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Precision Medicine and Multi-Omics Integration: Transforming Drug Discovery Through FAIR-Enabled Systems

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Abstract

Precision medicine is transforming drug discovery from empirical, population-based approaches toward data-driven, mechanistically informed strategies tailored to individual molecular profiles. Central to this transformation is multi-omics integration—the systematic analysis of genomic, transcriptomic, proteomic, metabolomic, and epigenomic data—which enables comprehensive characterization of disease mechanisms, therapeutic vulnerabilities, and inter- and intra-patient (single-cell) heterogeneity. By moving beyond reductionist, single-layer analyses, multi-omics captures emergent properties of biological systems, revealing causal relationships between molecular variation and clinical phenotypes that are essential for robust target discovery, validation, and lead optimization.

This mini-review examines how precision medicine and multi-omics are reshaping the drug discovery pipeline, emphasizing the critical roles of artificial intelligence (AI), FAIR data principles (Findable, Accessible, Interoperable, Reusable), and governance frameworks. We highlight advances in network-based integration, multi-view machine learning, and AI-driven target prioritization, demonstrating how these approaches accelerate hypothesis generation while maintaining reproducibility and traceability. Real-world applications—from HER2-targeted therapies in breast cancer to PARP inhibitors for BRCA-mutated tumors—illustrate the clinical impact of multi-omics-guided drug development.

Emerging technologies, including single-cell and spatially resolved multi-omics, promise unprecedented resolution for dissecting tissue heterogeneity, microenvironmental context, and therapeutic resistance mechanisms. Integration of these modalities with foundation models and knowledge graphs comprised of FAIR data will enable cross-modal reasoning, predictive modeling, and patient stratification at scale. However, persistent challenges—data heterogeneity, computational complexity, ethical considerations, and regulatory frameworks—require coordinated solutions. By synthesizing conceptual advances, practical applications, and emerging challenges, we articulate a vision for FAIR-enabled, AI-driven precision medicine as the foundation for next-generation therapeutic discovery.

Introduction

Precision medicine envisions therapeutic strategies tailored to individual molecular profiles rather than population averages, fundamentally reshaping drug discovery from empirical trial-and-error toward data-driven, mechanistically informed design [1,2]. High-throughput molecular profiling—spanning genomics, transcriptomics, proteomics, metabolomics, and epigenomics—now enables comprehensive characterization of biological systems across multiple layers, collectively termed multi-omics [3,4]. These technologies capture complementary dimensions of cellular state and disease biology, offering unprecedented opportunities to decode heterogeneity in disease mechanisms, treatment response, and clinical outcomes.

Historically, drug discovery relied on reductionist approaches targeting single genes or pathways, yielding important successes but contributing to high attrition rates and limited translatability [5]. Multi-omics transcends these limitations by enabling system-level interrogation, revealing emergent properties invisible to single-omic analyses [6,7]. When integrated with clinical phenotypes, multi-omics supports robust target discovery, refined patient stratification, and mechanistically grounded therapeutic development.

However, the expansion of omics data introduces formidable analytical and operation-

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al challenges [8]. The scale, heterogeneity, and complexity demand advanced computational approaches—machine learning, generative AI, and network-based methods—whose utility critically depends on data quality, interoperability, and governance [9,10]. The FAIR principles (Findable, Accessible, Interoperable, Reusable) have emerged as essential enablers for scalable, reproducible, and ethically responsible discovery [11,12].

This mini-review examines how precision medicine and multi-omics are reshaping drug discovery—from target identification through lead optimization—emphasizing conceptual advances, practical applications, and emerging challenges. We highlight the transformative roles of artificial intelligence, integration strategies, and governance frameworks in building the next generation of discovery systems.

2. Multi-Omics Integration: From Data Accumulation to Systems Understanding

Disease mechanisms arise from coordinated perturbations across genomic variation, gene regulation, protein networks, and metabolic fluxes—not isolated molecular events [13,14]. Multi-omics integration has therefore become central to systems biology, capturing this complexity within unified analytical frameworks rather than through fragmented, single-layer analyses [15]. Its value lies not in dataset size alone, but in enabling mechanistic insight into disease pathways, therapeutic vulnerabilities, and inter-patient heterogeneity [16].

Early omics studies focused on individual modalities, providing valuable but incomplete views. Genome-wide association studies (GWAS) identified thousands of disease loci, yet translating associations into actionable targets remains challenging due to indirect relationships between genetic variants and functional outcomes [17]. Integrative approaches address this by linking genomic variation to downstream molecular cascades—transcript abundance, protein expression, post-translational modifications, and metabolic states—enabling reconstruction of disease-relevant networks amenable to pharmacological intervention [18,19].

