

The Challenges, Opportunities and Applications of Personalized Medicine in Clinical Research

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Abstract

This review explores personalized medicine (PM) and its potential to improve healthcare by creating individualized treatment plans based on genetic and biomarker data. PM can optimize drug dosing, reduce adverse reactions, and increase clinical trial efficiency. Despite obstacles hindering its implementation, PM has significant potential in cancer, cardiovascular diseases, respiratory disorders, infertility, and infectious diseases. Future directions for PM include the development of new biomarkers and integration of genomic and proteomic data.

Keywords: Personalized medicine; Clinical research; Biomarkers; Applications; Artificial Intelligence; Healthcare

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I. Introduction

Personalized medicine is defined as the acclimatizing of medical treatment to the individual characteristics of each case predicted on their heritable and molecular data. The ability to predict which molecular treatment will be safe and effective for each patient and which one will be not, is increasing by this approach. The “right drug” at the right time for the right patient has replaced the concept of “one size fits all.”

Individualized drug can be considered as an extension of traditional medical approaches in understanding and treating the conditions. Equipped with tools that are more precise, physicians can elect a remedy or treatment protocol grounded on a case’s molecular profile that may not only minimize the dangerous adverse effects, but also ensure more successful outgrowth. Using individualized drug has eventually enabled to change the way we think about, identify and manage health problems. It has an instigative impact on both clinical exploration and case care effects to ensure more successful outcome. Using individualized drug has enabled the eventuality to change the way we think about, identify and manage health problems. It has an exciting impact on both clinical research and patient care [1]. It is a multi-faceted approach to patient care that not only improves the ability to diagnose and treat disease, it also offers the potential to detect disease at an early stage, when it is easier to treat effectively. The full implementation of individualized drug encompasses:

- i. Risk assessment: genetic testing to reveal pre-disposition to disease.
- ii. Prevention: behaviour/ lifestyle/ treatment intervention to prevent disease.
- iii. Detection: early detection of disease at molecular level
- iv. Diagnosis: accurate disease diagnosis enabling individualized treatment surgery.
- v. Treatment: active monitoring of treatment response and disease progression. [2]

Personalized medicine has a rapid-fire impact on how medicines are discovered and developed; how cases are diagnosed and treated; and how cases are diagnosed and treated; and how health care delivery is channelizing its coffers to maximize patient benefits. There are two major developments that provide evidence that the concept of personalized medicine can become a reality:

1. The BRAF inhibitor vemurafenib in patients with BRAF-mutated melanoma.
2. The ALK inhibitor crizotinib in patients with ALK- rearranged lung cancer.

1.1 Brief overview (history) of Personalized Medicine

Personalized medicine is not new to the field of medicine. The first incidence appeared in ancient times thousands of years ago. Since then, various therapeutic approaches have been established. The multitudinous technological improvements in this field have conceded personalized medicine as the next generation of diagnosis and treatment. Although there has been a lot of attention the last years, there are still several obstacles hindering its application in clinical practice.

From 2700 BC, until the Hippocratic period, personalized medicine developed fleetly. After this a significant gap appeared. This gap broke down the elaboration of personalized medicine. After the 1950s, substantiated drug gained attraction with impactful discoveries, shaping the future of drugs. Since 2005, although a lot of discoveries and technological advances have been fulfilled, minor applications have been observed. 1980s can be recognised as the era of biomarkers. It was during 1991 that personalized medicine appears as a scientific term. Plenty of new discoveries happened since then. VEGF-A recognised as importance therapeutic agent, first mass production of bio-chips, international HapMap project, FDA approves liquid biopsy test, the epidemic of COVID-19 are the major discoveries to name a few. The future lies in accurate diagnostic tool, targeted therapy, efficient prediction tools and its implementation in personalized medicine [3].

The purpose of this review article is to provide a concise overview of the concept of personalized medicine, its importance, including challenges associated with its implementation, potential opportunities, and current and future applications in clinical research.

