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LETTER TO THE EDITOR

Author's Reply to Webster and Woollett: "The End of Phase 3 Clinical Trials in Biosimilars Development?"

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I thank Drs. Webster and Woollett [1] for their letter to the editor. It was my main goal in authoring this article to trigger a discussion between biosimilar specialists on the relevance of the current clinical development model. I agree with Drs. Webster and Woollett that it may be possible to spend less than $50 million for a typical phase 3 biosimilar trial; the amount mentioned in my article corresponds to my own experience with large international Contract Research Organizations, providing full service and including the sourcing cost.

It remains that, in certain cases, it may be necessary to run a large phase 3 trial to alleviate possible remaining uncertainties concerning the similarity of a new biosimilar, but this type of decision should be made on a case-by-case basis, in discussion with regulators, and not systematically for all new biosimilars.

Compliance with Ethical Standards

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Conflicts of Interest Dr. Frapaise has no conflicts of interest to declare.

Reference

1. Webster CJ, Woollett GR. Comment on "The end of phase 3 clinical trials in biosimilars development?" [letter]. Bio Drugs. 2018. https://doi.org/10.1007/s40259-018-0297-y.

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