American Journal of
Biomedical Science & Research

www.biomedgrid.com
ISSN: 2642-1747

Review Article

Biomedicine 2026: Turning Points in AI-Driven Discovery, Digital Biomarkers and Longevity Therapeutics

Prof. Dr. Anabel Ternès von Hattburg*

Managing Director SRH Institute for Innovation and Sustainability Management, Germany

***Corresponding author:** Managing Director SRH Institute for Innovation and Sustainability Management, Germany

To Cite This article: *Prof. Dr. Anabel Ternès von Hattburg*, Biomedicine 2026: Turning Points in AI-Driven Discovery, Digital Biomarkers and Longevity Therapeutics. Am J Biomed Sci & Res. 2025 29(4) AJBSR.MS.ID.003828,* **DOI:** 10.34297/AJBSR.2025.29.003828

Received: December 15, 2025; **Published:** December 22, 2025

Executive Summary

The biopharmaceutical landscape stands at the cusp of a paradigm shift. Recent advances in Artificial Intelligence (AI) especially generative models and graph-based deep learning have begun to meaningfully accelerate the early stages of drug discovery. Simultaneously, the convergence of wearable digital biomarkers, molecular clocks, and high-throughput omics is creating a new infrastructure for precision diagnostics and longitudinal health monitoring. Finally, breakthroughs in aging biology, epigenetic clocks and "Seno lytic" interventions are laying the foundation for longevity therapeutics and proactive health span extension.

The biomedical field is undergoing profound transformation. Next-generation therapeutic modalities mRNA platforms, gene editing, cell therapies, and microbiome-based interventions are rapidly advancing toward clinical viability. In parallel, clinical research is evolving: decentralized and hybrid trial models, digital biomarkers, and Real-World Evidence (RWE) frameworks promise to expand access and accelerate development. Concurrently, regulators and ethicists face pressing challenges in data governance, safety oversight, and equitable access. This report explores these six interlocking trends, evaluates their current evidence base, highlights challenges, and outlines implications for biomedical research, clinical translation, and regulatory policy.

Trend - 1 AI and the Acceleration of Drug Discovery

The Promise of AI-Driven Drug Discovery

Traditional drug discovery is notoriously slow, costly, and inefficient: candidates often take a decade or more to reach market approval, with high attrition rates across preclinical and clinical stages. AI promises to transform this paradigm. Recent reviews demonstrate that modern deep learning, Graph Neural Networks (GNNs), Natural Language Processing (NLP) and generative chemistry can accelerate target identification, hit discovery, lead optimization and even safety prediction [3].

A recent comprehensive review noted that AI methods have matured from rule-based systems to powerful generative models capable of designing novel small molecules and peptides de novo - reducing the reliance on brute-force screening of vast chemical libraries [22].

Moreover, AI is being applied not just to structural design, but to entire pipelines: generative chemistry platforms are being integrated into automated "Design-Build-Test-Learn" (DBTL) cycles that promise orders-of-magnitude acceleration in early-stage discovery [13].

Recent Developments & Industry Momentum

In late 2025, the biotech company Excelsior Sciences raised US$ 95 million in Series A funding to build an AI-automated platform for small-molecule drug development with the aim to shrink a 4-month lead optimization cycle to two weeks [6]. Similarly, established Big Pharma companies are increasing investment: Eli Lilly announced a partnership with Nvidia to build a supercomputer optimized for AI-driven R&D workflows, accelerating molecule discovery and reducing reliance on animal testing [21].

Such industry momentum suggests that generative AI is evolving from academic proof-of-concept to industrial-grade platform signalling a shift in how drugs are discovered, repurposed, and developed.

What Works and What Remains to Be Proven

Peer-reviewed data show clear gains in computational speed, structural novelty, and virtual screening efficiency. Generative models have successfully produced molecules with predicted binding affinity and synthetic accessibility, outperforming traditional virtual screening in benchmark datasets [12].

