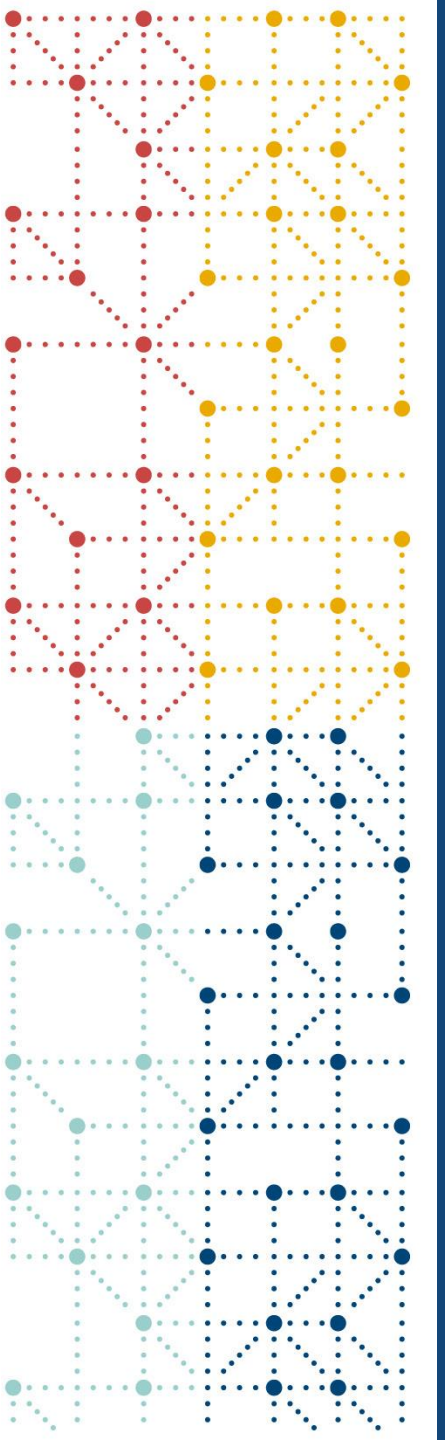
CDISC Pediatric User Group Kick-off Meeting

29th November 2023

John Owen, Head, PMO, CDISC

Agenda

1. Welcome and Introductions
2. What is a CDISC User Group
3. What do we need to do to get the User Group Active
4. Group Discussion and Questions
5. Next Steps



Welcome and Introductions

CDISC – Clinical Data Standards Interchange Consortium

***Mission**:*
To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- Global Non-profit Consensus-based Standards Development Organization
- 20+ Years of Regulatory Clinical Data Standards Development and Implementation
- Experienced Leadership Team and Dedicated Staff of 40+ Professionals and SMEs
- Volunteer Network of 1000+ Industry Experts
- 500+ Member Organizations
- Widely Adopted and Freely Available Clinical Research Data Standards
- Mature and Globally Accepted Standard Governance Processes
- Innovative Open-Source Technology for Standards Library and Metadata Management
- Involved in a wide range of emerging Industry Initiatives and Projects
- Collaborative Ecosystem of Relationships and Partnerships
  - Members, Regulators, Patient Foundations, Academia, SDOs and Industry

