

New Real-World Evidence Registry Launches

Registry Is an Initiative of the Real-World Evidence Transparency Initiative

Bethesda, MD, USA—October 26, 2021—the [International Society for Pharmacoepidemiology](#) (ISPE) announced today that the [Real-World Evidence Transparency Initiative](#) has launched the Real-World Evidence Registry. The Real-World Evidence Transparency Initiative is a partnership between ISPE, ISPOR—[The Professional Society for Health Economics and Outcomes Research](#), the [Duke-Margolis Center for Health Policy](#), and the [National Pharmaceutical Council](#).

The volume of and interest in real-world data (RWD) that is used in real-world evidence (RWE) studies has been growing exponentially. While randomized controlled trials (RCTs) remain the gold standard, much attention has focused on RWE studies that complement RCTs to evaluate treatment effectiveness. The advantages of RWE studies include the availability of timely data at a reasonable cost, large sample sizes that enable the analysis of subpopulations not well represented in RCTs and the identification of less common effects, and the ability to better represent what treatment effects can be expected in real-world practice. While RWE offers tremendous potential, concerns exist about its credibility, such as biases due to lack of randomization, data quality, and the potential for “data mining” (where analyses are conducted until the desired result is found).

The objective of the Real-World Evidence Transparency Initiative is to address potential concerns with RWE studies by establishing a culture of transparency for the analysis and reporting of RWE in healthcare. A key element to establishing credibility of and trust in RWE studies is transparency. The new Real-World Evidence Registry, hosted on [Open Science Framework](#) (OSF), developed and maintained by [Center for Open Science](#), provides researchers with a platform to register their study protocols before they begin work. Using open, centralized workflows enhances collaboration and facilitates the transparency needed to elevate the trust in the study results.

“We are very excited to have launched the Real-World Evidence Registry,” stated ISPOR’s Chief Science Officer Richard J. Willke, PhD. “This Registry builds on the work of the Real-World Evidence Transparency Initiative and the recommendations from that group’s 2020 publication. We see the Registry as a significant step toward improving the transparency and credibility of RWE studies.”

“We partnered with the Open Science Foundation to create a simplified registry in an effort to promote a more widespread culture of registering RWD study protocols noted Shirley V. Wang, PhD, Harvard Medical School. “Registration with the RWE Registry provides a citable DOI that can be linked to the investigator’s ORCID ID and project wiki space to share study analysis code and other supporting materials. The new site is designed to encourage protocol registration for investigators and sponsors who do not already have a mandate or workflow to register on another site (e.g., [clinicaltrials.gov](#) or the EU post-authorization study registry).”

Additional information can be found on ISPE’s real-world evidence strategic initiatives, the Real-World Evidence Transparency Initiative, the Real-World Evidence Registry via the links below:

- [Real-World Evidence Registry](#)
- [Real-World Evidence Transparency Initiative](#)
- [ISPE Real-World Evidence Task Force](#)
- [ISPE’s Position on Real-World Evidence](#)

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ABOUT ISPE

The International Society for Pharmacoepidemiology (ISPE) is an international organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including such areas as pharmacovigilance, drug utilization research, comparative effectiveness review, and therapeutic risk management.

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