

Precision Medicine in the Pharmaceutical Industry

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Abstract:

Precision medicine (PM) is the tailoring of medical treatment to the individual characteristics of each patient. It is currently one the most prominent approaches in modern healthcare and public health. It aims to provide a more precise prevention, diagnosis, and treatment of disease. The approach enables healthcare providers to provide a more accurate diagnosis and create customized treatment plans. It is rapidly having an impact on how drugs are developed, how patients are treated, and how healthcare delivery is channeling its resources to maximize patient benefits. With the evolution of science, healthcare and pharmacy are advancing towards precision medicine. Precision medicine has emerged as a transformative approach in the pharmaceutical industry. In this paper, we will explore how precision medicine can benefit the pharmaceutical industry.

Keywords: precision medicine, personalized medicine, predictive medicine, pharmaceutical industry, pharma.

INTRODUCTION

Traditionally, most medical treatments are designed for the "average patient," as a one-size-fits-all-approach. In contrast, precision medicine (PM) is an emerging field in medicine which refers to the tailoring of medical treatment to the individual patient. Because it deals with individuals, PM is highly personalized. This shift towards precision medicine is crucial as it not only reduces adverse side effects but also has the potential to lower treatment costs by eliminating ineffective treatment

plans. Widespread adoption of PM may have a serious impact on American economy and competitiveness.

Precision medicine, also known as personalized medicine, is a novel approach to disease treatment and prevention that takes into account individual variability in genetics, environment, and lifestyle for each patient. It is a medical model that customizes healthcare by making decisions, treatments, practices, or products tailored to each patient. Precision therapy takes a more focused approach to drug development compared to traditional medicine. It relies on genomics, AI, and big data analytics advances to understand the genetic factors influencing disease and health. It has become evident that many diseases are associated with gene mutations. With this awareness, we can comprehend how certain gene mutations lead to disease and why one person's heart disease, diabetes, or cancer may manifest differently from another's. Precision medicine promises improved patient outcomes, reduced side effects, and enhanced drug efficacy, marking a significant leap forward in approaching health and disease.

CONCEPT OF PRECISION MEDICINE

Today, most medical treatments are designed for average or “typical” patients. Most doctors today still prescribe therapies based on population averages. But experience has shown that treatments that work well for some patients may not work for others. Physicians need tools that will help them provide the best care by incorporating many factors that affect each patient. This is where precision medicine comes in.

Precision medicine (PM) is a medical model that proposes the customization of healthcare with medical treatments, tailored to the individual patient. The word “precision” in PM means both “accurate” and “precise.” Precision medicine is also known as personalized medicine, individualized medicine, or predictive medicine although there are differences between the terms [1]. Some regard PM as a new name for molecular medicine. Precision medicine matches each patient with the treatment that will work best for them. It takes individual variation in our genes, environment, lifestyle, and other individual factors into account. This is in contrast to a one-size-fits-all approach, in which disease treatment is developed for the average person, ignoring the differences between individuals. Figure 1 shows the difference precision medicine makes [2].

A brief history of precision medicine is illustrated in Figure 2 [3]. The announcement of Precision Medicine Initiative (PMI) by US President Barack Obama in January 2015 during his State of the Union address has brought PM to the forefront for health care providers, researchers, regulators, and stakeholders. Since the launching of PMI, PM has created immense possibilities for breakthroughs in medicine.

The medical community is now at the transition from the era of evidence-based medicine to the era of precision medicine [4].

PM is about prediction and diagnosis of health with a great precision at the molecular level taking into account genetic variations at a personal level. It takes into account individual variability in genetic and environmental factors and leads neither to undertreatment nor to overtreatment.

Precision medicine has the following attributes [5,6]:

1. An understanding of the etiology and pathogenesis of disease
2. The ability to detect specific causal factors
3. The ability to specifically treat the root causes(s) effectively
4. It is being driven by advances in science, genomics and other “omics.”

5. PM is based on widespread generic testing and integration of the genomic data with clinical information.
6. The delivery of targeted treatment to the patient at an appropriate time.
7. PM offers more targeted and cost-effective care.

Properly combining observational data with experimental data can facilitate PM. A model of precision medicine approaches is shown in Figure 3 [7].

PRECISION MEDICINE IN PHARMACEUTICALS

Most medical treatments are designed for the "average patient" as a one-size-fits-all-approach, which may be successful for some patients but not for others. Precision medicine is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles. The goal of precision medicine is to target the right treatments to the right patients at the right time.

