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Opinion Article

Diagnostic Biomarker: Key Factor for Precision Medicine

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DESCRIPTION

According to Food and Drug Administration (FDA) and National Institutes of Health (NIH), biological markers or bio markers are characterized as "a defined characteristic calculated as an index of normal biological processes, pathogenic processes, or responses to any exposure or intervention, including therapeutic interventions". Diagnostics bio markers are essential components in precision medicine to predict and track patient response to treatment or to classify different subpopulations of patients who are most likely to benefit from a given treatment. Any testable biological indicator can be used as a bio marker. Biomarkers can be, for example, cellular or molecular (DNA, RNA, protein, metabolites). To determine a biomarker, a tissue biopsy or liquid biopsy (blood, urine, saliva, etc.) is used. Other biomarkers (physiological, morphological, etc.) can also be measured and used for clinical or diagnostic imaging. Qualitative biomarkers can be used to detect pathogenic processes, whereas quantitative biomarkers are used to detect threshold pathogenic processes. Biomarkers are used in the majority of diagnosis especially in cancer. Biomarkers are the basis of all *in vitro* diagnostics. The detection of one or more biomarkers associated with normal biological or pathogenic processes or patient response to a given treatment is the first step in diagnostic development. Clinical validation of biological, physiological, or morphological markers determines whether the marker (or combination of markers) is accurate, adequate, and accurate to measure patient response to a given process or treatment. Molecular biology using genomic, transcriptomic, proteomic or metabolomic biomarkers aids in the development of precise diagnostics, majorly in precision medicine. To predict disease course, track disease evolution, identify different sub-populations of patients, and predict and monitor patient response to most therapies, this precision medicine domain needs the identification and clinical confirmation of a large number of biomarkers. As a result, a number of treatments, such as those for pancreatic cancer or Alzheimer's disease, also require the detection of particular biomarkers in order to determine a pathological biological method. Furthermore, diagnosis of certain pathologies like solid tumors would have been studied more if biomarkers from liquid biopsies (blood, urine, saliva) could be used as much as needed. Diagnostic tests are commonly used by doctors to clarify and confirm clinical decisions. In recent years, the need to pre-select patients based on drug names and classifications has become increasingly important in the diagnostic process. In the field of oncology, advancing diagnostics guides the use of targeted therapies which helps in improving clinical outcomes and minimizes toxicity in many patients. The promise of cancer biomarkers is demonstrated by the recent emergence of biomarker strategies for treatment selection and monitoring. Most diagnosis is based on biomarkers. The first step in diagnostic development is to identify one or more biomarkers associated with normal biological processes, pathogenic processes, or patient response to a given treatment. Clinical validation of biological, physiological, or morphological markers determines which markers or combinations of markers are reliable, relevant, and predictable for measuring patient response to a given process or treatment. In this area of precision medicine, numerous biologics are used to predict disease progression, monitor disease progression, identify diverse patient subpopulations, and predict and monitor patient response to most therapies. Diagnostics biomarkers are used in diagnosing diseases or pathogenic processes, monitoring patients during treatment, and determining patient response to exposure or medication. Marker identification and clinical validation are required for correct diagnosis. In fact, few treatments are prescribed based on specific drugs based on diagnostic results. Only a few companion diagnostics are currently on the market, except for breast cancer, colon cancer, or melanoma. Several other medical fields require the development and commercialization of new diagnostics. There is a need to use therapeutic biomarkers to guide such critical therapeutic decisions. The shift from biomarker candidates to diagnostic entity presents a real challenge for biopharmaceutical sponsors and diagnostic companies which have a certain bottlenecks regarding regulatory requirements. A good diagnostic biomarker will help detect all patients with the disease or a subset of the disease (100% sensitivity) and patients without the disease will not be diagnosed with the disease (100% specificity). Biomarkers are recognized as essential tools in therapeutic development, enabling more informed and improved clinical trial design through indicators of target engagement and enabling patient stratification as well. Researchers are currently combining human clinical data with information provided by diagnosticbiomarker which is called as multimodality testing. In future, images and digital biomarkers can be also be added to further improve diagnostic possibilities.

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