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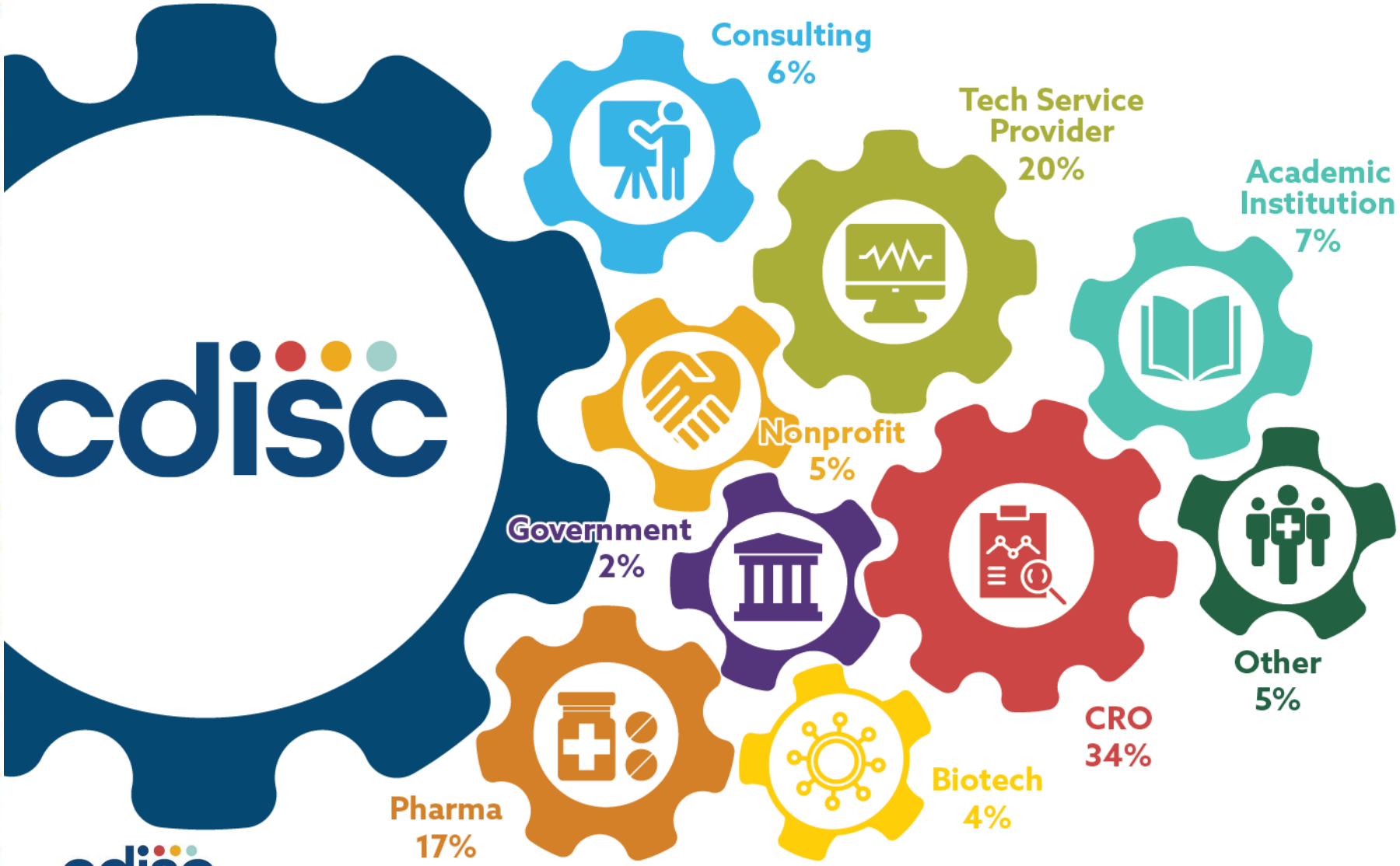
CDISC Membership

CDISC Members = Diverse Global Community



Member Benefits

- Training credits
- Discount on events
- Job postings on the CDISC jobs board
- Access to the members only area
- Membership recognition from CDISC at events
- Representation on he CDISC Advisory Council (CAC) – Platinum members only

Alliances and Collaborations

phuse

CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platform-independent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

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Upcoming 2023/2024 CDISC Events & Webinars

2023 Japan Academic Workshop

17 November 2023 - 17 November 2023

Join us for our first Japan Academic Workshop since 2021!

A half-day virtual event.

2023 Korea Interchange

11 December 2023 - 14 December 2023

Join us in Seoul for our first ever Korea Interchange!

2024 CDISC + TMF Europe Interchange

24 April 2024 - 25 April 2024

Save the date! The 2024 Europe Interchange will be held in Berlin, DE on 24-25 April.

2024 Japan Interchange

12 June 2024 - 13 June 2024

Registration now open! Register by 19 May to take advantage of the Early Bird discount!

The call for abstracts is now open! Submit an abstract for consideration by Friday, March 10th for review by our program committee.

