Rethinking Big Data Will Lead to New Advances in Personalised Medicine

The life sciences industry has waited a long time for big data to transform the potential of personalised medicine. With AI and machine learning now coming of age, R&D teams can finally seize the opportunity – as long as their data is also clean, standardised, interoperable, and secure.

To understand a treatment's potential for a specific patient, biopharma companies have to layer together data from multiple disparate sources. Some of these data sources will be common to all disease areas: for example, patient demographics, electronic medical records, and quality-of-life scores. However, the majority (including genetic information, imaging, and activity data from wearable devices) will be unique to each individual. Since the clinical effectiveness and safety profile of a personalised treatment will be different from patient to patient, all relevant stakeholders must be able to trust the data to make medical and business decisions confidently.

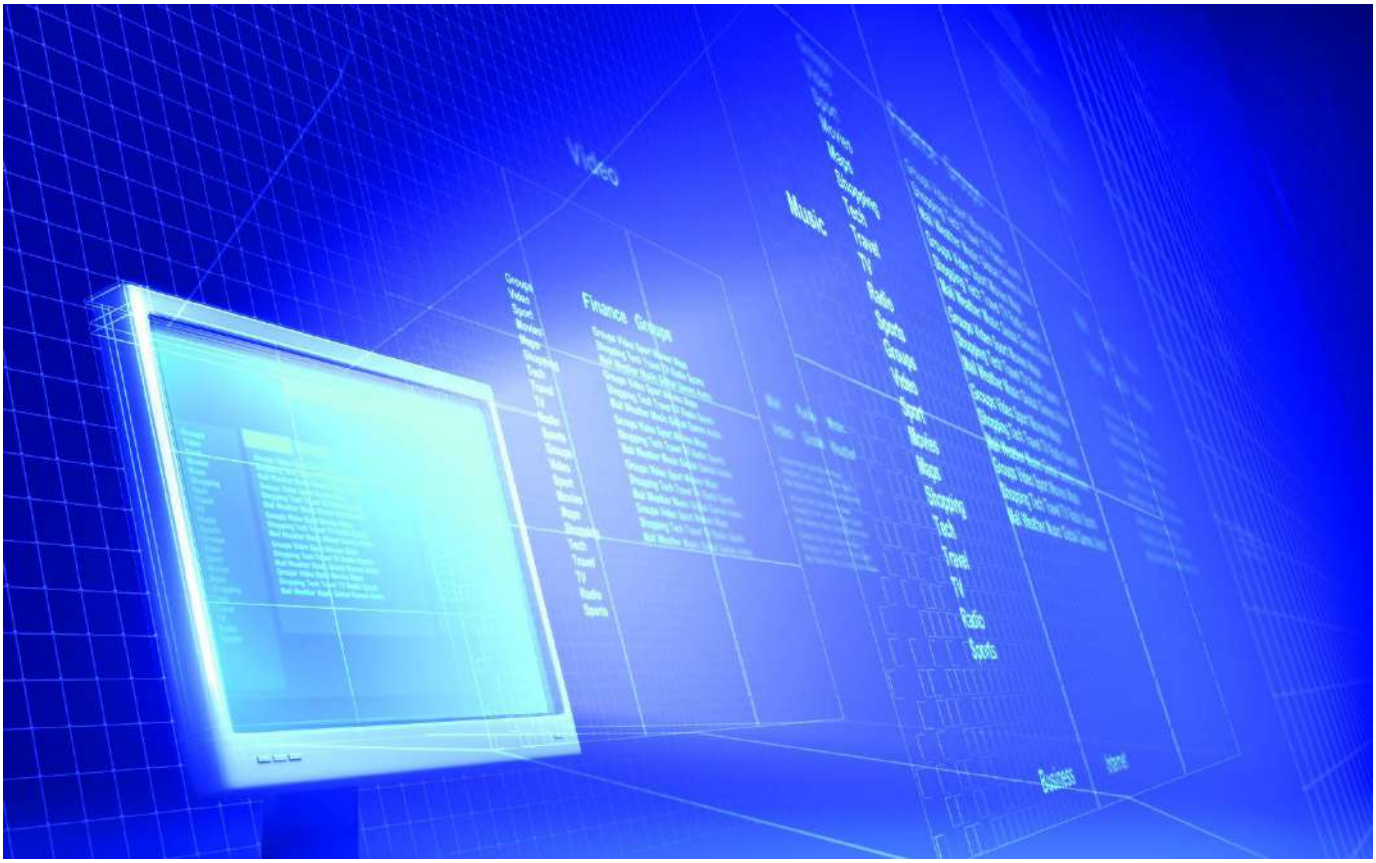
Reappraising the approach to quality, ownership, and interoperability will bring usable data to the core of their strategy, even when working with potentially millions of relevant data points. Leading biopharma companies are also rethinking their existing ways of working and systems to get to first-time-right submissions. With access to a clean data foundation, they can identify which functional areas are most critical to speed time to market so that patients aren't left waiting for innovative new treatments.