However, challenges remain. Many AI-historically nominated candidates still fail in clinical trials. For instance, a recent review points out that despite the promise, several high-profile AI-derived drug candidates were deprioritized after Phase I/II or failed to translate into clinical success [9].

Moreover, while AI can optimize molecular design, biological complexity is not solved protein dynamics, off-target effects, in vivo pharmacokinetics, immune responses, and human genetic variability remain major hurdles. As the recent review summarises: "AI augments but does not replace experimental validation." [3].

Implications for the Ecosystem

If AI-driven discovery continues to mature, the implications are profound:

a) Faster Lead Identification and Cost Reduction- earlier, cheaper medicinal chemistry could reduce R&D costs substantially and allow more frequent experimental cycles.

b) Fail-Fast Pipelines- quicker identification of non-viable candidates, fewer wasted resources, and faster pivoting if safety or efficacy concerns arise.

c) New Validation Paradigms regulatory systems will need to evolve: traditional in vitro / in vivo validation may give way to hybrid "in silico + minimal viable in vitro" approaches, with emphasis on transparency, reproducibility, and post-marketing surveillance.

d) Democratization of Discovery - smaller biotech firms, academic labs, or even consortia could leverage AI platforms earlier and at lower cost, potentially increasing innovation diversity.

In Sum: AI is not a magic bullet - but it has become a powerful accelerator in the drug discovery ecosystem, provided its outputs are grounded in rigorous biological validation.

Trend 2 - Digital & Molecular Biomarkers: Convergence and Clinical Validity

The Emerging Biomarker Infrastructure

Biomedical measurement is undergoing a transformation. Historically, diagnostics relied on intermittent sampling (blood tests, imaging, biopsies). Now, cheaper sensors, wearables, and high-throughput omics enable continuous, longitudinal, and high-dimensional biomarker profiling digital biomarkers such as heart-rate variability, activity, sleep metrics, combined with molecular biomarkers (epigenetic clocks, metabolomics, transcriptomics) provide rich, multi-layered data streams. A recent review outlines the rapid growth of digital biomarker development, emphasizing the convergence of wearable sensor data with molecular readouts and AI-based analytics [15].

Progress Toward Clinical Validity

In molecular biomarker research, epigenetic "clocks" based on methylation patterns have gained attention as predictors of biological age, morbidity and mortality. Recent cohort studies show strong correlations between advanced epigenetic age and cardiovascular risk, morbidity, and all-cause mortality, validating their potential as surrogate aging markers. (e.g., Horvath clocks, Levine's "Pheno Age", Grim Age see references below under reviews).

On the digital front, machine learning applied to wearable and sensor data has allowed detection of subclinical health changes, early stress signatures, sleep disruption, and circadian misalignment, offering powerful non-invasive monitoring tools [7].

Importantly, hybrid models combining wearable + molecular data are under development in pilot studies, enabling cross-validation and multimodal biomarker models that enhance predictive power and robustness. Regulatory bodies are beginning to take notice: frameworks for digital biomarker qualification are being proposed, and institutions such as the U.S. FDA are evolving guidance around digital health tools and real-world data.

Challenges and the Path to Validation

Despite momentum, several challenges remain:

Data Quality and Standardization: Sensor data vary by device, wear pattern, and user compliance; molecular assays vary by batch, lab, and preprocessing. Without standardization, reproducibility suffers.

Regulatory Validation: Most digital biomarkers remain unqualified for regulatory decision-making; many molecular clocks are research tools, not diagnostic devices. Large, longitudinal validation studies remain limited.

Interpretability: High-dimensional biomarker data often yield complex models - translating these into actionable clinical guidance (e.g., "your biological age is X; here's what you should do") remains non-trivial and ethically challenging.

Equity and Access: Sensor-based biomarker tracking depends on device availability; omics-based measures require lab infrastructure that may be unavailable in low-resource settings.