1.2 Milestone of Personalized medicine in clinical research

The concept of personalized medicine has a long history, as mentioned above, and with early research focused on the use of genetic testing to identify patients who may respond better to specific treatments. With the completion of the Human Genome Project in 2003, researchers were able to identify genetic variants associated with various diseases and drug responses, which paved the way for more targeted therapies. Biomarker discovery has also been a key focus of research, with the identification of specific genes or proteins that can predict a patient's response to treatment. Personalized medicine has now moved from the research lab to the clinic, with clinicians using genetic and biomarker information to make more informed treatment decisions for patients with a range of conditions.

However, there are still regulatory challenges that need to be addressed, such as data privacy, consent, and reimbursement for personalized treatments. Looking ahead, personalized medicine is expected to continue evolving rapidly with the use of artificial intelligence, machine learning, and other technologies that will enable even more precise diagnosis and treatments. This will also bring new challenges and opportunities for clinicians and researchers (Figure 1).

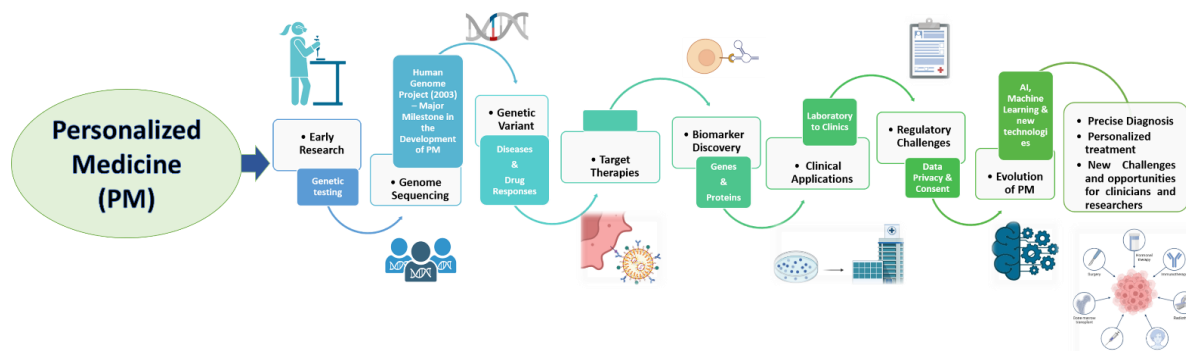


Figure 1: Overview of the key milestones in the development of Personalized Medicine (PM) and also illustrates how the field has evolved overtime

II. Challenges Of Personalized Medicine In Clinical Research

There are a number of medical, ethical, social, legal, economic and organizational challenges that need to be considered as the field of personalized medicine grows [4]:

Medical challenges:

- Clinical effectiveness should be improved by tailoring the treatment including their impact on quality of life
- Drug safety profiles should be improved
- Need for post marketing follow up and not just pharmacovigilance
- Improved knowledge of pharmacogenomics among physicians
- Reductions in adverse drug reactions by undertaking preventive measures

Legal challenges:

- Harmonization of laws in different context
- Protection of patient information generated
- Need for including biomarkers that's support indications and clinical decision making.
- Legal liability associated with targeted tests

Economic challenges:

- Budget impact of new technologies and other considerations for payment.
- Financial incentives for citizens.

Ethical challenges:

- Patient's understanding and patient's role in future decision making
- Moral quality - potential for stigmatization and demarcation
- Moral integrity - style this affects moral persuasions, preferences and commitments.

Social challenges:

- Requirement of support
- People's reaction for or against research.

The most limiting factor in the execution of personalized medicine appears to be the slow progress of translational exploration performing from limited funding and regulatory constraints. Standardization of operating procedures should be taken care of. High cost, inequality in healthcare, violation of privacy, discrimination, negative effect on patient-physician relationship is some of the negative effects concerning personalized medicine. However, the positive effects such as improving quality of healthcare, ensuring accessibility, effectiveness, affordability, public trust etc. are highly appreciable [5].

The implementation of personalized medicine is complex, but not unfeasible, that requires some critical steps:

- Exploring and implementing advanced technologies.
- Attempt to integrate molecular, clinical, regulatory and economic data to expedite drug development
- Awareness about existing issues
- Coordinated participation of molecular pathologists, bioinformaticians, oncologists, clinical investigators and other professionals involved in clinical decisions.
- Increasing the harmonization among research, policy and practice.
- Several infrastructures must be established: clinical trial structures, biobanks etc.

