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### ISPE RWE COVID-19 SUBGROUP

The Task Force has added another subgroup on COVID-19 related RWE. This group is co-led by Ann McMahon from US FDA and Montse Soriano-Gabarró from Bayer in EU. The subgroup received interests from 31 members, has identified “core” and “extended” members, and had a kick-off meeting with the “core” team to discuss the focus, goals and activities for this subgroup.

### RECENT ABSTRACT REVIEW ACTIVITY

The Task Force have helped review 99 abstracts that were submitted for the COVID-19 special sessions. This resulted in webinars open to the public that were planned between October and December 2020. The moderation of the webinars was done by the COVID-19 Subgroup in collaboration with the Digital Epidemiology SIG, Database SIG, and CER SIG. Replay of these webinars will be available at later time.

### TASK FORCE WORKSHOP

The Task Force had a workshop --- “*ISPE RWE Task Force: Current Status and Future Directions*” on Nov. 5<sup>th</sup>. The workshop provided updates on the progress of the Task Force and discussed how to optimize collaboration with different SIGs and committees. More than 100 ISPE members attended the workshop. For new ISPE members who would like to join the TF, please contact the subgroup co-leads directly (contact information is available at ISPE website: <https://www.pharmacoepi.org/strategic-initiatives/rwe-task-force/>). The workshop is available online for replay. <https://youtu.be/WXaYFOBIRXk>.

## COLLABORATE, COORDINATE, & CONSOLIDATE

The Task Force provided updates to the Board, highlighting current efforts to reach out to different SIGs/committees for collaboration and coordination. The Task Force will provide regular updates to the Board, and Board will assess the work of the TF in August 2022 and decide on the next steps of the Task Force.



## UPDATE ON FACILITATING COMMENTS

The Task Force facilitated ISPE's comments on the Medicines and Healthcare products Regulatory Agency (MHRA, UK) draft guidance on use of RWE in clinical trials, led by Vicky Osborne from the Website Content Subteam. The Medical Device subgroup led comments in response to a consultation request issued by the International Medical Device Regulators Forum (IMDRF) Medical Devices Clinical Evaluation Working Group on Post-Market Clinical Follow-Up (PMCF) Studies. Both were endorsement by ISPE Board.



## PLANNING WEBINARS

The Task Force is planning a series of webinars in 2021 that will focus on topics relevant to the different subgroups or provide updates about the work they are conducting. Please send us suggestions and feedbacks on specific topics that you may be interested in.



## SUBGROUP UPDATES

FOR A LIST OF SUBGROUP MEMBERS VISIT THE [RWE TASK FORCE WEBSITE](#)

### SPOTLIGHT: WEBSITE CONTENTS SUBGROUP

- Coordination of ISPE member commenting re: the draft MHRA guidance on use of RWE in clinical trials (led by V. Osborne)
- Completion of a Policy & Procedures Manual for RWE Website Content development, updating and retirement (of content) (led by M. Smith)
- Development of a RWE Website Content Committee Activities Implementation and Dissemination plan (co-led by R. Sobel, M. Smith, B. Layton)
- Identification of representative case studies from the literature/public domain for posting on the RWE Website (led by D.Ramcharran- in progress)



### SPOTLIGHT: RWE AND REGULATORY DECISIONS MAKING SUBGROUP

- Have designated sub teams to focus on each of the prioritized goals in the strategic plan of the working group
- In the October meeting, Anton Pottegård and Shirley Wang, part of the ISPE:ISPOR Taskforce to discuss and align between the two groups. The objective was to increase awareness of focus of the two groups and facilitate interaction to minimize duplication of efforts
- Two manuscripts had kick off meetings and one has started to make progress.



### SPOTLIGHT: ISPE RWE MANUSCRIPT DEVELOPMENT SUBGROUP

- Created a standard manuscript proposal template for manuscript ideas/proposals within the ISPE RWE task force
- Developed a manuscript coordination guidance for the ISPE RWE task force
- Completed and initiated ISPE endorsement process for 2 manuscripts, one focusing specifically on Oncology and the other on Pediatrics.
- Kicked off manuscript planning and development of 5 new manuscripts to be finalized in 2021
- Held a quarterly extended team member meeting to provide updates and discuss next steps, including steps to submit/lead new manuscript ideas



## RWE AND REAL-WORLD DATA SOURCES

- In recognition of the number of existing SIGs/groups within ISPE with an interest/focus on “data sources” (quality and content), and as part of the TF’s overall Landscape Assessment, core members initiated 1:1 discussions with current co-chairs of 10 SIGs. The purpose of this information gathering is to better educate our subgroup as to the collective SIGs’ current missions, activities, future goals/objectives and potential areas of overlap, as well as areas of potential collaboration – either between the RWE Subgroup and SIGS, or between SIGS themselves.
- Co-chair provided comments on draft survey developed by the Pediatric SIG designed to identify RWE data-sources appropriate for research in pediatric/maternal-child research.
- Held monthly meetings with core members to synthesize findings and continue to refine development of the Subgroup’s short and long-term goals, which we continue to agree should be externally-focused (education/outreach).

## RWE AND STATISTICAL MEDTHODS

- The subgroup collectively drafted a near-exhaustive list of established and emerging statistical methods with the intent of sharing with the larger ISPE community, perhaps through the website
- Next, we will build on the list by adding the following to each entry: the problem a method is trying to solve, descriptions of each method, identifying appropriateness of each method, key examples that could be used in a course, canonical references with PubMed links, issues, criticisms, and implementations
- The subgroup will meet again in early 2021.

To view subgroup member lists, visit the [RWE Task Force page](#) on the ISPE website.

View our past [July Newsletter](#)