Implications for Clinical Research and Healthcare

If these challenges are addressed, the convergence of digital and molecular biomarkers could revolutionize preventive medicine and longitudinal health management

a) Precision monitoring - individuals could be tracked continuously, with early detection of dysregulation or disease trajectories.

b) Personalized interventions - biomarker-guided lifestyle, pharmacological, or psychosocial interventions tailored to individual biology.

c) Real-world evidence generation - large-scale deployment allows generating real-world epidemiological data, accelerating discovery and reducing reliance on classical trials.

d) Public health and population screening - scalable biomarker platforms could enable earlier detection of chronic diseases, risk stratification, and targeted interventions, shifting health systems toward prevention rather than treatment.

In short, digital + molecular biomarker convergence stands to become the backbone of a new, data-rich era of medicine.

Trend 3 - Precision Longevity & Aging Therapeutics

From Aging Research to Translational Pipelines

For decades, aging was viewed as an inevitable, unmodifiable process. Now, advances in epigenetics, senescence biology, metabolomics and geoscience suggest that biological aging may be malleable. Several candidates "longevity therapeutics" including seno lytics, metabolic modulators, epigenetic modifiers and mitochondrial-targeted drugs are entering early-phase trials. A recent NIA (National Institute on Aging) symposium report identified epigenetic clocks, functional biomarkers, and senescence markers as leading tools for stratification and surrogate endpoints in longevity trials. Although the full report remains under restricted distribution, summary data presented at the 2025 "Biomarkers of Aging & Longevity" conference underscore growing consensus around translational potential. Meanwhile, epigenetic clock research continues to advance. A 2025 meta-analysis consolidating data from multiple cohorts reaffirmed that accelerated epigenetic age is predictive of all-cause mortality, cardiovascular events, and age-related morbidity, independent of chronological age and conventional risk factors. This supports their use as surrogate endpoints in clinical trials, potentially greatly reducing the time to evaluate anti-aging interventions.

Regulatory and Clinical Translation Challenges

Translating longevity science into therapeutics faces several major hurdles:

Definition of Endpoints: Aging is not a disease, so trials must rely on surrogate biomarkers. Regulators have not yet universally accepted epigenetic clocks or senescence markers as valid endpoints for drug approval. Long-term clinical outcomes (disease incidence, mortality) remain gold standard - but take decades.

Safety and Off-Target Effects: Seno lytics or epigenetic modifiers may affect non-senescent cells, disrupt homeostasis, or produce unexpected systemic effects. Comprehensive long-term safety data are lacking.

Heterogeneity of Aging: Biological age manifests differently depending on genetics, lifestyle, comorbidities a one-size-fits-all "longevity pill" is unlikely. Personalized approaches will be necessary.

Ethical, Regulatory, and Societal Implications: Widespread longevity therapeutics raise questions about fairness, allocation, long-term population effects, and equitable access.

Emerging Pipeline and Early Trials

In 2025, biotech and pharma companies report increasing investment in "geroscience pipelines" Seno lytic therapies for age-related chronic inflammation, metabolic modulators for insulin resistance, mitochondrial enhancers, and epigenetic modulators. Preclinical data show promise in reversing cellular senescence, improving metabolic profiles, and lowering inflammatory markers in animal models. Proof-of-concept Phase I trials are underway for a handful of candidates seno lytics and epigenetic compounds targeting age-associated pathologies, such as fibrosis, inflammatory disease, and metabolic syndrome. Moreover, integrated trial designs are emerging: for example, combining epigenetic-clock readouts, metabolic biomarkers, functional assessments (mobility, cognition), and longitudinal follow-up to assess both surrogate and functional endpoints. If successful, such multi-modal trials could redefine how aging interventions are evaluated.

Public Health and Preventive Medicine Implications

If even a subset of longevity therapeutics proves safe and effective, the ripple effects could be transformative:

Reduced Disease Burden: Delaying the onset of age-related diseases (cardiovascular, neurodegenerative, metabolic) could compress morbidity, improve quality of life, and reduce healthcare costs.

Shift from Disease Treatment to Health Span Promotion: Health systems would need to adapt to preventive and maintenance paradigms continuous monitoring, periodical biomarker screening,

personalized "longevity prescriptions."

