

Peer Review File

Article information: <https://dx.doi.org/10.21037/tbcr-21-43>

Reviewer Comments

Comment 1: The paper titled “Innovation drug approvals based on a bridging study: from concept to practice” is interesting, which take breast cancer as an example to describe the concept, types, strategies, statistical methods, and clinical practice of bridging studies, focusing on their development in China. However, there are several minor issues that if addressed would significantly improve the manuscript.

How to evaluate the sensitivity and similarity in bridging study? What are the differences between different diseases? It is recommended to add relevant content.

Reply 1: Thank you very much for your suggestion. We have added the suggested information regarding how to evaluate the sensitivity.

Comment 2: The literature citation in this study is not comprehensive enough, it is recommended to add the citation of " Implications of ICH-E5: Assessment of drug's sensitivity to ethnic factors and necessity of a bridging study for global drug development, Perspect Clin Res, PMID: 22145121".

Reply 2: Thanks a lot. We found this paper well and comprehensively written. We have cited it as reference 2.

Comment 3: What are the key issues that need to be solved in the research and development of innovative drugs? How to promote technological integration to improve the efficiency of drug innovation? It is recommended to add relevant content.

Comment 4: How to evaluate average bioequivalence between the generic copy of the new region and the innovative drug of the original region? What is the bridging reference formulation? It is recommended to add relevant content.

Comment 5: How to relocate drugs through the targeting network module? What is the relevance to bridging study? Please take breast cancer as an example for analysis.

Reply 3~5: Thank you for suggesting a broader content expansion. We could not agree more with your concerns, which are all important and something we are eager to learn more about. However, given the focused nature of this article, and the fact that the bridging study is related to all of this but is only one part of it, we don't want to broaden it too much. If possible, we look forward to having you collaborate with us on this in the future, and wonder if you would be willing to do so?

Comment 6: What are the biggest advantages and disadvantages of bridging research? It is recommended to add relevant content.

Reply 6: The biggest advantages and disadvantages are summarized in the last section “Summary and prospects”. However, we notice that our phrasing may not be clear. Thus, we have restated according to your concern.