Methodologically, integration strategies span correlation-based analyses, network models, Bayesian frameworks, and multi-view machine learning [20,21]. Network-based integration projects experimental data onto shared biological networks, identifying regulatory nodes, modules, and pathway perturbations. Machine learning extracts latent representations capturing cross-modal patterns, supporting target prioritization and patient stratification at scale [22]. However, data heterogeneity, batch effects, uneven quality, and missing data remain obstacles that obscure biological signal if unaddressed [23]. Meaningful integration requires semantic interoperability—shared ontologies, standardized metadata, consistent identifiers—without which cross-study analyses become unreliable [24].

Successfully implemented, multi-omics integration provides a foundation for informed target discovery and therapeutic design, bridging molecular variation and clinical phenotype while enabling AI-assisted, biologically grounded precision medicine [25].

3. Target Discovery and Identification: From Associations to Actionable Insights

Target discovery identifies biologically relevant molecules—proteins, RNAs, regulatory elements—modulatable to alter disease outcomes [26]. In precision medicine, this requires understanding molecular variability within and across patient populations. Multi-omics datasets link genotype to phenotype, elucidating disease-specific pathways through integrated genomic, transcriptomic, proteomic, and metabolomic profiling [27,28].

Public platforms like Open Targets exemplify multi-omics-driven target prioritization, combining genetic, transcriptomic, proteomic, and clinical data to rank targets by disease relevance, tractability, and safety [9]. Advanced frameworks—network analysis, pathway modeling, machine learning—identify key nodes in complex biological systems. Large-scale studies link single-nucleotide variants to altered protein networks, pinpointing therapeutic intervention points [29].

AI, particularly natural language processing and generative algorithms, accelerates discovery by mining literature and databases, revealing non-obvious target-disease relationships while ensuring traceable provenance when datasets adhere to FAIR principles [6,10]. FAIR-aligned infrastructures enable interoperability between institutional and public datasets, supporting reproducible, scalable workflows [11].

Target identification extends discovery by establishing causal relevance and therapeutic potential. GWAS identify disease-associated variants; proteome-wide association studies (PWAS) reveal abundance or functional alterations mediating phenotypes [30]. Transcriptomics contextualizes regulatory networks; metabolomics highlights biochemical consequences, providing holistic target evaluation [12,18].

Clinical examples illustrate multi-omics-guided identification: HER2 overexpression in breast cancer defined trastuzumab-responsive subsets, enabled by genomic amplification and proteomic validation [31]; BRCA2 mutations inform PARP inhibitor selection, matching therapeutic strategies to molecular profiles [32]. Despite advances, data heterogeneity, incomplete coverage, and computational complexity persist. Network-based analyses, machine learning, and pathway modeling navigate these challenges, prioritizing mechanistically validated, druggable, clinically actionable targets [33,34].

4. Target Validation and Lead Optimization: Closing the Loop

Target validation confirms that modulating a candidate produces meaningful therapeutic effects with acceptable safety, bridging molecular discovery and drug development [1,2]. Multi-omics integration is central, providing system-level perspectives capturing cascades from gene to RNA, protein, and metabolites [35]. Network-based and multi-view machine learning approaches identify critical interactions, pathways,

and regulatory modules, distinguishing causative targets from bystanders [20,36].

Correctly structured, comprehensive, and FAIR omics datasets will allow AI tools to mine that data and identify targets and hits with ease. Linking genomics, transcriptomics, proteomics, and metabolomics using sufficient metadata will make the outcome of the AI analysis contain not only the potential targets and hits, but a transparent and traceable path to them. This context makes the further experimental validation of substances of interest easier for the scientist.

Experimental validation complements computational predictions. CRISPR editing, RNA interference, crystallography, NMR, and cryo-EM enable precise interrogation of target function and drug binding [37]. Combining high-throughput assays with in silico modeling—molecular docking, structure-based simulations—allows rapid assessment before costly studies [38].

FAIR-aligned practices are critical. Standardized metadata, persistent identifiers, and interoperable formats enable reproducibility, cross-study comparison, and integration of public and proprietary datasets [11,24]. AI systems can reason over multiple datasets, identifying robust, clinically relevant targets while maintaining transparency [39].

Hit generation and lead optimization refine molecules for efficacy, selectivity, and safety. Multi-omics provides context: genomic, transcriptomic, proteomic profiles highlight disease-relevant pathways; metabolomic and phenotypic data reveal off-target effects and toxicity [40]. Network approaches assess polypharmacology, identifying compounds modulating multiple relevant nodes without adverse interactions [16].

AI and generative models accelerate discovery. Machine learning predicts target-ligand interactions, optimizes properties, and explores chemical space [10,41]. Structure-based simulations and folding predictions enable rapid in silico screening [42]. Combining AI predictions with multi-omics-derived constraints enhances specificity, reducing false positives [43].

