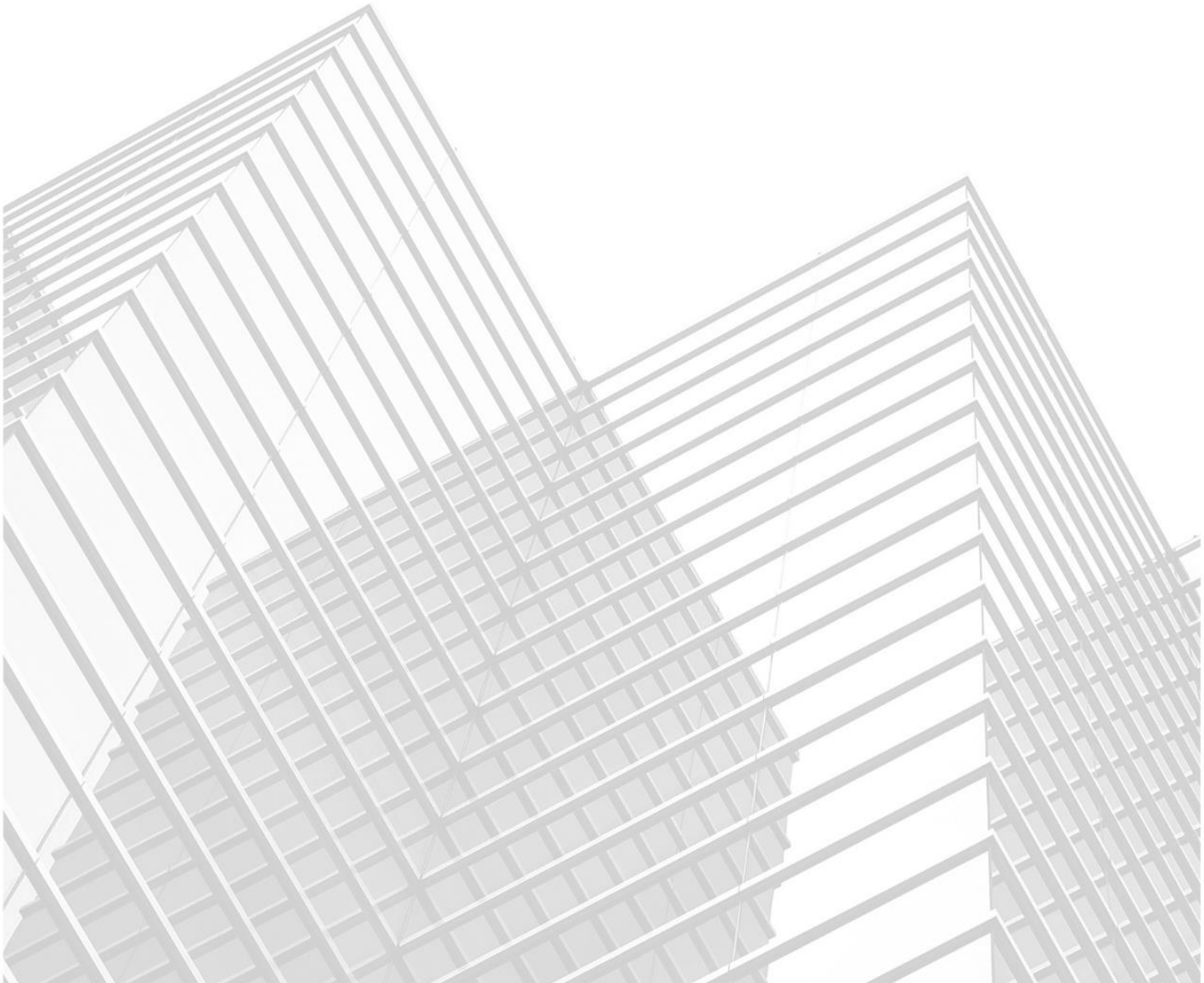
دائـــرة الـصـحـة
DEPARTMENT OF HEALTH

PRECISION MEDICINE POLICY
Annexure 1–Clinical Use and Research



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1.1 GUIDING PRINCIPLES OF IMPLEMENTING PRECISION MEDICINE IN PRACTICE

1.1.1 Patient-Centricity: Customized treatment modalities based on individual genetic profiles and preferences with a strong emphasis on privacy.

