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Intelligent drug delivery in personalized medicine: Multi-omics insights, digital simulation, and ai-driven formulation strategies: An illustration

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Abstract

Personalized medicine is rapidly evolving from a genomics-driven concept into a fully integrated bio-digital ecosystem that continuously adapts to the changing physiology of each individual. This manuscript presents a comprehensive overview of this transition, highlighting how multi-omics profiling, AI-powered simulations, intelligent drug delivery platforms, and adaptive regulatory frameworks collectively redefine modern healthcare. Multi-omics technologies spanning genomics, proteomics, metabolomics, exposomics, and microbiome analytics now enable high-resolution mapping of biological rhythms, environmental influences, and host–microbe interactions, offering a deeper and more dynamic understanding of disease susceptibility. Parallel advances in digital twin technology allow the creation of virtual replicas of individual organ systems capable of predicting disease progression, optimizing therapy, and supporting AI-generated synthetic control arms in clinical trials. On the therapeutic front, precision is further enhanced by stimuli-responsive nanocarriers, nanotheranostic systems, logic-gated biomaterials, and biofeedback-driven drug delivery devices that autonomously adjust treatment based on real-time biomarker fluctuations. AI-based formulation tools, excipient-interaction predictors, and personalized ADMET modelling expand the scope of individualized therapy, while 3D/4D-printing technologies enable on-demand, patient-specific dosage forms and micro-dosing strategies. The manuscript also examines global regulatory transformations by the FDA, EMA, PMDA, CDSCO, and NMPA, highlighting the shift toward biomarker-linked approvals, AI-supported diagnostics, companion-tool co-development, and adaptive pathways for highly stratified populations. Overall, this work synthesizes the biological, technological, and regulatory innovations driving personalized medicine into a proactive, predictive, and intelligent model of care one capable of tailoring interventions with unprecedented precision.

Keywords: Personalized Medicine; Multi-Omics and Digital Twins; Stimuli-Responsive Nanotherapeutics; AI-Driven Formulation Science; Global Regulatory Frameworks

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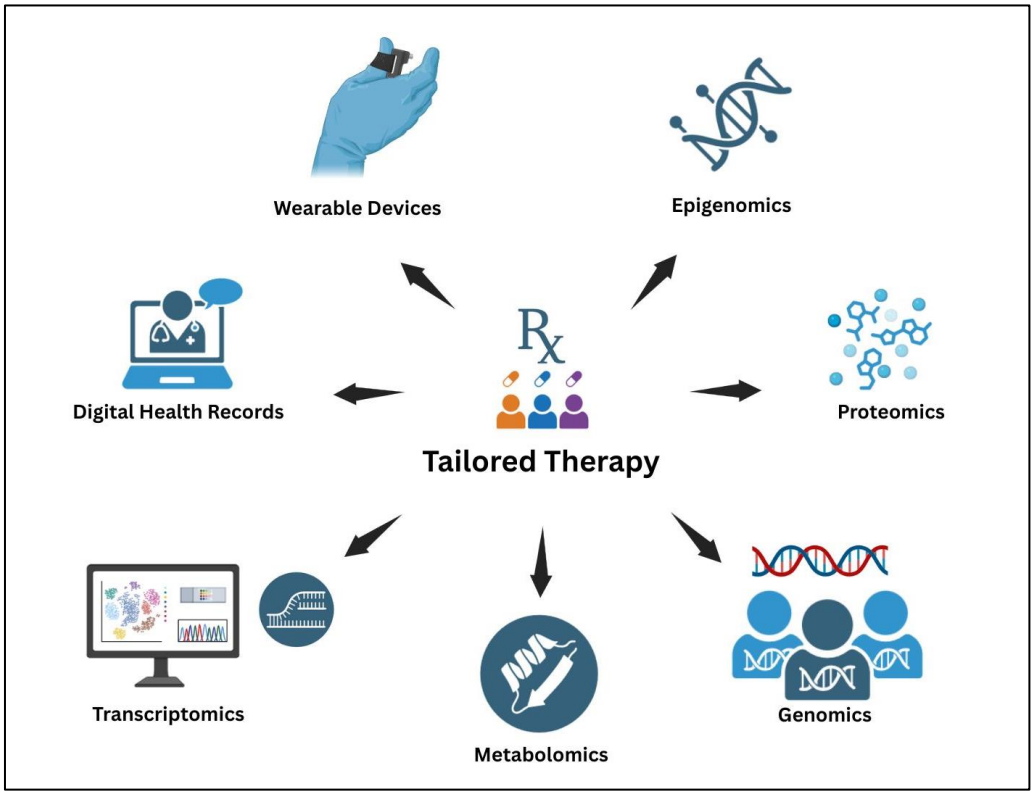
Graphical Abstract



