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Emerging role of pharmacogenomic biomarkers in biological therapy and safety

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Identifying pharmacogenomic biomarkers for therapeutic and safety outcome to biological therapy, echoes advancement towards personalized medicine in the 21st century. Biologics though regarded as "designer" drugs, produce desired therapeutic effect only in a fraction of the treated population, since genetic and non-genetic factors jointly influence variability in response to biological treatment. The demographic diversity and complexity in the prevalence of genomic variants (SNPs and non-SNPs polymorphisms) pose major challenges in development of suitable prognostic pharmacogenomic biomarkers as predictors of response to bio-therapeutic agents. However, a substantial number of pharmacogenomic markers have helped in appropriate patient selection for antineoplastic, anticoagulant, anticonvulsant, cardiovascular and anti-HIV therapies. The pharmacogenetic screening, thus serves as a useful diagnostic tool integrating individual's genetic information with the existing prescribing model to optimally treat the patients. Biologics are large complex molecules with rapidly changing stability profile which intensify the response variation due to genetic polymorphism. Non-clinical challenges, such as hemocompatibility, immunotoxicity, biodistribution, tumorigenicity, contamination etc., faced during biologics development prohibits designing a single testing strategy for all products. Adopting pharmaceutical 'Quality by Design' partly addresses these challenges enhancing safety and performance of biological products. Also, identifying useful predictive biomarkers will have a significant impact on drug development and successful outcome of new biologics. Healthcare authorities have stressed upon developing pharmacogenomic biomarker tests in clinical practice complementing the information available from clinical trials warranting greater success rate of high cost biological therapy.

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