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RESPONSE TO LETTER

Comment on "Development and Validation of a META-Algorithm to Identify the Indications of Use of Biological Drugs Approved for the Treatment of Immune-Mediated Inflammatory Diseases from Claims Databases: Insights from the VALORE Project". [Response to Letter]

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Dear editor

We would like to thank you for your interest in our manuscript,[1] which aimed to develop a META-algorithm to identify the indication for use of biological drugs in immune-mediated inflammatory disease (IMID) patients. We agree that this study makes a significant contribution to the field of healthcare and clinical epidemiology, as the lack of information on the indication of use in claims databases represents a well-known limitation for conducting post-marketing monitoring and observational studies on biological drugs.

The four limitations indicated by Dr. Rokhmalia et al have been carefully reported and discussed in our paper, and we appreciate the recommendations for future research addressing these limitations. Although applying algorithms for identifying indications for use in claims databases can achieve a high level of accuracy, it is practically impossible to reach 100% accuracy. Therefore, caution should always be exercised when interpreting the results derived from the META-algorithm developed in this study. Nevertheless, many sensitivity analyses have confirmed the robustness of our findings. Furthermore, the impact of these limitations on the accurate identification of the indication for use in biological drug users treated for IMIDs appears to be minimal. For instance, the META-algorithm was unable to identify an indication for use in only 5% of biological drug users on average. In specific IMIDs such as inflammatory bowel diseases (IBDs), which often lead patients to access healthcare facilities, the level of missingness can be as low as 1%, as reported in our study.

Misclassification of the indication for use may also have a very limited impact on the algorithm's accuracy. For example, less than 1% of certolizumab users were misclassified as being treated for IBDs, for which the drug is not approved. These patients are likely affected by IBDs and a concomitant IMID that the algorithm could not identify, which was the reason for prescribing certolizumab.

In conclusion, the newly developed META-algorithm is a tool that may greatly benefit scientific research and monitoring biological drug use at the loco-regional level using Italian claims databases, representing a significant advancement in

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pharmacoepidemiology. Additional validation of this META-algorithm using other sources, such as clinical registries, may help confirm its accuracy.

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Disclosure

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Reference

1. Spini A, L'Abbate L, Ingrasciotta Y, et al. Development and Validation of a META-Algorithm to Identify the Indications of Use of Biological Drugs Approved for the Treatment of Immune-Mediated Inflammatory Diseases from Claims Databases: insights from the VALORE Project. *Clin Epidemiol*. 2024;16:395–407. doi:10.2147/CLEP.S445120

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