Precision medicine (PM) investigates the biological basis of diseases, utilizing emerging technologies to support the development of innovative therapies tailored to the patients who will benefit most. It relies on the use of biological indicators called biomarkers to classify patients by their risk for certain diseases and/or response to treatment and to precisely characterize their genotype, or genetic code, and phenotype, or physical traits. It tells us how a person's unique genetic profile makes them susceptible to certain diseases. It is increasing our ability to predict which medical treatments will be safe and effective for certain patient populations. A genetic diagnosis often permits targeted prevention strategies; it also can help eliminate the need for further costly and invasive diagnostic testing. This implies that physicians can select a therapy or treatment protocol based on a patient's molecular profile that minimizes adverse drug reactions (ADRs) and ensures a more successful treatment outcome.

The pharmaceutical industry is constantly evolving, with new drugs being developed and released to the market every year. It is constantly searching for innovative solutions to accelerate drug discovery and research processes. Precision medicine has revolutionized the pharmaceutical industry, ushering in a new era of drug discovery, development, and delivery. It is particularly transformative for patients with rare diseases, where the small patient populations and lack of historical data have traditionally hindered the development of effective treatments. The effect of PM on pharma is shown in Figure 4 [8].

APPLICATIONS OF PRECISION MEDICINE IN PHARMACEUTICAL

Personalized medicine relies on the ability to analyze a patient's unique combination of genetic information, family history, diseases, and other vital data to devise treatment strategies that are specifically tailored to the individual. These are some of the ways precision medicine is making a significant difference in pharmacy [9,10]:

- *Cancer Treatment:* This is the most popular use of PM. One of the most common applications of this practice has been for women with breast cancer. Precision oncology is the branch of precision medicine that addresses cancer in precision medicine. Cancer treatment takes many forms: surgery, radiation therapy, chemotherapy, target-based therapy, and immunotherapy. In several areas of oncology, PM is the current standard of care. PM approaches cancer treatment and prevention by taking patients' individual variability in genes, environment, and behavior into account. Cancer is caused by a wide range of cell mutations. Identification of these mutations has led to the development of effective drugs. An overview of PM in oncology is shown in Figure 5 [11]. So-called tumor markers are often the key to a precise diagnosis and a decision in favor of certain treatment for cancer.

- *Chronic Diseases:* Chronic diseases – such as asthma, chronic obstructive pulmonary disease (COPD), heart failure, and chronic kidney disease (CKD) – affect billions of people worldwide. For example, asthma can be a devastating disease with 176 million attacks each year and debilitating symptoms. Chronic diseases are complex and heterogeneous, meaning that they can manifest in many ways, which can make accurate diagnosis challenging. Using a precision medicine approach could help to detect disease earlier and identify the causes of disease, which has the potential to inform and improve treatment decisions.
- *Rare Diseases:* Studying rare diseases poses unique challenges as patient populations are often small and dispersed. Personalized medicine is particularly transformative for patients with rare diseases, where the small patient populations and lack of historical data have traditionally hindered the development of effective treatments. This approach not only opens new avenues for treating rare diseases but also offers hope to patients who previously had limited options.
- *Drug Discovery:* In addition to existing drugs, pharmaceutical companies will need to develop new drugs. The landscape of drug discovery and development is experiencing a profound transformation due to the emergence of precision medicine. Traditionally, drug development in large pharmaceutical companies is regarded as a conservative and risk-averse discipline with highly regulated processes and slow adaptation to external innovation. The drug discovery process has been a lengthy, complex, and costly process with a high rate of failure. The initial step in the drug development process usually involves identifying biological targets that play key roles in disease pathways. The goal is to develop medicines and vaccines with potentially transformational outcomes for patients by treating the right patients with the right medicines. Precision medicine-based approaches for drug development and patient care have surged in the past decade. Some companies have started applying a precision medicine approach to their drug discovery, identifying and testing specific biomarkers that might guide the development of candidate drug molecules, starting with oncology. Targeting the right medicine to the right patient at the right time is a critical part of their approach to drug discovery. Their scientists are working hard to deliver the benefits of precision medicine. Figure 6 shows some drugs [12], while Figure 7 displays some drug scientists [13].
- *Clinical Trials:* One of the most crucial aspects of clinical trials is identifying and enrolling patients who are most likely to benefit from the investigational treatment. Clinical data can be classified as phenotypic (such as demographics, physiologic assessments, disease scorings, imaging, health questionnaires, digital patient assessments) or molecular (such as genomics, transcriptomics, proteomics, metabolomics). Restricting the number of well-selected clinical sites, strict standard operating procedures (SOPs), cross-site controls, and qualified analytical core facilities are essential for robust data generation. Biomarker-guided trial designs ultimately pave the way towards precision medicine, i.e. tailoring drug development to specific patient characteristics. Both pharmaceutical and diagnostic companies must ensure their drugs and tests are appropriately and successfully integrated into clinical practice.
- *Manufacturing:* The pharmaceutical industry's manufacturing and supply chain processes are witnessing a significant transformation, driven by the adoption of artificial intelligence (AI). Traditional pharmaceutical manufacturers continue to invest in more targeted, biomarker-driven indications. Many pharmaceutical companies are now investing in drugs that are targeted to a specific category of patients. The production of these high value tailored drugs necessitates a high level of flexibility and agility in manufacturing. When it comes to mass produced drugs, a changeover time of several hours is not problematic because the downtime is relatively reasonable compared to production time. However, manufacturing small batches in a big capacity line is unprofitable and inefficient because the changeover time can be longer than the production time. Figure 8 depicts drug manufacturing [13].