2024 China Interchange

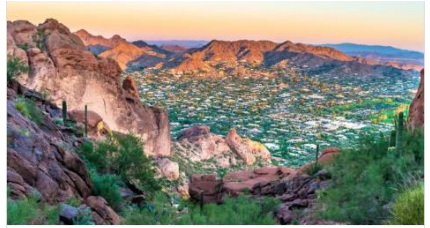
23 August 2024 - 24 August 2024

Shanghai | 23-24 August 2024

2024 Korea Interchange

26 August 2024 - 30 August 2024

Daegu, South Korea | End of August 2024



2024 CDISC US + TMF Interchange

23 October 2024 - 24 October 2024

Join us on the east coast for the 2023 US Interchange!

https://www.cdisc.org/events/webinars/upcoming

Data Standards and Data Science Group

CDISC In the Clinical Trial Process

Pre-Clinical


ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

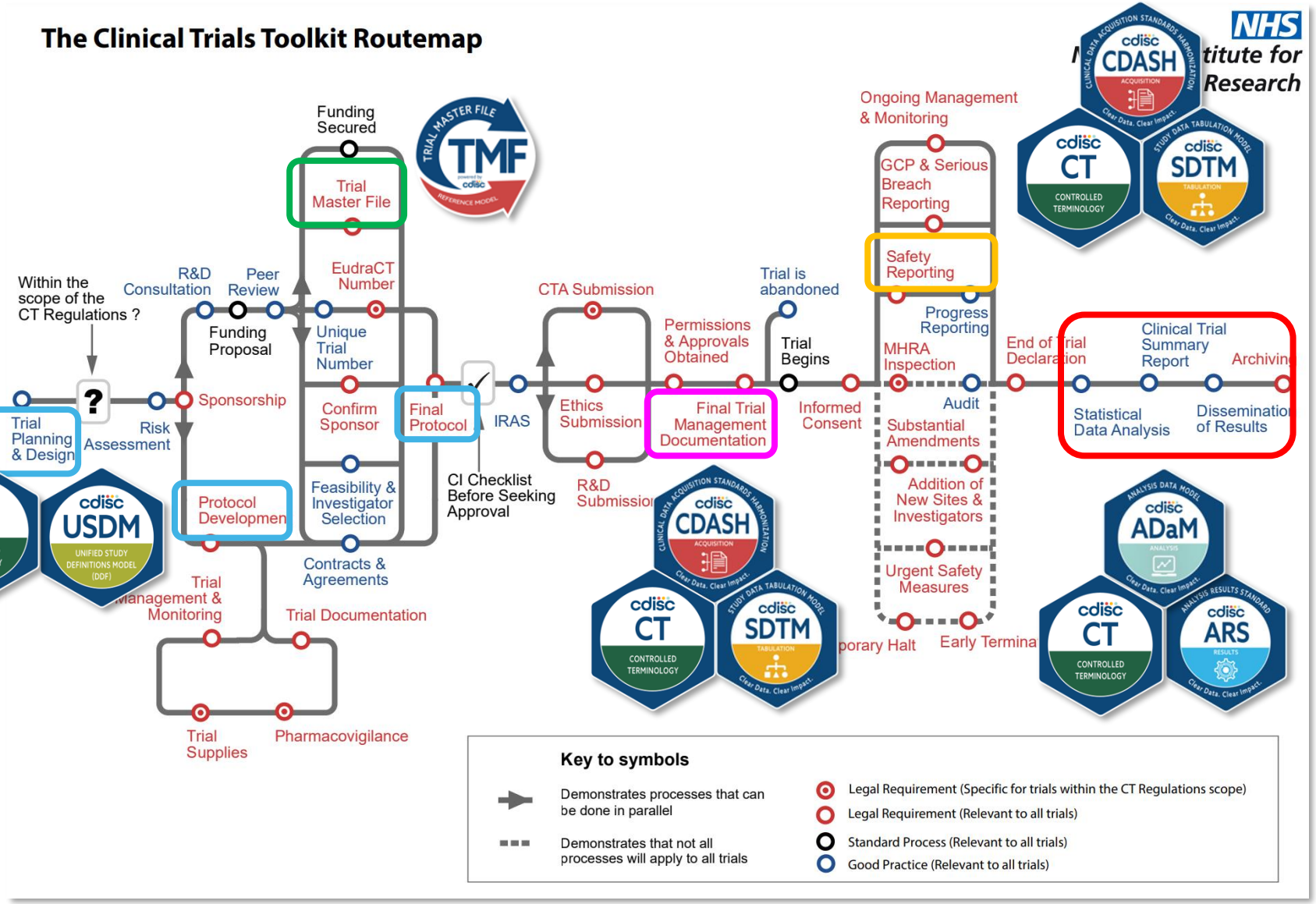
ICH HARMONISED GUIDELINE

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL
(CeSHarP)

