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DATA DILEMMA

As new regulations come into action, having high quality management is pivotal when dealing with data

CONSIDERING MERGERS

Mergers and acquisitions are commonplace in the industry, and the benefits are more than just monetary

Realising International Data Access through Data Collaborations

Enabling access to real-world data on a global scale is daunting, but surmountable by applying a new collaboration model with innovative technologies for consolidation of data

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International clinical trials and the commercialisation of new precision medicines across global markets require access to real-world data (RWD). With access to RWD on a global scale, pharmaceutical companies are empowered to derive valuable insights that translate into more patients for clinical trials, faster time to market, and increased revenues in international markets.

The Big Picture

Implementing precision medicine correctly will improve patient outcomes globally. Realising, delivering, and administering precision medicine in an international context is made possible by a long, protracted process of data-driven research, development, commercialisation, and continued improvement. The key activities during this process include:

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- Finding and enrolling eligible patients into global precision medicine clinical studies
- Commercialising new precision medicines across global markets

To guide these key activities, one needs access to RWD as valuable insights can be gleaned from these data that lead to shorter patient enrolment cycles, successful entry into new global markets by matching patients to new precision medicine treatments, and, ultimately, improved patient outcomes.

In other words, to carry out these key activities, it is helpful to be able to access real-world data spanning all available types of data sources, including patient medical records, insurance records, genomics data, trial data, etc. Furthermore, to carry out these key activities on an international scale, one needs access to RWD spanning countries across the globe. This condition is foundational and, without it, the overall goal of realising, delivering, and administering precision medicine in an international context becomes unreachable. As gaining access to these data and leveraging their potential is a demanding undertaking, exploration of these challenges has presented a viable approach to reach the goal of realising international data access for the enabling of global precision medicine.

The Challenge

The global environment for real-world patient data is big and complex. Data sources include hospitals and hospital networks, clinics and primary care sites, and private and public institutions, each operating at a regional or national level. Given the economic, political, and cultural variability, as well as the sheer size of the playing field, it is not surprising that it is a difficult task to successfully consolidate all this data at a global level.

If one considers factors beyond these that are more specific and inherent to the application of real-world data to precision medicine, such as patient privacy and data security, then one already sees a plethora of factors that pose significant challenges. These challenges are to those who would like to leverage the potential of real-world data for international clinical trials and the commercialisation of new precision medicines across global markets.

Additionally, each country has its own set of regulations promulgated by its respective ministry of health that influence, among other things, patient privacy and data security requirements. One is confronted with diversity in languages, as well as the size of a country, its political stability, and its associated market potential, which play key roles in determining the priority and level of resources brought to bear in a country of interest.

Success in today's world is highly dependent on one's ability to deliver high quality products and services in a timely fashion. The primary product within the domain of precision medicine is information. There is a high demand for precise, complete, high-integrity information that can be provided on-demand. What is really needed is to provide just-in-time, up-to-date information for diverse needs in precision medicine.

It is important to state that raw data alone is insufficient support for making decisions on research, development, or marketing. The data must be collected, cleansed, structured, and analysed to distil or derive valuable evidence and insights from it. This generation of real-world evidence (RWE) from RWD adds a layer of complexity to our undertaking. Suppliers of RWD are typically not best placed to generate RWE as they generally do not possess the necessary analytical capability or expertise.

Furthermore, significantly greater value of RWE arises when one analyses RWD pulled together from many sources.

The challenge is to integrate or consolidate RWD and RWE from multiple and varied sources into a comprehensive and unified resource which facilitates quick and effective decision-making. A suitable approach to satisfy this demand in a timely and affordable manner is proposed:

The Approach

The proposed approach involves a networked, symbiotic ecosystem in which real-world patient data from data sources is brought together in real time on a live platform which allows queries simultaneously and interoperably across all sources, while preserving data security and patient privacy. The ecosystem is symbiotic in the sense that no single stakeholder is able to offer end-to-end RWE services and, therefore, the sustainable offering of RWE services requires a reciprocal and mutually beneficial relationship between contributing members.

The approach requires the establishment of a regulated, high-trust environment for it to be an ecosystem capable of sustainable growth. It is proposed that one should build in de-identification techniques, so that patient information is permitted to flow with very low risk to data privacy, as well as oversight, control mechanisms, and a general principle of transparency. A key concept of this model is that the output is RWE, in the form of information services, rather than RWD. The benefit of this is that the original data (already de-identified), is never 'seen' by the end-consumer, providing an additional layer of privacy protection.