- *Translation Medicine:* Translational precision medicine comes with a paradigm shift from a one-size-fits-all to a biomarker-guided patient-centric medicine. The translational precision medicine concept integrates core components from both translational medicine (mechanism-based early drug development) and precision medicine (patient-centric late drug development) into an end-to-end biomarker-guided drug development cycle. Key success factors for adoption of this principle in pharmaceutical drug development include the combination of forward and reverse translation. Figure 9 compares translational medicine with precision medicine [14].

BENEFITS

In the realm of healthcare, the one-size-fits-all approach is rapidly giving way to personalized or precision medicine. Precision medicine takes into account differences between individual patients and seeks to take advantage of them with the aim to find the right drug for the right patient at the right time. It offers significant short- and long-term benefits, especially for chronic and complex diseases. It introduces the ability to use molecular markers that signal disease risk or presence before clinical signs and symptoms appear. Advances in precision medicine have already led to powerful new discoveries and FDA-approved treatments that are tailored to specific characteristics of individuals. As shown in Figure 10, precision medicine is saving lives [15]. Other benefits include [2]:

- *Safety:* The life sciences community strives to improve the safety and efficacy of its products, but much more work remains.
- *Cost:* The reasoning behind the claim of reduced costs through precision medicine is based on higher efficacy of treatments. Payment and reimbursement policies should not discourage interventions that may raise short-term costs but improve clinical and cost value over time. Policies that recognize the principles of PM will allow physicians to individualize treatment plans for patients through the early diagnosis of disease, target treatments to optimize clinical outcomes, and prevent unnecessary hospitalizations and care, thus reducing long-term costs.
- *Improved Patient Outcomes:* One of the most significant advantages is the potential for improved patient outcomes. By tailoring treatments to each patient's genetic profile, healthcare providers can select therapies that are more likely to be effective and have fewer side effects. This approach can be especially beneficial for patients with complex or rare diseases where conventional treatments may not be effective.
- *Enhanced Drug Efficacy:* Another critical benefit is improving drug efficacy. Personalized medicine allows for identifying specific genetic markers that predict how a patient will respond to a particular drug. This can lead to the development of targeted therapies that are more effective and have fewer adverse reactions.

CHALLENGES

In spite of its potential, personalized medicine faces several challenges. The adoption of personalized medicine in the United States is facing resistance from powerful entrenched forces, as is common with the emergence of any new paradigm. Pharmaceutical companies face rising costs in drug discovery and commercialization with a diminishing ability to increase revenue. Innovation is slow due to persistent challenges in discovery and development. One challenge of clinical application will be detecting and measuring all the important drivers of malignancy. Other challenges include the following [8]:

- *Inadequate Infrastructure:* Precision medicine requires the collection and analysis of vast amounts of patient data, including genetic data, medical histories, and environmental factors. However, the existing healthcare infrastructure is not equipped to handle such large volumes of data.

- *Regulation:* The regulatory landscape has traditionally been structured around mass-produced drugs intended for a broad patient population. Precision medicine involves the use of genetic data and other sensitive information, which raises concerns about privacy and security. There is a need for clear regulations and guidelines that can ensure the ethical and responsible use of patient data. Collaborating with regulatory bodies to define the procedures for precision medicine-driven clinical trials will necessitate smaller cohorts of patients. Regulators are working closely with the pharmaceutical industry to create pathways to approve personalized drugs.
- *Cost:* Cost is a major barrier to the adoption of precision medicine. Developing targeted therapies and diagnostic tools is an expensive and time-consuming process. The high cost of genetic testing and targeted treatments can hinder widespread adoption. Many healthcare providers and insurance companies are reluctant to invest in precision medicine due to concerns about cost-effectiveness. Pharmaceutical companies face rising costs in drug discovery and commercialization with a diminishing ability to increase revenue. Precision medicine treatments, particularly cell and gene therapies, can be prohibitively expensive, limiting their societal benefit.
- *Collaboration:* There is a need for greater collaboration between healthcare providers, insurance companies, and pharmaceutical companies. This can involve the development of new business models and partnerships that can share the risks and costs associated with precision medicine. Collaborations with leading academic and biotech partners have driven advances in sequencing technologies where we can now sequence an entire genome in a matter of hours with a device small enough to fit in your pocket. Shifting the healthcare market towards the future is imperative and requires the close collaboration and coordination of major stakeholders, including pharmaceutical and diagnostic manufacturers, regulatory bodies and policymakers, payers, and healthcare systems.
- *Inequity:* The current application of precision medicine is not always equitable. Certain populations, such as historically marginalized groups and people from lower socioeconomic backgrounds, are often left out of the latest research and therapeutic advancements. As a result, new precision medicine therapies and approaches may not adequately account for characteristics specific to these groups.
- *Privacy Concerns:* Precision medicine raises ethical questions concerning data ownership, consent, and potential misuse. Patients must have agency over their genetic and medical data and ensuring that their rights and privacy are respected is paramount.
- *Data Integration:* Integrating and analyzing diverse datasets, such as genomic, clinical, and lifestyle data, is challenging but essential for developing personalized treatments.