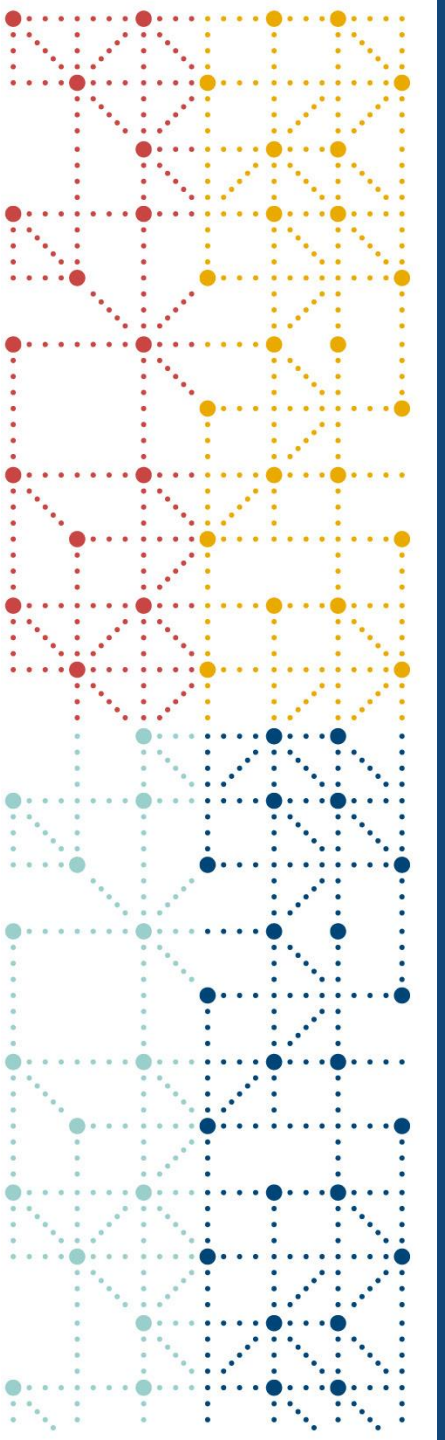
M11 TEMPLATE

Draft version
Endorsed on 27 September 2022
Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.



