White Paper

Enriching Evidence Generation in Healthcare

Generating superior insights by integrating disparate data

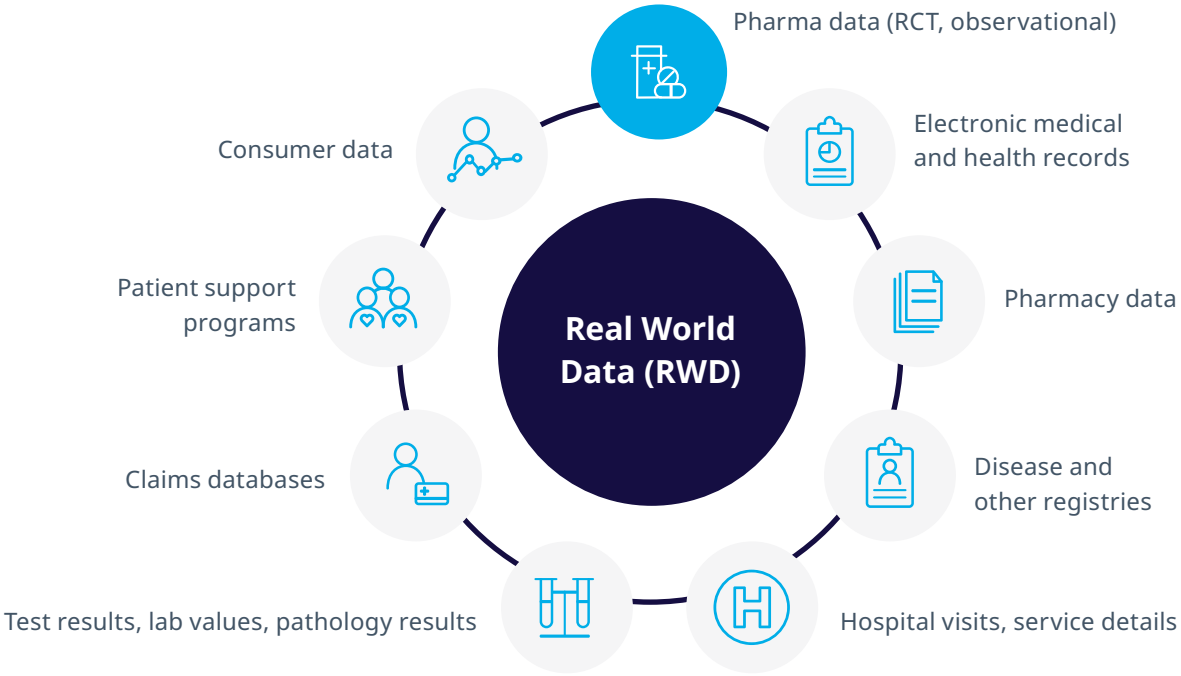
The upsurge of available healthcare data has created unique opportunities and challenges for life sciences companies. In this white paper, we highlight how the industry is gravitating towards integrating disparate data sources to generate superior evidence and insights not achievable through a single data source. Given appropriate emphasis on data privacy and protection, this methodology can be an efficient and economic approach to support decision making.

The availability of data within the healthcare industry has grown exponentially over the last decade, but much of these data are independently collected, not necessarily for evidence generation, and may only be reflective of distinct phases along the patient journey[1]. Organizations are therefore moving towards integrating data from various sources to answer the diverse questions posed throughout a product's life cycle. With the shift towards value-based care, life sciences companies have to increasingly illustrate a comprehensive picture of the health economics for novel therapies, as well as how therapies influence patient-centric outcomes[2].

The expansion of settings (e.g., urgent care centres) and channels (e.g., telehealth) for healthcare delivery also compels the need for comprehensive approaches to understand the broader patient journey and healthcare utilization. These shifts have highlighted the significance and untapped potential of real-world data (RWD), which captures information far beyond that of clinical trial data and with greater external validity[3]. However, the harmonization of various RWD sources are typically accompanied with challenges involving data access, linkage, as well as a lack of standardized methodological approaches[4].

In efforts to drive a unified foundation for the use of health data for innovation, policy-making, and regulatory activities, the EU established the European Health Data Space[5], where access to health data can be accomplished across member states with interoperability and privacy top of mind. The US Department of Health and Human Services also recently launched TEFCA[6], the Trusted Exchange Framework and Common Agreement, which is a system that allows nationwide interoperability of individuals' health information. While a similar system of fluid data sharing has not yet been established in Canada, integration of data can still be accomplished in an ad hoc manner. In Canada, RWD are widely available and can be integrated under the right circumstances[7]. These data can come from various sources such as patient registries, claims, electronic medical records (EMRs), and health administrative data, among many others.