III. Opportunities Of Personalized Medicine In Clinical Research

Personalized medicine is predominantly changing the way therapies are being developed. It has widespread impact on everything from genomics to medical devices, for its customized approach to healthcare. As a result, new business models for enterprises across the sector are being created. Importantly, individualized drug provides the background for experimenters as they explore how inheritable, environmental and lifestyle factor interact in our bodies to foster health or develop complaint. New technologies are enabling personalized medicine in bringing its critical benefits to market.

Great success has been achieved in oncology and onco-haematology by using the new approaches. The use of personalized medicine has not been limited to any particular disease. Clinical and population studies are laboriously developing in cardiology, endocrinology, neurology and psychiatry. It has been also applied in rare genetic disorders. The application of personalized medicine in treating different types of cancer, diabetes mellitus, cardiovascular diseases, respiratory disorders, infectious diseases are commendable. However, it is also applied to treat rare diseases and also to treat problems related to infertility.

Investment in personalized healthcare is expected to increase by more than 30% in the coming years. Today in oncology, more than 70% of innovative drugs are targeted drugs, their number should increase by 69% in the next 5 years. From 2015 to 2020, the number of drugs with personalized indications for their use increased by 70%.

IV. Role Of IRB In Personalized Medicine

The Institutional Review Board (IRB) is a vital component in maintaining the ethical and safe conduct of personalized medicine research studies. The primary function of the IRB is to review and approve research proposals to ensure that the rights and welfare of study participants are protected. Personalized medicine research studies, which often employ genetic data and other sensitive information, present unique ethical considerations that must be assessed by the IRB. The IRB must evaluate the research team's methods for safeguarding the privacy of participants and their genetic data. Additionally, the IRB must assess the research team's plans for communicating genetic test results to participants, along with providing appropriate counselling and follow-up care.

The National Institutes of Health (NIH) requires IRBs to possess expertise in genetics and personalized medicine to ensure that studies in these areas adhere to ethical, scientific, and participant welfare standards [6]. The National Cancer Institute (NCI) has developed guidelines for the ethical conduct of personalized medicine research, which underscore the importance of informed consent, privacy protections, and participant empowerment [7]. The IRB serves a critical function in overseeing personalized medicine research studies,

ensuring that such research is conducted in a manner that aligns with ethical standards and protects the interests of research participants.

V. Application Of Personalized Medicine In Clinical Research

- **Cancer:** Personalized medicine is a promising approach to cancer treatment, with various applications. Genetic testing is one way in which personalized medicine is used to identify biomarkers or genetic mutations in a patient's cancer, which can aid in determining the most effective treatment options. Targeted therapies can then be developed based on these identified mutations or biomarkers, which have fewer side effects than traditional chemotherapy. Immunotherapy is another personalized medicine approach that involves identifying patients likely to respond to the treatment by using their own immune system to fight cancer. In addition, personalized medicine can be used to optimize drug dosing based on a patient's genetic makeup to improve treatment outcomes and reduce the risk of adverse reactions [8]. Furthermore, it can help identify patients most likely to benefit from clinical trials, thereby increasing the trials' efficiency. The potential of personalized medicine in revolutionizing cancer treatment is significant, as it allows tailoring treatments to individual patients based on their unique genetic makeup and other factors.

- **Cardiovascular diseases (CVD):** Personalized medicine holds great potential for improving the prevention, diagnosis, and treatment of cardiovascular diseases. The field has a number of applications, including genetic testing, risk assessment, pharmacogenomics, lifestyle modification, and cardiac imaging. Genetic testing can identify patients at higher risk of developing CVD, while pharmacogenomics can help to optimize drug dosing and reduce the risk of adverse drug reactions. Lifestyle modification plans can be personalized for patients at high risk, and cardiac imaging results can be interpreted based on a patient's unique characteristics [9]. These personalized interventions hold promise for improving patient outcomes and reducing the burden of CVD.