1. Introduction

The last ten years have seen personalized medicine well advanced from its initial obsession with genomics. Although genetic biomarkers remain central to the identification of therapeutic targets and to treatment choice, they provide only a limited perspective on human health. In reality, health outcomes are the product of a dynamic interaction of biological rhythms, environmental determinants, behavioural patterns, microbial ecosystems, and increasingly, electronic health technology. This requires a more dynamic and integrated model of care that accommodates the complex and dynamic nature of individual physiology and the potential for disease. The convergence of biological understanding and technological advancement is compelling a fundamental transformation of the health care sector. In order to build a responsive and networked model of care, the emerging bio-digital paradigm brings into play the convergence of diverse technologies, including artificial intelligence, biosensors, digital health monitors, and intelligent therapeutic devices. To facilitate rapid and tailored medical decision-making, this framework allows for continuous improvement and analysis of health-related data. The focus of this transformation is the development of patient-specific virtual models, or "digital twins," that mimic some physiological processes with the aim of preventing health changes and informing clinical interventions. With the advancement of these computer models to accurately mimic the physiological and pathological condition of an individual, it is now possible to predict the onset of a disease and simulate the effect of treatment based solely on virtual means. The advent of this bio-digital space promises the new era of precision medicine, one that is not just defined by its individualization but by its responsive and active character in treating an individual's health in real time. In contrast to the conventional active care, which waits for symptoms to materialize before starting medical treatment, this shift is a turning point. The emphasis today is on predictive and preventive efforts so that medical practitioners can spot small deviations from normal health patterns and take action before a disease is fully established.

Current wearable and implantable biosensors are constantly monitoring numerous physiological parameters, including fluctuations in cortisol, glucose, and cardiac function, including arrhythmias. The real-time data streams are input to closed-loop systems that possess the capability to modify treatment protocols autonomously on the basis of biological cues. These technologies enable quick and properly tailored treatment interventions by offering a level of personalization that closely mirrors the body's natural rhythms. In the bio-integrated system, personalized medicine is evolving from a static notion to a dynamic and responsive model of care that can adapt to continuous physiological feedback, forecasting health risks, and real-time optimizing therapeutic strategies. This overview attempts to address the meeting of biological understanding and technological innovation that enables such a transition. This article

investigates the new platforms and technologies that enable personalized and responsive healthcare, outlines new developments that are driving the revolution, and offers critical appraisal of challenges that must be addressed in order to bring these developments into routine clinical practice.

2. Multimodal Omics and the Expanded Personal Health Blueprint

Multi-Omics for Precision Health: At the molecular level, multi-omics approaches, such as genomics, proteomics, metabolomics, and exposomics, are converging to transform our understanding of human health. Facilitated by advanced computation and artificial intelligence, this converging strategy allows precise description of genotype–phenotype relationships. By the integration of various omic disciplines into a genomics-first strategy, researchers can not only detect hereditary predispositions but also examine the alteration of such genetic characteristics by dynamic molecular and environmental processes. Importantly, exposomics as an emphasis on quantifying an individual's lifetime overall environmental exposures has revealed that determinants such as air pollution, diet, psychosocial stress, and behavioural factors tend to exert a more significant influence on the risk of disease than genetic inheritance by itself. The findings emphasize the necessity for incorporating real-time environmental information into individualized healthcare models for enabling more integrated, forward-oriented, and adaptive prevention and control of diseases (1,2).

Tracking Molecular Cycles and the Microorganisms' Role in Personalized Healthcare: Emerging omics profiling and micro-sampling technologies allow for the collection of high-frequency molecular information from tiny biological samples, such as microliter-volume blood drops. These technologies allow for the production of high-density, time-series molecular profiles of dynamic physiological changes, such as changes in glucose or cortisol levels, thus making it possible to continuously monitor metabolites, lipids, proteins, and cytokines (3). Simultaneously, the human microbial community has been recognized as a key regulator of host physiology, which is complex and sensitive in nature.