https://www.ct-toolkit.ac.uk/routemap/



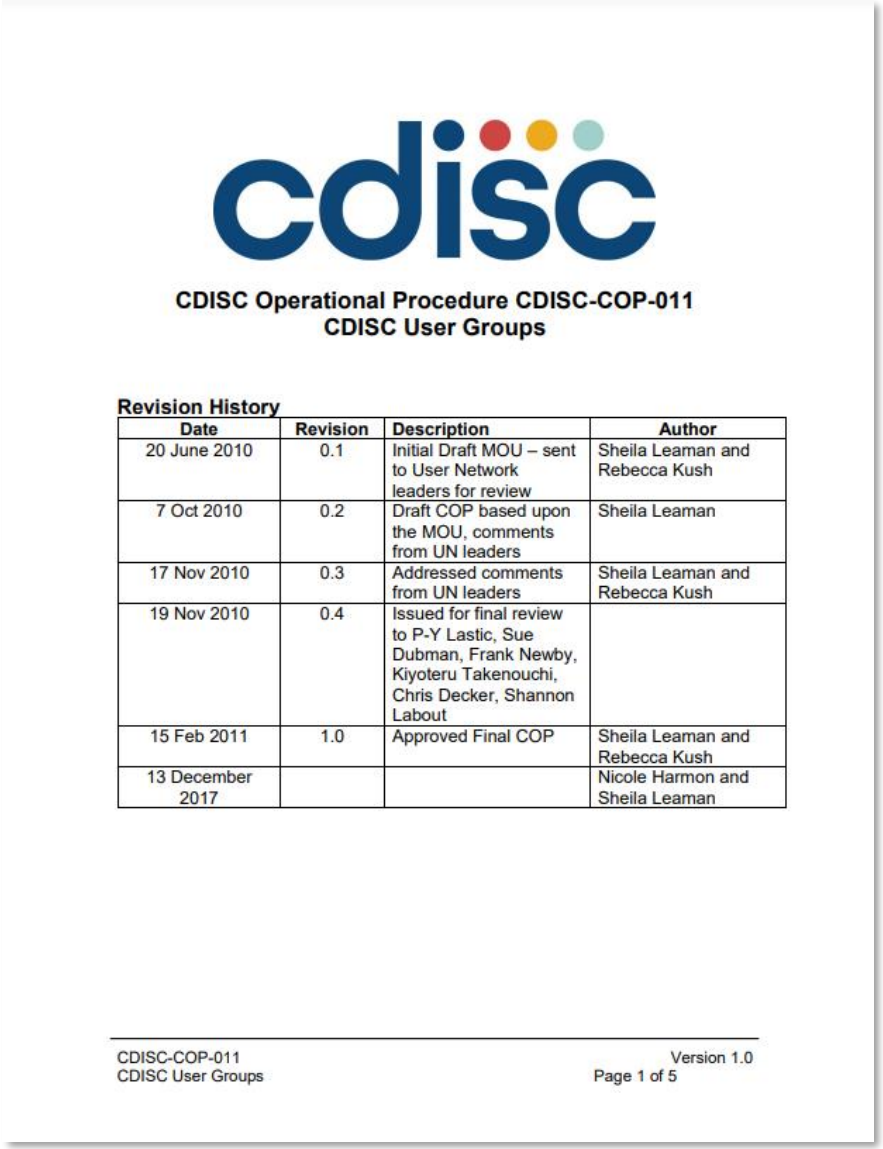
What is a CDISC User Group

Setting up a CDISC User Group

- Governed by CDISC Operating Procedure (COP) CDISC-COP-011
- Purpose of the COP:

Defines the **appropriate roles and expectations** between CDISC as an organization and stakeholders that represent users, members, and liaisons throughout the world

The Policy is developed in the spirit of **supporting and encouraging User Groups** to be successful through a mutually beneficial relationship with CDISC



CDISC Operational Procedure CDISC-COP-011
CDISC User Groups

Revision History

Date	Revision	Description	Author
20 June 2010	0.1	Initial Draft MOU – sent to User Network leaders for review	Sheila Leaman and Rebecca Kush
7 Oct 2010	0.2	Draft COP based upon the MOU, comments from UN leaders	Sheila Leaman
17 Nov 2010	0.3	Addressed comments from UN leaders	Sheila Leaman and Rebecca Kush
19 Nov 2010	0.4	Issued for final review to P-Y Lastic, Sue Dubman, Frank Newby, Kiyoteru Takenouchi, Chris Decker, Shannon Labout	
15 Feb 2011	1.0	Approved Final COP	Sheila Leaman and Rebecca Kush
13 December 2017			Nicole Harmon and Sheila Leaman

CDISC-COP-011 Version 1.0
CDISC User Groups Page 1 of 5

What is a CDISC User Group

- Autonomous volunteer-led organizations where CDISC users provide mutual support to help users utilize CDISC standards.
  - They are not, and should not represent themselves to be, part of CDISC the 501(c)3 organization (including as a subsidiary, controlled entity, etc).
- The purpose of user groups is to support the further implementation of CDISC standards.
- Composed of stakeholders who are actively meeting to discuss implementation of CDISC standards and can provide a feedback loop to the CDISC Standards Development Teams
- Fully independent bodies, whose legal and operational structure is at the discretion of their 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.

