Editorial

iMedPub Journals
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Insights in Biomedicine

2016
Vol.1 No.2:5

Tailored Patient Access Strategies and Observational Studies: The Driving Factors Behind Biosimilar Uptake for the Future

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Rec date: April 26, 2016; **Acc date:** April 29, 2016; **Pub date:** May 02, 2016

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Biosimilars have emerged as a new class of biopharmaceutical products, as a much needed antidote to the affordability issue predominant globally. Every country has its own progressing competitive landscape and multifaceted healthcare policies. This situation demands a tailored approach in designing patient access strategies. The emergence of various stakeholders has complicated the decision making landscape. The key to stakeholders' acceptance for effective biosimilar uptake lies in the integrated stakeholder management employing observational studies from the early stages of the product life cycle or in some cases even at the R&D stage.

Currently, biosimilar mAbs in particular are preferred only on biologic naïve patients due to lack of concrete guidelines on interchangeability. Therefore, the information on patient's eligibility for a biologic is very important.

It is also critical to provide the information on switching strategy to be employed in-case a biosimilar has failed and the patient has to be switched to another biologic. Unless such information is provided from observational studies, stakeholders involved right from approval to prescription process will always be in an apprehension to endorse a biosimilar.

Customized patient access strategies mainly emphasize on the following aspects:

- Identify the right patient pool through improvised patient journeys
- Understand the policy development in the region
- Key account management (KAM) or specialized teams dedicated to managing stakeholders
- Design patient education/support programs to improve patient access

Observational studies

These studies provide data on efficiency and safety of the drugs in larger and more diverse populations than those covered earlier in clinical trials. The information generated by analyzing the data helps various stakeholders in regulatory, prescription and reimbursement decisions. Patient registry is one such observational study which significantly benefits the biosimilar manufacturers in collecting clinical data to serve one or more predetermined scientific, clinical, or policy purposes.

Patient registries help in understanding the safety profile of a product in a real world scenario. The positive outcome from such studies created by multiple touch points with key prescribers facilitate:

- Increased awareness and acceptability of product
- Challenging the existing treatment paradigm and promoting biosimilar usage

Tailored patient access strategies as per prevailing market dynamics; collectively with observational studies is a formidable blend to enhance biosimilar consumption.