

## Key Role of Safety and Efficacy Biomarkers in the Field of Translational Research

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### DESCRIPTION

Translational research is an investigative process where it turns the nonclinical research outputs into clinical research results. The role of biomarkers extremely enhancing the guiding decisions from the preclinical evaluations to each and every phase of the clinical trials including post marketing studies. The translational biomarkers can predict, detect and monitor the drug-induced toxic effects during the human trails for testing the drugs. The biomarkers are classified into three types Type-0, Type-1, Type-2 biomarkers. Type-0 are the markers of the natural disease history and correlates with known clinical indications. Type-1 captures the intervention effects according to the mechanism of action of the drug. Type-2 predicts the changes in the endpoints in the clinical phases. During clinical trials the biomarkers are classified as safety biomarkers and efficacy biomarkers. Safety biomarkers are used to detect the toxicities of a particular drug at different therapeutic areas. In translational research are compound profile and preclinical toxicological data is essential before the trials begin where safety biomarkers plays an important role in obtaining such data during preclinical trials. These safety biomarkers mainly focus on the vital organs during the test. Several tests will be conducted on the vital organs like Aspartate aminotransferase (AST), Alanine aminotransferase Bilirubin, Serum creatinine, Complete blood count including Bone safety biomarkers tests and basic metabolite safety biomarkers. Efficacy biomarkers are used to demonstrate the early events in toxic changes and in disease progression. It is further divided as surrogate, predictive, pharmacodynamic, prognostic biomarkers. By using the surrogate biomarkers correlation between the measured level and the clinical outcome

is assumed, it will also explain the change in biomarker and change in the clinical outcome. Predictive biomarkers identify the changes in the biomarker between the groups with favourable and unfavourable effect from the exposure on the drug or environmental agent. The prognostic biomarkers identify the likelihood of a disease progression or clinical event. Pharmacodynamic biomarkers detects the changes in the response to the exposure to environmental agent or medical product. These are effectively used in the both clinical practices and early therapeutic development. The applications of safety biomarkers and efficacy biomarkers in translational research are to identify and justifies the target therapy, it identify the lead molecule to evaluate molecular targeted drugs in preclinical phase, dose optimization and helps in predicting the clinical outcomes.

### CONCLUSION

Safety and efficacy biomarkers play a crucial role in the preclinical and clinical research trails, the rapid changes in the growth measurement, computation and analysis will bring an explosive growth of the translational research field. Evidence based biomarker development keeps a pace with clinical and scientific needs. Biomarker accelerates the efficiency technologies which developed for the prevention, diagnosis and treatment of the disease. The use of biomarkers directly affects the quality of the research. The implications of the current biomarkers development includes complex composite biomarkers and digital biomarkers derived from the sensors and mobile technologies. The reproducibility and quality of the biomarker development is very useful for the ecosystem of the medical drug development.

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**Received:** 01-Sep-2022, Manuscript No. TMCR-22-19730; **Editor assigned:** 05-Sep-2022, Pre QC No. TMCR-22-19730 (PQ); **Reviewed:** 19-Sep-2022, QC No. TMCR-22-19730; **Revised:** 27-Sep-2022, Manuscript No. TMCR-22-19730 (R); **Published:** 04-Oct-2022, DOI: 10.35248/2161-1025.22.12.271

**Citation:** Kunupo A (2022) Key Role of Safety and Efficacy Biomarkers in the Field of Translational Research. *Trans Med.*12:271.

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