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Biomarkers: Drug Development and Phases in Discovery

Lakshmi Deeraja Manvi Gatta*

Department of Pharmacy, Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam, Andhra Pradesh, India

***Corresponding author:** Gatta LDM, Department of Pharmacy, Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam, Andhra Pradesh, India, E-mail: manvi.gatta@gmail.com

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Abstract

The success rate of drug development programs is improved by biomarkers and the availability of new therapeutics is thereby accelerated. The production of biomarkers is a multi-step and iterative process that starts with the discovery of biomarkers in samples of diseases and non-diseases.

A biomarker could be used as a proxy for a natural outcome, such as survival or permanent morbidity, in assessing possible drug therapies. If the biomarker, which has a direct correlation to better health, is altered by a medication, the biomarker acts as a surrogate endpoint to determine clinical gain.

Keywords: Biomarker; Drug; Clinical applications; Diseases

Description

In addition to basic and applied research and clinical applications, biomarkers are useful tools for patient stratification as they can be used to predict molecular and phenotypic alterations and to determine the effectiveness and safety of therapeutic intervention among pharmacogenetically heterogeneous individuals [1-3].

Validation

The analytical validation process of the production of biomarkers is characterized by an analysis of the biomarker's performance metrics to ensure that the test is accurate, reproducible and adequately sensitive and precise.

Qualification is a graded proof method that ties a biomarker to biological and clinical endpoints. The use of biomarkers for clinical applications relies on their clinical effectiveness for diagnosis of diseases, staging of diseases and choice of care.

When a proposed biomarker has been validated, it can be used to diagnose the risk of disease, the occurrence of disease in an individual or to customize therapies for the disease in an individual.

Drug Development

In the drug development process, some of the key fields where molecular biomarkers are used are: early drug development tests, safety studies, proof of concept studies, and molecular profiling.

In early drug development trials, molecular biomarkers are sometimes used. For example, in a phase I study, they are used to develop doses and dosing regimens for future phase II studies. It is generally observed that PD biomarkers react (either decrease or increase) proportionally with the dosage. In combination with safety data, this data helps to evaluate doses for Phase II studies.

In addition, molecular biomarkers for protection have been used in both preclinical and clinical studies for decades. They have been fully automated for both animal and human research since these studies have become mainstream tests.

Liver function (transaminasis, bilirubin, alkaline phosphatase) and kidney function are among the most common safety tests (serum creatinine, creatinine clearance, cystatin C). Others include skeletal muscle (myoglobin) or heart muscle damage (CK-MB, troponin I or T) markers, as well as biomarkers of the bone (bone-specific alkaline phosphatase).

Phases for Drug Discovery

In different phases of drug development, several different biomarkers can be discovered and created. The guidance of the FDA pharmacogenomics further identifies potential, probable and known true categories of biomarkers based on the scientific knowledge available on the marker.

Surrogate endpoints are relatively few biomarkers. Based on epidemiological, surgical, pathophysiological or other empirical data, a surrogate end point is supposed to predict clinical outcomes (benefit or damage, or lack of benefit) [4-6].

Pre discovery: Disease Mechanism

Discovery: Validate drug target,Drug MoA, Establish SAR

Pre-clinical: Build PK/PD models,Safety and efficacy end points,Guiding compound selection and retension.

Early clinical: Bioequivalence,Dose response, MoA of drug in humans

Late clinical: Define the target population,Dose selection and optimisation

Marketing: Monitortherapeutic response, side effects

Discussion and Conclusion

In the analysis of systemic autoimmune diseases, the use of multi-omics systems and multiplexed methods can not only recognise various valuable biomarkers, but also report areas for further growth and enhancement.

There is also a rising consensus that more than one biomarker is required to make specific decisions concerning efficacy or protection. As a consequence, in go/no-go decisions and at critical stages of drug production, early detection of these biomarkers is crucial.

In this sense, a major contribution to early clinical development may be made by using multiplexed technology and the multi-omics approach. It is therefore important for the efficient distribution of 'fit for purpose' biomarkers to consider the benefits of these methods and technologies, as well as their drawbacks, and how they could be used for the discovery of unique biomarkers.

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