



ISPE RWE COVID-19 DISCUSSIONS

The RWE Task Force discussed the current situation of COVID-19, and shared information on how ISPE members are collaborating with other stakeholders on the epidemiology of COVID-19 in different regions of the world. We will also work with the ICPE Core committee to help organize 4-6 webinars on COVID-19, with a “call for proposal” to be sent out soon.

RECENT MANUSCRIPT

The most recent retractions of two high-profile Surgisphere-related COVID-19 studies have received lots of attention. In addition to [ISPE President's public statement](#), the RWE Task Force has reached out to ISPOR transparency initiative team members, and drafted a manuscript on “Real-world Studies Require Increased Transparency to Ensure Appropriate Interpretation of Results”. This manuscript is now endorsed by ISPE after addressing members’ input and has been submitted. Several subgroups have planned to coordinate and reach out to several key clinical journals to offer ISPE membership as reviewers for high-profile RWE studies.

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COLLABORATE, COORDINATE, & CONSOLIDATE

The RWE Task Force was designed to coordinate and consolidate the rich experience in RWE among ISPE members and to foster collaborations with other organizations. The efforts of the RWE Task Force are specific to RWE and emphasize these goals of outreach and collaboration with external stakeholders. To better integrate with ongoing efforts in ISPE, the RWE Task Force discussed and agreed on the principles to **collaborate**, **coordinate**, and **consolidate** the efforts with different ISPE committees and SIGs, and different subgroups within the Task Force. Based on the recommendation from Meredith Smith and Rachel Sobel, the guiding principles include:

- **Collaborate:** Conduct an initial landscape assessment regarding which SIGs and Committees are doing work that is related to the individual RWE Task Force Subgroup, to what extent, and what and where are the gaps.
- **Coordinate:** Based on the landscape assessment, reach out to the relevant SIG and Committee leads to learn what opportunities exist for coordination and for ‘adding value.’ The RWE TF Subgroups are intended to help coordinate, amplify current work, and fill gaps, not duplicate the work of existing ISPE SIGs and Committees.
- **Consolidate:** Based on the interviews and information gathering, one will see opportunities for consolidating or leveraging certain activities, as opposed to duplicating them. As part of the consolidating process, prepare a short (next 12 months) and long-term (next 2-5 years) strategic plan that outlines what the subgroup’s goals and objectives will be, and how they will align with those of relevant SIGs and ISPE Committees (if applicable).



PROGRESS OF THE RWE TASK FORCE

- The RWE Task Force has had two group meetings among the co-leads of each subgroup.
- Each subgroup has finished the selection of “core” and “extended” members and have had the kick-off meetings to discuss on the objectives and deliverables of each subgroup.
- The Task Force and each subgroup has set up ISPE Exchange communities for communications.
- Please visit ISPE RWE Task Force website for information on membership of each subgroup (<https://www.pharmacoepi.org/strategic-initiatives/rwe-task-force/>).

SUBGROUP UPDATES

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

SPOTLIGHT: RWE AND MEDICAL DEVICE

- The RWE Task Force Medical Device Subgroup held a kickoff meeting on March 12th. Since that time, the Medical Device Subgroup has had monthly meetings with the Core team members to collaborate and connect across workstreams as well as monthly update meetings with Extended team members.
- To address the RWE Task Force focuses of outreach and collaboration, the Medical Device Subgroup has identified three initial audiences: societies/consortia/partnerships, journals, and the broader RWE community. To engage these audiences, the Medical Device Subgroup intends to partner with other entities, offer expertise for peer review and training for journals and publish manuscripts of interest to the broader medical device community.
- Members are working within five workstreams: orthopedic, cardiac, respiratory, partnerships, and methods. Each workstream meets monthly. Initial efforts include three priority manuscripts (overarching medical device RWE needs, cardiac, and ventilators), clarification of consistent medical device messaging for ISPE RWE Task Force efforts, determination of priority cross-cutting entities for partnerships, and preparation of opportunity statement for joint activities with other organizations.
- The RWE Task Force Medical Device Subgroup understands that coordination within ISPE is key to success. Thus, the RWE Medical Device Subgroup has a standing agenda item for updating the Medical Device SIG, is coordinating manuscripts with the RWE Task Force Manuscript Subgroup, and has clarified a general framework for addressing Medical Device-specific regulatory RWE needs with the RWE Task Force Regulatory Subgroup.



SPOTLIGHT: RWE AND ONCOLOGY

- The RWE and Oncology Subgroup held a kickoff meeting on April 20th and have had three monthly meetings with the core team members.
- The Objective of the RWE and Oncology subgroup is to collaborate with national and international organizations, professional societies, and relevant RWD stakeholders to facilitate the exchange of ideas, represent the goals of ISPE, support alignment across groups on emerging analytic methods, and advance the development of strategies for optimal use of RWE in the oncology therapeutic area.
- Members are working on Activities in 3 key areas thus far include:
 - Recommendations for new collaborations with key oncology stakeholders include the selection of 10 potential strategic organization for collaboration, including American Society for Clinical Oncology (ASCO); Friends of Cancer Research (FOCR); ESMO and Société Internationale de oncologie Pédiatrique (SIOP) among several others.
 - Manuscript suggestions and preliminary discussions with publications group to explore collaborations and provide valuable contributions to the RWE community.
 - Abstract submissions to conferences to raise external awareness at conferences such as SIOP, ENCR 2021, and ASCO.
- The subgroup communication plan is to use the ISPE exchange and Google docs for internal ISPE activities. Alignment with Oncology SIG is in progress to ensure differentiation of activities and maximize value with internal and external stakeholders for ISPE.



