ISPOR
Improving healthcare decisions

Real-World Evidence Special Interest Group – Initiatives, Feedback, and How to Participate

Monday, 4 November 2019
12:30 - 13:45

Speakers

- Suzanne Belinson, PhD, MPH, VP, Commercial Markets, Tempus, Chicago, IL, USA
- Peter Knox, MPP, Senior Director, Research, The Life Raft Group, Wayne, NJ, USA
- Elisabeth M. Oehrlein, PhD, MS, Senior Director, National Health Council, Washington, DC, USA

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- The Antitrust policy is available on the ISPOR website, under "About ISPOR."

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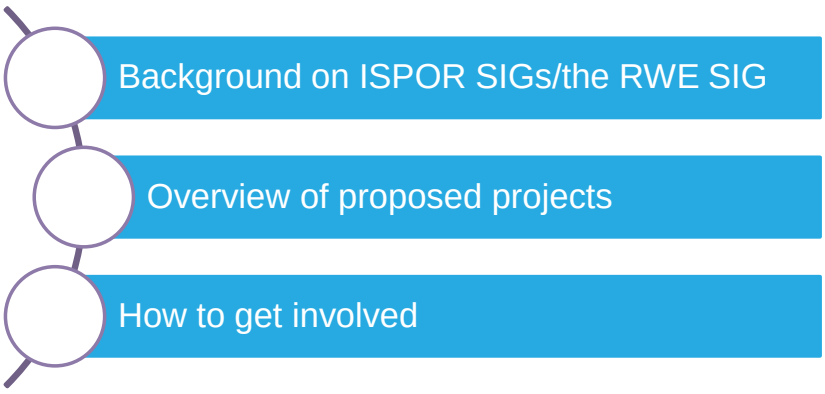
Agenda



Objectives for today

To consider how an RWE SIG can support ISPOR members in an age of increasing awareness and utilization of RW studies

Describe several proposed projects

Evaluate interest and finalize plans and priorities

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Special Interest Group

ISPOR Special Interest Groups (SIGs)

- **Mission:** To provide an opportunity for ISPOR members to identify current and trending topics and initiate platforms that focus on such topics.
- **Composition:** Any ISPOR member interested in a specific topic. A SIG must be multi-stakeholder and geographically diverse.
- **Goal:** To engage ISPOR members within the topic area to advance health economic and outcomes research and the use of this research in healthcare decisions.
- **Objectives:** To develop area topics into educational and/or scientific work products. To monitor and share information relating to area topics.

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Structure of Special Interest Group

Special Interest Group Leadership

- Chair-elect
- Chair
- Past chair
- Each position is a 1-year term, resulting in a 3 year commitment

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Responsibilities of Chair-Elect, Chair, Past Chair

- Provide overall direction and leadership
- Identify the topics SIG members would like to address
  - Categorizing topics into long, short term projects
  - Identify the appropriate platforms for delivery
- Work with the Working Group co-chairs to ensure the timeliness of the key project
  - Address any issues within the group
- Provide quarterly updates to the SIG membership
  - Current activities, new developments in field
- Report the progress of the SIG projects
  - Via the yearly business and project plan to HSPC
- Recruit new SIG members

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Working Group Co-Chairs Responsibilities

Key Project

- Serve until the project is complete (average 24 months)
- Lead the project
- Ensuring adherence to ISPOR processes and working group deadlines
- Address any conflicts or issues

Member Engagement Projects

- Serves for at least the year
- Work with SIG chairs to identify member engagement topics
- Identifying speakers, articles, topics for member engagement activities
- Ensuring that all member engagement activities occur

Those interested in leadership positions, please contact ISPOR at scientificgroups@ispor.org

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Background

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SIG RWE - Background

- Stakeholders increasingly describe a growing interest in using real-world data (RWD) sources to inform their decision making, recognizing that real-world evidence (RWE) is complementary to randomized controlled trials (RCTs)
  - Opportunity to systematically evaluate the use, benefits, and risks of medical products in more clinically diverse settings and patients, under conditions that reflect the use of treatments in actual clinical practice
- Stakeholders remain cautious as they evaluate how much they can trust RWE, especially in effectiveness assessments
  - Lack of randomization and the risk of bias
  - Quality of the RWD (e.g., data accuracy and completeness)
  - Generalizability of the results (linked to the representativeness of the RW population)
  - Transparency

SIG RWE - Background

- There is an increasing amount of information, including general regulatory guidance and scientific papers and publications
- The RWE topics are either addressed in:
  - General terms (position papers and frameworks) or
  - Scientific and technical terms (targeted towards researchers, including epidemiologists and outcomes researchers)

