Associate Editor

Comments to the Author:

One minor edit is requested.

Dear Dr. Sarkar,

Thank you for your response and the invitation to address the minor edit recommended by reviewer #1.

We have addressed this comment by rephrasing the opening statement in the *Background* section of the manuscript.

Sincerely,

Janick Weberpals, RPh, PhD

# Reviewer: 1

Comments to the Author

Many of the changes are responsive to my earlier concerns. I appreciate the specification of the data that was used but think it should be move to the Materials and Methods. I also appreciate the enhanced descriptions of the figures in the results. The update to the discussion is a helpful acknowledgment of the complexity of working with EHR data. The repositioning of the FDA related information is much more appropriate.

I would like to see a minor edit:

The new opening statement in the Background section implies that RWE can only be generated by linking claims and EHR data. I would prefer indication that RWE can be claims, EHR or linked data.

[RESPONSE] We thank the reviewer for this comment and fully agree that all of the mentioned real-world data sources can be used for evidence generation when they are fit-for-purpose for the study question at hand. With the opening statement we want to emphasize that linkages are needed in situations where detailed clinical data, e.g., vital signs or labs, are important but only partially observed.

We rephrased the opening statement in the Background section of the manuscript to clarify this aspect.

*“Administrative health insurance claims databases and electronic health records (EHR) are important data sources to generate real-world evidence (RWE) when they are found fit-for-purpose for the study question at hand. While administrative health insurance claims databases have traditionally been the backbone for the majority of pharmacoepidemiologic studies, a notable drawback lies in their inability to capture important clinical prognostic factors like vital signs and labs. […]”*

# Reviewer: 2

Comments to the Author

The authors have comprehensively addressed my comments in the last round with significant additional efforts and content.