The New Drug Development Playbook

By Sarah Asbury

The deep biology revolution is here. Multi-omics experiments sample an infinitely complex biological system, and the data from a single experiment is often too complex for a single person, even a highly trained one, to understand. The next generation of biotechnology innovators promise to unravel the biology embedded in these experiments using machine learning and artificial intelligence to turn massive troves of data into something translatable and commercializable. Young ambitious start-up companies have raised billions of dollars on their platforms to advance the drug development process into a future that is less expensive, more efficient, and extremely precise. The challenges in drug development are well-known: less than 10% of clinical trials succeed[1], only 5% of eligible oncology patients enrol clinical trials[2], and developing a single new drug costs $2.5 billion USD.[3] The new wave of AI-driven biotechnology companies aims to be the solution by using multi-omics and machine learning to disrupt the traditional drug development model.

One such company is Recursion pharmaceuticals, pioneering cellular cartographers whose venture derives biological maps from multi-omics experiments.[4] They have industrialized the drug development pipeline using an assembly line of robots to conduct gene perturbations at scale and rapidly phenotype results. A silicon-valley darling, Recursion has partnerships with both Nvidia[5] and Google Cloud[6], a motif for the new wave of biotech that has much in common with traditional tech companies. Each multi-omics experiment generates billions of bytes of information, and at scale, that becomes the 23 petabytes of experimental data stored in Recursion's proprietary biological and chemical database[5]. The amount of information generated is incomprehensibly massive and represents deeply entangled relationships between cell genetics, cell composition, and experimental condition measured across imaging, genetic, and molecular modalities.[4] Recursion builds machine learning models, accelerated by Nvidia's compute infrastructure and Google Cloud storage, to interpret these thousands of perturbation experiments.[5,6] The aim is to build a general biological map that can be broadly used to understand any biological condition – an expedition with lofty goals beyond single disease indications.[4,7] Recursion is effectively training a machine learning model to understand entire biological systems, which will inform new disease targets and help design more effective drugs. However, it is not yet known whether these parameters can be gleaned from careful cataloguing of bulk sequencing experiments, biological imaging, and molecular tests.

Once a target is identified, Recursion uses machine-learning accelerated protein target prediction to generate a library of potential drug compounds.[4] Recently, Recursion acquired precision chemistry biotech Exscientia, with expertise in machine learning to automate small molecule synthesis and generate best-in-class therapeutics; their partnership promises to accelerate development and refinement of chemical libraries.[8] Chemical drug candidates in Recursion's

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pipeline are put through a series of increasingly more complex biological tests, until finally the best targets are assessed in a futuristic preclinical model which utilizes animal enclosure sensor and video data processed by machine learning algorithms for rapid identification of drug toxicities, optimization of dosages, and identification of the best drugs to bring to clinical trial.[4,9,10]

Recursion's technology is an investment into the multi-omics and deep learning revolution, but whether they can successfully capitalize on it is an open question. The ambiguity is perhaps best represented in their most recent clinical reporting for their drug candidate REC-994, which showed excellent drug tolerance in the Phase II dose escalation clinical trial but no significant improvements in disease.[1,11,12] Regardless, Recursion has been extremely successful in attracting pharmaceutical partnerships, including a recent up-to $12 billion deal with Swiss pharmaceutical company Roche to generate conditional biological maps using their platform.[7] Roche's partnership represents a vote of confidence in their biological mapping platform to accelerate their own drug development pipelines. Recursion's partnership with Sanofi has also been successful, identifying a multi-cancer drug candidate and fast-tracking it to Phase I clinical trials in as little as 18 months – a very impressive timeline for drug discovery.[13] Overall, Recursion's platform for deep multi-omics biological mapping and proven drug candidate acceleration remains an attractive case study for the multi-omics drug development revolution.