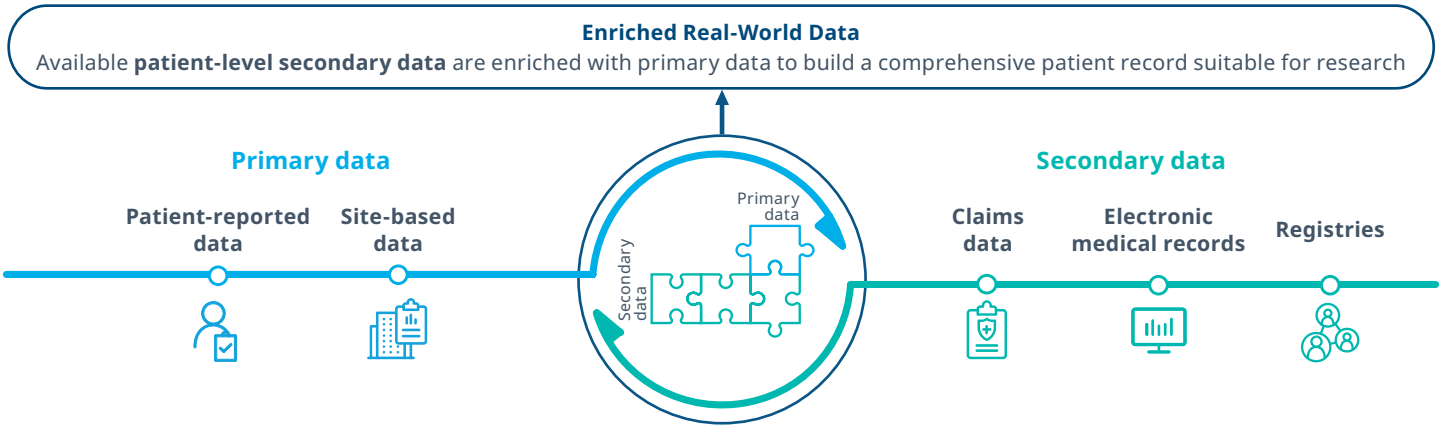
Multiple data sources can be integrated to gain comprehensive insights



Augmenting real-world data to inform regulatory decision making

Health Canada[8], along with the US FDA[9] and EMA[10], have provided frameworks for the systematic integration of RWD to support regulatory decision making. The use of RWD gained traction due in part to a desire to adopt data that are representative of the implementation setting, especially in areas where traditional randomized clinical trials may not always be feasible.

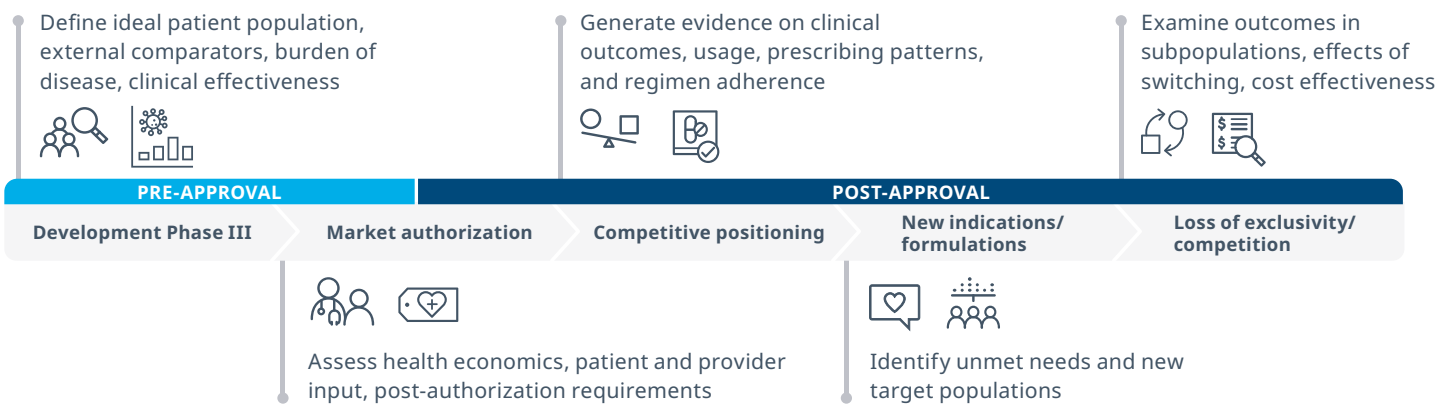
For example, medical records can be retrospectively used to create matched populations in single-arm interventional trials, which are commonly done in rare diseases and oncology[11,12]. Many COVID-19 vaccines also used RWD[13], which included matched cohorts and ultimately supported their receipt of full regulatory approvals. As the use of RWD is increasingly accepted by regulatory bodies, there is extensive potential in utilizing varied data sources to generate evidence for regulatory submissions. For example, administrative health data can be linked with disease registries to study the safety and outcomes for products that have recently entered the market[14].



Growing considerations for patient and economic outcomes in coverage decisions

As payer resources are limited, providing access to effective health interventions must be balanced with their costs. For example, to comprehensively understand the burden of disease, a study that links data from specialty clinic EMRs with administrative health data can be performed. This design can summarize patients' interactions with the healthcare system, from the first diagnosis-related visit through years of follow up. Analyses can include understanding patient characteristics, specialty physician interactions, treatments received, direct costs, and healthcare resource utilization. This information provides valuable inputs to health economics models used in reimbursement decision making. Furthermore, prescription claims data can be supplemented with primary data to determine whether an intervention helps to maximize time at school or work, or even decrease the burden on caregivers.

Various other evidence needs can be fulfilled by integrating disparate data sources



At IQVIA, "enriched studies" use methodologies that overcome the lack of consolidated data and allow more research questions to be addressed in a single study[15]. Canada is well positioned for the integration of health data due to the substantial role played by publicly funded healthcare; however current organization of the healthcare landscape paired with evolving privacy laws complicates efforts to consolidate the available data[7].

To overcome the lack of seamless information exchange across the healthcare industry, efforts are channeled into coordinating with individual agencies to link and enrich various data sources[16]. The ability to access provincial or national-level RWD data in Canada and securely use them with other data sources is fundamental to conducting these studies, for which IQVIA RWS has developed extensive capabilities and workflows. Utilizing appropriate methods to integrate the disparate nature of various data sources can therefore overcome the organizational limitations of RWD in Canada and generate augmented insights that help to resolve nuanced research questions.

Visit our website at **www.iqvia.com/canada/rws** to read more about enriched studies.

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