Real-World Evidence Collaborative White Paper Citations Tracker

The Duke-Margolis Center for Health Policy’s Real-World Evidence Collaborative is proud to have its white papers cited in a diverse number of publications. The following running list of citations is current as of December 2022.

Table of Contents
A Framework for Regulatory Use of Real-World Evidence Page 2
Characterizing RWD Quality and Relevancy for Regulatory Purposes Page 13
Determining Real-World Data’s Fitness for Use and the Role of Reliability Page 17
Understanding the Need for Non-Interventional Studies Using Secondary Data to Generate Real-World Evidence for Regulatory Decision Making, and Demonstrating Their Credibility Page 23
Adding Real-World Evidence to a Totality of Evidence Approach for Evaluating Marketed Product Effectiveness Page 25
A Roadmap for Developing Study Endpoints in Real-World Settings Page 28
Point-of-Care Clinical Trials: Integrating Research and Care Delivery Page 30
Aligning Shared Evidentiary Needs Among Payers and Regulators for a Real-World Data Ecosystem Page 30
A Framework for Regulatory Use of Real-World Evidence
“The First White Paper”


Brown, Jeremy P., Ian J. Douglas, Shahid Hanif, Robert M. A. Thwaites, and Andrew Bate. “Measuring the Effectiveness of Real-World Evidence to Ensure


Gregory Daniel, Christina Silcox, Jonathan Bryan, Mark McClellan, Morgan Romine, and Katherine Frank. “Characterizing RWD Quality and Relevancy for Regulatory Purposes.” Duke-Margolis Center for Health Policy, October 1,


Endpoint and a Post-Marketing Confirmatory Study under FDA's Accelerated Approval Regulations for Disease Modifying Osteoarthritis Drugs.”
*Osteoarthritis and Cartilage* 27, no. 4 (April 1, 2019): 571–79.


https://doi.org/10.1016/j.msea.2019.138143.

https://doi.org/10.1002/cpt.1317.


https://doi.org/10.1371/journal.pone.0278842.


Health Policy, November 25, 2019.


https://healthpolicy.duke.edu/publications/aligning-shared-evidentiary-
needs among payers and regulators.


Characterizing RWD Quality and Relevancy for Regulatory Purposes
“The Data Quality Paper”


Dreyer, Nancy A., Christina D. Mack, Robert B. Anderson, Edward M. Wojtys, Elliott B. Hershman, and Allen Sills. “Lessons on Data Collection and Curation From the NFL Injury Surveillance Program.” Sports Health 11, no. 5 (September 1,


Gressler, Laura Elisabeth, this link will open in a new window Link to external site, Danica Marinac-Dabic, Susan dosReis, Philip Goodney, this link will open in a new window Link to external site, C. Daniel Mullins, and Fadia Shaya. “Creation of Objective Performance Criteria among Medical Devices.” *BMJ Surgery, Interventions, & Health Technologies* 4, no. 1 (August 2022): e000106. https://doi.org/10.1136/bmjsit-2021-000106.


Jennifer R. Popovic. “Real-World Data as Real-World Evidence: Establishing the Meaning of Data as a Prerequisite to Determining Secondary-Use Value.”


Duke | MARGOLIS CENTER for Health Policy

Determining Real-World Data’s Fitness for Use and the Role of Reliability
“The Data Reliability Paper”


Hiramatsu, Katsutoshi, Annabel Barrett, Yasuhiko Miyata, and PhRMA Japan Medical Affairs Committee Working Group 1. “Current Status, Challenges, and Future


Levenson, Mark, Weili He, Li Chen, Sai Dharmarajan, Rima Izem, Zhaoling Meng, Herbert Pang, and Frank Rockhold. “Statistical Consideration for Fit-for-Use Real-World Data to Support Regulatory Decision Making in Drug


Understanding the Need for Non-Interventional Studies Using Secondary Data to Generate Real-World Evidence for Regulatory Decision Making, and Demonstrating Their Credibility

“The Credibility Paper”


Adding Real-World Evidence to a Totality of Evidence Approach for Evaluating Marketed Product Effectiveness

“The Totality of Evidence Paper”


Eskola, Sini Marika, Hubertus Gerardus Maria Leufkens, Andrew Bate, Marie Louise De Bruin, and Helga Gardarsdottir. “Use of Real-World Data and Evidence in Drug Development of Medicinal Products Centrally Authorized in Europe in


A Roadmap for Developing Study Endpoints in Real-World Settings
“The RWE Endpoints Paper”


**Point-of-Care Clinical Trials: Integrating Research and Care Delivery**
“*The POC Paper*”

- No Citations as of Quarter 1 2023 according to Google Scholar

**Aligning Shared Evidentiary Needs Among Payers and Regulators for a Real-World Evidence Ecosystem**
“*The SEO Paper*”

- No Citations as of Quarter 1 2023 according to Google Scholar