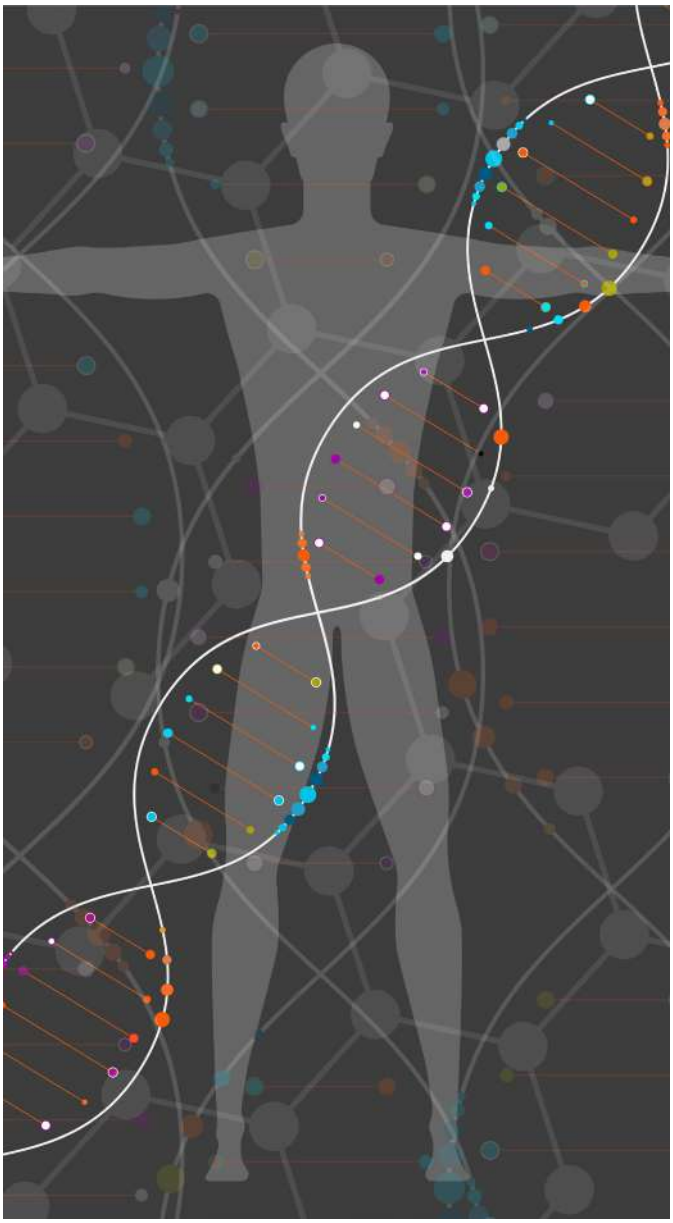
Accelerating Time to Patient

Historically, data collection initiatives have been broad in ambition and scope. These ranged from sequencing, imaging, and electronic health record data to text-based information such as interactions with health authorities and conference abstracts. The main objective was data completeness, and the scale of data points collected made it challenging to spot patterns or identify the most effective uses.