Microbiome diversity, ecological stability, and shifts in composition are inextricably linked to immune regulation and metabolic balance, as evidenced by longitudinal research conducted at various anatomical locations. Numerous chronic diseases have been linked with disruptions to microbial balance, which highlights the important role the microbiome has to mold an individual's health trajectory. Dysregulation in gut microbiome has been associated with insulin resistance and systemic inflammation. Recent advances in metaproteomic platforms enable us to analyse host-microbe protein interactions in-situ, and this may yield predictive information with regard to susceptibility to chronic diseases, including cardiometabolic diseases. These findings further emphasize the significance of incorporating microbiome-derived molecular data into precision health frameworks (4).

3. Digital Twins and Predictive Simulations in Personalized Therapy

AI-powered Human Physiology Modelling: The development of digital twin's computer representations that very accurately reproduce an individual's physiology is driven by advances in artificial intelligence, specifically physics-informed neural networks and generative models. These models can foresee illness trajectories across a variety of circumstances and simulate heart dynamics using non-invasive data such as echocardiograms. Complex, multistage diseases are already being effectively modelled by tools like Digital Twin Generators. In support of these initiatives, the Virtual Physiological Human project combines many organ systems into a single platform, allowing for complete, system-wide simulations for tailored intervention planning.

Real-time Simulations for Drug Response and Disease Progression: In real-time predictive modelling for chronic disorders like diabetes and cardiovascular diseases, digital twins are becoming more and more important. These platforms improve glucose regulation and allow early detection of cardiac events by combining live data from IoT-connected biosensors with mechanistic-AI hybrid models. Results have been reported to improve by up to 25% when compared to standard care (5). Tumor-specific digital twins, like SimBioSys' TumorScope, are being utilized in oncology to predict chemotherapy responses while maintaining spatial tumor heterogeneity, providing a more individualized and accurate treatment plan (6)

Digital Characters in Personalized Risk Analysis and Clinical Trial Design: The use of digital twin technologies in clinical research is changing the way that trials are planned and carried out. Emerging platforms such as Unlearn.ai develop data-driven models of virtual patient characters that mimic individual physiological reactions to placebos, without depending exclusively on conventional control arms. Some studies have reported a reduction of up to one-third in recruiting time and expense, and these artificial control groups maintain statistical integrity while drastically cutting down on trial durations and resource needs.

Digital twins have also been realized to be useful not just in risk stratification but in first-line screening, in addition to their use in optimizing clinical trials. Through the merging of data from multiple sources, such as imaging tests, laboratory tests, and data from wearable devices, these models allow for the early detection of vulnerable individuals and the creation of personalized prevention interventions. This expands the vision of proactive and precision medicine by allowing doctors to detect high-risk individuals earlier and apply preventive interventions that are customized to the person's own unique biological and behavioral pattern. By combining information from various sources, for example, imaging and blood tests, with outputs from wearable sensors, such models allow for early detection of those at risk and also facilitate the design of customized prevention strategies.

4. Adaptive Nanotherapeutics Targeting with Precision, Intelligently Responsive

Stimuli-Responsive Nanosystems in Disease-Triggered Delivery: Nowadays, polymeric nanoparticles are able to identify even the smallest changes in light, pH, enzyme activity, or reactive oxygen species (ROS), and only release their payloads when absolutely required. In tumor or inflammatory microenvironments, such approaches offer a higher therapeutic index and lower systemic toxicity. For example, biodegradable pH/redox responsive nanocarriers have shown promise in the treatment of autoimmune illnesses by releasing immunosuppressants only at inflammatory sites (7).

Nanotheranostics: Dual Diagnosis Treatment Roles: In the past five years, nanotheranostics have developed significantly in combining imaging and therapeutic ability. Stimuli-responsive nanoparticles have made it feasible to track drug release, absorption, and disease development in real time, especially in cardiovascular disease. Because these devices ensure both exact therapy and immediate feedback, they are perfect for customized treatment (8).

Engineered Biomaterials for Cellular Mimicry: Cell-mimicking hydrogels and nanocellulose composites are examples of novel biomaterials that replicate tissue mechanics and drug delivery in manners that resemble cellular behaviour (Figure 1). The logic-gated behaviour of these intelligent materials enables multi-stimulus triggered delivery that is tailored to each patient's pathophysiology (9).