- **Respiratory disorders:** In respiratory diseases, personalized medicine can improve treatment efficacy by accounting for the specific characteristics of each patient's disease. For example, genetic testing can identify specific mutations that may influence the development or progression of lung diseases like cystic fibrosis or alpha-1 antitrypsin deficiency, enabling the development of personalized treatment plans that target each patient's specific mutations. Biomarkers, such as exhaled nitric oxide or sputum eosinophils, can also be used to identify patients likely to respond to specific treatments, as well as those at risk of developing severe respiratory disease. Additionally, personalized medicine can help identify environmental triggers of respiratory disease, such as allergens or air pollution, and develop personalized strategies to manage symptoms [10]. Overall, personalized medicine holds promise for revolutionizing the treatment of respiratory diseases, improving patient outcomes and quality of life.

- **Infertility:** In the field of infertility, personalized medicine can be applied to improve diagnosis, treatment, and management of various infertility conditions. This includes genetic testing to identify genetic factors that may cause or contribute to infertility, hormonal testing to evaluate hormonal imbalances, tailoring *in vitro* fertilization (IVF) treatment to the specific needs of each individual patient, for example, doctors may adjust the dosage of hormones used during the IVF process based on the patient's hormonal levels and addressing lifestyle (diet, exercise and stress management) and environmental factors (toxins, pollutants) that may affect fertility [11]. By taking into account an individual's specific characteristics, personalized medicine has the potential to improve fertility outcomes by developing personalized treatment plans.

- **Infectious diseases:** Personalized medicine in infectious diseases involves tailoring medical treatments to individual characteristics for improved diagnosis, treatment, and management of infectious diseases. Examples include genetic testing (genetic mutations) to identify genetic factors that affect susceptibility to infections such as tuberculosis [12] or HIV [13], immune system testing to measure antibodies, for example, doctors can measure the levels of antibodies in a patient's blood to determine if they have previously been exposed to a particular infection and develop treatment plans, antimicrobial resistance testing to determine effective antibiotics, for example, doctors can perform antimicrobial susceptibility testing to determine which antibiotics are most effective against a particular strain of bacteria and personalized vaccine development targeting unique antigens of a specific strain of virus [14]. Personalized medicine has the potential to revolutionize infectious disease management by creating personalized treatment plans to optimize outcomes and minimize antimicrobial resistance.

VI. Future Directives Of Personalized Medicine In Clinical Research

- **Development of new biomarkers:** Personalized medicine is a field that aims to revolutionize healthcare by providing individualized treatments based on a patient's unique genetic makeup, environment, and lifestyle factors. Biomarkers are objective measures that play a critical role in this field by providing information on disease risk, progression, and response to treatment. In recent years, there has been significant research focused on identifying new biomarkers that can predict a patient's risk of developing specific diseases, such as cancer, cardiovascular disease, and neurological disorders. These biomarkers can also be used to monitor disease

progression and assess the effectiveness of treatments. Castelli et al., (2021) recently reviewed the current state of biomarker discovery in personalized medicine and identified multi-omics approaches, including genomics, proteomics, and metabolomics, as promising avenues for identifying novel biomarkers. However, the authors also highlight the need for more robust validation studies to ensure the clinical relevance and reliability of new biomarkers. Finally, they emphasize the importance of data sharing and collaboration among researchers to accelerate the development and implementation of personalized medicine [15].

- **Integration of genomic and proteomic data:** The integration of genomic and proteomic data is a crucial aspect of personalized medicine, which aims to develop individualized treatments based on patients' unique characteristics. The use of genomic and proteomic data together can provide a comprehensive understanding of disease pathways and mechanisms, which can guide the development of targeted therapies. In a study by Lu et al., (2023), the authors integrated genomic and proteomic data to identify potential biomarkers for gastric cancer. They identified a set of genes and proteins that were differentially expressed in gastric cancer patients compared to healthy controls. This integrated analysis revealed several pathways involved in gastric cancer progression, including the *PI3K-Akt* signalling pathway and the *Wnt* signalling pathway. The authors concluded that integrating genomic and proteomic data can provide a more comprehensive understanding of disease mechanisms and can guide the development of personalized treatments for gastric cancer. This study highlights the potential of integrating genomic and proteomic data in clinical research and personalized medicine [16].