Benefits

- CDISC User Groups are free to set their own goals and agendas.
- Common goals of such groups often include, but are not limited to:
  - Share CDISC implementation experiences periodically
  - Discuss draft standards and provide comments to CDISC
  - Discuss mature standards and feedback to CDISC on usefulness
  - Discuss new ideas to be channelled into CDISC
  - Network among colleagues
  - Share recent conference participation and learning
  - Support CDISC utilization across languages, across cultures, and across user communities

How CDISC Supports User Groups

- As a nonprofit with limited resources, CDISC seeks to support user groups with realistic commitments of staff time and other resources
- CDISC support for User Groups is always subject to CDISC leadership judgments on feasibility and resource availability
  - With support from c4c CDISC is able to provide dedicated support until the end of the project.
  - Newcastle are able to provide administrative support to the user group.
- CDISC may be able to help support the group in the following areas:
  - A formal letter of authorization, indicating the User Group is an official CDISC User Group and expressing the geographic, language, or other membership scope of the User Group
  - Electronic copy of the of the CDISC logo and a limited license to re-use the CDISC logo and name (subject to conditions)
  - Coordinate with User Groups when CDISC staff are on work-related travel in the area, to arrange for a ‘CDISC Day‘ or other presentations for that User Group Offer updated presentation materials on CDISC activities
  - Provide Wiki pages for User Groups
  - Advertise User Group meetings and accomplishments in the CDISC Newsletter, website and through social media

What is the role of the User Group

- Provide feedback on implementation challenges and opportunities to help CDISC in improving standards including but not limited to:
  - feedback on examples, implementation use cases,
  - key lessons learned,
  - presentations for Interchanges,
  - articles,
  - sample CRFs
- Disseminate information to User Group participants on joining CDISC Working Groups, 3C, and other volunteer opportunities available at CDISC
- Disseminate information to User Group participants on joining CDISC via membership from its members

Limitations of the CDISC User Groups

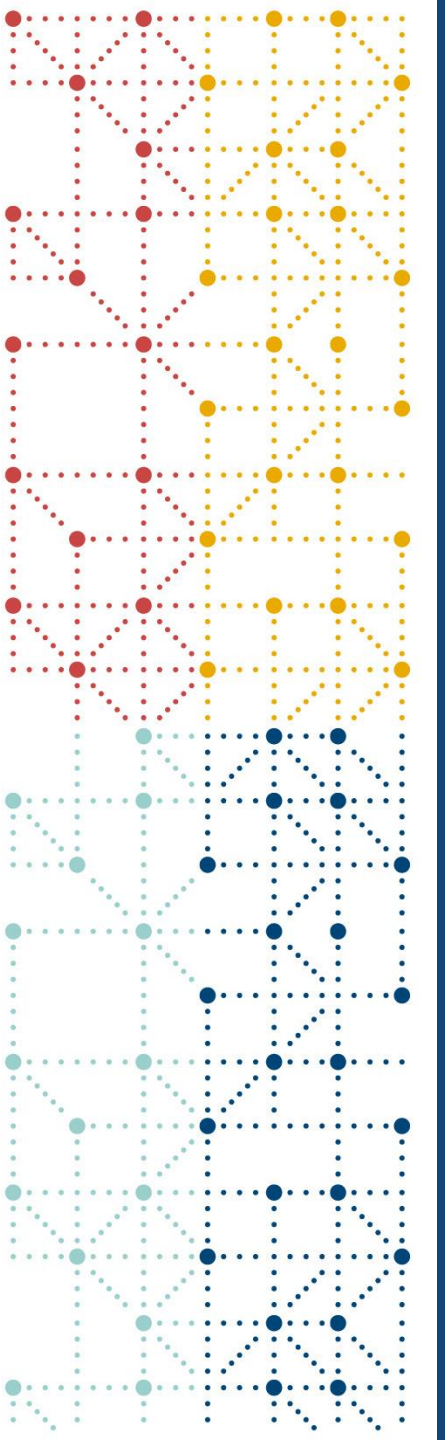
- CDISC User Groups Members are prohibited from competing with CDISC Educational Courses.
  - including distribution of CDISC-branded educational materials.
- CDISC User Groups Members are prohibited from speaking on behalf of CDISC
- The CDISC logo may not be modified. The CDISC logo may not be edited into a derivative logo specific to the User Group.
- The CDISC name and logo may never be used in a context such that it would appear to a casual observer that CDISC or the User Group are endorsing a commercial product, company, or service.

