OPEN ACCESS Freely available online

ISSN: 2155-9627
Journal of Clinical Research & Bioethics

Perspective

Significance of Biomarkers in Drug Discovery and Treating Chronic Diseases

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DESCRIPTION

A biomarker is a dynamic and informational biological substance (i.e., cellular, biochemical, molecular, genetic, protein, metabolite, specific post-translational modification or physiological or physical sign) that can be objectively measured and evaluated as an indicator of the pharmacologic responses to a therapeutic intervention. Many different biomarkers can be discovered and developed in various stages of drug development.

One of the oldest biomarkers used to diagnose certain complications was the arterial palpitation, which was formerly proved in ancient Chinese, Indian, Egyptian and Greek drug. This was followed by blood pressure trials, which were conducted for the first time in the middle of the 18th century. Current efforts for the discovery and development of disease-related biomarkers will assist in optimal decision-making throughout the course of drug development and improve the understanding of the disease processes even though many challenges needs to be addressed. Since the beginning of the 21st century, biomarkers have gained prominence in medicine discovery, development and approval processes.

Robust and validated biomarkers are needed to improve diagnosis; monitor drug activity and therapeutic response and guide the development of safer and targeted therapies for various chronic diseases. Biomarkers have been used for centuries as indicators of human health or for the diagnosis of pathological conditions.

In case of drug discovery, development of suitable biomarker can contribute to understanding the mechanism of action of a medicine, opting right cases for a clinical trial, monitoring and prognosis of toxicity issues and guiding regulatory as well as medicine development decisions. The biomarkers also measure the performance of novel therapies using clinical outcomes, such as mortality or disease progression which is very much time-consuming to obtain enough information from clinical endpoints.

Use of biomarkers in late medicine development is the evaluation of dose- response and optimal regimen for desired pharmacologic effect, safety labels to determine dose- response for toxicity, and determination of the part of differences in metabolism. Once validated, for illustration, a biomarker can be used in cure selection for phase 2 and phase 3 clinical trials grounded on the biomarker's PK/ PD relationship and projected therapeutic indicator as well as to differentiate seeker compounds from other compounds. The biomarkers that measure PK/ PD relationship also give precious feedback to discover whether the mechanism does or doesn't translate to clinical trials. Target specific biomarkers can also be used to stratify patients by disease type or response to treatment.

The main drawbacks for medicine development and biomarker development are extreme costs (expensive) and time-intensive which is very challenging for a sponsor to develop both contemporaneously.

GENOMIC BIOMARKERS

Rapid development of regulations in biomarkers field began in early 21st century and is closely linked to the development of the 'personalized drug' conception involving delivery of acclimatized therapy to a particular patient, based on his genetic and epigenetic information. Genomic biomarkers are DNA or RNA characteristics that are a crucial part of medicine development and essential for successful regulatory approval.

Exemplifications of the use of genomic biomarkers in medicine development include:

1. Understanding of the mechanistic basis for lack of efficacy, occurrence of adverse medicine responses or medicine- medicine interactions,

2. clarifying differences in response in clinical trials as well as differences in pharmacokinetic (PK) and pharmacodynamic (PD) parameters,

3. Enrichment and stratification in clinical trials to facilitate accelerated development.

In order to substitute the clinical meaningful end-points with the biomarkers as the surrogate end-points has been limited due to the specialized challenges and poor experimental design. A better coordinated experimental and clinical design, more standardized multi-omics and multi-parametric technology and analysis platforms, as well as a collaborative effort between scientists, clinicians, biopharmaceutical industry and regulatory authorities should expedite the discovery of validated and qualified biomarkers to a much greater extent.

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Received: 25-Feb-2022, Manuscript No. JCRB -22-16157; **Editor assigned:** 28-Feb-2022, Pre QC No. JCRB -22-16157 (PQ); **Reviewed:** 14-Mar-2022, QC No JCRB -22-16157; **Revised:** 18-Mar-2022, Manuscript No. JCRB-22-16157(R); **Published:** 28-Mar-2022, DOI: 10.35248/2155-9627.22.13.408.

Citation: Cai Y (2022) Significance of Biomarkers in Drug Discovery and Treating Chronic Diseases. J Clin Res Bioeth.13: 408.