ISPE POSITION ON REAL-WORLD EVIDENCE (RWE)

2026 UPDATE
Endorsed by the ISPE Board of Directors November 4, 2026

EXECUTIVE SUMMARY

The International Society for Pharmacoepidemiology (ISPE) is a global leader in advancing real-world evidence (RWE) through innovation in pharmacoepidemiology, methods development, education, policy, advocacy and multidisciplinary collaboration.

The Society and its members have led foundational efforts in causal inference methods, external control designs, and federated data networks. The Society also supports the transparency and reproducibility frameworks needed to evaluate fit-for-purpose real-world-data (RWD) and to generate reliable, decision-grade RWE to support decision-making by regulators, payers, clinicians, and patients.

This position paper describes the evolving role of RWE in medical product development and evaluation, highlights ISPE's leadership in the field, and outlines priorities for future progress, including methodological advancement, appropriate use of emerging technologies, and patient-centric evidence generation. ISPE affirms that high-quality, fit-for-purpose RWE is essential for informed regulatory, clinical, and policy decision-making in medical product development worldwide. ISPE supports the rigorous, transparent, and ethical generation and use of RWE and calls for continued collaborative efforts to advance the field.

ISPE POSITION ON REAL-WORLD EVIDENCE (RWE)

The International Society for Pharmacoepidemiology (ISPE) is an international professional organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and the development of pharmacoepidemiologic methods, policy, education, and for advocating for issues salient to the field of pharmacoepidemiology worldwide [1].

Pharmacoepidemiology uses epidemiological approaches to characterize diseases and study the use, benefits and risks of therapeutic approaches in human populations – including medical products (drugs, biologics, vaccines, medical devices) and other interventions [2].

The field of pharmacoepidemiology continues to evolve as the use of RWD expands, in parallel with advancements in technological and methodological capabilities. RWD are broadly defined as information regarding patient health status and/or the delivery of health care routinely collected from a variety of sources outside of traditional clinical trials, such as data from administrative claims, electronic health records, registries and other healthcare databases. [3-5].

Real-world evidence (RWE) is defined as the clinical evidence about the usage and potential benefits and risks of medical products derived from the analysis of RWD [3-

5]. Such evidence may also include descriptive epidemiology to understand natural history and patient characteristics as well as evaluation of health outcomes.

The generation of valid RWE relies on the proper application of expertise in pharmacoepidemiology using robust scientific methods and selecting fit-for-purpose RWD sources to ensure data integrity, scientific rigor, study transparency and relevance to the decision-making requirements of patients, clinicians, payers, policymakers, and regulators.

Over the past decades, ISPE and collaborative partners have been at the forefront of advancing the science and practice of RWE generation and analysis through research, methods development, education, policy, and advocacy, both within the field of pharmacoepidemiology as well as in the broader scientific community. These contributions include methodological innovations for causal inference, such as the new-user, new-user-active-comparator and self-controlled study designs, as well as use of negative and positive controls for exposures and outcomes, the development of target trial emulation methods, and applications for RWD-derived external control arms to RCTs [6-14]. ISPE has also played a key role in the development and advancement of confounding adjustment methods such as propensity score, disease risk score, and sensitivity analyses as well as approaches to mitigate immortal time bias [15-19].

Built on decades of rigorous pharmacoepidemiology and methods development in RWE, progress for the responsible use of RWD and the robust generation and dissemination of RWE, ISPE has catalogued many of these methods. These are available in the *Core Concepts in Pharmacoepidemiology* review series [20]. ISPE has also shaped international guidance on the appropriate use of RWD and RWE, especially in a regulatory context, combined with evidence from clinical trials in health technology assessment (HTA) [21]. ISPE has further contributed various reproducibility, replicability, transparency and harmonization initiatives [22-26].

ISPE affirms that high-quality, fit-for-purpose RWE is essential for informed regulatory, clinical, and policy decision-making in medical product development worldwide. ISPE supports the rigorous, transparent, and ethical generation and use of RWE, and calls for continued collaborative efforts to advance the field.

