	CDISC Pediatric User Group Leadership Minutes
	Date: 23rd January 2024 Place: MS Teams Time 9:00-10:00 (GMT) / 10:00-11:00 (CET)
Attendees	John Owen, Avril Palmeri, Anando Sen, Johan Vande Walle, Levi Hoste, Teresa Berkery
Welcome and introductions	• The members of the team introduced themselves. • JO commented that the leadership team needs an industry representative. JVW commented that there should also be representation from the wider rare disease community and suggested reaching out to Franz Schaefer, lead of ERKNET, ERDERA Application, at Heidelberg. **Action: AP will follow up on these suggestions.**
Summary from kick-off meeting in November	• JO commented that CDISC user groups are being referred to as user networks. **Action: JO will confirm internally which of these the paediatric group should use.** • JO introduced slides outlining what a CDISC user group is and how it operates and interacts with CDISC. • c4c will fund JO's time as project manager and administrative support from AP until April 2025 when the project ends. CDISC will continue to provide limited support after that, but the intention is that user groups become self-sustaining. • CDISC provide a formal letter of authorization and an electronic copy of the CDISC logo and limited license to re-use the logo and name. CDISC can also help with the organisation of face-to-face meetings, such as at the CDISC interchanges. • The leadership team is responsible for ensuring the CDISC user group wiki is accurate and up to date, providing yearly updates, being primary point of contact for new users, providing an open forum for collaboration and to liaise with CDISC to provide appropriate responses to enquires. • The expected commitment from the leadership team is to attend the CPUG-LT meetings (one for each CPUG meeting), including some offline preparation work. The recommended number of CPUG-LT volunteers is 3-6.
What do we need to do to get the user group active?	• Form the CPUG-LT. • JO will start working on the CPUG charter document for review based on a CDISC template. • Determine a meeting cadence (preference at the kick-off meeting was for meetings every two months). • Create and populate the wiki page and create the CPUG email distribution list. • JO has met with the CDISC comms group and is working with them to develop a communications plan to announce the formation of the group and recruit new members. This will be put into effect before the next CPUG meeting. The CDISC comms group will also work with c4c to jointly promote the pediatric training modules later this year. • Decide on the first few topics to look at.
Group discussion and questions	• Based on the poll sent to CPUG members, the most popular choice for meeting cadence was to meet every two months. Wednesdays and Thursdays were the most popular days. Meetings will need to be scheduled in the afternoons European time to allow for US participation. CPUG-LT meetings will take place

	two or three weeks before the full meeting to allow time for planning. **Action: AP will send out a Doodle poll for dates in late February based on JO's availability. If this time generally works well for most people, it may become a recurring meeting time rather than ad-hoc scheduling.** • JO shared a slide suggesting topics from CPUG members during the kick-off meeting. Topics must fit within the scope of network around the use and implementation of CDISC standards. • JVW commented it is important to make sure data stay in the same system when children transition to adulthood to ensure long-term data. What would be the specific action that the CPUG could do around this as it is bigger than CDISC standards. • The long list of suggestions can be narrowed down into three main categories: Training, Implementation and Gaps. • JO will reach out to the CDISC education group to present the plan for the CDISC paediatric training module at the first CPUG meeting and to gather feedback. • LH asked if the new pediatric specific standards have been derived from existing non-paediatric specific standards. **Action: AS has developed a paper (about to be published) outlining the process of developing the PUG and he will share this with LH.** • When looking at gaps, we need to decide whether to narrow down to specific diseases or therapeutic areas. This could lead to the CPUG working to develop examples as there is not funding to develop a version 2 of the Pediatrics User Guide. • Topics that come up in this group will be added to the list. • We would like to encourage members of the CPUG to present to the group to increase engagement.
Next Steps	• AP will look into contacting industry and rare disease representatives for the CPUG-LT. • JO will confirm if we are a user group or a network. • JO will reach out to the education group to present on the next CPUG call. • AP will send out a Doodle based on JO's availability for late February. • AP will share the PUG paper with LH.