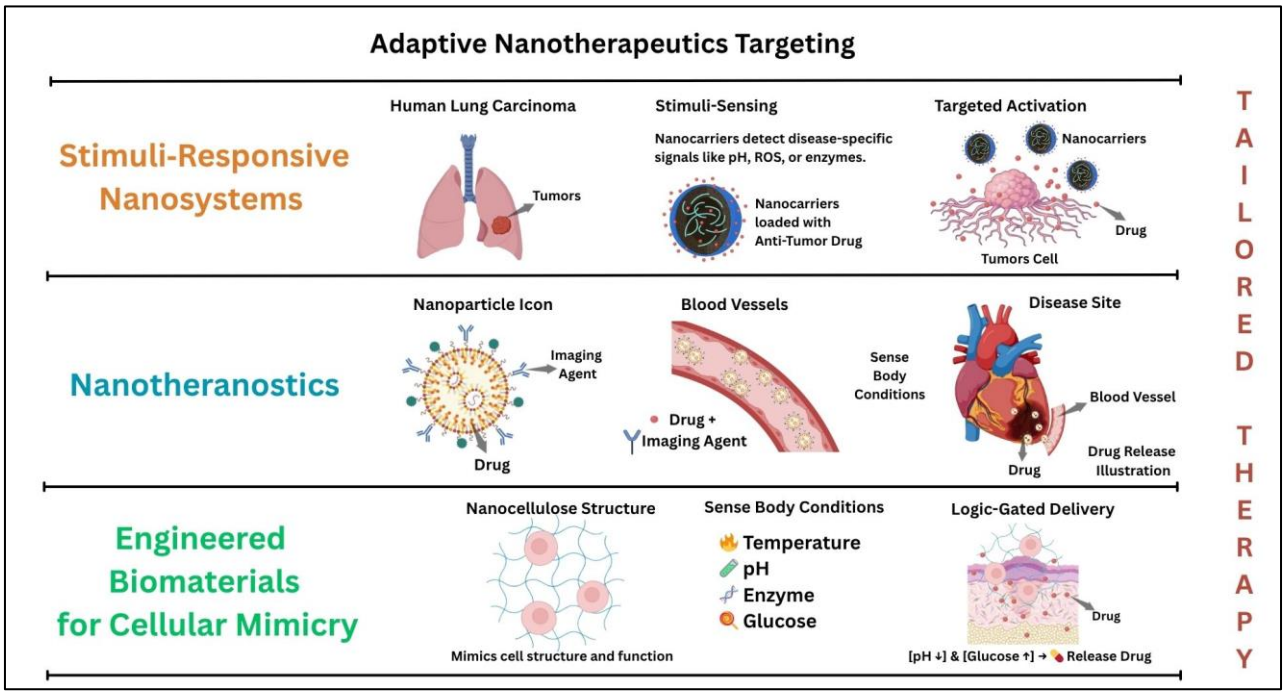


Figure 1 Adaptive Nanotherapeutics targeting

5. Biofeedback Driven Drug Delivery: Closing the Loop

Smart Wearables & Biosensors in Therapeutic Feedback Systems tracking: Biosensors that are wearable or implanted have quickly developed into seamless health monitors that provide mechanical, chemical, and electrical sensing for real-time biomarkers. Notably, the ability of enzyme-based electrochemical aptamer sensors (E AB) to

continuously assess drug levels or biomarkers has made it possible to dynamically monitor the toxicity or efficacy of therapy (10)(11).

Closed-Loop Drug Delivery for Chronic & Fluctuating Conditions models: Self-regulating delivery patches and implants that integrate sensors, artificial intelligence (AI) decision-making, and regulated release are being supported by research. For instance, in diabetics, glucose-responsive microneedle patches independently control the supply of glucagon and glucose. Drug reservoirs combined with implantable biosensors allow for automatic cardiovascular care adjustments depending on real-time physiological inputs.

Personalized Dose-Tuning in Real Time: Closed-loop systems can now provide accurate, patient-specific dose as physiology advances. Under simple external stimulation, electrically activated nanoparticles and electric field-responsive hydrogels react to enable controlled drug release of drugs like insulin or chemotherapeutics. These developments have made drug delivery a highly targeted and customized process.

6. Precision Formulation Science and AI-Driven Pharmacological Intelligence

Excipient Strategies in the Era of Personalized Therapeutics: Pharmaceutical excipient choice has long been based on empirical strategies and has not given inter-individual variation of biological responses any importance, rather overlooking it, especially in patients with genetic polymorphisms affecting immunological function, transporter proteins, or drug-metabolizing enzymes. Therefore, drugs developed on a "one-size-fits-all" model can result in unpredictable therapeutic effects or unwanted side effects, particularly in clinically vulnerable populations or genetically heterogeneous populations.

