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Publication planning for biosimilars

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Abstract

Congress activities and manuscripts remain the foundation for the dissemination of information on any new drug and form an integral part of the development process. Publication planning is essential to enable the timely dissemination of medical and health economic information to the appropriate audiences. The approval and patent issues for biosimilars provide unique challenges in the planning and execution of a publications program. However, biosimilars will enter the arena of an established biologic agent, making education of physicians and patients of paramount importance, especially regarding the equivalent efficacy/safety profile of the biosimilar, assurance of reproducible manufacturing processes, and any potential health economic benefits. The biologic agent in question will have been supported by a concerted publications plan to communicate the results of their clinical trials and the importance of this therapy in the treatment of the disease or diseases. This creates a degree of "inertia" on the part of prescribers and patients who will be reticent to switch from an effective therapy. For a biosimilar, overcoming this inertia, requires a well-planned publications program to inform physicians of their equivalence in terms of product quality, efficacy and safety, and any potential advantages in terms of economic burden for the patient.

Biography

Paul studied Biochemistry at the University of Surrey in the UK and did his Doctoral research into the physiological roles of nitric oxide (NO) at Weill Medical College of Cornell University. Paul has published in peer-reviewed journals on subjects ranging from biochemistry to bioethics. After serving on the faculty at Weill, Paul worked as a freelance consultant for start-up biotechs, before transitioning full-time to medical publications. He has been a publications professional for over 7 years and has been involved in programs spanning all stages of drug development in a variety of therapeutic areas. These have included several biologic agents in the fields of multiple sclerosis and oncology.