Questions for the group

5 minutes

- Do you use CDISC Standards Y/N
  - If Yes which ones
    - SEND – Pre-Clinical
    - CDASH – Data Collection
    - SDTM – Data Tabulation
    - ADaM – Data Analysis
    - Other
- Describe what you want to get out of being a member of the CDISC Pediatric User Group
- How often do you think the full group should meet
    - Monthly
    - Bi-monthly
    - Quarterly
- Do you have a preferred day that is better to meet (select as many as you can)
  - M T W T F
- List out three topics that you would like to user group to discuss/present
- What best describes you organization
- What is the role within your organization? e.g., Project Manager for Data Manager, Head of Standards, Physician etc.

https://vclock.com/set-timer-for-5-minutes/



What do we need to do to get the User Group Active

Getting the User Group Active

- Form a CDISC Pediatric User Group Leadership Team (CPUG-LT)
- Work on a CPUG Charter Document
- Determine a meeting cadence
  - CPUG all-hands Meetings
  - CPUG-LT Meetings
- Create a CPUG WIKI Site
- Create a CPUG email distribution list
- Work with the CDISC comms group to announce the formation of the group and recruit new members
- Decide on our first few topics to look at

CDISC Pediatrics Education Curriculum

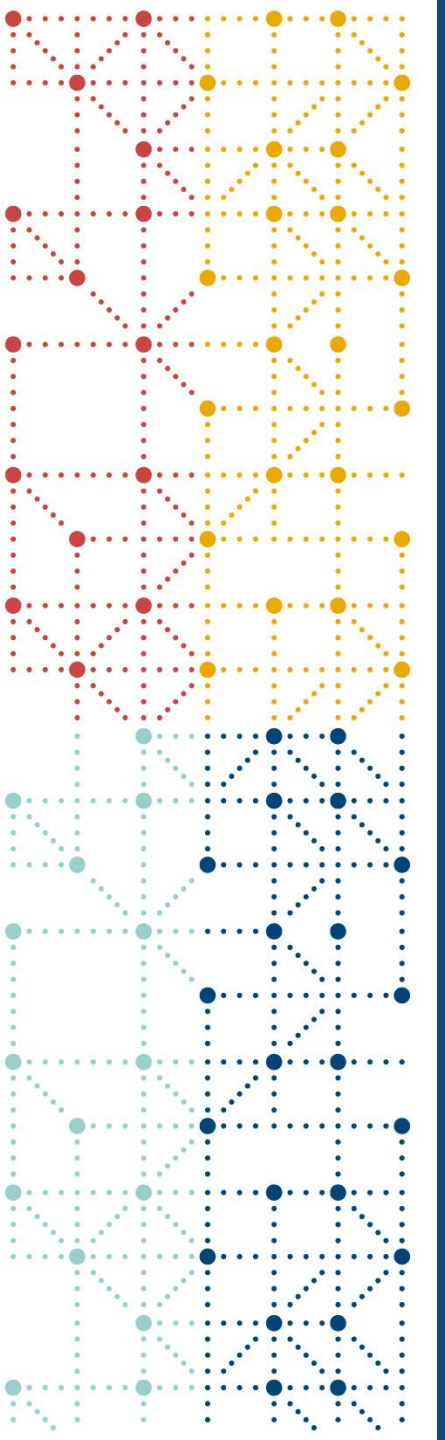
- Development of a CDISC Pediatric education curriculum providing new CDISC users with an on-line structured course to learn and implement CDISC standards related to the CDISC Pediatrics User Guide v1.0 and Pediatric Clinical Trials.
- Funding through c4c.
- The education curriculum will provide structure to assist the understanding of CDISC standards in relation to Pediatric Clinical Trials.
- Benefits
  - Increased use base of CDISC standards, in particular in the Academic user base
  - Increased Educational offerings from CDISC, in particular in the new area of education curriculum
  - The CDISC Pediatrics User Group has the potential to provide input into the education curriculum requirements and test what is developed

