BIOSIMILAR TRIALS: PATIENT RECRUITMENT AND BARRIERS IN BRAZIL

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INTRODUCTION

• Biologic and biosimilar drugs represented a hallmark in drug development.
• Along with the requirements of similarity, even after comparability exercise, a phase 2, pivotal trial, head-to-head trial is required to show that there are no differences between reference and biosimilar drugs (1, 3).
• Much has been discussed about study design issues and biosimilarity evaluation. However, little has been discussed about its impact on clinical trial conduction in special related to recruitment issues.
• Overall, trials usually face issues and challenges during recruitment. The success of a CT depends on its capability to enroll a determined number of study participants within a planned time-frame (4).
• Therefore, we aimed to identify barriers, and propose actions to overcome these issues.

METHODS

• The barriers faced in ongoing biosimilar CTs were identified according to Libbs Farmacêutica (sponsor) experience.
• In order to comprehend the barriers in biosimilarity trials, Libbs Farmacêutica organized a meeting with investigators and clinical research coordinators (e.g. nurses or pharmacists from the investigational site) currently involved in ongoing biosimilarity trials.
• After identifying the main barriers, an action plan was proposed to solve the identified issues.

RESULTS

• The barriers faced and identified can be classified in two categories (Figure 1):
  - Overall barriers related to clinical research (Figure 2). Barriers related to the biosimilar drug (Figure 3).
• Overall barriers related to clinical research can be affected due to different factors such as physician factors, patient factor, operational factors and study design.
• Main barriers related identified directly to the biosimilar drug are related to the negative attitude towards biosimilar drugs (Figure 3), caused due to misconception or lack of knowledge related to biosimilar drugs and its development process among patients and physicians.

DISCUSSION

• Although biosimilar drug represented one of the main barriers in the study, physician and patient factors were identified as the most impacting factor leading to low accrual in the study (4).
• Modification of physician and patient’s attitude toward participation in clinical trial is the main challenge and can be overcome through continuous education.
• Along with the complexity of the study protocol, our findings are in concordance with prior studies. Overall, the increasing demand and diminished resources experienced by the health care system impacts on accrual to cancer clinical trials.
• The development of a national network reference to investigative sites among physicians can act as facilitators through promotion of communication and enhancing integration.

LIMITATIONS

• The findings presented may not be generalizable because of the qualitative methods used in this study.

CONCLUSIONS

• Multidimensional approaches such as publication plan, screening and enrollment strategies, awareness activities is the best strategy to raise awareness in multicenter trials.
• The development of biosimilar drugs is needed in order to the delivery of high quality biosimilar products are needed in order to increase drug access.