Utilizing Deep Learning for Improving Excipient Precision: Recent advances in artificial intelligence, especially in deep learning, have provided a more sophisticated method for excipient selection. Emerging models, like convolutional neural networks (CNN), based on data sets that include clinical adverse events alongside embedded physicochemical characteristics, have exhibited high precision for the detection of prospective incompatibilities with excipients and allergic reaction risk. Apart from their efficacy, formulators can use these tools to carry out pre-screening of excipients depending on their personal safety profiles. Development of the DE INTERACT system, wherein molecular fingerprint information and pharmacogenomic markers are combined to predict with unprecedented precision drug–excipient interactions, is a milestone in the discipline. This AI tool excels specifically in the detection of incompatibilities regarding immune-related predispositions variations, efflux transporter expression (e.g., P-glycoprotein), and CYP450 enzyme activity. Models such as DE INTERACT assist in the creation of safer and better formulations designed specifically to the individual biological makeup of each patient by the early detection of patient-specific excipient hazards.

Formulation Platforms Developed by Formulation AI: In translating this technology into real-world applications, platforms such as Formulation AI provide cloud-based platforms through which researchers can enter new chemical entities and receive AI-suggested excipients and stabilizers that are specifically designed for individual patient subgroups. These platforms use multi-omics datasets to propose personalized and safe formulation strategies that are effective.

AI in Predicting Bioavailability, Metabolism, and Drug–Drug Interactions: The biggest obstacle to real customisation is still pharmacokinetic variation. AI-based prediction platforms such as TxAgent, DeepDDI, and PK-Sim AI extensions are now enabling simulation of ADMET (Absorption, Distribution, Metabolism, Excretion, Toxicity) profiles based on an individual's multi-omic data, including CYP450 polymorphisms, UGT variants, microbiome activity, and organ function metrics (12). For example, AI models that take into account liver enzyme profiles, microbiome metabolism, and CYP450 genotyping can predict inter-individual drug behaviour with high accuracy. These platforms can also map out intricate networks of drug-drug interactions, which is particularly useful in polypharmacy conditions like geriatrics or oncology. 1) Forecast metabolism in polymorphic patients, 2) Avoid interactions in polypharmacy regimens, 3) Adjust dose/timing in hepatic or renal compromise. Graph neural networks and transformer models have now achieved >90% accuracy in predicting clinically relevant DDIs, even for new drug combinations (13). These tools now enable clinicians to Predict metabolism in patients with genetic polymorphisms (e.g., CYP2D6 poor metabolizers), Detect and avoid drug–drug interactions in complex polypharmacy regimens (e.g., geriatrics, oncology).

3D-Printed Medications and Micro-dosing Strategies: Modern 3D printing technology makes it possible to create customized, precisely dosed solid oral dosage forms with strength, shape, and release kinetics that are unique to each patient. APIs can be included into multi-compartment tablets with customized release patterns using fused deposition modelling (FDM) or inkjet printing, making them perfect for elderly or paediatric patients with particular metabolic needs. Additionally, titration based on real-time therapeutic response is made possible by AI-guided micro-dosing,

which lowers the risk of toxicity. Point-of-care manufacturing in hospitals, isolated locations, or even extended space missions is made possible by these advancements (14,15).

3D-Printed and Micro-dosed Precision Therapies: The dream of on-demand, patient-specific medicines are becoming reality. Recent clinical advances show; 3D-printed tablets (University of Queensland, 2024) combining up to 5 APIs with customized strength, flavour, and Braille labelling for visually impaired patients; AI-designed layered capsules printed via FDM showing controlled release profiles for drugs like isoniazid and acetaminophen. Meanwhile, micro-dosing algorithms powered by reinforcement learning allow adaptive titration of dose based on real-time therapeutic feedback especially useful in neurology, psychiatry, and diabetes management.

Smart Microneedles and Bio-responsive Materials: Microneedle systems have evolved into intelligent delivery tools: (1) Glucose-responsive microneedle patches deliver insulin in response to rising sugar levels, offering a closed-loop alternative to pumps, (2) 3D-printed microneedles with integrated biosensors allow both drug release and feedback monitoring ideal for vaccination, pain management, and hormonal therapy. New materials such as hydrogels and electro responsive nanofibers are being explored to deliver drugs with logic gated behaviour, enabling AND/OR conditional release based on biomarkers, pH, or temperature.

Toward 4D Printing and Space-Compatible Therapeutics: In a visionary leap, 4D-printed dosage forms which respond dynamically over time or under stimuli have been proposed for space health, emergency care, and implantable systems (16). NASA-funded projects are already testing bioprinting of insulin-producing cells and onboard compounding systems for astronauts, with implications for remote or rural Earth-bound care.