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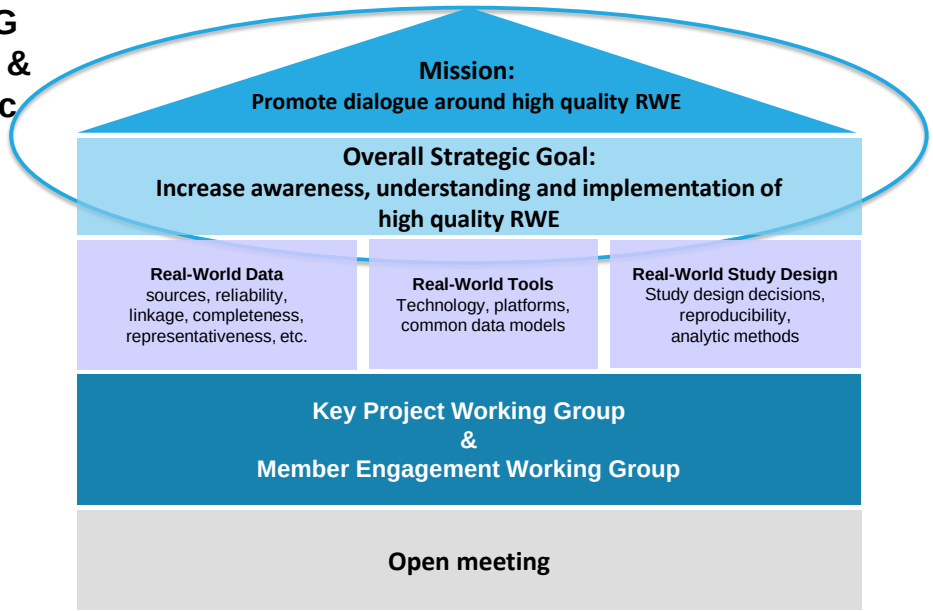
RWE SIG Mission & Strategic Goals



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Why do we need a special interest group now

- Promote dialogue on RWE, thereby increasing awareness and understanding of how RWE can be utilized to support healthcare decision making.
- Help develop RWE-specific educational opportunities for ISPOR members.
- Support ISPOR task force activities addressing RWE and aligned topics, particularly the development of new good practice guidelines.
- Encourage adherence to existing methodological good practices thereby increasing stakeholder trust in the RWE generated by ISPOR members.
- Contribute to ISPOR external policy initiatives
  - such as responding to requests for comment on RWE-specific topics including the draft FDA guidance to industry and future EMA guidance (including and following comments to the EMA Regulatory Science to 2025 strategic reflection).

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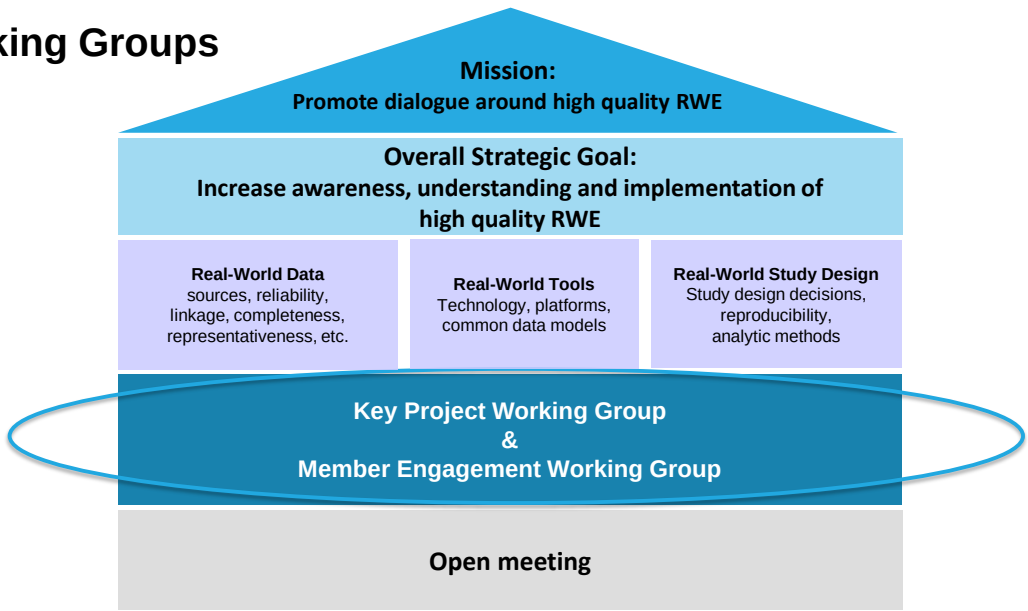
Working Groups



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Key Project

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Project Ideas

Projects

Real-World Data	Real-World Tools	Real-World Study Design
sources, reliability, linkage, completeness, representativeness, etc.	Technology, platforms, common data models	Study design decisions, reproducibility, analytic methods

- **ISPOR Book of Terms: RWE** (start in 2019)
- **Willingness and barriers towards transparency in formally reporting RWE** (start in 2019)
- **EMR/Claims database use cases** (start in 2019)
- **Data transferability** (later in time)
- **Enriching EMRs for better evidence** (later in time)
- **Patient centricity in RWE** (later in time)

Educational webinars, Spotlight, *Value in Health*

Open meeting: please share your interest in these projects!

All related to one or more of the top 3 RWD/RWE components.