CONCLUSION

Precision medicine is an innovative approach for tailoring disease treatment and prevention. It has the potential to maximize quality of life, increase life expectancy, improve disease prognosis and decrease mortality. The goal of precision medicine should be to integrate various data points captured from the patient to form one holistic and individualized picture. The application of precision medicine can shift from developing treatments that are simply more effective in a subset of patients to a more personalized and dynamic approach to patient care.

PM represents a paradigm shift in healthcare, focusing on treatments tailored to individual patients' genetic profiles and specific needs. It has not been integrated into healthcare systems as quickly as patients, doctors, technology developers, or governments had hoped. Governing bodies must work with industry to maximize the public benefits of precision medicine. More information about

precision or personalized medicine in pharmaceutical can be found in books in [16,17] and in the following related journals:

- *Personalized Medicine*
- *Clinical Pharmacology & Therapeutics.*
- *Journal of Translational Medicine*
- *Journal of Personalized Medicine*

REFERENCES

1. “Precision medicine,” *Wikipedia*, the free encyclopedia
https://en.wikipedia.org/wiki/Precision_medicine
2. F. A. Khan, “5 Benefits of precision medicine,” February 2020,
<https://www.reprocell.com/blog/5-benefits-of-pm>
3. R. March, “The changing landscape of precision medicine,” January 2023,
<https://www.astrazeneca.com/what-science-can-do/topics/technologies/precision-medicine-history.html>
4. Editorial, “Diagnosis and treatment in the era of precision medicine – Precision medicine and tailor-made medicine,” *Personalized Medicine Universe*, vol. 6, 2017, pp. 1-3.
5. M. Boguski, “Precision diagnosis for precision medicine,”
<https://www.thejournalofprecisionmedicine.com/wp-content/uploads/2015/10/BOGUSKI.pdf>
6. R. Barker, “Precision medicine: What’s all the fuss about?” *Scandinavah Journal of Clinical and Laboratory Investigation*, vol 76, 2016.
7. C. Sandhu, A. Qureshi, and A. Emili, “Panomics for precision medicine,” *Trends in Molecular Medicine*, vol. 24, no.1, January 2018, pp. 85-101.
8. P. Lucki, “How can precision medicine benefit the pharmaceutical industry?” May 2023,
<https://www.linkedin.com/pulse/how-can-precision-medicine-benefit-pharmaceutical-industry-paul-lucki/>
9. M. N. O. Sadiku, Y. Wang, S. Cui, S. M. Musa, “Precision medicine: A primer,” *International Journal of Advanced Engineering and Technology*, vol. 3, No. 2, pp. 55-57, April 2019.
10. J. S. Mattick, “Four ways precision medicine is making a difference ,”
<http://theconversation.com/four-ways-precision-medicine-is-making-a-difference-90459>
11. R. J. Mody et al., “Precision medicine in pediatric oncology: Lessons learned and next steps,” *Pediatric Blood & Cancer*, vol. 64, 2017.
12. “How precision medicine is impacting pharmaceutical manufacturing,” February 2021,
<https://graniten.com/how-precision-medicine-is-impacting-pharmaceutical-manufacturing/>
13. “The future of AI in healthcare: Advanced pharma manufacturing, limitations, & precision medicine,” Unknown Source
14. D. Hartl et al., “Translational precision medicine: An industry perspective,” *Journal of Translational Medicine*, vol. 19, Article number: 245, June 2021.
15. “Personalized medicine: Advanced technology is saving lives,” February 2024,
<https://www.pharmaceuticalprocessingworld.com/personalized-medicine-advanced-technology-is-saving-lives/>

16. A. Halim, *Biomarkers, Diagnostics and Precision Medicine in the Drug Industry: Critical Challenges, Limitations and Roadmaps for the Best Practices*. Academic Press, 2019.
17. G. de Vries and J. Blachman, *The Patient Equation: The Precision Medicine Revolution in the Age of COVID-19 and Beyond*. Wiley, 2020.

