July 3, 2023

Editorial Board

Pharmacoepidemiology and Drug Safety

Subject**:** Submission of Manuscript **"The FAIRification of research in real-world evidence: A practical introduction to reproducible analytic workflows using Git and R"** in response to the call for papers on *Pharmacoepidemiology Research Reproducibility*.

Dear Editors,

I am writing to submit our manuscript titled "The FAIRification of research in real-world evidence: A practical introduction to reproducible analytic workflows using Git and R" for consideration in the special issue on research reproducibility and transparency in *Pharmacoepidemiology and Drug Safety*. We believe that our article aligns perfectly with the objectives and themes of this special issue.

Transparency and reproducibility are fundamental aspects of conducting rigorous real-world evidence (RWE) studies that can inform decision-making. While significant progress has been made in documenting and reporting study protocols (e.g., HARPER) and results, the establishment of robust version control systems (VCS) and code sharing practices in RWE lags behind other quantitative disciplines such as computational biology and health informatics but are increasingly mandated by regulators, funding agencies and HTA bodies. Our manuscript addresses this gap by providing an informative introduction and overview of VCS and discuss how they can be used for a FAIR (Findable, Accessible, Interoperable, and Reproducible) implementation of RWE.

The main body of the manuscript consists of a practical tutorial to facilitate the adoption of reproducible analytic workflows in the pharmacoepidemiology community. We offer detailed step-by-step instructions, accompanied by practical examples, to demonstrate how the Git VCS and the R programming language can be seamlessly integrated into RWE study workflows. By doing so, we empower pharmacoepidemiologists to conduct reproducible analyses and ensure the traceability of changes throughout the research process. We also emphasize the benefits of collaboration, dissemination, and archival through dedicated project repositories, which provide a comprehensive audit trail of all relevant study documents.

We believe that our manuscript will be of great interest to the readership of Pharmacoepidemiology and Drug Safety. It not only highlights the importance of reproducibility in pharmacoepidemiological research but also equips researchers with the necessary tools and guidance to implement reproducible analytic workflows themselves effectively.

We believe that our work will make a valuable contribution to the journal and further the goal of advancing transparency and reproducibility in pharmacoepidemiological research and in the conduct of RWE studies.

Thank you for considering our submission. We look forward to your positive response.

Yours sincerely,

Janick Weberpals, RPh, PhD