Tempus, another pioneer of the AI-driven healthcare revolution, focuses on multi-omic data integration to transform how patients enrol in clinical trials. Drugs increasingly target narrower patient subsets with specific molecular and genetic markers.[2] Founded in 2015, Tempus took advantage of this trend by building the world's largest library of clinical and multi-omic biomarker data alongside software infrastructure to transform their database into actionable insights for physicians, researchers, and allied health professionals.[14,15] Their value is clear: Tempus enables clinicians to quickly identify clinical trials their patient may be eligible for across 2000 healthcare institutions and help researchers recruit eligible patients across the network of 50% of the United States oncologists.[2,15] Comprehensive patient profiles span clinical records, imaging, and molecular information to help match them to clinical trials in what is referred to as the TIME Trial Network.[2] Further, Tempus offers in-house sequencing panels to measure clinical trial eligibility markers, and simultaneously their multi-omic patient database, so that clinical researchers can retrospectively analyze which subsets benefit from their drugs.[16,17] Tempus is revolutionizing the clinical trial management system and cleverly pairing it with their genomics services to create a fully personalized medicine clinical trial ecosystem.

Biomarker-informed clinical trials are popular in modern pharmaceutical clinical pipelines. Indeed, Tempus has been used by 95% of the largest public companies.[15] For example, British pharmaceutical giant GSK partnered with Tempus in 2020 to gain access to Tempus' clinical and multi-omic database.[18,19] They further expanded their partnership in 2022, confirming the value Tempus brought to their clinical trials.[18,19] Tempus' software suite facilitated GSK to rapidly launch a Phase II study and new clinical sites based on areas of concentrated patient eligibility in under 3 months, resulting in GSK partnership renewal. Their collaboration aligns with GSK's clinical strategy: to invest in drugs with genetic validation.[19] These drugs tend to have a deeper biological rationale, and by investing in them, GSK leadership is betting on increased success rate in clinical trials. Janssen also partnered with Tempus starting in 2020, where they joined their TIME trial network to increase enrollment in their United States trials and rapidly open new sites in key institutions based on clinical and molecular traits of local patient populations.[20] Janssen is amongst other large companies – like GSK, Pfizer, and Astrazeneca – that are all taking advantage of the Tempus clinical and multi-omic database and sequencing technologies to further understand which multi-omic biomarkers are predictive of patient response to both standard of care and drugs in clinical development.[15] Tempus represents the realization of precision medicine in clinical trials, using machine learning and multi-omics to enrol the right patients to the right clinical trials at the right time. Although Tempus has attracted major pharmaceutical partners, only longitudinal analysis can determine whether their collaborations have indeed improved clinical trial outcomes.

Insitro, a younger emerging biotechnology company, is also slated to become a major player in the multi-omics and AI-driven drug development revolution. Insitro hopes to combine the ability of multi-omics to make

precise measurements of entire biological systems and the power of machine learning to deconvolve complex experiments into drug insights from multifaceted disease states.[21] Founded in 2018 by Daphne Koller, Insitro had raised $400 million by 2021 to leverage multi-omics and machine learning to make drug development cheaper and less risky.[22,23] Their recent academic paper uses the UK Biobank, a massive multi-omic and clinical phenotyping database with over half a million participants, and demonstrates the company's R&D capabilities.[24] They train a model to predict liver fat content from MRI images, which are costly to produce, from cheaper modalities like blood biomarkers. Using both measured and predicted liver fat content, they identify several novel genetic targets associated with non-alcoholic fatty liver disease.[24] Here they demonstrate the ability of machine learning to expand genetic targets in an academic setting but hope to translate these findings to an actionable drug candidate. Recently, they partnered with Eli Lilly to further develop several potential liver disease drug candidates targeting the genes identified via artificial intelligence.[23] They also saw success in another partnership with Bristol Myers Squibb, delivering a milestone achievement to identify novel genetic targets for ALS drug development.[25] Insitro's early success suggests they may be able to make drug development more efficient and targeted through AI-driven genetic models – but whether these translate to clinical success have yet to be proven.

Advances in sequencing, multi-omics, and machine learning provide the power to analyze biological systems at scale. Biotechnology start-ups are capitalizing on this opportunity, developing ways to make drug development more efficient, more precise, and hopefully, cheaper. Traditional pharmaceutical companies have recognized the value of the new drug development playbook and are thus partnering with ambitious AI-driven companies ready to prove their worth in enhancing clinical pipelines. Underlined by massive databases and machine learning, the deep biology revolution has begun.

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