- **Use of Artificial Intelligence in data analysis:** The field of personalized medicine is rapidly advancing, and the incorporation of AI into data analysis can significantly enhance patient outcomes. AI can analyse large and intricate datasets, identify patterns and correlations, and generate predictive models for guiding treatment decisions. Johnson et al. (2021) have reviewed the current state of AI in personalized medicine, emphasizing the importance of developing robust and interpretable AI algorithms to extract clinically relevant insights from complex data. They have also highlighted the necessity of collaboration between clinicians, data scientists, and other stakeholders to ensure ethical and effective use of AI in personalized medicine. The article also stresses the significance of data privacy and security in AI algorithm development and implementation. Ultimately, AI has the potential to revolutionize personalized medicine by providing more accurate diagnoses, more effective treatments, and better patient outcomes [17].

- **Shift towards value-based healthcare:** The shift towards value-based healthcare in clinical research through personalized medicine is gaining momentum, as it aims to provide better outcomes for patients while reducing costs. Personalized medicine involves tailoring treatments to the individual patient based on their unique genetic makeup, lifestyle factors, and environment, and has the potential to improve patient outcomes while reducing the risk of adverse events. In a review article by Minvielle et al., (2021), the authors discuss the implementation of value-based healthcare in personalized medicine and its potential benefits. They highlight the importance of integrating data from various sources, including clinical trials, electronic health records, and patient-generated data, to develop personalized treatment plans that are tailored to the individual patient's needs. The authors also discuss the role of patient engagement and education in promoting value-based healthcare in personalized medicine. They suggest that the adoption of value-based healthcare in personalized medicine has the potential to improve patient outcomes, reduce healthcare costs, and advance precision medicine research. This review article emphasizes the need for a shift towards value-based healthcare in clinical research through personalized medicine to improve patient outcomes and reduce costs [18].

VII. Conclusion

- **Summary of key findings**

Personalized medicine involves customizing medical treatments for each patient based on their unique genetic and molecular characteristics. It improves the ability to diagnose and treat diseases and offers potential for early detection of diseases, accurate diagnosis, and individualized treatment. While personalized medicine has rapidly impacted drug discovery and development, patient diagnosis and treatment, and healthcare delivery, its implementation in clinical practice faces challenges, such as medical, legal, economic, ethical, and social challenges. Translational research progress has been slow due to limited funding and regulatory constraints. Standardization of operating procedures is necessary to mitigate the negative effects of personalized medicine, such as high cost, inequality in healthcare, violation of privacy, discrimination, and negative effects on patient-physician relationships. Nevertheless, personalized medicine has potential benefits in cancer treatment, cardiovascular diseases, respiratory diseases, infertility, and infectious diseases. The future of personalized medicine involves the development of new biomarkers, including multi-omics approaches and data sharing, and integration of genomic and proteomic data to develop individualized treatments.

- **Future outlook**

Personalized medicine, tailors' medical treatment to individual patients based on their unique genetic, environmental, and lifestyle factors. Genomic sequencing technologies are key drivers of personalized medicine,

with the cost decreasing and increasing feasibility for clinical decision-making. -Omics data, such as transcriptomics, proteomics, and metabolomics, are also used to develop targeted treatment plans. Artificial intelligence and machine learning algorithms are used to analyse patient data and develop personalized treatment plans by identifying patterns and relationships. The future outlook for personalized medicine in clinical research is promising due to technological advancements, increasing understanding of genetics, environment, and health relationships, and availability of more personalized treatment options for patients.

▪ **Potential Impact**

Personalized medicine has a significant and far-reaching potential impact in clinical research. It can improve patient outcomes by identifying effective treatments based on unique genetic, environmental, and lifestyle factors, thereby reducing adverse effects. Personalized medicine can also accelerate drug development by identifying patient populations that benefit most, thus reducing trial time and cost. It can lower healthcare costs by avoiding ineffective treatments and reducing trial and error. Personalized medicine can enhance research capabilities by enabling analysis of large amounts of patient data to identify patterns and relationships, leading to new insights into disease mechanisms and treatment approaches. As technology advances and understanding of genetics and disease improves, personalized medicine has even more promising applications in the future.

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