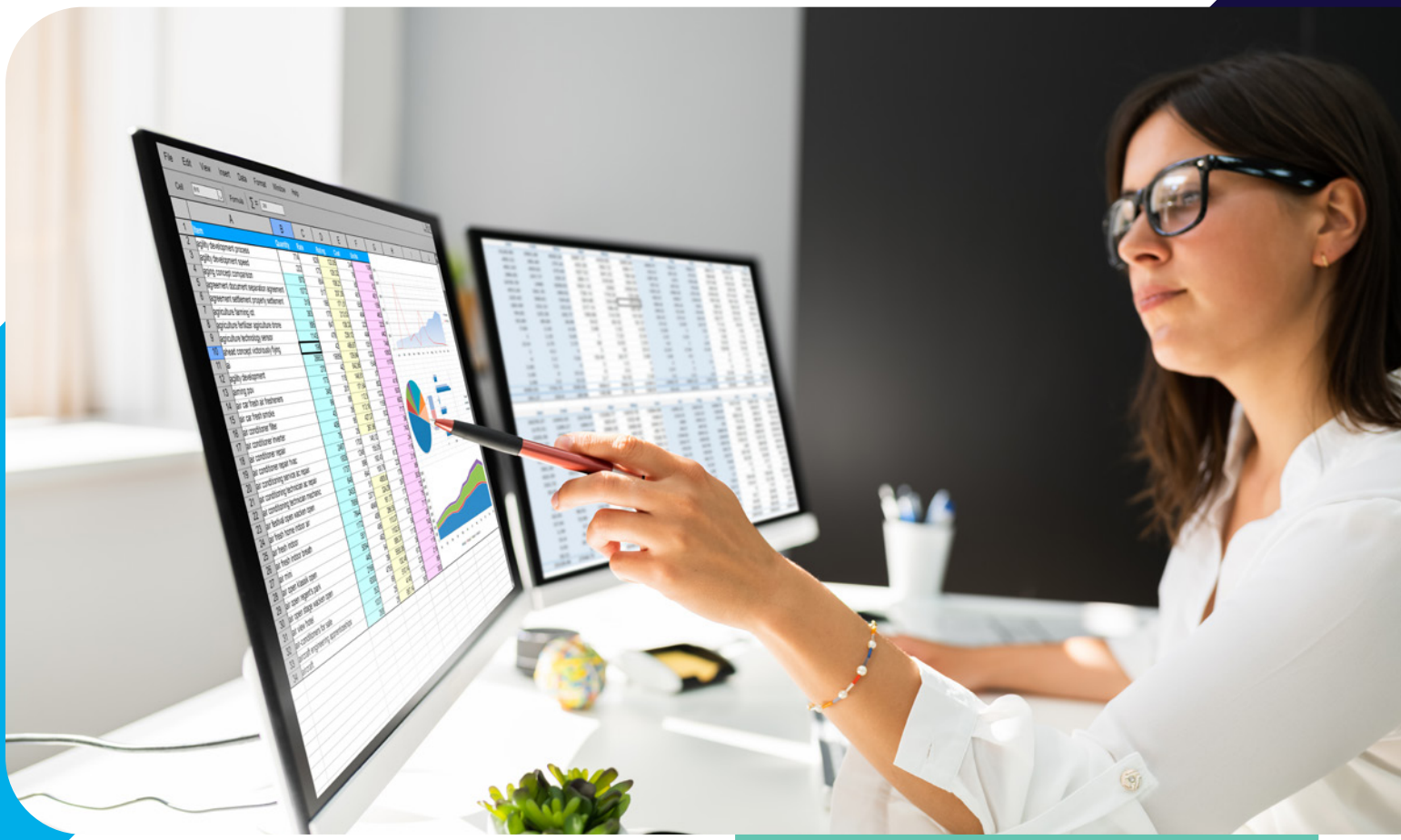
White Paper

Real World Evidence in Canada: Are pharmaceutical innovators ready for success in the evolving landscape?