The potential value of a dataset hinges on the insights it can deliver. Insights can accrue, exponentially,

RWD Suppliers	Sources of patient data who provide them for precision medicine evidence generation	Hospitals, clinics, patient registries, organisations managing insurance claims data, central laboratories, data aggregators, patients, medical device companies, wearables technology companies, etc
RWE Producers	Organisations that transform RWD to RWE	Organisations that transform RWD to RWE by assigning of codes from standardised medical terminologies such as ICD-10, ATC, LOINC, etc RWE analysis organisations applying technics such as Machine Learning, Natural Language Processing (NLP) to derive RWE from RWD, etc Data scientists
RWE Providers	Make the evidence produced efficiently and economically available for RWE consumers, including consolidating inputs from multiple and diverse RWD suppliers and RWE producers	RWE producers RWD solution and service Providers who implement RWE ecosystems for the delivery of RWE services CROs
RWE Consumers	Organisations running drug development	Pharmaceutical companies pursuing RWE, or market access of their newly approved products CROs
RWE Beneficiaries		• Patients • Healthcare professionals • Hospitals • Pharmaceutical companies • CROs

▲ **Table 1:** Stakeholders and examples of organisation types in a precision medicine value chain

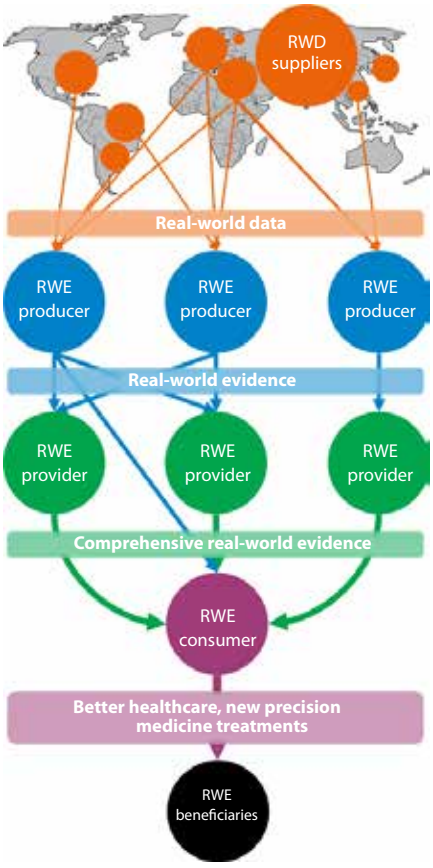
the more data is available. A key benefit of this approach is that the utility of such an integrated ecosystem increases with the participation of more data suppliers.

The Collaboration Model

The model posits an ecosystem which provides information services to support precision medicine needs. In this model, data suppliers may offer their data, data analysers may interrogate the data and derive meaningful insights, and medical professionals may access these useful insights and incorporate them into their work, generating medical advancements.

As many organisations have something of value to contribute, but are limited by their existing resources and professional relationships, such that they are usually not able to cover an end-to-end value chain that results in the delivery of an internationally available RWE information service, then a network of symbiotic relationships/ partnerships is an appropriate mode of cooperation to leverage the potential of the vast array of contributors to a precision medicine value chain.

Stakeholder roles are illustrated in the following diagram:



▲ **Figure 1:** Diagram of a collaboration model for RWE from many RWD sources, showing the relationship between stakeholders

As shown in Figure 1, the RWE Consumer can acquire RWE from many sources, directly from RWD suppliers or consolidated RWE by one or more RWE providers.

RWD ecosystem architecture	Distributed system architecture
RWD ecosystem trust centre	De-identification techniques Regulating data access with approval and tracking mechanisms
Preparing RWD for international use	Translating medical terminologies into English, including: diagnoses, medications, procedures, lab tests Mapping local medical terminologies to international medical terminologies
Preparing ecosystem for international use	Translation of user interface into local language
Ensuring high performance	Data indexing Parallel processing Local data processing across a federated ecosystem

▲ **Table 2:** Technology considerations to be made

The former requires the RWE consumer to interact with many RWD suppliers and to develop algorithms of their own to render the RWE mutually relevant. The latter puts the onus on the RWE provider to perform the consolidation of RWE from many RWE producers, and simplifies the procurement processes of the RWE consumer. This also gives scale and speed to the services offered to the RWE consumer.

In this model, it is proposed that the RWD ecosystem is implemented on a technology platform that is run by a RWE provider, as that allows the RWE consumer a single point-of-contact with the rest of the ecosystem that also comprises analytical RWE based on data sources provided by many RWD suppliers. It is then the responsibility of the RWE provider to aggregate data from as much of the data available overall as possible.

The Technologies

What information technologies are necessary to make this RWD/RWE ecosystem possible and to support precision medicine needs? A technology platform that enables the following is suggested:

- Sourcing and standardising of any type of medical RWD
- Building and execution of complex queries on all RWD in the ecosystem
- Application of data analysis techniques on all RWD in the ecosystem
- User to act on actionable RWE

For the technology platform to enable these capabilities on a global scale a number of preparations and technology considerations have to be made (see Table 2).

Constructing the Future Model

Although an enormous task, the proposed approach enables small, but important, contributions to the achievement of the strategic goal of accelerating drug development, and, thereby, bringing medical innovation to patients and physicians more swiftly. Advantages include the use of much existing data that hitherto were not available internationally and, hence, could not be leveraged, the simplification of drug development processes, and the ability to work on up-to-date data – all of which contributes to enabling precision medicine for patients and improving patient outcomes.

“The RWE Consumer can acquire RWE from many sources, directly from RWD suppliers or consolidated RWE by one or more RWE providers”

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