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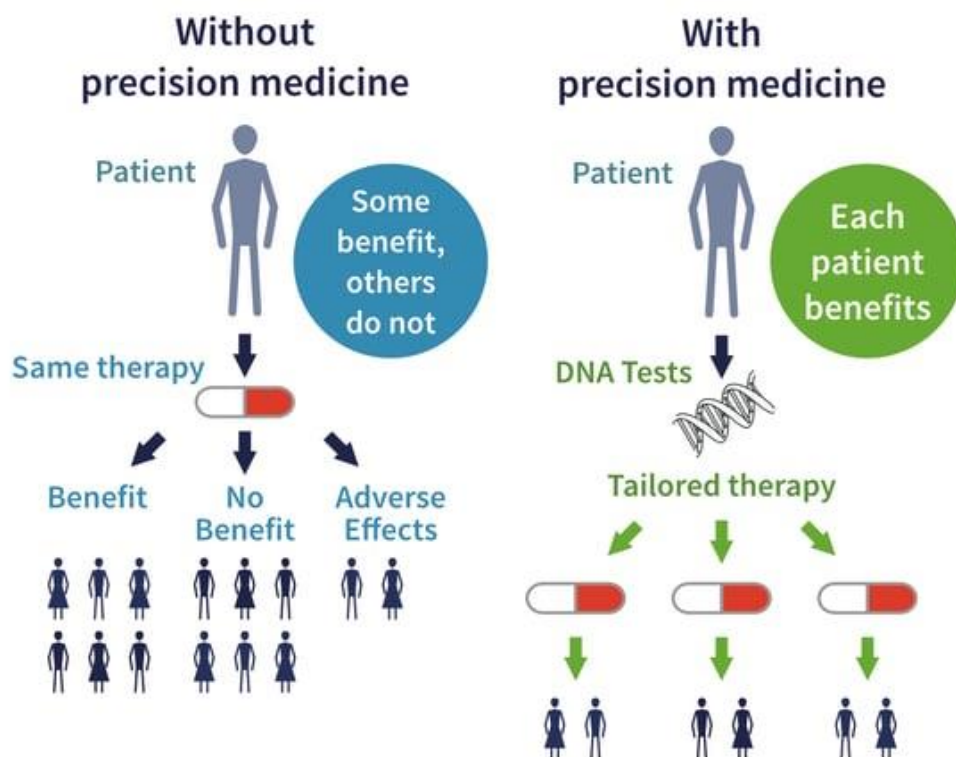


Figure 1 the difference precision medicine makes [2].

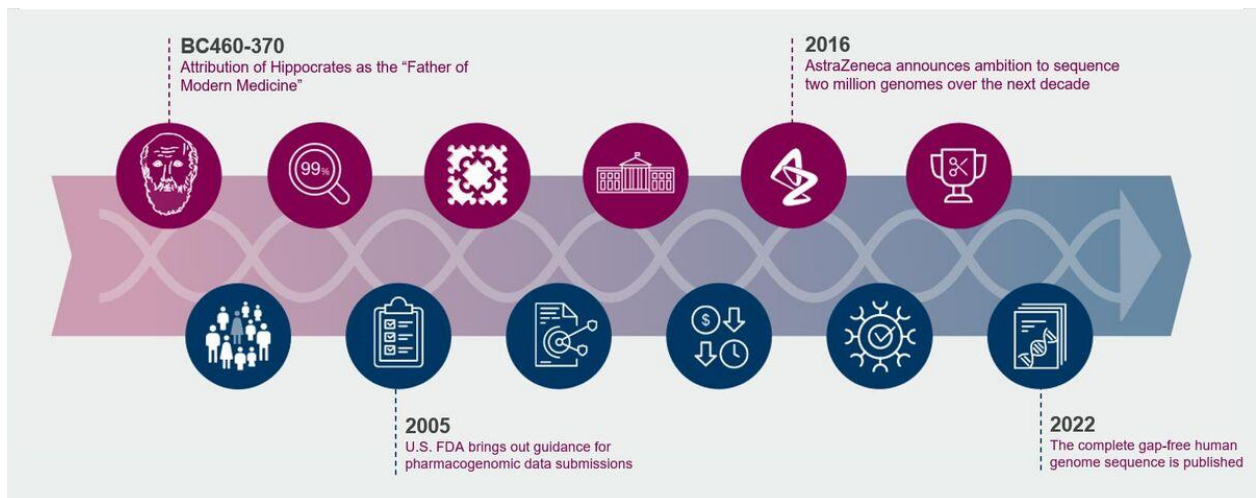


Figure 2 A brief history of precision medicine [3].

