



## 2023 ANNUAL REPORT

**SIG/Committee Name:** Regulatory and Health Technology Assessment Engagement (R&HE) SIG

**Date:** 1 March 2023

**Co-Chairs:** Robyn von Maltzahn and Ashley F. Slagle

**Board Liaison:** Roxanne Jensen

**Mission:** This SIG routinely and actively engages 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.

**Number of SIG Members:**

Project/Objective	Actions/Deliverables	Methods, Theory or Application Project	Project Chair	Project Members	Timeline
1. Continue to provide comment on regulatory and HTA publications/draft guidances	Monitoring releases, drafting and providing comments to regulatory bodies or HTAs	Application	Ashley Slagle	Robyn von Maltzahn; Joy Whitsett; Cristina Ivanescu; Mayank Rehani; Calvin Ho; Bernice Gulek	<ul style="list-style-type: none"> <li>Ongoing in real time as documents are released</li> </ul>
2. To conduct and publish research to better understand HTA and regulatory approaches to the use of PROs and other PED	Interview study of HTA reps and pharma staff with experience: to identify HTA areas of interest and use of PED, including PROs <ul style="list-style-type: none"> <li>Need to develop a concept protocol and then submit this to the board for approval</li> </ul>	Application	TBD	Ashley Slagle; Robyn von Maltzahn; Mayank Rehani; Bernice Gulek	<ul style="list-style-type: none"> <li>Concept protocol submitted to board Q4 2023</li> <li>Conduct research 2024</li> </ul>
3. To provide a platform for education and knowledge sharing regarding FDA, EMA, HTA (other) activities. Anticipate partnering with other SIGs (e.g., Industry SIG)	<ul style="list-style-type: none"> <li>Webinar / Symposium</li> <li>Online platform (e.g., Teamwork; group emails)</li> <li>Now working on finding a person/project members who is/are willing to lead this</li> </ul>	N/A	TBD	TBD	As relevant issues arise

**Issues Requiring Board Attention:**

Board approval for comments to submit to regulatory bodies or HTAs will be sought – timelines depend on release of guidances and requests for comments from those agencies/authorities.