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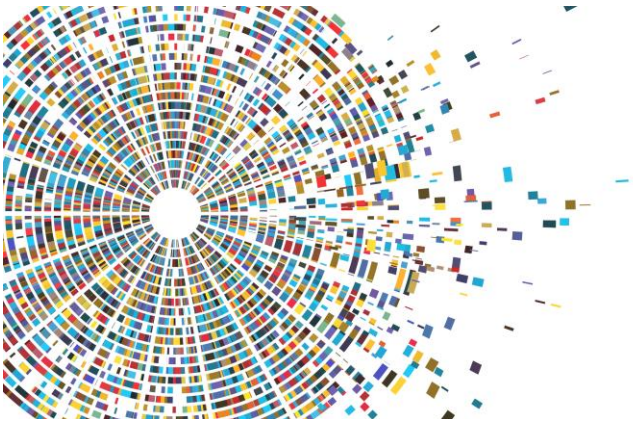
REAL-WORLD EVIDENCE TASK FORCE

April 2020 ISSUE

MISSION STATEMENT

The ISPE RWE Task Force promotes global knowledge exchange of scientific methods and standards, education, and policies related to the development, implementation, and interpretation of Real World-Evidence generated from Real-World Data to study the utilization, effectiveness, and safety of treatment interventions in population health. The task force will:

1. Coordinate and consolidate the 30+ years of rich expertise in the science of pharmacoepidemiology research by effectively connecting ISPE members from more than 50 countries; and
2. Foster collaborations with other societies, agencies, academic institutions, and patient advocacy groups



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STRUCTURE OF THE RWE TASKFORCE

The ISPE RWE Task Force includes two co-chairs, 11 subgroups each with two co-chairs (usually one from the US and one from the EU or another international member), and liaisons with regulatory agencies. This document includes a detailed description of each subgroup and a link to our online resource where you can find more information, including subgroup member names.

CORE AND EXTENDED MEMBERS OF THE SUBGROUPS

ISPE members have expressed strong interest in participating, particularly for the "RWE and Regulatory Decision-making," "RWE and Real-world Data Sources," "RWE and Oncology," and "RWE Manuscript Development" subgroups. To maintain efficiency, collaboration and diversity of viewpoints, each subgroup agreed to limit the "core" members to approximately 10-15 individuals from a mix of geographic locations and affiliations (academic, industry/service provider, and government/regulatory, student/recent graduate), and prioritize those who indicated the group as their first choice.

"Core" members are expected to commit the time and effort to: (1) participate in regular conference calls with other core subgroups; (2) assist in the coordination of strategy and activities between the subgroup and related subgroups within the broader RWE Task Force; and (3) helping lead or drive other deliverables agreed on by the subgroup.

The remaining interested ISPE members who responded to the initial call for volunteers will be able to serve and contribute as an "extended" team member of a subgroup. "Extended" members will receive regular communications from the subgroup co-chairs.

Most subgroups have finished selecting their "core" and "extended" members, and have communicated with everyone that has expressed interest. The "core" and "extended" member list of different sub-groups may be updated depends on the need and members' continuous contributions.

PROGRESS OF THE RWE TASK FORCE

- The RWE Task Force held two calls with the co-chairs of each subgroup. Everyone agreed to ensure close communication and coordination between the different subgroups.
- To assist with communication, communities were set up in the ISPE Exchange for the RWE Task Force and subgroup leads.
- The task force has submitted several workshop/symposia proposals for the 2020 ICPE in Berlin.
- The task force Initiated a response to the NEJM article on the use of observational data ("RCT and RWE - Magic and Myth or Ying and Yang in scientific inquiry," led by Almut Winterstein, Anton Pottegård and Cindy Girman).

SUBGROUP UPDATES

FOR A LIST OF SUBGROUP MEMBERS VISIT THE RWE TASK FORCE WEBSITE

RWE REPRODUCIBILITY AND TRANSPARENCY AND COLLABORATION WITH ISPOR



- The Transparency Initiative, a partnership between ISPOR, ISPE, Duke Margolis, and NPC, is preparing a paper for joint publication in PDS on Value in Health, focused on the why, what, and how of RWE study registration. The final draft is being prepared for ISPE review and endorsement
- A Structured Template and Reporting Tool for RWE (STaRT-RWE) based on the deliverables from the inaugural ISPE-ISPOR Joint Task Force on RWE for Healthcare Decision-Making is being developed as part of a public-private collaboration with the FDA
- The subgroup will initiate follow-up projects to encourage reproducible and transparent practices for communicating about RWE study conduct

RWE AND REGULATORY DECISION-MAKING

- Submitted a symposium abstract for the ICPE Berlin meeting

RWE AND REAL-WORLD DATA SOURCES

- May consider organizing the group by regions or disease areas, as data sources may be regionally specific
- Will discuss with Database SIG on additional collaborations

RWE AND ONCOLOGY

- Submitted a symposium abstract for the ICPE Berlin meeting
- Met with Friends of Cancer Research and discussed potential collaborations on methods
- Reached out to ASCO on how to buildup collaborations

RWE STATISTICAL METHODS

- No update at this time

RWE AND COLLABORATION WITH DIA

- Will reach out to ISPE members who are on the panel for the DIA annual conference on RWE

RWE AND COLLABORATION WITH DUKE MARGOLIS

- Many ISPE members are already in different subgroups on behalf of their institutions. The subgroup will leverage the expertise that exists there
- Duke Margolis added ISPE as formal sponsor

MANUSCRIPT DEVELOPMENT

- The external control manuscript is now published (https://onlinelibrary.wiley.com/doi/full/10.1002/pds.4975)
- Submitted a symposium abstract for the ICPE Berlin meeting (in collaboration with Oncology subgroup)
- The subgroup will develop different topics and get the endorsement from the ISPE EC. The subgroup will invite people to propose different topic ideas

RWE WEBSITE CONTENTS

- ISPE RWE position statement has been posted online (view the statement here)

RWE METHODS TRAINING

- Plan to do a series of webinars with the Education Committee, targeting non-ISPE members such as DIA
- Plan to develop a questionnaire to other societies on the need for RWE training

RWE AND MEDICAL DEVICE

- Identified high priority therapeutic areas for medical devices

To view subgroup member lists, visit the RWE Task Force page on the ISPE website.

NEXT STEPS



The planned subgroup co-chairs meeting scheduled to take place during the ISPE mid-year in Orlando will be rescheduled as a virtual meeting. Co-chairs for each subgroup will share their preliminary plan of next steps and discuss their coordination across the different subgroups.

The RWE Task Force will work with the ISPE Strategic Planning Committee to finalize the 5-year strategic plan related to RWE and work on determining the next steps.

Communications with ISPE members will include a regular newsletter and a dedicated webpage on RWE: https://www.pharmacoepi.org/strategic-initiatives/rwe-task-force/. The RWE Task Force welcomes comments and suggestions; co-chair contact information is located on the RWE webpage.