7. Regulatory Considerations

The integration of personalized medicine into clinical practice challenges traditional regulatory frameworks that were designed for "one-size-fits-all" therapeutics. The individualized nature of these interventions whether tailored drug formulations, pharmacogenomic-guided therapies, or AI-driven treatment algorithms necessitates a paradigm shift in regulatory oversight. Regulatory bodies like the U.S. FDA, EMA, and India's CDSCO have begun evolving their policies to accommodate personalized therapeutics. For instance, the FDA's Drug Development Tools Qualification Program and Biomarker Qualification Program offer qualification frameworks for genomic, proteomic, and digital biomarkers employed for patient stratification. Likewise, the EMA's adaptive pathways offer early access to medicines for small populations on the basis of RWE and surrogate endpoints. One of the critical concerns is the co-approval of companion diagnostics and therapeutics. Therapeutic product and diagnostic validation regulatory harmonization are essential to avoid market access delays. Additionally, AI-driven formulation engines and digital twins add one more layer of complexity, where the algorithms themselves become the subject of regulatory evaluation for transparency, reproducibility, and bias. To promote safe adoption, regulatory science must co-evolve with innovation. Close collaboration between regulators, developers, and clinicians is required particularly through rolling submissions, real-time monitoring of data, and patient-centred trial. The future of personalized medicine thus rests on adaptive, adaptable, and technologically sophisticated regulatory models' ones that balance innovation with good patient safety.

Global Regulatory Responses to Personalized Medicine: Personalized medicine has transformed the regulatory arena all over the world, subjecting institutions to the need to break away from conventional patterns. With more emphasis on biomarkers, computer-assisted diagnosis, artificial intelligence platforms, and patient-tailored treatments, regulators at the national and regional levels are revising guidelines for safety, efficacy, and approval to accommodate customization (Figure 2). Country-wise overview follows:

The United States Food and Drug Administration (FDA): Has played a leadership role worldwide by facilitating personalized medicine by virtue of a broad array of regulatory reformations. The Precision Medicine Initiative (PMI) encourages the application of genomic data and multi-omics approaches in the development of therapeutic interventions, thereby facilitating the development of targeted therapies on the basis of patient-specific biomarkers (17). The FDA also encourages rapid access to new drugs by Breakthrough Therapy Designation and Fast Track Approval, particularly in oncology. For example, Keytruda® (pembrolizumab) was the first to be approved based solely on a genetic marker (MSI-H/dMMR) regardless of tumor site (18). The Digital Health Centre of Excellence also oversees AI-driven diagnostic and monitoring technologies that augment customized medical therapies. Companion diagnostics also face rigorous testing in the IDE and PMA paradigms for analytical and clinical consistency. An example is Kymriah® (tisagenlecleucel), a CAR-T therapy indicated for paediatric acute lymphoblastic leukaemia, utilizing autologous T-cells genetically engineered to identify CD19 a gene-based personalization breakthrough (19). Such guidelines position the FDA as the vanguard of incorporating precision therapies into the practice of medicine, while keeping patient safety in mind.