Equity and Access: Ensuring global access to longevity interventions will be critical; without that, disparities in aging outcomes may widen.

In essence, precision longevity is no longer science fiction - it is a nascent clinical reality.

Trend - 4 Next-Gen Modalities: mRNA, Gene Editing, Cell & Microbiome Therapies

Expansion of mRNA Therapeutics Beyond Vaccines

The success of mRNA vaccines during the COVID-19 pandemic has catalysed renewed interest in RNA-based therapies beyond infectious disease spanning cancer immunotherapy, genetic disorders, and chronic diseases. Recent reviews highlight how advances in mRNA design, lipid nanoparticle delivery systems, and manufacturing pipelines have overcome historic limitations of instability and immunogenicity. The result is a versatile platform capable of rapidly producing functional proteins, antibodies, or peptides tailored to patient-specific needs [2,16-18].

Clinical trial pipelines are already populated: as of 2025, over 120 trials are evaluating personalized mRNA cancer vaccines across melanoma, pancreatic cancer, glioblastoma, and other tumour types. Early-stage results show encouraging immunogenicity, and manufacturing advances promise scalable production [18,17].

mRNA therapeutics are also being explored for genetic diseases, metabolic disorders, and protein replacement therapies - potentially offering a flexible alternative to conventional gene therapy or protein infusion [18].

Gene Editing and CRISPR-Based Modalities: Promise and Biosafety Challenges

Gene editing using CRISPR-Cas systems and synthetic biology has entered an era of accelerating translational activity. Recent reviews document expanding applications in diagnosis, prevention, and treatment of infectious, genetic, and chronic diseases [10].

Yet gene editing raises critical biosafety and regulatory concerns. The same review flags risks such as off-target edits, insertional mutagenesis, immune responses to viral vectors or Cas proteins, and ecological hazards when synthetic biology is applied to microbiome or environmental organisms [10].

To mitigate risk, the field is developing safer delivery systems (e.g. lipid nanoparticles, non-viral vectors), sensitive off-target screening, and tighter control of editing activity. Regulatory agencies have begun to issue guidance for gene-editing therapies, but globally harmonized frameworks remain nascent.

Microbiome Therapies & Organoid / Organ-on-Chip Models

An equally fast-moving field is microbiome-based therapeutics and diagnostics. A recent review in Nature Medicine (2025) summarises how multi-omic approaches, computational modelling, and translational studies have started to convert basic microbiome science into clinical applications including microbial therapeutics for recurrent Clostridioides difficile infection, microbiome-modulating interventions, and diagnostic biomarkers [11].

In parallel, tissue-engineering advances organoids, organs-on-chips, microphysiological systems offer improved human-relevant preclinical models for drug screening, toxicology, and disease modeling, potentially reducing reliance on animal testing and increasing predictive validity. These platforms are increasingly used in partnership with RNA or gene-editing therapies to evaluate safety, efficacy, and organ specific effects.

Clinical Trial Landscape and Regulatory Shifts

Regulators are responding to these technological advances. For instance, the U.S. Food and Drug Administration (FDA) has updated its frameworks to accommodate novel modalities, including under its Digital Health Canter and accelerated pathways for gene, cell, and RNA-based therapies (FDA guidance updates 2024-2025). In parallel, regulatory bodies in Europe are exploring harmonized standards for microbiome therapeutics, synthetic biology, and personalized mRNA platforms [1].

However, critical gaps remain - particularly in long-term safety data, standardized manufacturing quality, off-target monitoring, and post-market surveillance.

Trend 5 - Trials, Data & Real-World Evidence: Decentralized Trials and AI-Augmented RWE

Decentralized and Hybrid Clinical Trial Models

The traditional clinical trial model centralized sites, scheduled visits, high logistic burden is being challenged by Decentralized Clinical Trials (DCTs), hybrid designs, and Real-World Data (RWD) integration. A comprehensive 2025 review highlights that DCTs now encompass remote consenting, telemedicine visits, wearable sensor data, home delivery of study drugs, and electronic patient-reported outcomes. Decentralized elements reduce patient burden, increase geographic and demographic reach, and facilitate faster recruitment and retention [5].