Today, the go-to-market and approval requirements of personalised treatments are more complex than anything seen before. As a result, biopharma companies seek to make appropriate use of their study data far sooner, which shifts the focus from data collection to governance and ownership. Gaining more control and oversight will change the dynamics in their relationships and contracts with third parties. Connected systems are becoming critical so relevant stakeholders can view the data at any time rather than waiting for data to be sent back in meta-data formats, or final text-based documents.

It is also becoming easier for sponsors to pinpoint the most impactful inefficiencies during the clinical development phase – vital to compressing time to market so that personalised medicines remain commercially viable. Analysing data on the cycle times between two critical clinical milestones could indicate whether inefficiencies and operational challenges typically arise during protocol design, site selection, initiation, or elsewhere. These insights can support the whole organisation to become more productive. A single source of accurate data can create competitive advantages by driving better decision-





making on patent filings or patient recruitment, or efficiency gains in outsourcing, procurement, or portfolio rationalisation.

Analytical and data science capabilities have improved but limitations remain. Raw data is not standardised and limited industry (or even intra-company) reference models exist. If common pain points around cleaning, ownership, and standards can be resolved, the volume and frequency of access to study data will increase. This will require a transparent data model with stringent user access controls to address privacy and cyber-security concerns.

Useful Big Data Requires Clean Data

Clarity of purpose is key when prioritising data initiatives. If the objective is to significantly reduce the time from 'first patient, first visit' to database lock, it's best to choose a group of experts before data is collected and cleaned to decide the approach and exact use cases. Data scientists, subject matter experts, and even external experts (e.g., HCPs, KOLs), could all help to make decisions and test hypotheses for improvements for this key clinical development milestone.

Many biopharma organisations have the right people and technology in place but struggle with effective governance. This may require collaboration between functions that have not worked together much, such as research and basic science, business, and IT/digital. Leadership commitment is a prerequisite for companies to start thinking this way. Management teams must test, learn, and further experiment with different working models before deciding which one best suits the company's culture.

Once cross-functional roles and responsibilities have been defined, people, processes, and technology must align to wider corporate goals, the agreed problem statements, and hypotheses. Agile resourcing is essential. An urgent drug safety issue, for example, could have immediate clinical (and downstream commercial) repercussions for a company unless the right experts come together to tackle the challenge. Clean data sets from a single source of truth are critical for statisticians, molecular biologists, chemists, medical experts/geneticists, and data scientists to work through to get the drug back on track.

Once the use cases for big data have been well defined and executed, we will see closer collaboration between teams within organisations all working toward a common goal. The result will be higher-quality documentation, reduced cycle times, and more right-first-time submissions. The growing impetus for direct data APIs with regulatory and health authorities (HAs), and potentially contract research organisations (CROs) and other third parties, could lead to more cooperation. The benefits of faster regulatory decisions will be felt directly by patients.

Smarter Data Use Throughout Drug Development

The costs and risks of developing personalised medicines challenge even the most efficient R&D functions. Now, we need a mindset shift to: "There are no big problems, there are just a lot of little problems." Pivoting to smarter data use will help companies break down the long and complex drug development journey, and pinpoint which 'little problem' to solve first.

When big data is clean, standardised, and interoperable, other exciting possibilities can be explored, such as finding novel biological targets or net new patient populations. Eventually, a centralised approach to data management could support the long-held ambition of connecting real-world data (such as patient data, electronic medical records, digital therapeutics, etc.,) to clinical development, so we can improve the patient experience.

These advances move us toward the shared goal of providing life-enhancing medicines to patients who need them.

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