User Group Leadership

- Are you interested in being part of the CDISC Pediatric User Group Leadership team?
- The User Group leaders are responsible for:
  - Ensure that their User Group information in the CDISC User Group Wiki is accurate and up to date
  - Provide a yearly update to the designated contact on User Group activities
  - Be the primary point of contact for new users
  - If using a CDISC User Group Wiki area, ensure it is regularly maintained, including current meeting schedules, announcements and presentations.
  - Provide an open forum for exchange of information and a collegial, welcoming environment
  - In the event that a regulator, member of the media, a community stakeholder, or member of the public contact a User Group, liaise with the CDISC primary contact to provide an appropriate response to the inquiring party.
- Expected commitment
  - Attend CPUG-LT meetings (1 for each CPUG meeting) including some off-line preparation work
  - CDISC PM and Newcastle Secretariat resource support available to the end of the c4c project.
- Recommend 3-6 volunteers
  - Target: academic and industry, data and clinical
  - Complete the presented poll or Email Avril if you are interested

Questions for the group

- Are you interested in being on the Leadership Team for the CPUG
  - Yes
  - No



Group Discussion and questions

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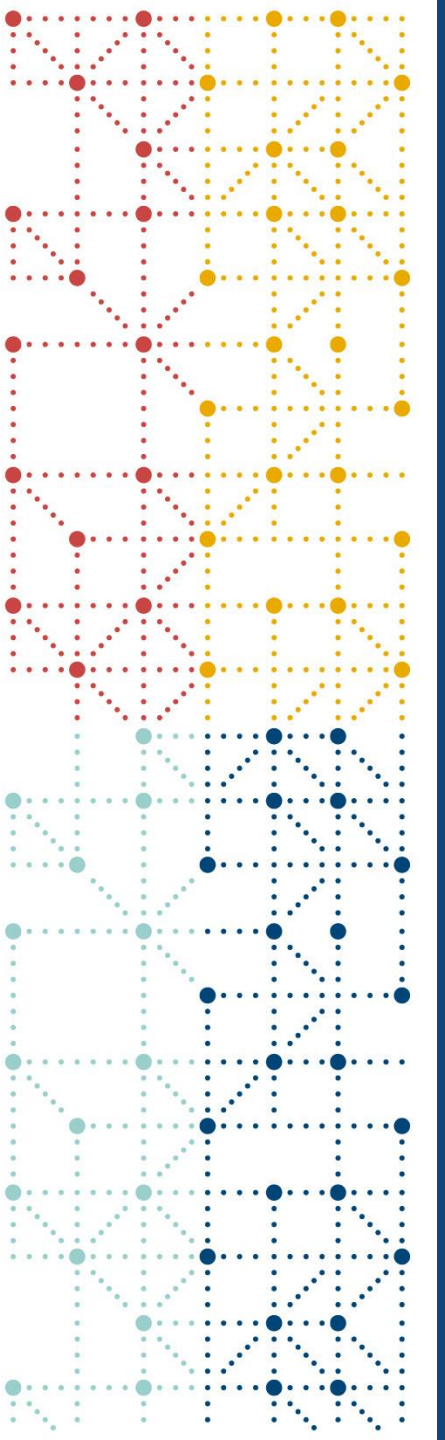
- Other User Groups/Networks
  - https://wiki.cdisc.org/display/PUB/CDISC+User+Networks
  - https://wiki.cdisc.org/display/PUB/CDISC+User+Network+Guide
- Topics for next meeting
  - Suggestions from the poll
    - Review if there are further areas where we can develop paediatric standards, in particular for safety data capture and analysis
    - ADaM in PUG
    - How to address disease-specific paediatric data standards
    - CDISC to OMOP to FHIR and other conversions
    - Data linkage
    - Ethical restrictions to data usage
    - PPI perspective on improving use of data
    - PAEDIATRIC FEATURES in all the clinical trials lifecicles. (profit vs NO profit)
    - Training,
    - Use of RWD in studies,
    - Increasing use for academia
    - Safety data standards, with adaptation to size and disease specificities



Next Steps

Next Steps

What	Who
Volunteer to be part of the CPUG-LT	All
Arrange first CPUG-LT meeting to work on CPUG Charter/Topics for next meeting	John/Avril
Set-up CPUG WIKI and Email Distribution list	John/CDISC
Arrange comms activities to disseminate information to the community on the CPUG	John/Avril
Set date(s) for next CPUG Meeting	John/Avril


Thank you &
Happy holidays