Business Strategy: Tara Raveendran

What does Roche's takeover of Flatiron Health mean?

On 6 April, Roche completed the acquisition of 87% of the privately held US cancer data analytics firm Flatiron Health that it did not already own for $1.9 billion. In addition to the eye-watering valuation, what is remarkable about this transaction is that it marks the first formal interest of a big pharma player in the emerging field of real-world data analytics, a space that is currently dominated by Silicon Valley start-ups and tech firms. We have seen evidence of the healthcare industry 'dipping its toes' in real-world data, with AstraZeneca Plc as an early partner on CancerLinQ, the ASCO-supported real-world data cancer database, and Novartis making a push into a number of digital and real-world data initiatives. However, the Flatiron acquisition is the most substantial to date, with the enticing proposition of integrating regulatory grade real-world data into the drug development process.[1]

Flatiron Health was founded in 2012 by two ex-Google employees with a vision to integrate and enhance the workflow in cancer clinics. The platform is built around anonymised patient data extracted from a proprietary cancer-specific electronic medical record, OncoEMR, and a suite of software products that use the real-world data from these records to provide clinical and care insights. With an extensive network of around 260 community oncology practices in the US, comprising physicians representing around 1.5 million patients (an estimated one in eight of all those diagnosed with cancer in the US), Flatiron offers not just an aggregation of real-world data but a curated, regulatory-grade database that allows for the real-time monitoring of drug efficacy and usage.[2]

Cancer as the early testing ground

Cancer has proven to be an early test case for real-world data platforms, not least because of the advancement of our understanding of the disease based on the explosion of academic and clinical knowledge. This has in turn driven remarkable progress in how we treat and manage cancer, from the sophistication of genetic testing to the emergence of life-extending therapeutics such as Keytruda and Opdivo. However, this increase in the complexity of cancer care has also widened the gap between randomised clinical trial results and the evidence needed for real-world clinical decisions. Real-world data offers the opportunity to capture the clinical experience and data of the more than 95% of cancer patients treated outside of clinical trials.

In terms of potential applications, the opportunities of real-world data to enhance both the drug development process and commercial access underpin the value of such a platform to industry. Real-world data and the evidence it generates can be used to improve the selection of patients for clinical trials, hence accelerating development timelines and reducing costs, and eventually support outcomes-based reimbursement negotiations and influence clinical treatment algorithms.

The challenge to the broader acceptance and use of real-world data remains around the acceptance of this data by independent authorities. For new cancer drugs, conventional randomised clinical trials remain the gold standard. However, particularly in cancer, clinical trial data is increasingly relevant for a narrow patient population in pre-defined clinical settings within pre-specified drug combinations. In this context, real-world data may play a complementary role to existing data, to support both the drug development process and regulatory decision making. Real-world data can also be used to solve a major ethical issue in clinical research – the use of control groups in trials. As a supplement to the growing role of data from single-arm trials in cancer, as in the case of accelerated approvals, data from previous trials and real-world data from cancer patients can be used to construct so-called 'synthetic' control groups.

One example is data presented by Roche for its second generation ALK inhibitor Alecensa (alectinib) versus Novartis' Zykadia (ceritinib). In this retrospective analysis, a ceritinib control arm was derived from Flatiron's real-world database using eligibility criteria similar to the alectinib trials. Median overall survival in the real-world data arm was similar to that reported in the Phase 2 single-arm ASCEND-2 trial of ceritinib (15.6 months versus 14.9 months respectively). This was used then as an external reference against which to compare the overall survival of Roche's alectinib (24.2 months).[3] While promising, there is still work to be done with regulators to define the acceptable margin between real-world data derived outcomes and historic control arms to validate the approach for broader application. But this example does highlight the potential for real-world data to positively impact the drug development process and facilitate market access and clinical use.

Creating value from data

Real-world data undoubtedly has the potential to revolutionise clinical care, playing a growing role in selecting the right patients for trials, and providing information to payers to help ensure the right treatment reaches the right patient at the right price. Such data is also used to inform regulators and the clinical development progress, and help health systems optimise standards of care.

In addition to Flatiron, there are a number of notably advanced clinical data platforms such as Tempus and COTA. Tempus provides genomic and clinical data from cancer patients to doctors to enable them to personalise cancer treatments for patients. Like Flatiron, Tempus provides real-time insights and analytics free of charge or at a relatively low cost to physicians and patients in exchange for their data. The curated patient data is then monetised as a product itself. Roche's recent acquisition of Flatiron is a strong validator of this approach. However, the business model relies on the willingness of patients and physicians

Fig 1: Real World Data & AI platforms

Platform/Company	Description
CancerLinQ (ASCO/AstraZeneca)	ASCO-supported cancer patient database
COTA (private)	Real-world data platform using proprietary data on outcomes, therapy and currently accesses c.2mn US cancer patients[5]
Flatiron Health (Roche)	Oncology-specific RWD platform based on proprietary EMR data Currently accesses c.1.5m US cancer patients.
Precision Health AI (private)	AI-driven platform that extracts and synthesises data from EMRs of cancer patients to provide insights to industry
Tempus (private)	Real-world data integration platform using data from CancerLinQ. Currently has access to data from c.1/3rd of all US cancer patients[5]
Syapse (private)	Cancer-focused platform that integrates clinical and molecular data with health outcomes that can provide insights to providers and payers
Value of Evidence in the Real-wOrld (VERO) (Novartis)	A technology-enabled real-world platform that integrates data from a number of sources (eg IMS real-world data claims and EMRs); is currently being developed across a number of specific therapy areas including MS, retinal disease and heart failure

Source: Company data, Shore Capital

to share their data. In a tacit acknowledgement of the value of this trust, Roche emphasised its commitment to maintain Flatiron as an autonomous subsidiary, with access to data on a non-exclusive basis, even after the acquisition. It remains to be seen whether this commitment to non-exclusivity of patient data is sufficient to maintain an open relationship with doctors and patients or if ownership by a large pharma company could be a deterrent for oncologists and their patients.

Big data in health care – the time is coming

Big data analytics and its artificial intelligence-driven algorithms have permeated all manner of industries from finance to technology, some faster than others. Health care is one of the last sectors to realise its disruptive and transformative potential. The interest of big pharma in new sources of data, especially real-world data, could dramatically change both drug development and medical practice. Roche is a first-mover. Yet it is also somewhat of an exception because it already has in-house diagnostic expertise and access to proprietary datasets. For example, since 2014 Flatiron has been linking its data on patient outcomes to genetic data on the same patients' tumours obtained via Roche's majority-owned Foundation Medicine's tumour profiling tests. Flatiron has also benefited from Roche's strategic collaboration with the clinical-decision support and payer-focused real-world dataset of Syapse Inc.[4]

Health care is poised to be the next industry transformed by the power of big data though the timelines for this technology-driven healthcare revolution remain uncertain. What is clear is that there is significant value in extracting and consolidating clinical data from medical records in real time. Ultimately these real-world derived insights have the potential to transform drug development and improve patient outcomes.

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