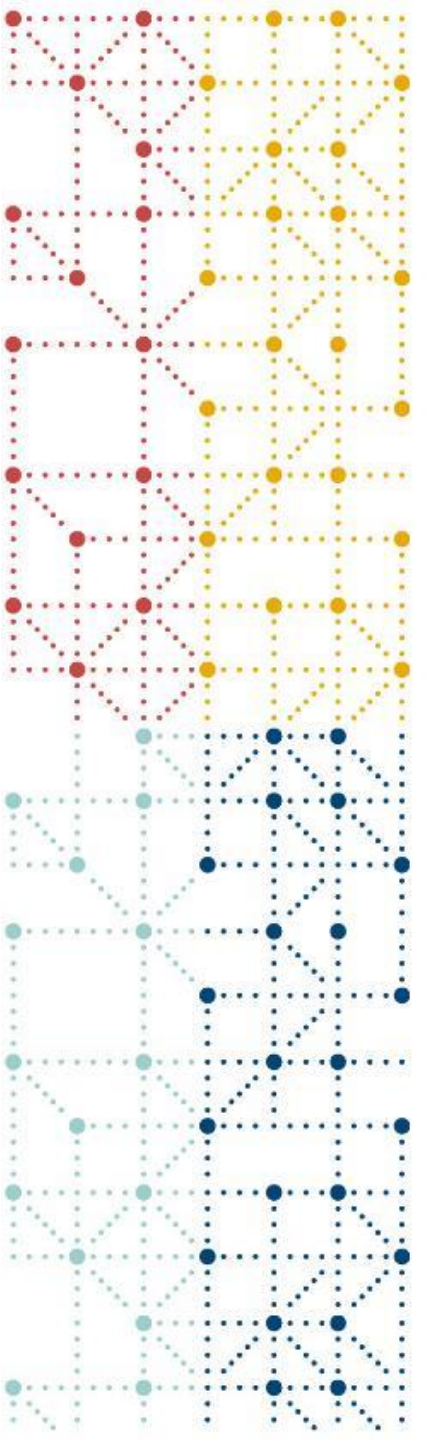
UG Training Development

CDISC Training Development Tools

- Collaboration Tools
  - Wiki
  - SharePoint
- Authoring Tools
  - Adobe Creative Suite
  - HP5
- Delivery Tools
  - iSpring
  - Zoom
  - Totara LMS

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

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Training Development Schedule

Planning   Manuscript   Draft   Production

Possible Pediatrics UG Training Structure

CDISC Standards in the Clinical Research Process

Introduction to CDISC

Foundational Standards Overview

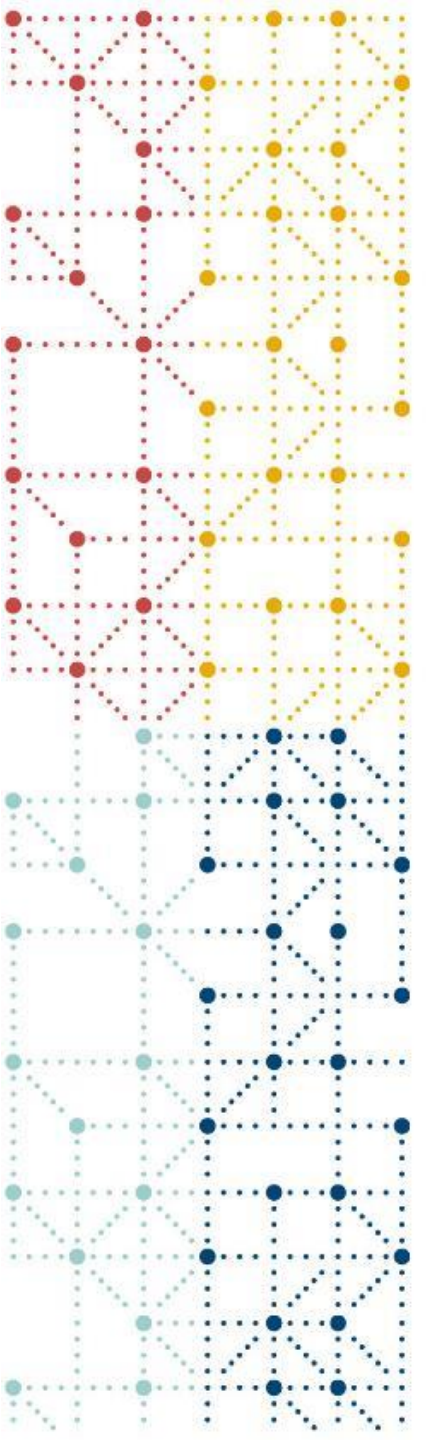- CDASH model
- SDTM model
- ADaM model

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

Pediatrics Community Feedback

Post-Training User Surveys

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?

CDISC Standards in the Clinical Research Process

John Ezzell
Head of Education, CDISC
jezzell@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 grop, 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 in 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
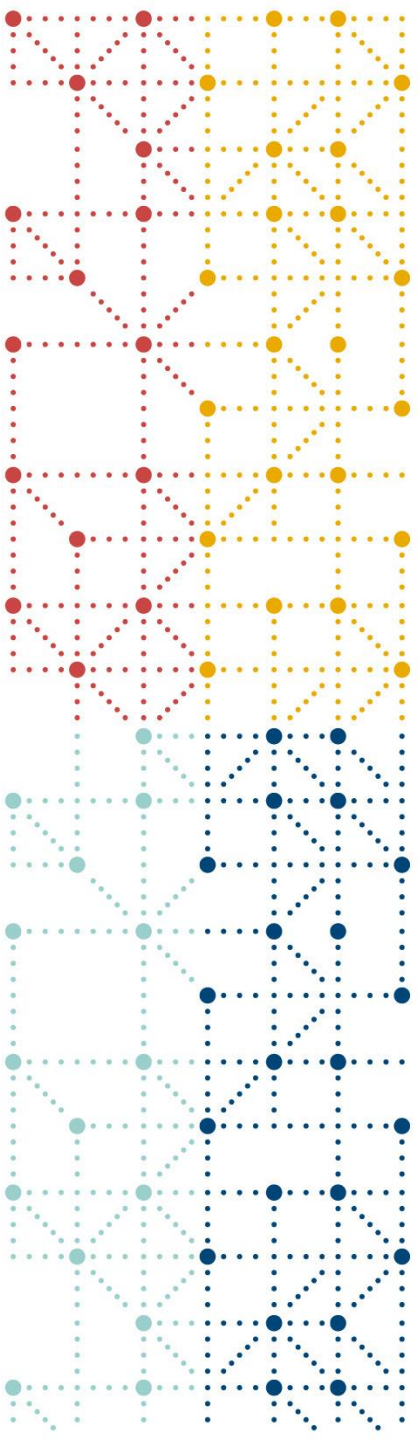
Thank you for being part of the CPUN