

2024 ANNUAL REPORT

SIG/Committee Name: Digital Health and eCOA SIG

Date: 29 February 2024

Leadership: Alisa Heinzman, Megan Turner, Ana Popielnicki

Board Liaison: Tom Willgoss

Mission: The Digital Health and eCOA SIG will broadly cover topics of interest related to the scientific rigor, development, validation, and implementation of PRO, ClinRO, PerfO, ObsRO, and Proxy measures in electronic modes of data collection as well as digital measures. The SIG promotes the visibility of digital measures and eCOA related to the development and use of COAs by facilitating collaborations between academia, industry, consultants, COA developers, and pharmaceutical sponsors.

Project/Working Group/ Initiative Title	Actions/Deliverables	Description	Project Chair(s)	Project Members	Date Executed/ Estimated Timeline
1. UX/UI Working Group	Manuscript to be submitted for publication in JPRO	Description (working manuscript title): Lost in Translation: A systematic review of UI-UX practices applied in eCOA design.	Project chair: Anna Richards	Project members: Anna Richards Beatrice Tedeschi Jeanne Landgraf John Chaplin Justin Raymer Marlene Knupfer Megan Turner Vlad Zah	Manuscript development in progress. Target to submit for publication by October 2024
2. Digital Measures Definitions Resource (To be confirmed, not all will progress for 2024 production)	A glossary of terms for digital measures	Idea from Igor Matias, University of Geneva, QoL Lab	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
3. Digital Health and eCOA Case Studies (To be confirmed, not all will progress for 2024 production)	TBD	 SIG Members see evidence of Digital Health and eCOA in practice, but it isn't visible to the public. Examples: How are we using digital technology for patient-centric endpoints and to improve the patient experience? Cognitive measures: there is no existing guidance. How do stakeholders build/handle them? 	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.



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4.	Strategies to Speed Up eCOA Implementation (To be confirmed, not all will progress for 2024 production)	TBD	Investigate ways to handle eCOA Implementation more quickly. Examples: 1. eCOA Libraries 2. Item Banks	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
5.	Combining Operational and Human Factors for DHTs (To be confirmed, not all will progress for 2024 production)	TBD	Investigate the Human factors of Digital Health and eCOA through UX/UI and User Modeling.	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
6.	Use of Technology for PRO reporting: A Collaboration with Industry SIG (To be confirmed, not all will progress for 2024 production)	TBD	Collaborate with the Industry SIG to investigate uses of technology outside of common eCOA implementation such as: 1. Digital Bots 2. ConvoRos (COAs via chatbot) 3. SMS	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.
7.	COA Measure Owners Forum (To be confirmed, not all will progress for 2024 production)	TBD	Collaboration with the eCOA and PRO Consortia. A forum whereby COA measure owners/developers, eCOA providers and sponsors could convene for mutual education opportunities in the context of eCOA licensing.	TBD	TBD	To be discussed in next SIG membership monthly meeting (18Mar24), request leads and members for each project.

Concerns/Questions/Comments:

SIG Leadership conducted an informal survey among members to vote for each of the above-listed projects, which resulted from the inaugural meeting at the 2023 AC. Survey results will be discussed during the next monthly meeting (18Mar2024), and the selected topics will be distributed on a volunteer basis to subgroups with an assigned leader. We expect a subset of these initiatives to progress in 2024.