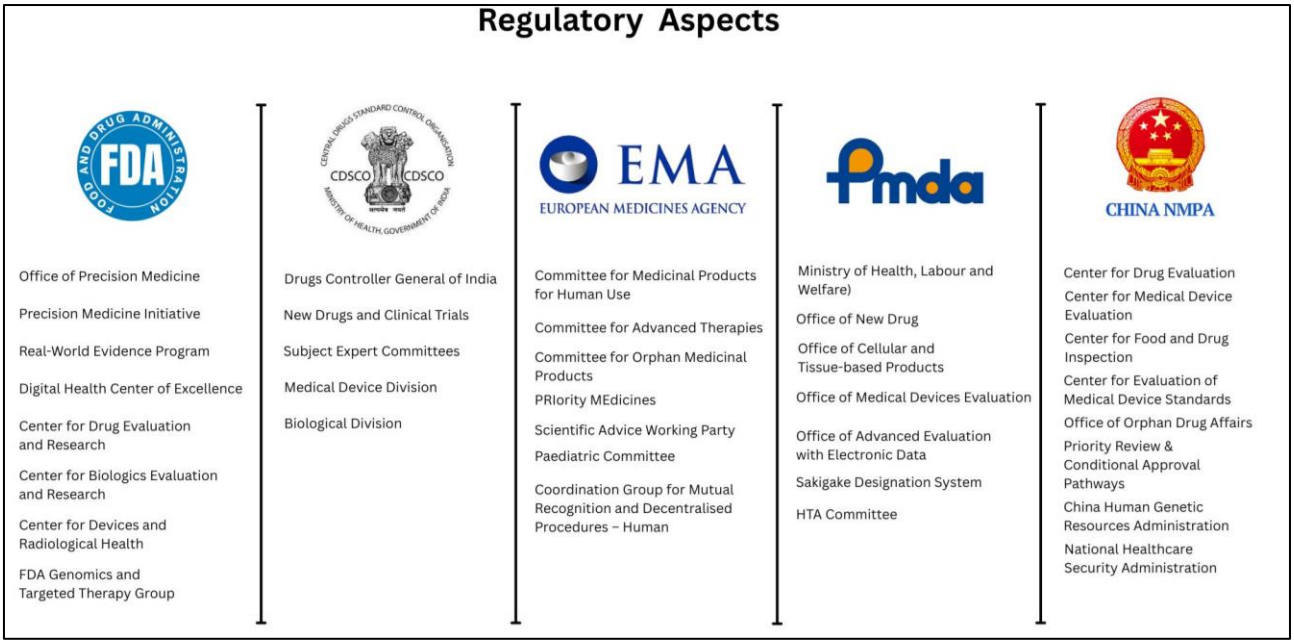


Figure 2 Regulatory Aspects based on each Country

***The European Medicines Agency (EMA)*:** Has taken a lead in formulating adaptive regulatory approaches that will facilitate personalized medicine, namely through its Adaptive Pathways and PRIority MEdicines (PRIME) initiative. These approaches enable early access to precision medicines in small, stratified populations based on real-world evidence and surrogate endpoints (20). The EMA also enhances early stakeholder discussion via Scientific Advice to align therapy and companion diagnostic co-development. EU regulatory challenges are to guarantee quality and homogeneity within member states, to address heterogeneous HTA systems, and to integrate multi-omics-based stratification into standard clinical trials(21). The agency continues to assess AI-supported diagnostics under its Medical Devices Regulation (MDR), but lack of harmonized digital health guidelines is a problem. An example is Onpattro® (patisiran), the first RNAi-based personalized medicine approved by EMA for hereditary ATTR amyloidosis based on gene-silencing of TTR mutations. Overall, EMA's developing infrastructure is critical in driving patient-focused innovation without jeopardizing safety and data integrity.

Japan's Pharmaceuticals and Medical Devices Agency (PMDA): Sakigake Designation System allows for the development of personalized medicine through streamlining the process of approval of innovative therapy with outstanding clinical value (22). The PMDA incorporates pharmacogenomic data in labelling, requiring pre-approval genetic data particularly for medications such as irinotecan (UGT1A1 polymorphisms) (23). Some of the challenges to regulation include limited companion diagnostic facilities, restricted genomic databases, and reluctance to implement AI-powered platforms based on changing ethics policies. The PMDA, however, promotes early consultation models actively, filling gaps between regulators and researchers. Japan is also making international harmonization contributions through ICH and has initiated AMED-PMR (Personalized Medicine Research) for drug-genotype matching. An example is an actual product, Iressa® (gefitinib), which was introduced in Japan before other nations for EGFR mutations in NSCLC based on indigenous genomic prevalence. PMDA continues to set East Asia's regulatory course toward personalized care flexibility.

India CDSCO's Emerging Personalized Medicine Guidelines: The Central Drugs Standard Control Organization (CDSCO), is gradually evolving its frameworks to accommodate personalized therapies. Under the New Drugs and Clinical Trials Rules (2019), CDSCO permits waiver of local trials for orphan and stratified medicines with strong global evidence. The Indian Council of Medical Research (ICMR) is also advancing the Indian Genome Project, supporting drug-response mapping across Indian subpopulations. Key regulatory hurdles include the lack of formal companion diagnostics regulation, inadequate infrastructure for molecular stratification in clinical trials, and limited integration of genomic medicine in public health systems. However, India's low-cost biosimilar and generic models provide unique opportunities to scale affordable personalized care. An example includes trastuzumab biosimilars for HER2+ breast cancer, where diagnostic-guided targeting is now standard in urban oncology centers (24). India's regulatory vision now emphasizes indigenous innovation in genomics, AI, and digital therapeutics as it enters the precision medicine era.