1.1.2 Ethical Stewardship of Genetic Data: Ethical management of genetic information to ensure data security and patient confidentiality.

1.1.3 Interdisciplinary Collaboration: Integrated healthcare through interdisciplinary collaboration informing genetics-based patient care.

1.1.4 Empowerment of Clinical Decision-Making: Autonomy for physicians in clinical decisions, recognizing their essential role in personalized healthcare and actively engaging patients in the decision-making process.

1.1.5 Innovation and Research Advancement: Continuous commitment to genetic research and innovation for the development of new diagnostics and therapies.

1.1.6 Infrastructure and Technological Enhancement: Allocating adequate resources for clinical genetics infrastructure and technology to enable effective precision medicine implementation.

1.1.7 Equitable Access to Care: Equitable access to genetic diagnostics and treatments for all individuals, reducing healthcare disparities.

1.1.8 Evidence-Based Practices: Application of precision medicine grounded in scientific evidence and clinical expertise for effective and tailored treatments.

1.1.9 Value Optimization in Healthcare: Focus on healthcare innovations to create value, improve system efficiency, and enhance patient outcomes.

1.1.10 Available Mechanisms for Reimbursement: Develop and optimize reimbursement strategies for personalized medicine services.

1.1.11 Ethics, **Privacy, and Transparency**: Prioritize informed consent, data security, and patient autonomy to protect sensitive genetic and health information. Ensure accountability and transparency in data use, addressing disparities and maintaining public trust.

1.2 PRIORITY AREAS

As the precision medicine landscape evolves, the DoH is committed to transitioning healthcare into a model that is more predictive, preventive, and personalized. This vision is encapsulated through the identified priority areas, highlighting the overall objective, and measures in implementation.

1.2.1 CURRENT FOCUS AREAS

1.2.1.1 Genomic Medicine: Promote ethical and equitable genomic medicine and ensure accessibility, informed consent, confidentiality, affordability, evidence-based practice, and public engagement with relevant laws and regulations.

1.2.1.2 Targeted Therapies: Prioritize the development of targeted therapies and enhance targeted therapy development through strategic research, efficient clinical trials, and streamlined regulatory frameworks to address individual patients' molecular disease mechanisms and optimize patient access to innovative therapies.

1.2.1.3 Personalized Diagnostics: integrate advanced diagnostic technologies to drive precision medicine practice in clinical settings and utilize personalized diagnostics for informed treatment decisions.

1.2.1.4 Pharmacogenomics: optimize treatment decisions using pharmacogenomics and utilize pharmacogenomics to understand genetic variations affecting drug response, allowing for informed treatment decisions.

1.2.1.5 Ethical and Regulatory Developments: establish ethical guidelines and ensure regulatory compliance and implement robust data governance and uphold ethical standards in clinical trials.

1.2.2 PROSPECTIVE DEVELOPMENTS

1.2.2.1 Multiomics Strategies: support comprehensive multiomics data integration and encourage advanced research and support integration of multiomics data integration with EHRs to allow for personalized treatments

1.2.2.2 Cutting-Edge Biotechnology: embrace cutting-edge biotechnology methods including gene editing and CRISPR technology for personalized medicine and promote responsible biotechnological innovation.

1.2.2.3 Wearable Health Technologies: encourage the adoption and integration of dependable and user-friendly wearable health technologies for continuous monitoring of individual health parameters and facilitate personalized healthcare management through wearable health technologies that allow for continuous monitoring

1.2.2.4 Data-Driven Healthcare Approaches: establish systems for comprehensive health data collection and analysis and personalize healthcare strategies using advanced analytics.

