

## Cancer biomarker discovery in Medicine

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### Introduction

Precision medicine puts forward customized healthcare for cancer patients. An important way to accomplish this task is to stratify patients into those who may respond to a treatment and those who may not. For this purpose, diagnostic and prognostic biomarkers have been pursued. The traditional mechanism-driven functional biomarkers have the advantage of actionable insights, while data-driven computational biomarkers can fulfill more needs, especially with tremendous data on the molecules of different layers (e.g. genetic mutation, mRNA, protein etc.) which are accumulated based on a plenty of technologies.

Besides, the technology-driven liquid biopsy biomarker is very promising to improve patients' survival. The developments of biomarker discovery on these aspects are promoting the understanding of cancer, helping the stratification of patients and improving patients' survival. Current developments on mechanisms-, data- and technology-driven biomarker discovery are achieving the aim of precision medicine and promoting the clinical application of biomarkers. Meanwhile, the complexity of cancer requires more effective biomarkers, which could be accomplished by a comprehensive integration of multiple types of biomarkers together with a deep understanding of cancer. Biomarkers are the pillars of precision medicine and are delivering on expectations of molecular, quantitative health.

These features have made clinical decisions more precise and personalized, but require a high bar for validation. Biomarkers have improved health outcomes in a few areas such as cancer, pharmacogenetics, and safety. Burgeoning big data research infrastructure, the internet of things, and increased patient participation will accelerate discovery in the many areas that have not yet realized the full potential of biomarkers for precision health. Here we review themes of biomarker discovery, current implementations of biomarkers for precision health, and

future opportunities and challenges for biomarker discovery. Impact statement Precision medicine evolved because of the understanding that human disease is molecularly driven and is highly variable across patients. This understanding has made biomarkers, a diverse class of biological measurements, more relevant for disease diagnosis, monitoring, and selection of treatment strategy. Biomarkers' impact on precision medicine can be seen in cancer, pharmacogenomics, and safety. The successes in these cases suggest many more applications for biomarkers and a greater impact for precision medicine across the spectrum of human disease.

The authors assess the status of biomarker-guided medical practice by analyzing themes for biomarker discovery, reviewing the impact of these markers in the clinic, and highlight future and ongoing challenges for biomarker discovery. This work is timely and relevant, as the molecular, quantitative approach of precision medicine is spreading to many disease indications. Thousands of biomarker tests are either available or under development for lung diseases. In many cases, adoption of these tests into clinical practice is outpacing the generation and evaluation of sufficient data to determine clinical utility and ability to improve health outcomes. There is a need for a systematically organized report that provides guidance on how to understand and evaluate use of biomarker tests for lung diseases. We found that the status of biomarker tests in lung diseases is highly variable depending on the disease. Nevertheless, biomarker tests in lung diseases show great promise in improving clinical care. To efficiently translate biomarkers into tests used widely in clinical practice, researchers need to address specific clinical unmet needs, secure support for biomarker discovery efforts, conduct analytical and clinical validation studies, ensure tests have clinical utility, and facilitate appropriate adoption into routine clinical practice.