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"Precision Medicine: Advancements, Applications, and Future Directions - Perspectives from India"

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Abstract: *Precision medicine (PM) focuses on customizing medical attention to genetic, environmental, and lifestyle factors pertaining to the individual's life. In India, growing initiatives like the Genome India Project and Indian Cancer Genome Atlas aim to map genetic diversity for personalized therapies. PM has shown significant promise in oncology, asthma, diabetes, and rare genetic disorders. Integration with technologies such as AI and multi-omics enhances disease prediction and targeted therapy. Despite rapid progress, challenges like data privacy, regulatory gaps, limited infrastructure, and public awareness persist. Addressing these hurdles is vital to realize the full potential of precision medicine in Indian healthcare.*

Keywords:*1. Precision Medicine 2. Genomics 3. Personalized Healthcare 4. Artificial Intelligence 5. India Healthcare Development*

INTRODUCTION:

Precision medicine (PM), despite varying definitions, is widely recognized to be a method that employs diagnostic instruments and focused therapies that are customized to each person's own genetic, biomarker, or psychological profile. Customizing therapy or preventative measures according to an individual's unique disease processes or symptoms is the emphasis of the earlier idea known as "personalized medicine," which is sometimes used interchangeably with PM.Medical care has historically been provided according to a one-size-fits-all approach, in which patients who exhibit comparable symptoms are given the same treatments. But because of this broad approach, there is now a need for more precise diagnostic and treatment methods that offer individualized treatment depending on patient characteristics. It's interesting to note that the management of infectious illnesses has long mirrored the ideas of precision medicine, with tailored medications being led by the identification of particular pathogens and the consultation of data repositories. Technological developments have strengthened public health protection and improved our understanding of resistant organisms, which has further improved the treatment of infectious diseases.[1]The U.S. National Academy of Sciences coined the phrase "precision medicine" in 2011 and described it as a new method of treating and preventing disease that takes individual differences in genetics, environment, and lifestyle into account.[2]Over the past 20 years, substantial advancements in science and technology have made this profession conceivable..[3]Even though the Human Genome Project took 13 years to finish, advances like next-generation sequencing have drastically cut down on the time and expense of doing genomic investigations, increasing the accessibility and applicability of precision medicine in contemporary healthcare.

IMPORTANCE OF PRECISION MEDICINE IN MODERN HEALTHCARE:

Integrating personalized medicine into existing healthcare systems is complex and difficult. However, I must emphasize that personalized medicine is an evolution and not a revolution in medicine. The idea of customized medicine has been around for a few decades, and throughout time, more and more people are using individualized methods to medical care. In recent years, the expansion of customized medicine has been driven by the introduction of new technology. Regardless, these advancements build upon a considerable amount of research and practice within the medical field.

In this way, rather than being a sudden, radical shift, customized medicine may be viewed as an evolution of medical practice. Building on current knowledge and technology, customized medicine is a continuous process that will continue to change as new technologies and discoveries are made. Some notable benefits

of personalized medicine are enhanced precision in diagnoses, tailoring treatment plans to suit individual patients, efficiently directed treatment that improves outcomes, reductions in adverse effects, superior preventative care, greater patient participation, reduced costs of healthcare, and stimulated research and innovation.[4]

OVERVIEW OF ITS RELEVANCE TO INDIA:

India presents a special potential for PM because of its 1.3 billion people and high rates of communicable and non-communicable diseases. The endeavor to create the Indian Genome Variation database began in 2003. In 15,000 people from various parts of India, it sought to offer information on single nucleotide polymorphisms and repetitions in over a thousand genes, both known and unknown. The Human DNA Profiling Bill was drafted by the Indian government as early as 2012, completed during the 2015 monsoon season, and reintroduced in 2019 as the DNA Technology Bill.This law allows for the regulation of the use of DNA technology to determine a person's identification.