China NMPA's Precision Drug Fast Track: China's National Medical Products Administration (NMPA) has aligned its regulatory practices with precision medicine goals through the Priority Review & Approval Procedure and the China Precision Medicine Initiative (2015–2030). This includes developing national biobanks and integrating genomics into oncology trials (25). The NMPA has accelerated evaluations of gene therapies, RNA-based treatments, and biomarker-driven trials, though hurdles remain in clinical data transparency, AI regulation, and lack of centralized diagnostics policy. China's digital health and AI ecosystem is growing rapidly but requires harmonization with regulatory standards. Avitinib, a third-generation EGFR T790M inhibitor, was approved in China ahead of the U.S. and EU, showcasing local genomic-data-based drug approval (26). China's aggressive push for tech-integrated regulatory science signals its ambition to become a leader in East Asian precision healthcare.

Table 1 "Regulatory-Approved Precision Therapeutics and Companion Diagnostic Platforms"

Drug Name	**Target / Personalization Basis**	**Therapeutic Area**	**Regulatory Body**	**Companion Diagnostic / Tool**	**Year Approved**	**Notes**	**Reference**
Kymriah® (tisagenlecleucel)	CAR-T Cell Therapy (CD19 antigen)	Acute Lymphoblastic Leukemia	FDA	Genetically engineered autologous T-cells	2017	First CAR-T therapy approved	(27)
Keytruda® (pembrolizumab)	MSI-H/dMMR biomarker	Multiple cancers	FDA	Microsatellite Instability Testing	2017	First FDA approval based on biomarker, not tumor origin	(28)
Iressa® (gefitinib)	EGFR mutation (exon 19/21)	NSCLC	PMDA, FDA, EMA	EGFR mutation testing kit	2002 (Japan), 2003 (USA), 2009 (EU)	First EGFR-targeted therapy	(29)
Onpattro® (patisiran)	RNAi-based (TTR gene silencing)	Hereditary ATTR amyloidosis	EMA, FDA	TTR mutation confirmation	2018	First RNAi drug approved	(30)
Vitrakvi® (larotrectinib)	NTRK gene fusion	Solid tumors	FDA, EMA	NTRK fusion assay	2018	Tumor-agnostic personalized therapy	(31)
Zolgensma® (onasemnogene)	SMN1 gene replacement	Spinal muscular atrophy	FDA, EMA, PMDA	Genetic diagnosis of SMN1 deletion	2019	World's most expensive gene therapy	(32)
Avitinib	EGFR T790M mutation	NSCLC	NMPA	EGFR T790M assay	2017 (China)	Approved in China ahead of global agencies	(33)
Trastuzumab (Herceptin®)	HER2 overexpression	HER2+ Breast Cancer	FDA, EMA, CDSCO	HER2 IHC or FISH testing	1998 (USA), 2002 (India)	Benchmark in companion diagnostics	(34)

StrataNGS	Multi-gene NGS panel	Multiple tumors	CLIA (USA, used in trials)	Foundation for treatment decision	Ongoing	Enables precision trial enrollment	(35)
Abecma® (idecabtagene)	CAR-T for BCMA	Multiple Myeloma	FDA, EMA	BCMA-targeted autologous cell product	2021	First CAR-T for multiple myeloma	(36)

8. Conclusion

Personalized medicine is rapidly transitioning from a genomic prediction tool into a deeply interconnected bio-digital framework that continuously interprets an individual's biology, environment, and physiology. This manuscript highlights how multi-omics platforms, microbiome analytics, AI-driven digital twins, and real-time biosensor technologies collectively enable healthcare models that can anticipate disease risk, refine therapeutic response, and optimise interventions with remarkable precision. Parallel advancements in stimuli-responsive nanotherapeutics, closed-loop drug delivery systems, and AI-guided formulation science further strengthen the shift from conventional, generalized treatment approaches to fully individualized therapeutic design.

Equally critical is the global regulatory evolution. Agencies such as the FDA, EMA, PMDA, CDSCO, and NMPA are actively reshaping approval pathways, integrating biomarker-based decision-making, companion diagnostic co-development, adaptive clinical trial designs, and oversight of AI-enabled health technologies. These reforms demonstrate a growing recognition that personalized therapies require regulatory frameworks as adaptive and dynamic as the technologies themselves. Collectively, the emerging synergy between biology, digital intelligence, smart materials, and progressive regulatory science positions personalized medicine at the forefront of the future healthcare landscape. Its success will depend on continuous innovation, ethical deployment of AI, robust data governance, and international regulatory harmonization. Ultimately, personalized medicine promises a healthcare paradigm that is proactive, predictive, and precisely tailored moving treatment away from reactive models toward truly individualized, real-time clinical decision-making.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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