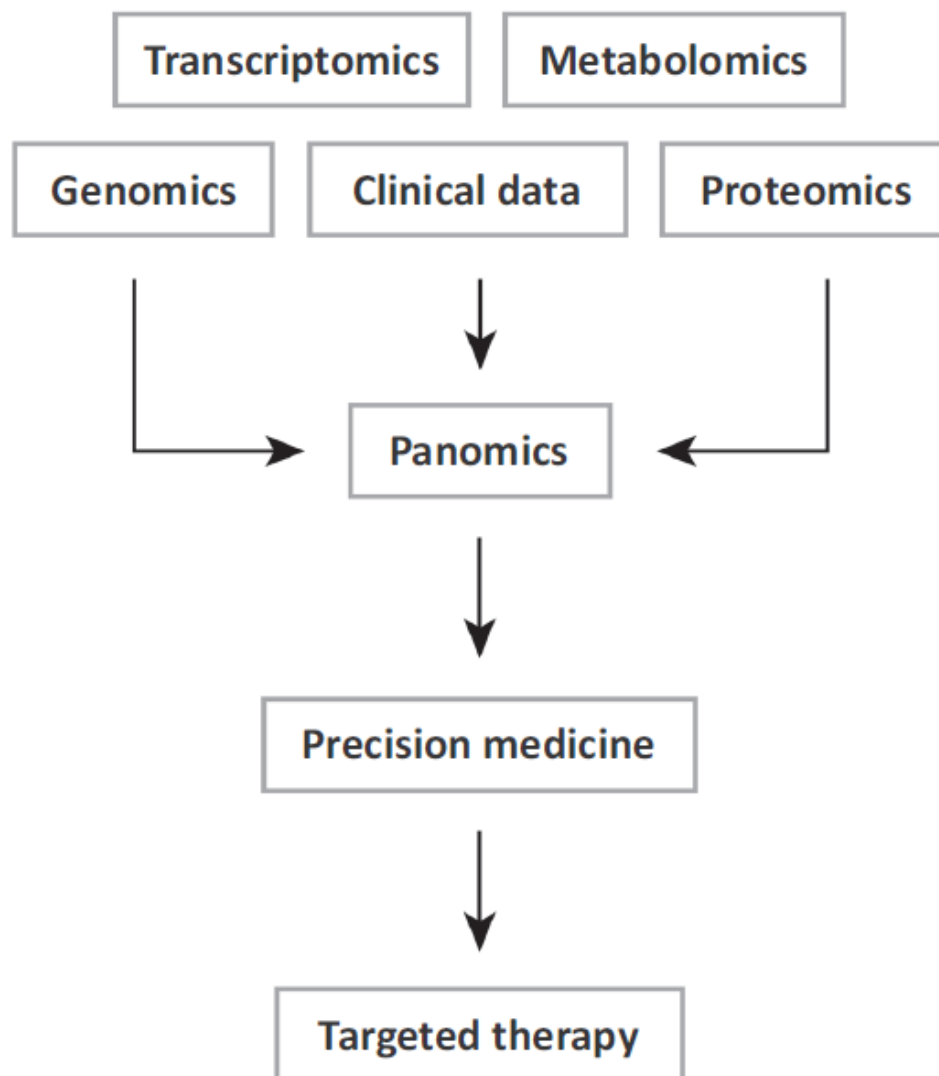


Figure 3 A model of precision medicine approaches [7].

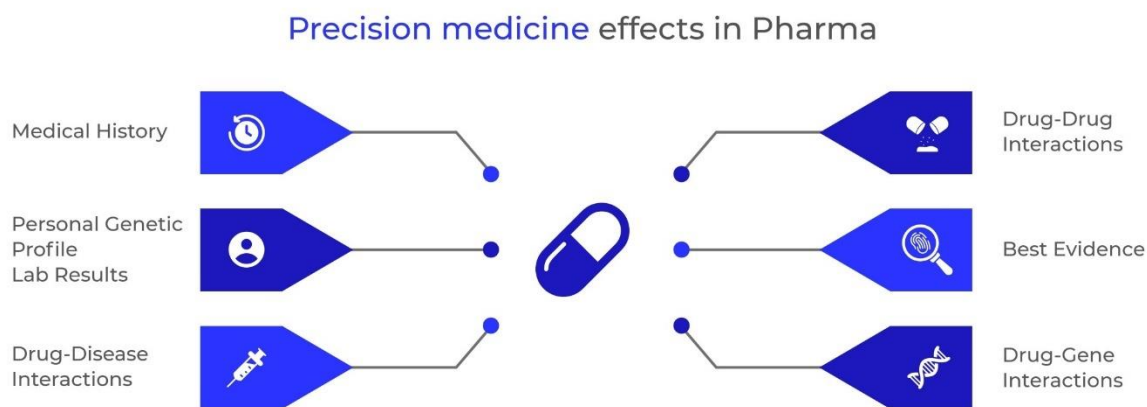


Figure 4 the effect of precision medicine on pharma [8].