Willingness and barriers toward transparency in formally reporting database research now and in the future

Member Engagement Project

- Manuscript(s) such as *Value in Health*.
- ISPOR educational webinar / Issues panel at future ISPOR conference.

- Attitudes
- Behaviors
- Barriers to adoption
- Minimum disclosure levels

- Practical recommendations to the new Transparency task force.

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Member Engagement Projects

Webinar

- What is the Health Insurance Portability and Accountability Act (HIPAA) and When Does it Actually Apply?
  - Traditional real-world data sources
  - Patient-generated real-world data
- **Target Audience:** Researchers, patient group staff
- **Timeline:** Spring 2020

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Member Engagement Project

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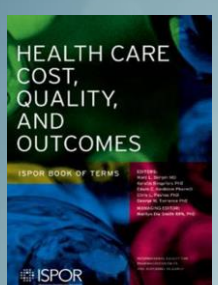
ISPOR Book of Terms 2020

ISPOR is updating its seminal 2003 *Healthcare Cost, Quality, and Outcomes: Book of Terms.*

Volunteer Authors Needed! Please sign up today to co-author an HEOR term in the ISPOR Book of Terms 2020!



ISPOR Book of Terms 2020

- **Term Monograph:** Each entry focuses on an important HEOR term, briefly describes it, explains its use and value, describes any related issues.
  - Related sub-terms are briefly defined in the entry to provide context and aid in description.
  - Provide 5 references (current, seminal (if possible), peer-reviewed, AMA style)
  - Any ISPOR resources related to the topic, eg, an ISPOR Good Practices Task Force or SIG Report.
  - Length: 1200 – 1500 words (approximately 2-3 pages, 1.5 spacing with line numbers)
- **Target Audience:** Decision makers, students, new HEOR professionals, payers, clinicians, patient representatives, etc. Readers represent a global audience. *Emphasis is on clarity and appropriateness for this level.*
- **Timeline:** Finalized entries go online for review in January 2020

ISPOR Book of Terms 2020: All Terms (32)

- 21st Century Cures Act
- Adaptive Pathways
- Administrative Claims Systems
- Artificial Intelligence/ Cognitive Computing
- Causal Diagram
- Common Data Model
- Coverage with Evidence Development
- Data Coding Systems
- Directed Acyclic Graph
- Distributed Data and Research Networks
- Drug Interaction
- Drug Safety
- Electronic Data Capture
- Electronic Medical & Health Records
- Eligibility
- Enrollment
- Epidemiology
- Exploratory Treatment Effective Studies
- Exposure Risk Window
- Hypothesis Evaluating Treatment Effectiveness (HETE) Studies
- Observational Study
- Pharmacoepidemiology
- Prevalence
- Real World Data
- Real World Evidence
- Retrospective Analysis
- Risk
- Risk Adjustment
- Source Data Range
- Study Bias
- Study Design Diagram
- Washout

ISPOR Book of Terms 2020: Terms Available for Volunteers (19)

- Adaptive Pathways
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ISPOR Book of Terms 2020 Next Steps

- Sign up volunteers to create monographs for available terms
- Review and finalize monographs
  All monographs must be received by TBD
- Monographs posted online 3rd week of January
  They can then be reviewed by all ISPOR members
- **For questions or to sign up, please see a SIG member!**

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Next Steps

- **How are you currently handling RWE within your organization?**
  - How is it viewed/perceived?
  - How are findings integrated with those from other data streams?
  - Do you have dedicated RWE personnel?
  - Are you planning on future expansion in this area?

- **What do you see as some barriers and challenges to its more widespread use?**
  - Within your organization
  - Outside your organization/in general

Member Engagement Project

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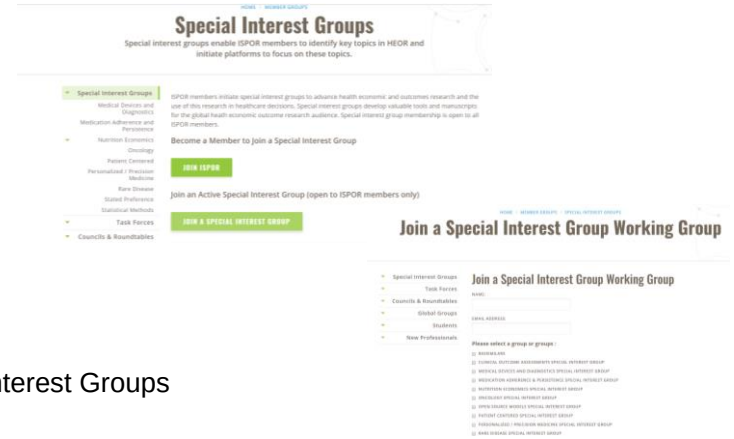
ISPOR Special Interest Group

How to JOIN our Special Interest Group



- Sign up now
  - Sign up sheet
  - Provide a business card

- Go to the Website
  - Members groups
  - Special Interest Groups
  - Click on Join A Special Interest Groups

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Thank you for interest