

SIG/Committee Name: Regulatory and Health Technology Assessment Engagement (R&HE) SIG
Date: 1 April 2022
Co-Chairs: Robyn von Maltzahn and Ashley F. Slagle
Board Liaison: Jakob Bjorner

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. To provide comment on regulatory and HTA publications/draft guidances	Monitoring releases, drafting providing comments to regulatory body or HTA <ul style="list-style-type: none"> - Have identified sources to track - Currently work on to implement a process for tracking and identifying documents 	Application	TBC	Ashley Slagle Robyn von Maltzahn; Joy Whitsett; Cristina Ivanescu; Mayank Rehani; Calvin Ho; Bernice Gulek	<ul style="list-style-type: none"> • Identified sources to track Q1 2022 • Process in place Q3 2022 • Ongoing in real time as documents are released
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"> - Need to develop a concept protocol and then submit this to the board for approval 	Application	TBC	Ashley Slagle; Robyn von Maltzahn; Mayank Rehani; Bernice Gulek	<ul style="list-style-type: none"> • Concept protocol submitted to board Q4 2022 • Conduct research 2023
3. To provide networking and discussion opportunities for SIG members	Virtual happy hours (informal but with topic of interest identified in advance) <ul style="list-style-type: none"> - Identified this as an interest at our first meeting - Now working on finding a person/project members who is/are willing to lead this 	Application	TBC	Open to all SIG members	Set up by end of 2022
4. To provide a platform for education and knowledge sharing regarding FDA, EMA, HTA (other) activities	<ul style="list-style-type: none"> • Webinars • Online platform (e.g., Teamwork; group emails) <ul style="list-style-type: none"> - Identified this as an interest at our first meeting - Now working on finding a person/project members who is/are willing to lead this 	N/A	TBD	Open to all SIG members	As relevant issues arise