Biomarkers Journal
ISSN: 2472-1646

Open access Opinion

Classification and Applications of Biomarkers

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INTRODUCTION

Imaging biomarkers (computed tomography, positron emission tomography, magnetic resonance imaging) and molecular biomarkers can be classified based on various parameters, including their characteristics. Nonimaging biomarkers with biophysical properties that allow them to be measured in biological samples are referred to as molecular biomarkers. These include nucleic acid–based biomarkers such as gene mutations or polymorphisms and quantitative gene expression analysis, peptides, proteins, lipids metabolites, and other small molecules. Biomarkers are also classified according to their application, such as diagnostic biomarkers, disease staging biomarkers, disease prognosis biomarkers, and biomarkers for monitoring clinical response to an intervention. Multiple endpoints are typically combined to produce a single variable, such as an index or score, when using a composite endpoint.

DESCRIPTION

Another type of biomarker is one that is used to make decisions during the early stages of drug development. Pharmacodynamic biomarkers, for example, are markers of a specific pharmacological response and are of particular interest in dose optimization studies. Biomarkers are important tools that can provide critical information on the complex chain of events and molecular mechanisms underlying TBI pathophysiology. Creating a profile of distinct classes of biomarkers that reflect core pathologic mechanisms could help us identify and characterise the initial injury as well as secondary pathologic cascades. As a result, they are a logical adjunct in TBI diagnosis, tracking progression and activity, guiding molecularly targeted therapy, and monitoring therapeutic response. As a result, significant effort has been expended in the last 25 years to identify novel biomarkers. However, because of inconsistent regulatory standards and a lack of reliable evidence of analytical validity and clinical utility, the role of brain injury markers in clinical practise has long been debated. We provide a comprehensive overview of the markers that are currently available, as well as a description of their potential role and applications in TBI diagnosis, monitoring, drug discovery, and clinical trials. We discuss the recent inclusion of brain damage biomarkers in diagnostic guidelines and provide perspectives on the validation of such markers for clinical use in this review. Biomarkers used in clinical trials include those used as study endpoints as well as those used as exploratory biomarkers. Exploratory biomarkers are used to build a suitable panel that can then be tested and validated for use as an endpoint in future clinical trials. Turk et al. distinguished “exploratory endpoints” from biomarkers used to define a primary endpoint, multiple primary endpoints, secondary endpoints, and composite endpoints in an account of clinical trial endpoints.

CONCLUSION

There are different types of biomarkers based on their main clinical application, according to the FDA-NIH Biomarker Working Group: diagnostic, monitoring, pharmacodynamic/response, predictive, prognostic, safety, and susceptibility/risk biomarkers. Each type of biomarker has the potential to improve diagnosis, prognosis, and clinical outcomes by providing additional information about the disease or intervention under consideration. Furthermore, biomarkers can help us learn more about the mechanisms underlying disease and, as a result, identify potential new therapeutic key targets. Thus, biomarkers can be identified at any stage of the disease’s progression, from onset to recovery or chronicity. Such biomarkers may be useful in identifying patients who are candidates for immunosuppressive therapy reduction, identifying patients at risk for acute rejection or infection, and managing the timing and rate of immunosuppressive weaning. Serial longitudinal immune monitoring may enable the continuation of an individualised immunosuppressive regimen.

Received:	01- March -2022	**Manuscript No:**	IPBM-22-13467
Editor assigned:	03- March -2022	**PreQC No:**	IPBM-22-13467 (PQ)
Reviewed:	17- March -2022	**QC No:**	IPBM-22-13467
Revised:	22- March -2022	**Manuscript No:**	IPBM-22-13467 (R)
Published:	29- March -2022	**DOI:**	10.35841/2472-1646-8.3.124

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Citation Michel Herranz (2022) Classification and Applications of Biomarkers. Biomark J 8:124.