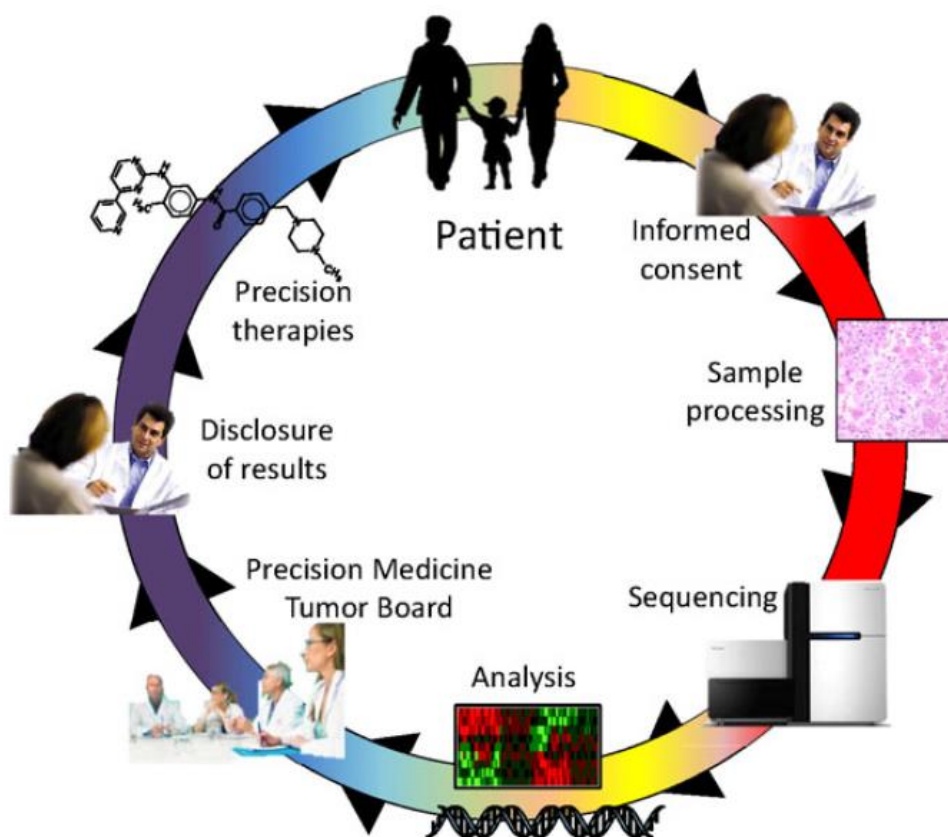


Figure 5 an overview of precision medicine oncology [11].



Figure 6 some drugs [12].



Figure 7 some drug scientists [13].



Figure 8 Drug manufacturing [13].