In order to construct a reference genome, the Department of Biotechnology started the "Genome India Project" on January 3, 2020, with the aim of collecting 10,000 genetic samples from Indian citizens. Among the exciting innovations is this one.The initiative would use whole-genome sequencing to create a comprehensive database of genetic diversity for Indian communities and create new avenues for the development of next-generation personalized medicine, or PM. Ayurgenomics for PM, which combines Ayurveda and genomics, is another emerging field of study. In order to build an omics database of Indian cancer patients, the Indian Cancer Genome Atlas was launched in partnership with the Cancer Genome Atlas and the Department of Biotechnology.In order to prevent and treat inherited genetic problems, the Indian government has started a program in 2019 called Unique Methods of Management and Treatment of Inherited problems. The program's goal is to create NIDAN Kendra, which employs human genetics-trained physicians to evaluate expectant mothers and newborns. The flagship human protein reference database and other platforms like Human Proteinpedia have also produced databases tailored to India, such as the Indian proteomic database. In addition to these joint initiatives, individual researchers are working to define the proteome and genomes of certain illnesses in India.

In addition to economics, the nation has advanced quickly in the digitization of healthcare. The goal of the 2017 national health strategy is to use information and communication technology to give its citizens access to high-quality, reasonably priced healthcare. Ayushman Bharat is one of the health care projects that is already running on a strong IT infrastructure. Maternal and child health, NIKSHAY, and other IT platforms are already being used by health plans to provide timely services to consumers. Benefits of PM for diagnosis and multidrug therapy have already begun to be used by the National Tuberculosis Elimination program. PM will be the basis for an increasing number of national program algorithms for diagnosis and treatment in the future.

In order to create a cutting-edge digital health system and encourage the use of clinical decision support tools by medical practitioners and experts, the National Digital Health Mission was established in 2019. The Ayushman Bharat digital mission was just inaugurated by the PM. Individual health data will be included in health IDs as part of the digital mission, which will also support research, PM, and the intraoperability of hospital services at different levels.

India has therefore advanced in the field of PM over the last ten years. We still have a long way to go in terms of relevant data availability, clinicians and public health specialists who know how to use complicated data, and societal understanding and acceptance of PM before it becomes a standard practice in clinical and public health decision making.[5]

THE SCIENCE BEHIND PRECISION MEDICINE:

THE ROLE OF GENOMICS

Because it makes it possible to identify genetic changes that affect a disease's susceptibility, course, and response to therapy, genomics is essential to precision medicine. A molecular knowledge of illness has been made possible by developments in human genetics and genetic epidemiology, which have resulted in novel categorization schemes and focused treatments. Pharmacogenomics-driven treatments that maximize effectiveness and reduce side effects are made possible by the discovery of biomarkers that predict individual reactions to medications through genome sequencing. Genomic profiling has been

recognized by scientific and regulatory discourse as a crucial element of personalized medicine, including it into therapeutic and diagnostic approaches while guaranteeing its clinical validity and usefulness.[6]

THE ROLE OF PROTEOMICS

Because proteomics makes molecular diagnostics possible through protein analysis, which can supplement nucleic acid-based diagnostics, it is essential to precision medicine. By identifying disease-specific protein biomarkers, proteodiagnostics enhances patient stratification and focused therapy selection. Similar to pharmacogenomics, pharmacoproteomics helps identify patients who react and those who do not to certain medications by subtyping them based on patterns of protein expression. By connecting biomarker-driven patient categorization to focused therapeutic treatments, this method improves drug discovery and development, eventually increasing treatment efficacy and lowering side effects.[7]

THE ROLE OF BIOMARKERS

Because they provide disease-specific diagnoses, patient classification, and focused treatment interventions, biomarkers are essential to precision medicine. They offer molecular signatures that aid in locating targets that may be taken action on, directing the choice of treatment and enhancing therapeutic results. FDA-approved treatments, especially in oncology, have resulted from the identification and confirmation of biomarkers made easier by sophisticated analytical methods including genomics, molecular imaging, genomics, metabolomics, proteomics, and next-generation sequencing. Biomarkers for precision medicine applications in cardiology, hepatology, nephrology, and neurology are being investigated in addition to cancer. Personalized treatment approaches are being developed as a result of the continuous quest for clinically meaningful biomarkers, which will ultimately improve healthcare efficiency and save costs.[8]

COMPREHENSIVE REVIEW OF METHODS

PHARMACOGENOMICS AND PERSONALIZED DRUG THERAPY:

PHARMACOGENOMICS FUNDAMENTALS

Pharmacogenomics is the study of how people react to drugs by utilizing genetic data. Clinical choices, such as changing the drug dose or choosing an alternate treatment, might be guided by the identification of certain gene variations that are associated with an individual's reaction to a medication. Similar to how they examine gene variations linked to illnesses, researchers find genetic loci associated with known medication responses and utilize this information to predict outcomes in people with unknown reactions. Multigene analysis and whole genome profiling of single nucleotide polymorphisms (SNPs) are examples of contemporary pharmacogenomics techniques. These cutting-edge methods are starting to be used in clinical settings, especially in the development and discovery of new drugs.