SPOTLIGHT: RWE AND REGULATORY DECISION-MAKING

- Had a first core team meeting in May and a second in June. Core team will continue to meet monthly.
- Currently soliciting SIG membership and expertise of core and extended team using an established Google Sheets file.
- Mission and specific goals for the subgroup discussed and updated (see below), expanded scope of remit to include HTA bodies.
- Created a preliminary list of manuscripts – soliciting interest.
- Update from ISPE members on CIOMS and ICH RWE initiatives at 6/25/2020 core team meeting.



Mission of this subgroup:

- Develop feedback, papers and workshops on regulatory RWE guidelines and papers, including use of 'fit-for-purpose' methods for regulatory and HTA decisions; raise awareness of sound study designs and methods and assessment of RWD quality standards to inform when RWE and patient-centered research is most useful and appropriate for regulatory and HTA purposes.

Specific Goals of the subgroup, updated at the 6/25/2020 team meeting:

- Compile list of key papers and guidance/framework documents for RWE and regulatory decisions, build inventory of case studies where RWE was used for regulatory decisions (include ICH 2019 reflection paper, Baumfeld Andre 2019).
- Coordinate with Duke-Margolis working group (Co-Leads: C Mack, D Miller) to hook into Duke-Margolis / FDA activities.
- Identify ways to connect with EMA, ICH, and groups developing other regional guidelines as well as HTA key bodies.
- Develop a list of topics to focus on for ISPOR abstract submissions.
- Develop a list of topics to focus on for ICPE 2021 abstract submissions.
- Consider DIA abstract submissions, coordinating with working group led by Arnold Chan and Patrice Verpillat.
- Create initial list of manuscripts for RWE working group to generate, coordinate with Publication Dev workgroup (Mehmet Burcu and Darren Toh co-leads).
- Consider what RWE webinars may be beneficial from regulatory and HTA perspective.
- Map timing of RWE guidance forthcoming from regulatory authorities and HTA bodies, identify stakeholders for deliverables and evaluate whether we can connect with them.
- Develop a 3- or 5-year strategic plan for the RWE and regulatory decisions working group for messaging and influence before, in response to, and after the FDA RWE Guidance is issued, as well as other regional guidance docs.

RWE AND REAL-WORLD DATA SOURCES

- Had the Core team meeting on June 12th, 2020. Agreed the short description of this subgroup: "Outreach/collaboration with big data vendors (could involve Database SIG); *Develop* and/or align methods development efforts among other RWE Working Groups for database evaluation", which can be updated later.
- Identified potential overlap and collaborations with existing ISPE sponsored groups, include:
 - RWE TF WG #4 "RWE and Statistical Methods"
 - RWE TF WG #5 "RWE and Collaboration with DIA"
 - RWE TF WF #9 "RWE Methods Training"
 - Database SIG
 - Oncology SIG
 - Possibly Others?

RWE TRANSPARENCY AND COLLABORATION WITH ISPOR

- This subgroup has initiated a Special Joint Task Force between ISPE and ISPOR “Developing a Standard Protocol Template to Enhance Communication and Improve Validity Assessment for Decision-Making Informed by Hypothesis-Evaluating Real-World Evidence Studies”. The kick-off meeting was held in July.

RWE STATISTICAL METHODS

- Had initial team meeting, brainstormed the plan and deliverables from this subgroup. Plan to inventory related initiatives and activities, and catalogue statistical methods used in RWD.
- Discussing outreach to journals and development of a potential database of peer review volunteers to provide to journal editors as a resource to identify relevant RWE expertise.

RWE AND COLLABORATION WITH DIA

- Have reached out to ISPE members who are active at DIA to discuss on potential collaborative opportunities.

RWE AND COLLABORATION WITH DUKE MARGOLIS

- Have confirmed Core and extended members and engaged with ISPE members who are in different working groups of Duke Margolis, to ensure ISPE’s representativeness.

MANUSCRIPT DEVELOPMENT

- Team had several meetings. Have shared the current manuscripts under development and preliminary list of future topics with other subgroups for alignment and coordination. It is agreed that we should share and keep this list “live”, and other subgroups can add the topics, or express their interest to join the effort for better coordination.

RWE WEBSITE CONTENTS

- The RWE Website Content subgroup has been meeting monthly. Key accomplishments to date:
 - Working in close coordination with ISPE Staff and Publications and Communications Committee, we have overseen enhancements to the RWE portion of the ISPE Website:
 - Names of RWE Taskforce Members, and Committee Chairs, and Newsletter are now posted.
 - A description of the RWE Taskforce’s Mission Statement, and goals has been added.
- Established 5 Website Content Sub Teams based on gap analysis:
 - RWE Resources (Meredith Smith) – complete, 6/2020
 - ISPE Leadership in RWE (Rachel Sobel) – ongoing
 - Regulatory Policy (Vicki Osbourne) – ongoing
 - RWE Case Studies (Darmendra Ramcharran) – ongoing
 - Learning Resources Sub Team (Bradley Layton) - ongoing
- Developed a detailed and prioritized project plan for each sub team, with both “quick wins” (i.e., those to be accomplished by 3/21) and longer-term goals.

RWE METHODS TRAINING

- Conducted kickoff call for core subgroup members on April 3rd.
 - Reviewed overall Task Force mission/structure, subgroup mission, member roles and responsibilities.
 - Discussed webinar proposal to bring RWE methods training to relevant organizations and internal and external stakeholders.
- Next steps:
 - Identify RWE needs from other organizations and initial target audience for RWE methods training.
 - Following on successful webinars, consider courses, workshops, overview papers to advance RWE methods training.

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

View our past [April Newsletter](#)