

	CDISC Pediatric User Group Minutes
	<p>Date: 29th November 2023 Place: Zoom Time 3:30-4:30 (GMT) / 4:30-5:30 (CET)</p>
Attendees	John Owen, Avril Palmeri, Becca Leary, Anando Sen, Thomas Luethy, Giorgio Reggiardo, Claudia Pansieri, James Webbe, Johan Vande Walle, Eva Degraeuwe, Gabriele Ahne, Corinna Engel, Kasey Baker
Welcome and introductions	<ul style="list-style-type: none"> JO presented some introductory slides giving an overview of CDISC, including its mission to develop and support data standards for medical research. He discussed membership benefits, collaborations with external organizations and ongoing projects related to data standards and data science. He also presented the Clinical Trials Toolkit Routemap which places each of the CDISC standards within the clinical trial process.
What is a CDISC user group?	<ul style="list-style-type: none"> JO presented information about what a CDISC user group is and reviewed the operating procedure. CDISC user groups are autonomous, volunteer-led organizations where CDISC users provide mutual support to help users utilize and implement CDISC standards. There is also the opportunity to review and comment on draft standards of interest to pediatrics. A full description of the role, benefits and limitations of the user groups, in addition to the support provided by CDISC is available in the slides accompanying these minutes. The group were asked to complete a poll with the following questions: <ul style="list-style-type: none"> Do they use CDISC standards and if so, which ones. What they want to get out of being a member of the user group How often the group should meet – monthly, bi-monthly or quarterly Preferred day of the week Three topics of discussion for the group Description of organization Role within organization Interest in volunteering for the CPUG leadership team (see below) The poll is available as a MS Form for those who were not on the call or who were not able to complete it during the call.
What do we need to do to get the user group active?	<ul style="list-style-type: none"> To get the user group active, volunteers are needed from within the group to form a CDISC Pediatric User Group Leadership Team (CPUG-LT). The CPUG-LT will work on a charter and determine a meeting cadence and have additional ongoing responsibilities described in the meeting presentation. A CPUG wiki site and email distribution list will be created. JO and AP will work with the CDISC comms group to recruit new members. The CPUG-LT will decide on the first few topics to discuss. The poll linked above provides an opportunity to register interest in volunteering for the CPUG-LT. The CPUG could become involved in a new initiative to create an educational curriculum to provide new CDISC users with an online, structured course where they will learn how to implement CDISC standards as well as providing training on how to use the CDISC Pediatrics User Guide. The training is funded by c4c and the idea is to increase the use of CDISC standards, particularly in the academic community.

<p>Group discussion and questions</p>	<ul style="list-style-type: none"> • JO shared the wiki homepage for the CDISC user groups and a guide to tools and usage for supporting user networks. • JO also shared suggestions for upcoming topics suggested by call participants: <ul style="list-style-type: none"> ○ 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 ○ Pediatric Features in all the clinical trials lifecycles. (profit vs NO profit) ○ Training ○ Use of RWD in studies, ○ Increasing use for academia ○ Safety data standards, with adaptation to size and disease specificities
<p>Next Steps</p>	<ul style="list-style-type: none"> • Volunteer to be part of the CPUG-LT (All) • Arrange the first CPUG-LT meeting to work on CPUG charter/topics for next meeting (JO/AP) • Set up CPUG wiki and email distribution list (JO/CDISC) • Arrange comms activities to disseminate information to the community on the CPUG (JO/AP) • Set date(s) for next CPUG meeting (JO/AP)