Hybrid DCTs blending in-clinic and remote components are particularly common in phase II/III studies, while fully remote trials remain less frequent but are growing, especially for low-risk interventions and observational studies [19-23].

Real-World Evidence and AI-Augmented Data Synthesis

Complementing DCTs, real-World Evidence (RWE) frameworks are gaining regulatory acceptance. Digital Therapeutics (DTx), sensor platforms, Electronic Health Records (EHRs), and claims data feed into AI/ML-powered analyses to monitor long-term safety, efficacy, and adherence post-approval. A 2024 framework proposes

guidelines for design, testing, monitoring and evidence generation for DTx covering data collection methodology, endpoints, and regulatory risk management [14].

Moreover, hybrid statistical and AI-ML methodologies are emerging to integrate Randomized Controlled Trial (RCT) data with real-world data, using Bayesian adaptive designs and causal inference frameworks to improve generalizability while preserving rigor [4].

Large regulatory and HTA initiatives, such as the European Union's DARWIN EU and the broader Met Real cluster, are working to standardize data-sharing, federated analyses, and regulatory use of RWE in drug evaluation and monitoring suggesting that RWE will become an integral part of regulatory decision-making and post-marketing surveillance [19].

Implications: Data Quality, Equity, and Regulatory Acceptance

While DCT and RWE models promise speed and inclusivity, they also raise methodological and ethical challenges. Statistical issues such as missing data, variable adherence, and bias must be addressed carefully [5] Data security, privacy, and integrity are also major concerns; decentralized trials rely heavily on digital technologies, requiring robust cybersecurity and compliance with data protection regulations [20].

Yet the benefits are substantial: faster recruitment, broader demographics, continuous monitoring, real-world patient behaviour data, and lower costs. For therapeutic areas with rare diseases, chronic conditions, or long-term interventions - such as mRNA therapies, gene editing or microbiome treatments DCT+RWE may offer the only feasible path to scalable, inclusive trials.

Trend 6 - Governance, Ethics & Regulatory Evolution

Data Privacy, Security, and Ethical Governance

The acceleration of digital biomarkers, decentralized trials, and real-world data raises urgent governance challenges. Real-time data streams from wearables, biosensors, and mobile apps contain sensitive personal health information; regulatory frameworks must ensure data privacy, consent, transparency, and equitable access. The increasing use of digital health technologies underscores the need for robust data governance policies, standardization of digital endpoints, and cybersecurity safeguards especially as regulatory bodies update guidelines (e.g., FDA Digital Health centre, ICH E6(R3), EU EHDS) to reflect modern practice [20].

Safety oversight for novel therapies

Next-generation modalities such as gene editing, synthetic biology, personalized mRNA, and microbiome therapies offer unique therapeutic potential but also novel risk profiles. Biosafety risks include off-target genetic modifications, horizontal gene transfer (in microbiome therapies), immunogenicity, long-term unknown effects, ecological impact, and manufacturing variability [10].

Regulatory frameworks must evolve accordingly. Current accelerated approval pathways (e.g., for rare diseases) may need adaptation for gene editing or microbiome therapies, potentially involving smaller initial cohorts followed by rigorous post-market RWE, long-term follow-up, and periodic re-evaluation. Indeed, regulatory agencies have begun to signal openness to novel pathways [8].

Global Harmonization, Access and Equity

Many of these modalities require complex manufacturing, distribution logistics, and regulatory harmonization across jurisdictions. To avoid inequities, regulatory harmonization particularly for global markets will be critical, along with policies promoting affordable access, transparent pricing, and equitable distribution. Ethical frameworks must also address consent, data rights, long-term monitoring commitments, and intergenerational implications of therapies that alter biology (e.g., epigenetic or gene-editing interventions; [1].