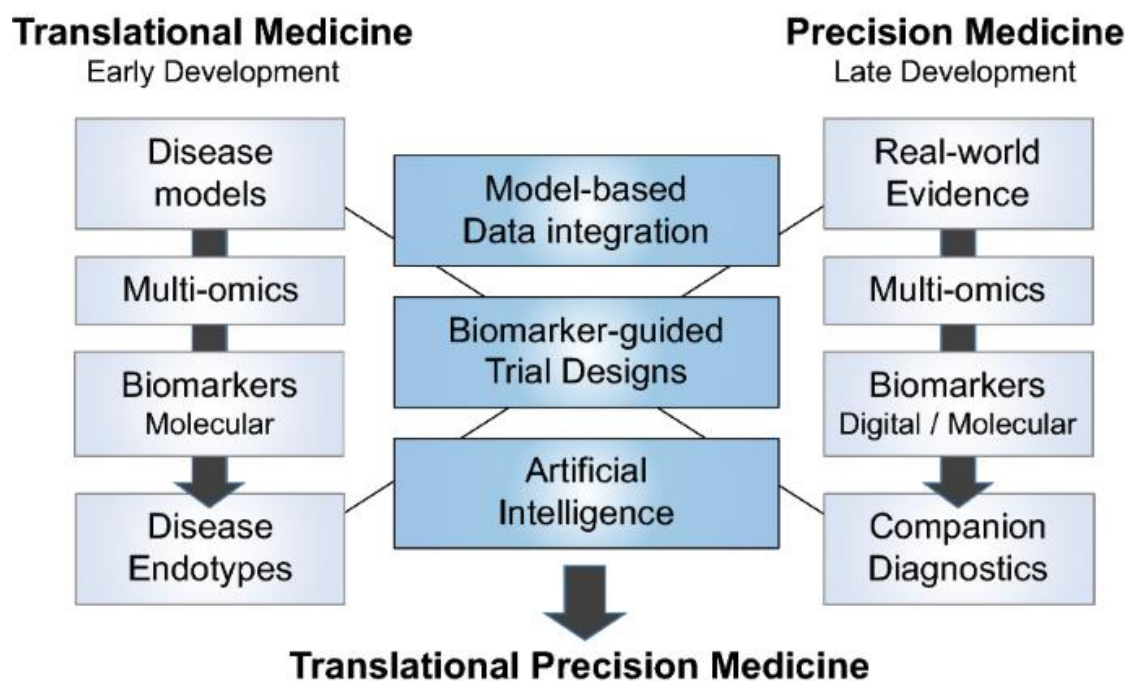


Figure 9 Comparing translational medicine with precision medicine [14].

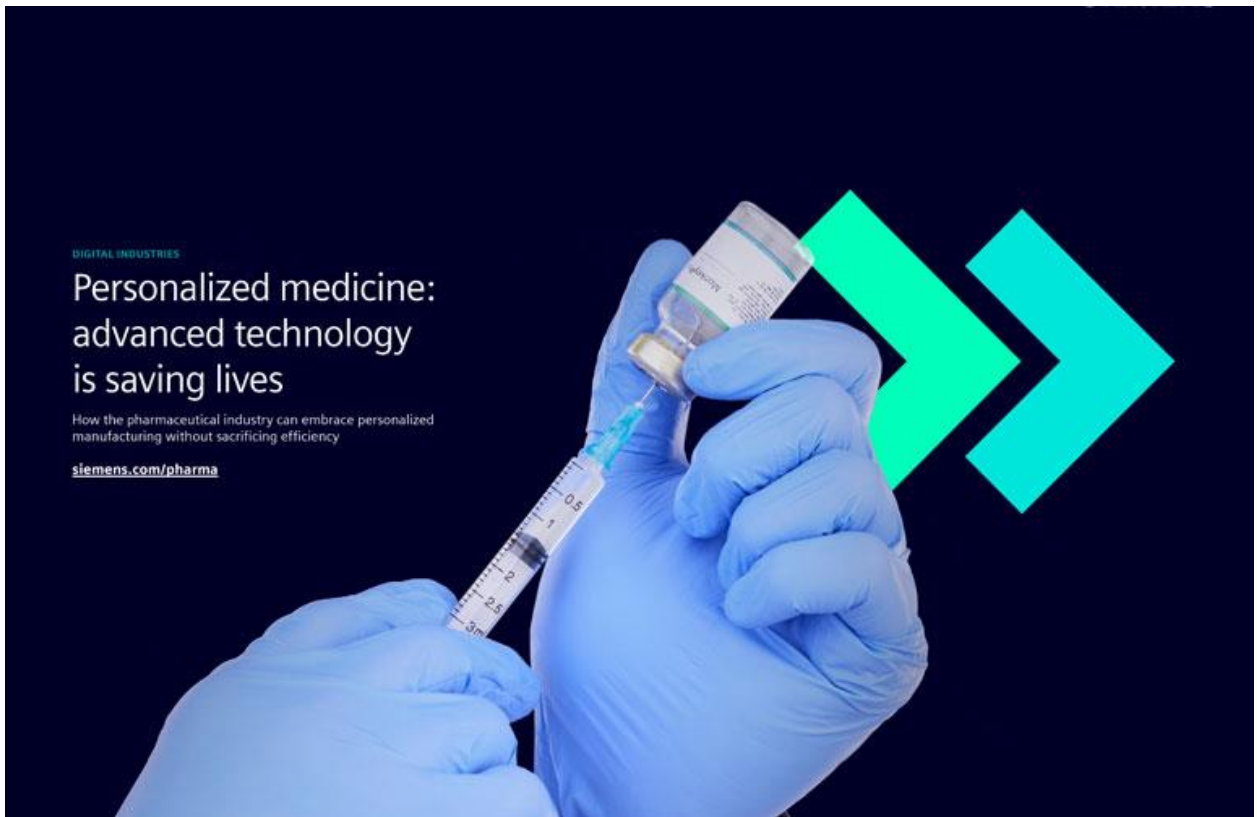


Figure 10 Precision medicine is saving lives [15].