1.2.2.5 Interdisciplinary Partnerships: foster interdisciplinary partnerships and advance precision medicine through shared goals and facilitating knowledge exchange

1.2.3 LEADERSHIP AND GOVERNANCE: establish a governance structure to oversee precision medicine initiatives and ensure effective leadership and collaboration among stakeholders to foster inclusive decision-making processes and collaboration among stakeholders

1.2.3.1 Measures:

1.2.3.1.1 Establish a governance structure that ensures the absence of conflict of interest while facilitating collaboration and contributions from a diverse array of stakeholders, including clinicians, researchers, patients, regulators, industry representatives, payers, and ethicists, fostering inclusive decision-making processes.

1.2.3.1.2 Articulate a comprehensive vision delineating SMART organizational goals, scope, and intended impact, along with strategic plans for implementation and resource requirements.

1.2.3.1.3 Delineate clear lines of accountability within the governance structure, outlining specific roles and responsibilities to ensure efficient oversight and the achievement of strategic goals.

1.2.3.1.4 Establish advisory committees as integral components of oversight mechanisms, tasked with monitoring progress, evaluating performance, and addressing concerns or disputes.

1.2.3.1.5 Promote a culture of integrity across all levels of the precision medicine implementation areas, emphasizing digital health standards and protocols compliance including other ethical factors in genomic data utilization and patient care with a focus on prioritizing patient consent, and safeguarding data privacy.

1.2.3.1.6 Utilize effective communication tools to educate and inform stakeholders about initiatives and implement feedback mechanisms to gather insights and guide decision-making.

1.2.3.1.7 Develop and enforce necessary operational protocols, workflows, and standard operating procedures aligned with the strategic objectives outlined in this policy, ensuring alignment with the overall organizational strategic goals.

1.2.3.1.8 Integrate methods and tools to advance precision medicine alongside holistic risk management strategies within the governance framework specified in Sections 3.7 and 3.8.

1.2.3.1.9 Allocate resources towards training and development initiatives aimed at strengthening workforce capabilities and fostering continuous professional growth, thereby enhancing competencies and adaptability in the field of precision medicine for clinicians, researchers, and healthcare administrators alike.

1.2.3.1.10 Encourage innovation in precision medicine through supportive policies that offer guidance on ethical data management, genetic testing protocols, and data protection. Additionally, it involves facilitating research and development endeavors by providing funding opportunities and frameworks that enable advancements of novel therapies and technologies.

1.2.3.1.11 Establish business models designed to manage big data and complex intersection datasets.

1.2.3.1.12 Deploy an internal audit, management review, and change control mechanism to uphold consistent adherence to established documented procedures and promote continual improvements.

1.2.4 RESOURCES AND CAPACITY BUILDING: Develop advanced technological and clinical infrastructure, interdisciplinary expertise, and financial capabilities to support precision medicine by gathering, analyzing, and applying vast amounts of data for personalized healthcare and sustain initiatives.

1.2.4.1 Measures:

1.2.4.1.1 Technological and Clinical Infrastructure

1.2.4.1.1.1 National and Regional Sequencing Facilities: Build capabilities to expand or establish sequencing facilities equipped with cutting-edge technologies to ensure accuracy, efficiency, and accessibility for all eligible individuals.

1.2.4.1.1.2 Interoperable Electronic Health Records (EHR) Systems: Adopt EHR systems capable of securely interfacing with each other to store and manage individual genomic data and other relevant clinical information, ensure data standardization for seamless exchange, and facilitate secure, authorized data sharing supported by documented consent forms (Appendix 1 and 2).

1.2.4.1.1.3 Biobanks and Data Repositories: Establish and maintain secured biobanks and repositories for genomic and other relevant data, to facilitate research on genotype-phenotype correlations, biomarker discovery, and validation of therapeutic targets.