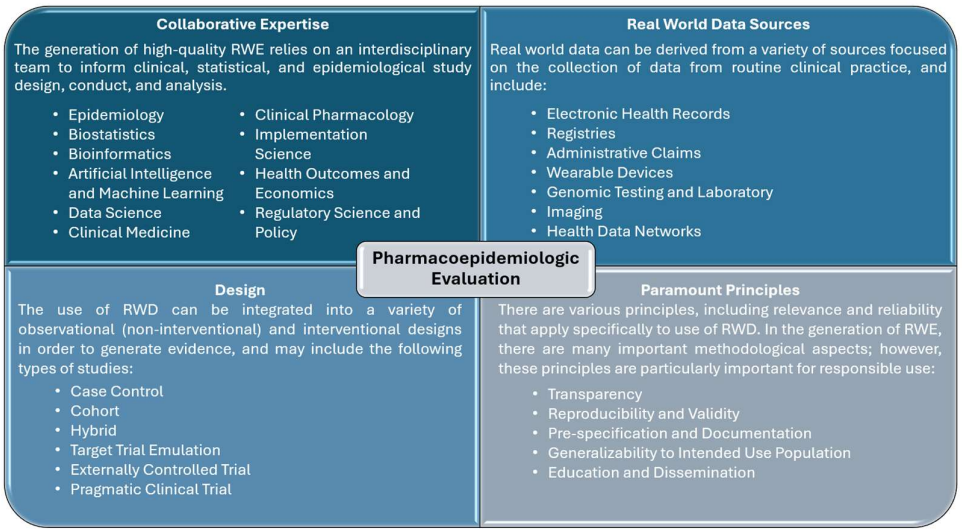
Evidentiary Applications of RWE in Medical Product Development and Evaluation

The Expanding Role of RWE in Medical Product Development and Regulatory Review across regions.

Randomized controlled trials (RCTs) are still generally deemed the gold standard for regulatory approval of new molecular entities and other health technologies in different parts of the world. Increasingly, however, RWE derived from relevant and fit-for-purpose RWD, can generate pivotal evidence on the safety and effectiveness of

medical products if well-constructed with broad interdisciplinary expertise, robust data, appropriate study design and adherence to methodological principles **(Figure 1**).

Figure 1.
Fundamental Components of Pharmacoepidemiologic Evaluation for Real-World Evidence (RWE) Generation



RWE has already served as substantial evidence of safety and effectiveness for regulatory decisions and is increasingly used in payer policy (e.g. HTA), while also continuing to fulfil its longstanding role in post-marketing medical product evaluation and as complementary evidence in clinical development.

Importantly, RWE can address known limitations of RCTs by studying patient outcomes in routine clinical practice among the intended use population via broadening study eligibility criteria, increasing geographic diversity, and allowing for a longer follow-up period [27]. In instances where RCTs lack feasibility or clinical equipoise, RWE may be the appropriate choice. Additionally, such evidence can provide complementarity to RCTs by capturing real-world outcomes, patient heterogeneity, and long-term effects of interventions observed as part of clinical care. For example, the linkage of RCT participants to RWD sources can enable augmentation of a control arm, afford longitudinal follow-up beyond the trial period to continue monitoring treatment effect, support postmarketing studies, detect rare or delayed adverse events, and characterize health intervention impacts in diverse patient populations and health care settings. In addition, decentralized and pragmatic randomized clinical trials can be implemented in settings that are more real-world than traditional RCTs, providing more relevant evidence for regulators, payers, clinicians and patients.

ISPE Contributions to Advancing RWE Standards and Collaborative Initiatives

Generation of high-quality RWE relies on robust methods, statistical and data science applications, bias evaluation, subject-matter expertise, and clinical pharmacology foundations, all core components of formal education in epidemiology [28].

Through the efforts of its members, ISPE has pioneered multi-sector collaborative RWD and RWE initiatives, thus helping set specific data and methodological standards for the generation of valid, reliable, and decision-grade RWE.

ISPE is a leader in the development of methods and best practices for the use of RWD, engaging in collaborative efforts on use of externally controlled trials, long-term extension studies to clinical trials, validation studies of study outcomes and novel endpoints, methods to control for measured and unmeasured confounding, evaluation of safety in patient subgroups, and other innovative study designs [29-31]. Arguably most importantly, these methods have been applied to regulatory, HTA, and clinical care decisions. In addition, ISPE has contributed to RWE training and education, enhancing research resources through initiatives such as the *Core Concepts in Pharmacoepidemiology* review series, textbooks and the peer-reviewed publications in journals such as Pharmacoepidemiology and Drug Safety (PDS), the official journal of ISPE [32-34]. ISPE members also have actively driven development and pharmacoepidemiology standards and the creation of RWE guidance across international (e.g., ICH, CIOMS) and regional domains [25, 26, 35-39].

Furthermore, ISPE continues to advocate for ethical RWD access and use across regions, fostering the development of novel design solutions and analytic frameworks that address the challenges of complex, high-dimensional multi-modal data streams, and mitigate biases unique to these contexts. Specific contributions disseminated to the broader research and public health community, via ISPE-sponsored collaborative efforts, include significant advances in RWD linkage procedures through issuance of guidelines on appropriateness, feasibility, evaluation, and reporting of data linkages [40-42]. Additional contributions include the conceptualization and establishment of federated RWD networks to facilitate privacy-preserving data access and analysis, promotion of health equity research, guidance on algorithm validation, and the understanding of RWD source heterogeneity through the DIVERSE Initiative [43,44].