The amount of the drug needed to reach its intended target in the body (pharmacokinetics) and the efficiency with which the target cells—such as heart tissue or nerve cells—respond to the drug (pharmacodynamics) are the two main factors that researchers take into account when analyzing how drugs work in different people. In order to comprehend and maximize pharmacological therapy using pharmacogenomics, both elements are crucial.

PHARMACOKINETICS:

The four primary processes of pharmacokinetics—absorption, distribution, metabolism, and excretion—combine to form ADME. The process by which a medication enters the circulation, usually following oral or inhaled administration, is referred to as absorption. However, by putting the medication straight into the bloodstream, intravenous (IV) administration skips this phase. Distribution explains how much of the medication reaches the targeted target and how it moves throughout the body following absorption. Some medications, for example, cannot pass across the blood-brain barrier. The process of metabolism entails the drug's internal breakdown, frequently facilitated by the activity of liver or stomach enzymes. This mechanism can occasionally result in metabolites with additional therapeutic benefits. Last but not least, excretion is the drug's departure from the body, which might-some medications, for example, cannot pass across the blood-brain barrier. The process of metabolism entails the drug's internal breakdown, frequently facilitated by the activity of liver or stomach enzymes. This mechanism can occasionally result in metabolites with additional therapeutic benefits. Finally, excretion is the process by which the

medication is eliminated from the body; this can happen through bile, urine, or in certain situations, even exhaling.

PHARMACODYNAMICS:

Pharmacodynamics is the study of a drug's molecular interactions with a particular target. These targets may be ion channels, cell surface receptors, or internal structures like regulatory proteins or enzymes. For example, beta-agonists used to treat asthma and beta-blockers used to treat hypertension both target the beta-2 adrenergic receptor. Differences in how patients react to various drugs have been connected to variations, or polymorphisms, in this receptor.[9]

THE ROLE OF AI AND BIG DATA IN PRECISION MEDICINE

BIG DATA'S CONTRIBUTION TO PRECISION MEDICINE:

Electronic Health Records (EHRs): EHRs record extensive patient data throughout time, enabling analytics for individualized medical choices as well as diagnostic and treatment histories.

Genome sequencing: Gene-based risk prediction, prevention, and tailored medication therapy are made possible by the discovery of disease-linked mutations in genomic data.

Biosensors and wearable technology: These tools continually monitor vital signs, giving real-time health information for personalized therapies and early warnings.

Diagnostic Imaging: AI-enabled medical imaging improves pattern recognition, speeding up diagnostic and treatment choices across a range of specializations.

Lifestyle and Environmental Information: In addition to genetic information, environmental exposures and behavioral data contribute to the explanation of an individual's illness risk for comprehensive customization.[10][12][16][19][20]

ARTIFICIAL INTELLIGENCE IN ACTION:

Predictive analytics: By evaluating a variety of patient data, AI models forecast the beginning and course of diseases, enhancing preventative healthcare.

Genomic and Biomarker Analysis: AI finds biomarkers unique to an illness, assisting in prognosis, early identification, and the creation of focused therapies.

Medication Development and Repurposing: AI uses molecular modeling and simulation to quickly find novel medication ideas and reuse old ones.

Customized therapy Pathways: Using genetic information, clinical data, and historical response patterns, machine learning customizes therapy regimens to each patient's unique profile.[11][12][13][14]

CLINICAL IMPACT AREAS:

Cancer: AI enables precision oncology and improved survival rates by identifying actionable mutations and forecasting response to treatments. [21]

Cardiovascular Health: AI analyzes EHRs and cardiac imaging to forecast cardiovascular events and customize therapy for arrhythmias or hypertension.

Pharmacogenomics: AI-analyzed genetic data informs medication selection and dose, reducing side effects and enhancing effectiveness.