1.2.4.1.1.4 Clinical Decision Support Systems (CDSS): Utilize CDSS that combine genomic information with other clinical data to offer thorough insights, assist healthcare professionals with evidence-supported suggestions, and improve the process of clinical decision-making.

1.2.4.1.1.5 Data Analytics: Employ the use of advanced analytics tools, including machine learning, to analyze complex datasets to identify patterns, predict outcomes, and personalize treatment strategies.

1.2.4.1.1.6 Clinical Trials and Research Infrastructure: Establish clinical trial networks and research consortia, subject to DoH approvals, for conducting large-scale studies aimed at validating precision medicine methods, evaluating the effectiveness of treatments, and appraising the clinical value of biomarkers and tailored therapies

1.2.4.1.1.7 Manufacturing Infrastructure: Establish manufacturing facilities, subject to DoH approvals, that adopt best practices to produce high-quality, personalized medical treatments, ensuring strict cleanroom standards, rigorous quality control, and thorough documentation.

1.2.4.1.2 HUMAN RESOURCES

1.2.4.1.2.1 Diverse Workforce: Build a diverse workforce with expertise in genomics, bioinformatics, data science, and other relevant fields, strengthening human resources capacity in precision medicine, and ultimately accelerating the translation of scientific discoveries into improvements in patient care and population health.

1.2.4.1.2.2 Interdisciplinary Training Programs: Develop interdisciplinary training programs that integrate expertise from fields such as genetics, genomics, bioinformatics, data science, clinical medicine, and public health to build a skilled workforce capable of advancing precision medicine research and application.

1.2.4.1.2.3 Public Engagement and Education: Conduct outreach campaigns, educational initiatives, and communication efforts in collaboration with DoH, to inform the public about the potential benefits and limitations of precision medicine. Emphasize the importance of informed participation in both research and clinical applications.

1.2.4.1.2.4 Collaborative Research Initiatives: Foster collaboration between academia, industry, healthcare organizations, and the

DoHto facilitate knowledge sharing, skill exchange, and collaborative research projects in precision medicine.

1.2.5 FUNDING AND LOGISTICS

1.2.5.1 Secure funding and establish logistical frameworks to support precision medicine initiatives and ensure sustainable financial and logistical support for precision medicine.

1.2.6 CLINICAL PRACTICE IMPLEMENTATION: Integrate precision medicine into clinical practice to optimize patient outcomes and tailor medical treatments and interventions based on individual genetic, environmental, sociodemographic, and lifestyle factors.

1.2.6.1 Measures:

1.2.6.1.1 Genomic Sequencing Technologies: Adopt tools for analyzing patients' genetic information, and identifying genetic variations associated with disease susceptibility, drug metabolism, and treatment response in the clinical setting. Integrate genomic sequencing into routine care to personalize treatment plans based on individual genetic profiles in compliance with the DoH Standard for Laboratory Accreditation for Genomic-Related Services and Products.

1.2.6.1.2 Molecular Diagnostics: Incorporate molecular diagnostic tests into clinical workflows for detecting biomarkers, gene mutations, and molecular alterations linked to diseases like cancer.

1.2.6.1.3 Clinical Decision Support Systems: Advance technological and clinical infrastructure as indicated in Section 3.6.1.4 to assist healthcare providers in making evidence-based treatment decisions.

1.2.6.1.4 Electronic Medical Records (EMRs): Integrate precision medicine data into healthcare facility Health Information Exchange (HIE's) systems (i.e., EMRs) and Malaffi to allow access to healthcare professionals to analyze patient-specific genetic and molecular data, facilitating personalized treatment planning and clinical decision-making.

1.2.6.1.5 Multidisciplinary Care Teams: Promote collaboration among healthcare professionals across specialties like genetics, oncology, pharmacology, and informatics to implement precision medicine in clinical practice, interpreting complex genomic data, devising personalized treatment plans, and coordinating patient care effectively.