Results from IQVIA's inaugural real-world evidence benchmarking survey



Real-world evidence in Canada

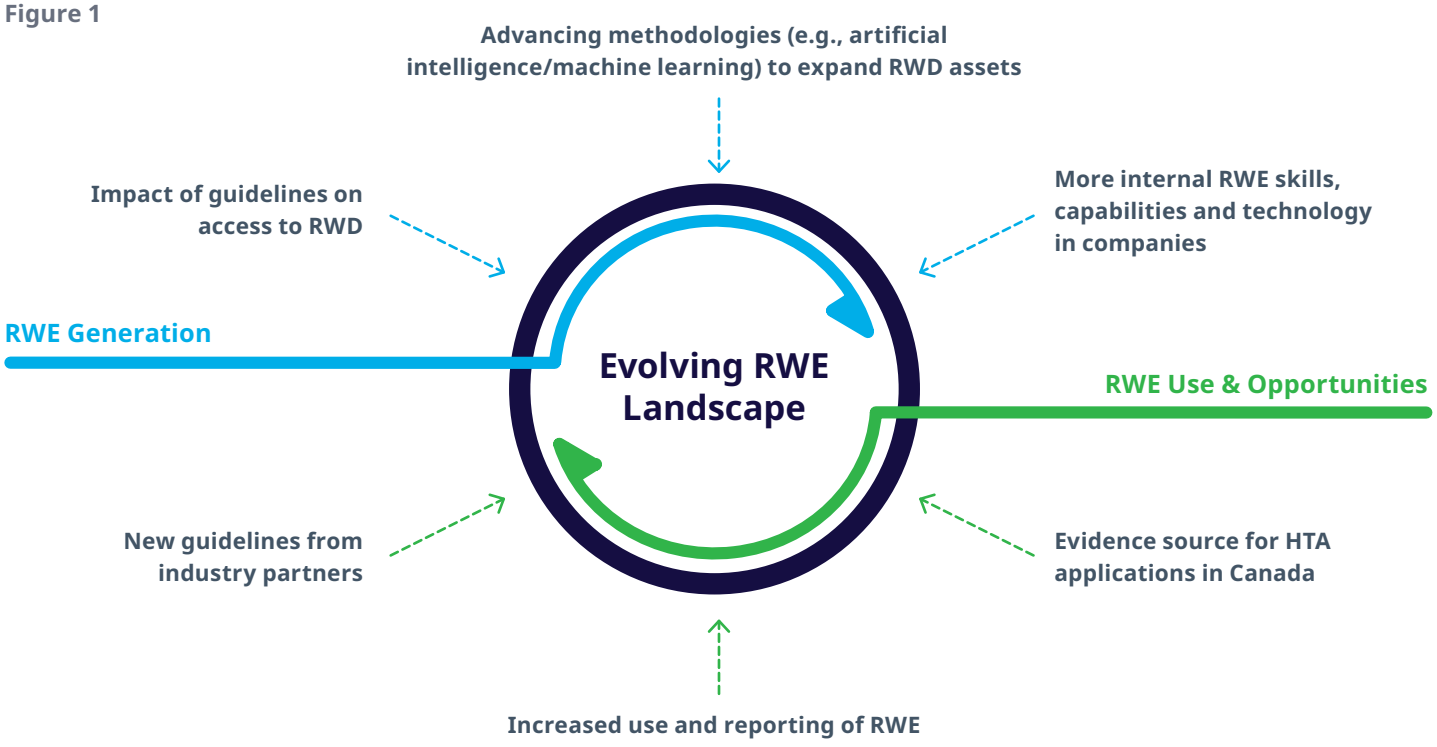
Real-world evidence as an approach to assessing the impact, efficacy, and safety of pharmaceuticals is rapidly growing in importance globally.[1,2] Recently, in Canada, there has been an increasing demand for RWE to play a role in decision making.[3] This is, in part, due to improved perspectives of stakeholders on the usefulness and benefits of RWE, in particular the ability to address gaps in evidence from clinical trials.