Uncommon Genetic Disorders: AI improves diagnostic accuracy in instances with little precedent by matching symptoms to patterns of uncommon diseases.[15][16][17][18]

BARRIERS AND CHALLENGES:

Data Security and Privacy: Maintaining ethical compliance and public trust in precision technology depends on protecting sensitive patient data.

System Interoperability: Non-standardized data formats reduce the efficacy of AI applications and impede cross-platform interaction.

Algorithm bias: Inequities in results across a range of patient populations may result from underrepresentation in training data.

Clinical Integration: Clinical trust, regulatory permission, and a smooth integration into healthcare processes are all necessary for adoption.

FUTURE INNOVATIONS:

Explainable AI (XAI): XAI increases clinical decision confidence and transparency by enabling healthcare practitioners to comprehend AI thinking.

Federated Learning Models: These models increase the resilience of AI while protecting patient privacy by training across several locations without centralizing data.

Multi-Omics Integration: Bringing together proteomics, metabolomics, and genomes provides more accurate treatment plans and better understanding of complicated illnesses.

Digital Health Engagement: Patients may monitor their health and provide real-time data to medical systems using wearables and smartphone apps.

CHALLENGES IN IMPLEMENTING PRECISION MEDICINE IN INDIA:

Precision medicine has a number of important obstacles to overcome, much like any new healthcare paradigm. In addition to a significant financial commitment, managing and analyzing the enormous amounts of data involved calls for highly qualified staff and cutting-edge technical infrastructure. There are significant ethical issues with ensuring data security and anonymity. Furthermore, the turnaround time for analysis—typically about 26 hours—remains too long for application in urgent or acute care contexts, and data noise might make interpretation more difficult. Another challenge is assessing the authenticity and quality of such intricate datasets. Building capacity quickly is crucial, especially when it comes to educating healthcare workers and increasing access to top-notch AI, machine learning, and contemporary lab technology. Furthermore, an overemphasis on customized care runs the danger of taking resources and attention away from more pressing public health issues.
[24]

INDIA'S PRECISION MEDICINE:

With a predicted cumulative annual growth rate (CAGR) of 16%, the precision medicine industry in India is expanding quickly. Industry projections indicate that it will surpass a $5 billion market value by 2030. This industry currently makes up around 36% of India's bioeconomy, along with other cutting-edge disciplines like gene editing, cancer immunotherapy, and biologics. The new "BioE3" policy framework also places a strategic emphasis on the development of precision therapies.

The Central Drugs Standard Control Organization (CDSCO) authorized NexCAR19, India's first domestically produced CAR-T cell treatment, in October 2023. The creation of a specialized government-sponsored center for CAR-T treatment came next. Furthermore, efforts to use artificial intelligence to advance precision medicine have been started by organizations like the Apollo Cancer Centre and partnerships between Siemens Healthineers and the Indian Institute of Science (IISc), Bengaluru.

The role of biobanks in precision medicine:

Biological samples, including DNA, blood, tissues, cells, tissues, and organs, obtained from willing subjects and accompanied by genetic and medical information, are stored in biobanks. The success of precision medicine depends on these samples, which are essential for biomedical research. The advantages of precision medicine could only be available to a select few if the biobank population is not broad and varied.

Recent research has shown how beneficial they are. One research, for example, used biobank data to match diagnosed patients with those who had unidentified uncommon genetic illnesses (published in Nature Communications on August 29). The biggest biobank of organoids produced from sarcoma patients was shown in a different study that was published in Cell on October 3. To learn more about sarcomas and find specific treatments, high-throughput drug screening was performed using these organoids, which are tiny lab-grown organ models.

INDIA'S BIOBANKS:

There are now 19 recognized biobanks in India that hold a variety of biological specimens, such as tissues and cancer cell lines. The completion of an important achievement this year was the Genome India project, which sequenced 10,000 genomes from 99 ethnic groups to support study on uncommon genetic disorders and other subjects. Another pan-India effort, Phenome India, has gathered 10,000 samples to aid in the development of prediction models for cardio-metabolic diseases. Finding new genes or genetic variations to create focused therapies for pediatric illnesses is another goal of the Pediatric Rare Genetic

Disorders (PRaGeD) program.
But even with these developments, there are still major barriers to utilizing precision medicine to its fullest extent due to India's biobanking regulations.

