Today's Panel



Richard Willke, PhD
ISPOR



Xavier Kurz, MD, PhD
European Medicines Agency



John Concato, MD, MS, MPH
Food and Drug Administration



Shirley Wang, PhD
Brigham and Women's Hospital
and Harvard Medical School

RWE Subprogram at ISPOR 2022

Spotlight Session (Monday, 1:30 pm)
Improving the acceptability of RWE: What's New in 2022?

Spotlight Session (Wednesday, 10:00 am)
Target Trial Emulation with RWD: Evidence on Feasibility, Challenges, and Opportunities

Workshop (Tuesday, 10:15 am)
Lessons Learned from Health Technology Assessment Pilot Projects to Assess Real-World Evidence's Usefulness in Reassessments of Effectiveness and Value

Workshop (Tuesday, 4:30 pm)
Combining Real-World and Clinical Trial Data to Study the Effectiveness of Thrombolytics for Treating Patients with COVID-19 Associated Acute Respiratory Distress Syndrome

Issue Panel (Wednesday, 8:00 am)
Is the Global Real-World DATA (RWD) Supply-Chain Broken? Choosing between RWD Quality Versus Locality in Supporting Single Arm Submissions

Issue Panel (Tuesday, 1:30 pm)
Standing up Computable Phenotypes for Generating Real World Evidence: What Are Computable Phenotypes and Can They Really be Standardized and Reused?

RWE Poster Tour – (Monday, 12:15 pm) *New Program Feature*

HOME / STRATEGIC INITIATIVES

Real-World Evidence

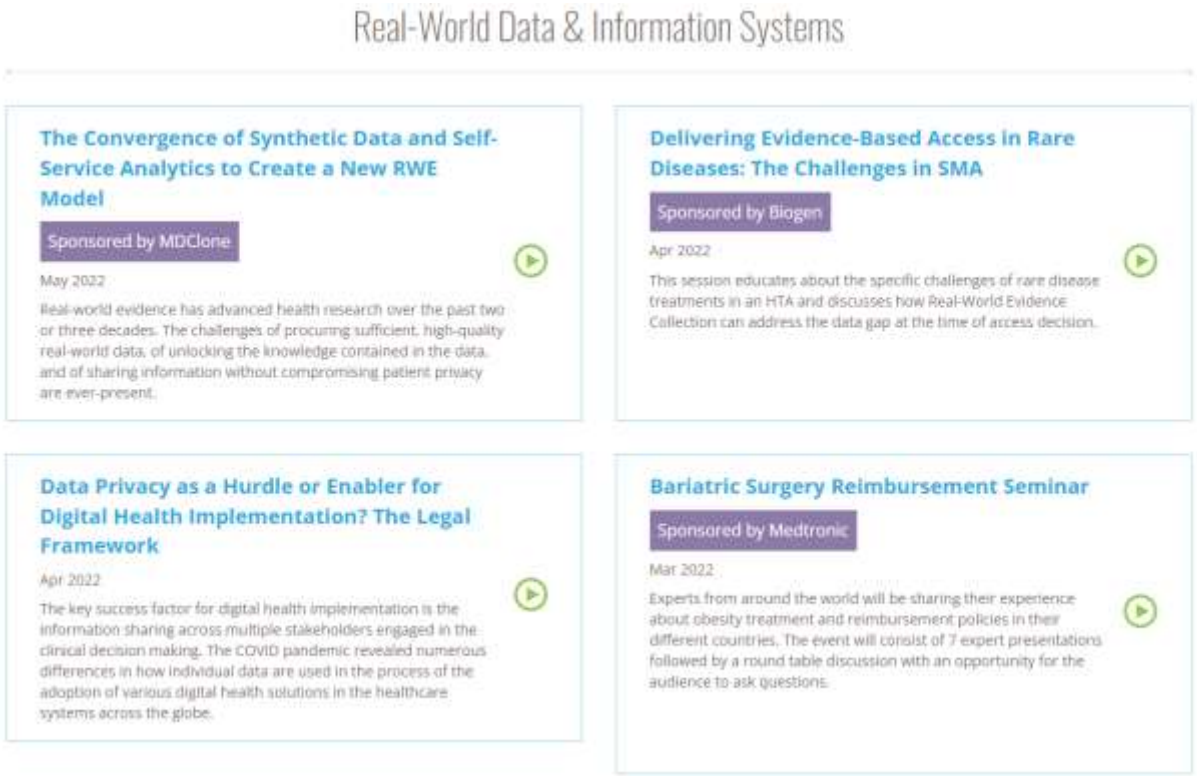
The Society is actively working to improve standards and practice for the collection and analysis of real-world data.

- Strategic Plan
- Science Strategy
- Real-World Evidence
  - About Real-World Evidence
  - Real-World Evidence Transparency Initiative
  - Real-World Evidence Registry
- Patient Engagement in HEOR
- Payer Engagement in HEOR
- Diversity at ISPOR



https://www.ispor.org/strategic-initiatives/real-world-evidence

Recent ISPOR RWE-Related Webinars



https://www.ispor.org/conferences-education/education-training/webinars

Joint ISPE-ISPOR Good Practices Reports:

Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Healthcare Decision Making →

Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0 →

Making Real-World Evidence More Useful for Decision Making (editorial) →

HOME / STRATEGIC INITIATIVES

Dialogue With Decision Makers

The Society facilitates dialogue, deliberation, and consensus building through its conferences, summits, and roundtables.

ISPOR is actively involved in informing health policy decisions by engaging members in public calls-for-comment. Recent dialogue with decision makers involving the Society include:

- Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry
- Real-World Data: Assessing Registries To Support Regulatory Decision-Making for Drug and Biological Products; Draft Guidance for Industry
- US Food and Drug Administration Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products (PDF)
- European Medicines Agency Guidelines on Registry-Based Studies (PDF)
- ISPOR final response to HMA_EMA Big Data Summary Report (PDF)



ISPOR Speaks

Registering Study Protocols: Helping Real-World Evidence Come of Age

VALUE & OUTCOMES SPOTLIGHT November/December 2021

RWE Registry

www.ispor.org/RWEregistry

