

**SIG/Committee Name: Regulatory and Health Technology Assessment Engagement (R&HE) SIG**
**Date: March 3, 2024**
**Leadership: Ashley F. Slagle, Robyn Carson, Wen-Hung Chen**
**Board Liaison: Tom Willgoss**

**Mission:** This SIG will routinely and actively engage with regulatory agencies and health technology assessment (HTA) bodies to address critical applied measurement issues raised by these entities or that emerge from their public communications (e.g., guidance documents, reflection papers, workshops). This collaboration embraces a broad measurement perspective and enables us to build scientifically-based patient-focused recommendations regarding the use of clinical outcome assessments (COAs) in the evaluation of therapeutic interventions aimed at advancing human health and well-being.

<b>Project/Working Group/ Initiative Title</b>	<b>Actions/Deliverables</b>	<b>Description</b>	<b>Project Chair(s)</b>	<b>Project Members</b>	<b>Date Executed/ Estimated Timeline</b>
1. Review & comment on regulatory and HTA publications/draft guidance	2023: Comments provided on FDA PFDD Guidance 4 (Complete)	Develop monitoring & dissemination process; Draft & submit comments to regulatory or HTA groups	TBD	Determined as needed aligned with expertise & availability	Ongoing throughout 2024
2. Understand current global regulators & reimbursement authorities' perspectives on methodological expectations & impact of PED	2024: Research Plan; Perspective Paper	Develop research plan & initiate research; Develop perspective paper on multi-stakeholder evidence requirements & core set of evidence to address in partnership with Industry SIG	TBD	TBD	<ul style="list-style-type: none"> <li>Q224: Research Plan</li> <li>Q324: Perspective Paper</li> </ul>
3. Facilitate Discussions with Representatives across Stakeholder Groups to Understand Value & Opportunities to Leverage PED Beyond the Label	2024: Symposium at 2024 Annual Meeting; Quarterly Discussions with RHE SIG	Partner with Industry SIG to foster discussion with external thought leaders representing industry, regulatory & reimbursement authorities to identify value & opportunity for PED beyond the label; Facilitate quarterly discussions with RHE SIG members to discuss timely topics & opportunities for application of PED beyond the label	TBD	TBD	Quarterly beginning in Q2; Symposium: October 2024 (pending acceptance)

**Concerns/Questions/Comments:**