REGULATORY OBSTACLES IN BIOBANKING IN INDIA:
In contrast to nations like the United Kingdom, China, Japan, and the European Union, United States, India does not have a complete legal framework for biobanking. There are significant gaps in the current rules, such as the Department of Biotechnology's data management policies and the ICMR's National Ethical rules for Biomedical and Health Research Involving Human Participants.

Current permission processes, for instance, frequently ask participants to assent to the collection of biological samples without providing enough information about the intended use, the individuals who will have access to the data, or the duration of data retention. Furthermore, there are major ethical issues with the possible abuse of genetic data, such as the possibility of prejudice within the family.

The lack of a centralized regulating body and the absence of sanctions for ethical transgressions or data breaches exacerbate the issue by raising the possibility of inappropriate sample handling or unapproved data sharing. Pharmaceutical corporations, both local and foreign, might have unrestricted access to Indian biological samples in the absence of strict control, especially during joint research and drug development procedures.[25]

CLINICAL APPLICATIONS IN INDIA:
ONCOLOGY PRECISION MEDICINE:
The main aim of traditional radiation and chemotherapy is the cancer cells' propensity for fast cell division. But this method frequently affects healthy, fast-dividing cells, such those in blood, intestinal lining, and hair follicles, resulting in serious adverse consequences and toxicity.

On the other hand, tailored therapy or precision oncology aims to reduce these side effects while preserving the effectiveness of treatment against cancer. Finding certain molecular targets at several levels—extracellular, cell membrane, intracellular, and intranuclear—is how this is accomplished. Therapeutic approaches frequently target ligands that attach to cell surface receptors and control important biological processes at the extracellular level.

Vascular Endothelial formation Factor-A (VEGF-A) is essential for vascularization, a process that is essential for the formation of solid tumors. A monoclonal antibody called bevacizumab selectively binds to soluble VEGF-A, preventing it from interacting with VEGF receptors and preventing angiogenesis. This technique has demonstrated efficacy in treating a variety of cancer types, including colorectal, lung, renal, ovarian, and glioblastoma multiforme, both alone and in conjunction with chemotherapy.[26][27][28][29]
Cell surface receptors initiate signaling cascades that support cell survival. It is feasible to exploit the amplification or abnormal expression of these receptors in cancer by employing receptor-targeted monoclonal antibodies, which help target cancer cells directly while causing the least amount of harm to healthy cells.

The ErbB receptor family, sometimes referred to as one of the most extensively studied receptor families in precision oncology is the epidermal growth factor receptor-tyrosine kinase (EGFR-TK) family. EGFR (ErbB1 or HER1), ErbB2 (HER2 or neu in rodents), ErbB3 (HER3), and ErbB4 (HER4) are the four members of this category. One of them that is crucial for tumor progression is ErbB2 (HER2/neu).
By combining with other HER receptors to create homodimers or heterodimers, its overexpression triggers downstream signaling pathways that support the growth and survival of cancer cells, resulting in carcinogenesis. [30] About 20 to 25 percent of patients of gastric and breast cancer had over expressed HER2/neu.[31] Monoclonal antibodies like trastuzumab and pertuzumab, which have both shown survival advantages in advanced malignancies as well as in the adjuvant context, have been successfully used to target the over expression of HER2/neu. Antibody-drug conjugates (ADCs), a treatment strategy that combines a monoclonal antibody with a chemotherapeutic medication, can also be used to target

HER2 receptors. Trastuzum abemtansine, an ADC that combines trastuzumab with a microtubule-inhibiting drug, is an illustration of this. This ADC has two modes of action when it binds to the HER2/neu receptor: trotuzumab suppresses HER2 signaling, and the internalization of the microtubule agent causes cytotoxicity inside the cancer cell. Therefore, HER2/neu may be addressed using a variety of modalities, such as intracellular tyrosine kinase inhibitors (TKIs), monoclonal antibodies, and ADCs, providing a multimodal therapeutic strategy.

PRECISION MEDICINE IN CHRONIC DISORDERS:

Chronic illnesses are perfect candidates for precision medicine tactics because of their high incidence and frequent complications, which necessitate a variety of pharmacological therapies. Improved illness risk prediction and more specialized treatment choices are becoming possible with the ongoing development of multi-omics technology. Patients are benefiting more and more from early and precise diagnosis, customized therapies, and successful preventative measures as our knowledge of genes and biomarkers grows.