Conclusion & Call to Action

Biomedicine in 2026 stands at a historic inflection point. Next-generation modalities, enriched data infrastructure, decentralized and hybrid trials, real-world evidence, and evolving regulatory landscapes together form a powerful ecosystem with potential to transform how we discover, deliver, and regulate therapies. The first three trends AI drug discovery, biomarker convergence, and longevity therapeutics do not exist in isolation. Rather, they are synergistic components of a broader transformation in biomedicine:

a) AI accelerates drug discovery; digital and molecular biomarkers enable rapid validation and longitudinal tracking; longevity interventions leverage both for development and monitoring.

b) Hybrid platforms (AI + biomarkers + wearable data + omics) provide infrastructure for "living medicine": continuous monitoring, adaptive interventions, and real-time feedback.

c) Regulatory frameworks must evolve: from static approvals to dynamic, data-driven approval + post-market surveillance, real-world evidence and adaptive licensing.

d) Ethical, economic, and societal dimensions will become central: access, data privacy, equity, long-term safety, and intergenerational fairness.

For researchers, clinicians, regulators, and funders, these developments offer both unprecedented opportunity and serious responsibility.

Biomedicine in 2026 stands at a turning point. The convergence of AI-powered discovery, digital & molecular biomarkers, and longevity therapeutics promises to reshape how we understand, measure and intervene in human health. The coming decade may

transition medicine from disease-reactive to prevention-and-maintenance, from episodic to continuous, from one-size-fits-all too deeply personalized.

The next few years may well determine whether these emerging trends remain niche innovations or become the backbone of 21st-century biomedicine. For researchers, now is the time to push, test, validate and lead.

To navigate this transition responsibly, stakeholders must commit to:

a) Robust validation and transparency. AI-designed molecules, gene-edited therapies, personalized mRNA and microbiome treatments must undergo rigorous preclinical and clinical testing, with transparent data sharing and long-term follow-up.

b) Harmonized regulatory frameworks. Agencies like FDA, EMA and global counterparts should converge on standards for digital biomarkers, decentralized trials, real-world evidence, and novel modalities - including safety monitoring, data governance, post-market surveillance, and equitable access.

c) Ethical stewardship and equity. Policymakers, industry, academia, and civil society should collaborate to ensure fair access, data privacy, informed consent, and generational justice, especially for interventions affecting genome, epigenome, or microbiome.

d) Interdisciplinary collaboration. Progress depends on integration: molecular biologists, data scientists, ethicists, clinicians, regulators, and patient communities must engage in co-creation of protocols, trials, and governance systems.

The coming years may determine whether these innovations remain niche advancements or become the foundation of a new, scalable, equitable, and future-oriented era of medicine - one where personalization, prevention, and human-centric health systems take canter stage.

Acknowledgements

None.

Conflict of Interest

None.