FAIR principles underpin reproducibility throughout. Standardized metadata, provenance tracking, and interoperable formats allow AI models to utilize diverse datasets while maintaining traceability [12,44]. Real-world examples—AI-guided oncology hit generation, rare disease candidate design—demonstrate transformation into efficient, rational, scalable processes [45,46].

5. AI, FAIR, and Governance: Building Accountable Discovery Systems

The integration of AI, multi-omics, and FAIR principles has transformed drug discovery into a data-intensive, computationally driven discipline [47,48]. However, this transformation demands rigorous ethical, regulatory, and governance frameworks to ensure responsible and equitable deployment [49].

AI models require extensive, high-quality datasets [50]. FAIR principles ensure data can be located, integrated, and reused while maintaining provenance and reproducibility [11]. Embedding FAIR-aligned practices reduces silos, enhances generalizability, and ensures predictions are traceable and interpretable [24]. Standardized metadata, versioning, and semantic interoperability form the technical backbone of reproducible AI-driven discovery [12].

Ethical and regulatory considerations are intertwined with governance. Patient-level omics data are sensitive; privacy must be safeguarded through federated learning, controlled-access repositories, and compliance with GDPR or HIPAA [51,52]. Transparency in AI decisions is critical, as outputs may influence therapeutic development, stratification, or trial design. Bias in training data—population underrepresentation, technical artifacts—can propagate inequities if unmitigated [53].

Governance frameworks must address AI accountability. Clear policies for data stewardship, algorithm validation, and risk assessment prevent misuse and maintain trust [54]. Interdisciplinary collaboration—bridging bioinformatics, computational biology, ethics, law, clinical expertise—is increasingly necessary [55].

By combining FAIR governance, ethical oversight, and regulatory compliance, AI-enabled multi-omics platforms realize their potential without compromising safety, equity, or integrity, ensuring innovation aligns with societal and clinical responsibilities [56].

6. Emerging Technologies: Single-Cell and Spatial Multi-Omics

Single-cell and spatially resolved omics are revolutionizing our ability to dissect tissue heterogeneity and microenvironmental context [57,58,59]. These technologies enable unprecedented resolution, capturing molecular diversity within tissues and revealing disease-relevant interactions obscured in bulk analyses [60,61].

Single-cell multi-omics simultaneously profiles genomic, transcriptomic, epigenomic, and proteomic information from individual cells, exposing rare cell populations, developmental trajectories, and therapeutic resistance mechanisms [62,63]. Spatial transcriptomics and proteomics add anatomical context, mapping molecular profiles onto tissue architecture to reveal cell-cell communication, spatial gradients, and niche-specific regulation [64,65].

Integrating these modalities with FAIR-compliant infrastructures and AI pipelines promises enhanced cross-modal reasoning, predictive modeling, and patient stratification [66,67]. Foundation models pretrained on massive single-cell datasets enable diverse downstream analyses, from disease prediction to drug response forecasting [68,69]. However, challenges persist: data volume, dimensionality, batch effects, and integration complexity demand robust computational strategies and standardized analysis pipelines [70,71].

Despite hurdles, single-cell and spatial multi-omics are poised to transform precision medicine by enabling context-specific target identification, uncovering mechanisms of treatment resistance, and supporting digital twin approaches for personalized therapy optimization [72,73].

7. Conclusion and Outlook

The convergence of precision medicine, multi-omics, AI, and FAIR governance is creating a transformative paradigm for drug discovery—one that is data-rich, patient-centric, and technologically sophisticated [74,75]. Multi-omics provides system-level understanding, revealing causal relationships hidden in single-layer studies. AI accelerates discovery, from target identification through lead optimization, while FAIR principles ensure scalability, reproducibility, and interpretability [76].

Looking forward, emerging technologies—single-cell multi-omics, spatial transcriptomics, generative AI, foundation models—promise deeper mechanistic insights and precision therapeutic design [77,78]. Integration into knowledge graphs comprised of FAIR Data and AI pipelines will enable cross-modal reasoning, predictive modeling, and improved stratification [79,80].

Challenges remain: data heterogeneity, batch effects, technical noise require robust integration strategies [23]. Ethical and regulatory frameworks must evolve, ensuring privacy, equity, and accountability [51,54]. Federated learning, provenance-aware workflows, and FAIR adherence will be critical in maintaining reproducibility, transparency, and compliance [52,56].

By refining analytical frameworks, embracing emerging modalities, and addressing ethical challenges, the field can accelerate development of precision therapeutics, delivering more effective, safe, and personalized medicines to patients worldwide [81,82].

Conflict of Interest

The authors declare no competing financial interest.

Ethical Approval

Not applicable

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