PERSONALIZED MEDICINE AND ASTHMA:

Two subtypes of CD4+ T helper cells that are crucial for immune regulation are Th1 and Th2 cells. Th2 cells in asthma contribute to airway inflammation by secreting the cytokines IL-4 (which stimulates IgE synthesis), IL-5 (which activates eosinophils), and IL-13 (which stimulates mucus secretion and IgE production). The "type 2 (T2) high" endotype is a distinct subtype of asthma, and type 2 innate lymphoid cells (ILC2s) have been identified as important sources of IL-5 and IL-13. Conversely, the "type 2 (T2) low" endotype is characterized by the production of IL-1 and IL-17. These endotypes all belong to the broader category of asthma syndrome and show different biological mechanisms that connect specific molecular pathways to clinical traits.

Refractory T2-high asthma can be treated with precision therapy using targeted monoclonal antibodies. For example, benralizumab targets the IL-5 receptor, mepolizumab and reslizumab suppress IL-5, omalizumab binds circulating IgE, and dupilumab, an IL-4 receptor alpha (IL-4RA) antagonist, inhibits both IL-4 and IL-13 signaling. T2-low or "neutrophilic" asthma may be treated with combined CXCR1/CXCR2 antagonists or chemokine receptor CXCR2 antagonists. [32]

PRECISION MEDICINE AND DIABETES:

Among the several subtypes of diabetes mellitus, monogenic variants present important opportunities for precision medicine by tailoring treatments according to specific genetic changes. For instance, dietary and exercise modifications typically have a positive effect on the mild, non-progressive hyperglycemia associated with glucokinase gene mutations in maturity-onset diabetes of the young type 2 (MODY-2).

In contrast, mutations in the hepatic nuclear factor 1α (HNF-1α) gene in MODY-3 and HNF-4α in MODY-1 result in a type of diabetes that progressively worsens and is notably responsive to low-dose sulfonylureas. Another example is neonatal diabetes, which is caused by mutations in the KCNJ11 gene, which codes for a potassium channel subunit, and has reacted well to high-dose sulfonylurea treatment.

The promise of personalized diabetes care is further advanced by genome-wide association studies (GWAS), which continue to identify novel genetic variants that may affect an individual's response to various antidiabetic treatments, including insulin sensitizers, sulfonylureas, and incretin-based therapies.[33]

DEVELOPMENTS IN PRECISION MEDICINE IN INDIA:

The goal of the January 2020-launched Genome India Project (GIP) is to sequence 10,000 Indian genomes in order to comprehend the genetic diversity of the nation. This information is necessary to offer the Indian people customized healthcare solutions.

The ICGA or Indian Cancer Genome Atlas:

The goal of the ICGA is to compile a thorough genetic database of cancer patients in India. Through the identification of distinct genetic mutations that are common in the Indian population, this program helps to enable tailored cancer therapy.

Since its launch in 2019, the IndiGen initiative has successfully sequenced more than 1,000 Indian genomes. Clinicians and researchers may use the data to diagnose uncommon genetic illnesses more

quickly and to enhance public health initiatives.

AI Integration in Healthcare:
AI technologies for precision medicine have been developed as a result of partnerships between healthcare organizations and academic institutions such as IISc and IIT Madras. Notably, the Garbhini-GA2 model improves prenatal care by reliably estimating fetal age in Indian women.[22]

Infrastructure and Data Management: Managing and evaluating huge genomic datasets necessitates a high level of technological know-how and infrastructure, which presents practical and budgetary difficulties.

Privacy and Ethical Issues:
To preserve public confidence and adhere to legal requirements, it is critical to guarantee data anonymization and handle ethical concerns pertaining to genetic data.

Workforce Training:
To successfully apply precision medicine techniques, healthcare personnel urgently need to get genomics and bioinformatics training.

Regulatory Framework:
The prompt launch of novel treatments may be hampered by the absence of uniform rules governing early-stage clinical studies.

Public Knowledge:
The uptake and efficacy of customized therapies may be impacted by patients' and healthcare professionals' lack of knowledge about precision medicine.
India's national programs and research partnerships demonstrate the country's dedication to promoting precision medicine. In order to fully realize the promise of customized healthcare in the nation, it will be imperative to address the issues listed.

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