1.2.6.1.6 Patient Education and Engagement: Incorporate patients and caregivers into the care plan. Develop education programs on precision medicine, genetic testing, and personalized treatments to foster informed decision-making and engagement. Empower patients to understand genetic test results and advocate for personalized care to align healthcare with their preferences and values.

1.2.6.1.7 Ethical and Regulatory Considerations: Ensure that the clinical application of precision medicine adheres to ethical principles and relevant DoH standards, safeguarding patient privacy, data security, and ensuring equitable access to benefits. Obtain informed consent (Appendix 2) for precision medicine clinical applications (Appendix 3 and 4), ensuring patients are fully informed about the nature, risks, and benefits of personalized treatments and genetic testing.

1.2.6.1.8 Targeted Preventative Measures: Understand the individual's risk profile and implement precision preventative screening based on the

genetic predisposing factors besides vigilant lifestyle modifications and behavioral change interventions.

1.2.7 RESEARCH AND DEVELOPMENT: Establish a robust framework for advancing research and development (R&D) in precision medicine and foster innovation for enhanced individual and population health

1.2.7.1 Measures:

1.2.7.1.1 Genomic Sequencing Technologies: Promote collaborative efforts between researchers and diagnosticians to conduct comprehensive analysis of individuals' genetic codes through Whole-genome sequencing (WGS) and whole-exome sequencing (WES) to facilitate the identification of variations across the entire genome or exome, respectively, enhancing our understanding of genetic influences on health and disease.

1.2.7.1.1.1 Ensure proficient personnel, robust quality management, and secure data protocols in facilities for controlled access to genomic data, guiding personalized healthcare strategies through validated tests interpreted by qualified professionals.

1.2.7.1.2 Molecular Profiling Techniques: Support the advancement and utilization of diverse and reliable molecular profiling techniques such as gene expression analysis, proteomics, metabolomics, and epigenetics to enable multifaceted analysis of biological samples, encompassing gene expression, protein function, and metabolic profiles.

1.2.7.1.3 Biomarker Discovery and Validation: Foster the thorough identification and validation of clinically relevant biomarkers for disease diagnosis, prediction, prognosis, and treatment response monitoring within precision medicine. Employ techniques such as high-throughput screening, bioinformatics analysis, and validation studies to discover and validate biomarkers for precision medicine applications.

1.2.7.1.4 Clinical Trials and Translational Research: Facilitate the design of clinical trials integrating genomic and molecular data to validate personalized treatment effectiveness, subject to DoH approvals. Documented procedures must promote translational research, to facilitate the swift and safe application of research findings from the laboratory to clinical settings, ensuring improved patient care.

1.2.7.1.5 Data Integration and Analysis: Promote integration and analysis of diverse biomedical data for precision medicine. Adopt advanced bioinformatics tools, machine learning algorithms, and data visualization techniques to facilitate data integration, analysis, and interpretation to identify disease-associated patterns, predict treatment responses, and uncover novel therapeutic targets. Implement provisions to ensure compliance with DoH policy on Trusted Research Environment.

1.2.7.1.6 Patient-Centric Research: Prioritizes patient involvement, preferences, and outcomes. Engage patients in study design and securing consent to foster trust and ensure ethical practices.

1.2.7.1.7 Ethical and Regulatory Considerations: Obtain informed consent (Appendix 1), protect patient privacy and confidentiality, and ensure responsible use of genomic and health data. Compliance with the DoH Standard for Human Subject Research is mandatory to uphold patient rights and promote ethical research conduct.

1.2.8 MANAGEMENT OF EMERGING RISKS IN PRECISION MEDICINE: Proactively identify, assess, and mitigate potential risks in precision medicine and protect the progress of precision medicine endeavors through comprehensive risk management.