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Commentary

Precision Medicine and Patient-Centric Care

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ABOUT THE STUDY

Medical practice today is largely empirical. Physicians typically rely on pattern matching to make a diagnosis based on a combination of patient history, physical examination, and test data. Therefore, certain treatments are often based on the experience of physicians with similar patients. One of the consequences is that a "typical patient" with a particular illness is prescribed. Under this paradigm, treatment decisions are made by trial and error, and patients sometimes become victims of unpredictable side effects or, in theory, of drugs that work for some people affected by this particular illness. Has little or no effect. Increased use of BM and Companion Diagnostics (CDX) will enable the transition from empirical care to Precision Medicine (PM) (the right patient, the right dose, the right drug at the right time). In the near future, healthcare professionals may move away from the concept of "one size for everything" and switch to PM instead. It is well known that the response to a particular treatment depends on the heterogeneity of the population of good and bad respondents. Patients and treatment responses vary based on variables such as genetic predisposition, cohort heterogeneity, ethnicity, slow or fast metabolism, epigenetic factors, and early and late illness. These parameters affect whether a particular person responds well or does not respond well to a particular treatment.

The goal of PM is to enable clinicians to quickly, efficiently and accurately predict the most appropriate course of action for their patients. To do this, clinicians need tools that are compatible with clinical workflows and are economically feasible. These tools can simplify the process of managing the underlying biological complexity of human illness. To help create and improve these tools, the PM ecosystem is constantly evolving and is the solution to the problem. The PM ecosystem begins linking and exchanging information among clinicians, laboratories, research firms, and developers of clinical information systems. These efforts are expected to lay the foundation for an ever-evolving healthcare system that can significantly accelerate the advancement of PM technology. Precision medicine emphasizes the importance of combining established clinical indicators with molecular profiling to develop diagnostic, prognostic, and therapeutic strategies tailored to the needs of each patient group. To use the PM ecosystem optimally, you need to interpret the data correctly. The PM ecosystem combines omics and clinical data to determine the best course of action for a particular patient group. The drug is currently approved after a long approval process. This approach should potentially ensure a faster, faster path to drug development for the next generation of drug therapies. Focusing on a specific patient population in the regulatory approval process should facilitate the rationalization of regulatory approval and lead to clinical and commercial success.

The shift towards a deeper understanding of disease based on molecular biology will also inevitably lead to a new, more precise disease's classification, incorporating new molecular knowledge to generate a new taxonomy. This change will result in a revised classification of intrinsic biology, leading to revisions of diseases signs and symptoms. For this change to occur, however, larger data bases, accessible to all, will be needed that dynamically incorporate new information.

The emerging use of personalized laboratory medicine makes use of a multitude of testing options that can more precisely pinpoint management needs of individual groups of patients. PM seeks to dichotomize patient populations in those who might benefit from a specific treatment (responders) and those for whom a benefit is improbable (non-responders). Defining cut-off points and criteria for such a dichotomy is difficult. Treatment recommendations are often generated using algorithms based on individual somatic genotype alterations. However, tumors often harbor multiple drivers' mutations. Physicians, therefore, need to combine different streams of evidence to prioritize their choice of treatment. The implementation of PM often relies on a fragmented landscape of evidences making hard for physicians to select among different diagnostic tools and treatment options.

In the case of cancer immunotherapy, predictive biomarkers (BM) for immunotherapy differ from the traditional BM used for targeted therapies. The complexity of The Tumor Microenvironment (TME), the immune response and molecular profiling requires a more holistic approach than the use of a

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single analyses BM. To cope with this challenge, researchers have adopted multiplexing approach, where multiple BMs are used to empower more accurate patient stratification. To select specific patient's groups for immunotherapy, histological analysis now include concomitant analysis of immuno-oncology BMs, such as PD-L1 and immune cell infiltrates as well as more comprehensive immune and tumor-related pathways. In the case of cancer immunotherapy, multiplexed immunoprofiling generating a comprehensive biomarker dataset that can correlate with clinical parameters is key for the success of PM.

Precision medicine is a transformational analytical tool that is gaining momentum. It leverages advanced analytics, Big Data, deep learning, and statistical models, allowing clinicians to comprehensively explore the composition of an individual patient's distinct ailment and demographic and genetic factors. Personalization is indeed the future of healthcare, and the percentage of drug pipelines including precision-medicine-based targeted therapies continues to increase. And to what indications is it most applicable? Because of the heterogenic component of cancer, as well as issues related to treatment cost and patient mortality, oncology is the primary area for precision medicine. However, the use of precision medicine, as well as the supporting use of biomarkers and companion diagnostics, is now actively moving from oncology to a variety of non-oncological therapeutic areas.

Patient-centric, precision-medicine-oriented healthcare needs to give rise to patient-centric, precision-medicine-oriented clinical trials. Instead of being viewed as mere data points, clinical trial patients are increasingly seen as core and integral to the process. There is an art and science to communicating with patients, and true patient-centricity requires an organizational mind shift by executive sponsors, protocol designers, site leadership, and operations to prioritize patient goals. Patient-centricity in clinical trials starts with understanding the person's reasons for participating and showing sensitivity to their goals, interests, and motivations. It must strive to measure what is clinically meaningful to patients as outcome measures. Clinical trials are starting to have more two-way communications between patients and providers/investigators, as well as between patients and CROs/biopharmaceutical companies. Patient input is sought on informed consent forms, protocols, and trial designs.