Notable ISPE RWE initiatives during the pandemic era include the publication of the COVID-19 Real World Evidence Primer, and the guidance for the use of electronic health records for COVID-19 comparative effectiveness research [45-46].

Other major initiatives include PRINCIPLED, a process guide for inferential studies using healthcare data from routine clinical practice to evaluate causal effects of drugs, fostering generation of reliable and reproducible evidence and HARPER, the HARmonized Protocol Template to Enhance Reproducibility, to improve transparency and quality through protocol standardization [22, 47].

Drawing on its members' extensive expertise in epidemiology, biostatistiscs, and data sciences, ISPE is committed to and well-positioned to advance new methods building on causal inference principles that strengthen the reproducibility, transparency, and validity of RWE. ISPE also advocates the use of such scientific evidence to drive public policies and practice and protect patient's health [48].

Recognizing that patient perspectives are central to meaningful clinical evidence generation, ISPE continues to promote patient-centric evidence generation through early engagement of patients and other stakeholders in study design, outcome selection, and dissemination of findings, and by encouraging methods that support equity, align with patient needs and drive evidence-based decision-making. ISPE also continues to support multidisciplinary collaborative initiatives that bring together epidemiologists, statisticians, data scientists and other experts across organisations such as academia, regulatory and HTA bodies, policy makers, industry, clinical professionals, and patient organisatio*ns* to harmonize standards, share best practices, and accelerate the global adoption of high-quality RWE and RWD.

Future Directions in RWE

The vision of ISPE is to continue leading and promoting the responsible scientific use of RWD sources, methods, and robust analytical approaches for reliable, decision-grade RWE generation. These efforts will be key to accelerate the clinical development and post-approval evaluation of medical products for utilization, safety, efficacy, and effectiveness. ISPE urges experts, practitioners and researchers to apply robust epidemiologic principles, prespecify protocols, assess fit-for-purpose RWD sources, and use transparent, reproducible analytic approaches. Continued methodological innovation will be needed to address confounding, bias, missing data, measurement error, and the challenges posed by complex and heterogeneous data sources. ISPE encourages regulators, HTA bodies, and policymakers to define clear evidentiary standards for the appropriate use of RWE and to support frameworks that enable responsible data access, linkage, interoperability, and cross-regional harmonization. ISPE also encourages industry sponsors and service providers to integrate RWE thoughtfully across the product lifecycle, from study design through post-approval evaluation, in partnership with patients and other stakeholders.

As innovative technologies and approaches, particularly those powered by artificial intelligence (AI), mature, and as RWD sources and related digital health technologies flourish, ISPE will continue to play a key role in shaping the next frontier of methodological development, translational applications, and policy impact with collaborative, multidisciplinary expertise. To that effect, established in 2025, ISPE's Digital Technology and Artificial Intelligence (DTAI) Special Interest Group provides an interdisciplinary forum to share good practices, build methodological skills, and foster education and collaboration in digital technology and AI in pharmacoepidemiology.

Traditional RCT designs, supported by innovative technologies use of RWD, and the, are also evolving towards more pragmatic, hybrid and patient-centric approaches in many settings [49], requiring collaborative strategies that safeguard data integrity and support high-quality evidence generation. ISPE will also continue to contribute to the field through research, methodological development, policy, advocacy, guidance development, training and education, to help ensure that emerging approaches generate reliable, actionable evidence for patients and decision makers.

As a global leader in RWE, ISPE will be instrumental in advancing high-quality clinical evidence generation that improves medical product development, health care decision making, and patient outcomes and health.

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Acknowledgements: Donna Rivera, PharmD, MSc, FISPE, Bethesda, MD, USA, Mehmet Burcu, PhD, MSc, FISPE, Rahway, NJ, USA and Montse Soriano Gabarró, MD, MSc, FISPE, Berlin, Germany led this effort in collaboration with other contributing ISPE members (John Diaz Decaro, PhD, MS, Los Angeles, CA, USA; Cynthia Girman, DrPH, FISPE, Chapel Hill, NC, USA; Vera Ehrenstein, MPH, DSc, Aarhus, Denmark; Efe Eworuke, Ph.D, MSc, B.Pharm, Clarksburg, MD, USA; Jessica Jalbert, PhD, FISPE, New York, NY, USA; Hu Li, MD, PhD, San Francisco, CA, USA; Fredrik Nyberg, MPH, PhD, MD, FISPE, Gothenburg, Sweden; Grammati Sarri, MSc, PhD, FISPE, London, UK; Meredith Smith, PhD, MPA, FISPE, Boston, MA, USA; Rachel E. Sobel, DrPH, FISPE, Tarrytown, NY, USA ; Sengwee Toh, ScD, FISPE, Boston, MA, USA) and with the administrative support of Tien Tran, Pharm, Baltimore, MD, USA.