References

1. Afrihyia E, Forkuo AY, Chianumba E Ch, Mustapha AY, Omotayo O (2025) FDA Drug Regulations and Pharmaceutical Innovation: Balancing Expedited Approval with Safety and Market Accessibility. In: World Scientific News, WSN 205: 192-218.
2. Androsavich John R (2024) Frameworks for transformational breakthroughs in RNA-based medicines. Nat Rev Drug Discov 23(6): 421-444.
3. Bhat Ajmal Rashid, Ahmed Sumeer (2025) Artificial Intelligence (AI) in drug design and discovery: A comprehensive review. Silico Res Biomed 1: 100049.
4. Chen K, Zheng Z, Zhu P, Jiang S, Li N, et al. (2025a) A Hybrid Prior Bayesian Method for Combining Domestic Real-World Data and Overseas Data in Global Drug Development. arXiv: 12308.
5. Chen J, Di J, Daizadeh N Lu Y, Wang H, Shen YL, et al. (2025b) Decentralized Clinical Trials in the Era of Real-World Evidence: A Statistical Perspective. Clin Transl Sci 18(2): e70117.
6. Choudhury Kamal (2025a) Excelsior Sciences raises $95 million to speed small molecule drug development using AI. Reuters December 3rd, 2025, online via: *https://www.reuters.com/business/healthcare-pharmaceuticals/excelsior-sciences-raises-95-million-speed-small-molecule-drug-development-using-2025-12-03/*
7. Dhudum R, Ganeshpurkar A, Pawar A (2024) Revolutionizing Drug Discovery: A Comprehensive Review of AI Applications. Drugs Drug Candidat 3(1): 148-171.
8. Erman, M. (2025) US FDA unveils new pathway to approve personalized therapies. Reuters November 13, 2025, online via *https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-unveils-new-pathway-approve-personalized-therapies-2025-11-12/*
9. Gangwal A, Lavecchia A (2024) Unleashing the power of generative AI in drug discovery. In: Drug Discovery. Drug Discov Today 29(6): 103992.
10. Gao Z, Gao Y, Wang S, Li X, Cao W, et al. (2025) Application progress and biosafety challenges of gene editing and synthetic biotechnology in diagnosis, treatment and prevention of infectious diseases, In: Biosaf Health 7(5): 312-322.
11. Gilbert Jack A, Azad Meghan B, Bäckhed Fredrik, Martin J Blaser, Mariana Byndloss, et al. (2025) Clinical translation of microbiome research. Nat Med 31: 1099-1113.
12. Kadan A Ryczko K, Lloyd E, Roitberg A, Yamazaki T (2024) Guided Multi-objective Generative AI to Enhance Structure-based Drug Design. arXiv.
13. Kandregula Narendra (2025) Accelerating drug discovery with generative AI: Aa paradigm shifts in pharmaceutical innovation and development. World J Advanced Res Rev 25(03): 1645-1658.
14. Kim M, Patrick K, Nebeker C, Godino J, Stein S, et al. (2024) The Digital Therapeutics Real-World Evidence Framework: An Approach for Guiding Evidence-Based Digital Therapeutics Design, Development, Testing, and Monitoring. J Med Internet Res 26: e49208.
15. Lin LH, Qi JJ (2025) The Artificial Intelligence-driven Revolution in Solid Tumor Drug Development. Oncol Adv 3(2): 112-119.
16. Mark Akinola Ige, Xiaohu Ren, Yang Yang, Haiping Zhang, Chenguang Shen, et al. (2025) RNA-based therapeutics: Transforming medicine through innovation in design, delivery, and disease treatment. Mol Ther Nucleic Acids 36(4): 102721.
17. Matthias Magoola, Sarfaraz K Niazi (2025) Current Progress and Future Perspectives of RNA-Based Cancer Vaccines: A 2025 Update. Cancers 17(11): 1882.
18. Makkar SK (2024) Advances in RNA-based therapeutics: current breakthroughs, clinical translation, and future perspectives. Front Genet 16: 1675209.
19. Jonas Peltner, Cornelia Becker, Julia Wicherski, Silja Wortberg, Mohamed Aborageh, et al. (2025) The EU project Real4Reg: unlocking real-world data with AI. Health Res Policy Sys 23(1): 27.
20. Poondla N, Brathwaite JS, Sheth M (2025) Unlocking the Power of Digital Biomarkers in Clinical Trials. Clinical Res 39(4).
21. Reuters (2025) Lilly partners with Nvidia on AI supercomputer to speed up drug development. Reuters. *https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-partners-with-nvidia-ai-supercomputer-speed-up-drug-development-2025-10-28*

22. Xiangru Tang, Howard Dai, Elizabeth Knight, Fang Wu, Yunyang Li, et al. (2024) A survey of generative AI for de novo drug design: new frontiers in molecule and protein generation. Brief Bioinform 25(4): bbae338,

23. Hongwei Wang, Nadia Daizadeh, Yuan Li Shen, Jie Chen, Frank W Rockhold, et al. (2025) Decentralized Clinical Trials in the Era of Real-World Evidence: A Critical Assessment of Recent Experiences. Clin Transl Sci 18(9): e70328.