These changes are driving the growth of RWE for market access strategies and, increasingly, for regulatory and clinical decision making.[2,4] Common sources of real-world data (RWD) include administrative and claims datasets. However, the breadth of available data is growing with new and innovative methodologies that can leverage large, deep, and complex data sources such as electronic medical records (EMRs) including unstructured clinical notes, biomarkers, lab data, wearables, and digital biomarkers.

Historically, there has been a lack of regulation governing the reporting and use of RWE in Canada resulting in different quality and standards. An integral part of robust RWE studies is generalizability.[5] However, the complexity of our healthcare environment, with multiple provincial and national agencies involved in data collection and management processes, makes this difficult to achieve. Recently, the landscape is evolving, with organizations such as the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Pharmaceutical Advertising Advisory Board (PAAB) working to publish guidelines on the use of RWE in the pharmaceutical space.[3,6]

These guidelines, in combination with innovative data and methodologies, will create expanded opportunities for the use of RWE in the development and commercialization of pharmaceuticals. Guidelines will also increase the standards to which companies must adhere to collect, analyze, and interpret these data to ensure high quality, decision grade evidence is generated. Though these standards will have a positive impact on the use of RWE more broadly, it may challenge the cost-effectiveness of RWE because of stricter requirements for studies which must be considered by companies in their strategic plans.

Figure 1



With a view to better understanding the current environment, IQVIA Canada's Real World Solutions team asked RWE leaders across the spectrum of innovators in Canada about how prepared they are to capture the strategic value of RWE. The main findings from the survey highlight significant gaps between current best practices and the future demands of regulatory bodies and other stakeholders. The survey found that most companies recognize the value proposition of RWE and utilize traditional RWD and methodology for their market access strategies but face both institutional and external barriers which limit the RWE they generate and how they use it in practice.

This paper will present each of the identified gaps in further detail with a discussion of their impact and approaches to address these gaps.

IQVIA's inaugural RWE benchmarking survey was representative of the Canadian pharmaceutical landscape

The purpose of this study was to understand the current landscape of real-world evidence generation at Canadian pharmaceutical companies. Our aim was to explore the development of corporate and brand strategies, organizational readiness in terms of capabilities, and the resources needed to address the evolving environment. The survey included 30 questions across five key thematic areas: company-wide and brand-level RWE strategies, RWE capabilities, and current and future RWE use.

Survey invitations were sent during Q2 2023 to approximately 200 employees working in functional areas that utilize RWE at emerging biopharma (EBP), mid- and large-size companies with operational units in Canada. After 12 weeks, the survey had an overall response rate of 17% with 33 respondents from 24 different pharmaceutical companies. Most (85%) respondents were at a manager level or above and work in Medical Affairs (45%), Market Access (27%), or HEOR (12%).

Companies developed brand-specific RWE strategies more often than company-wide strategies, but it is still critical to have overarching RWE objectives

Only 64% of brands had a brand-level strategy and most of these were not regularly updated. Brand-specific RWE strategies are essential to ensuring that companies are generating the 'local' evidence needed to support the market access strategy for their product.

Company-wide strategies were less common than brand-level strategies. Only 48% of respondents had a company-wide RWE strategy and just 69% of those said those strategies were updated regularly. Only 40% of respondents said their company kept up to date with new guidelines on the appropriate use of RWE. None of the EBP companies surveyed had a brand-level RWE strategy. It is important for companies to have an overarching strategy for RWE to harmonize studies and evidence generation needs across countries, and to identify any gaps in evidence that need to be filled through further RWE studies. Similar study designs and approaches can also be leveraged across brands. Companies should also have plans to continuously develop their internal capabilities and experience with RWD/RWE so that they can conduct robust studies aligned with future guidelines.

Figure 2

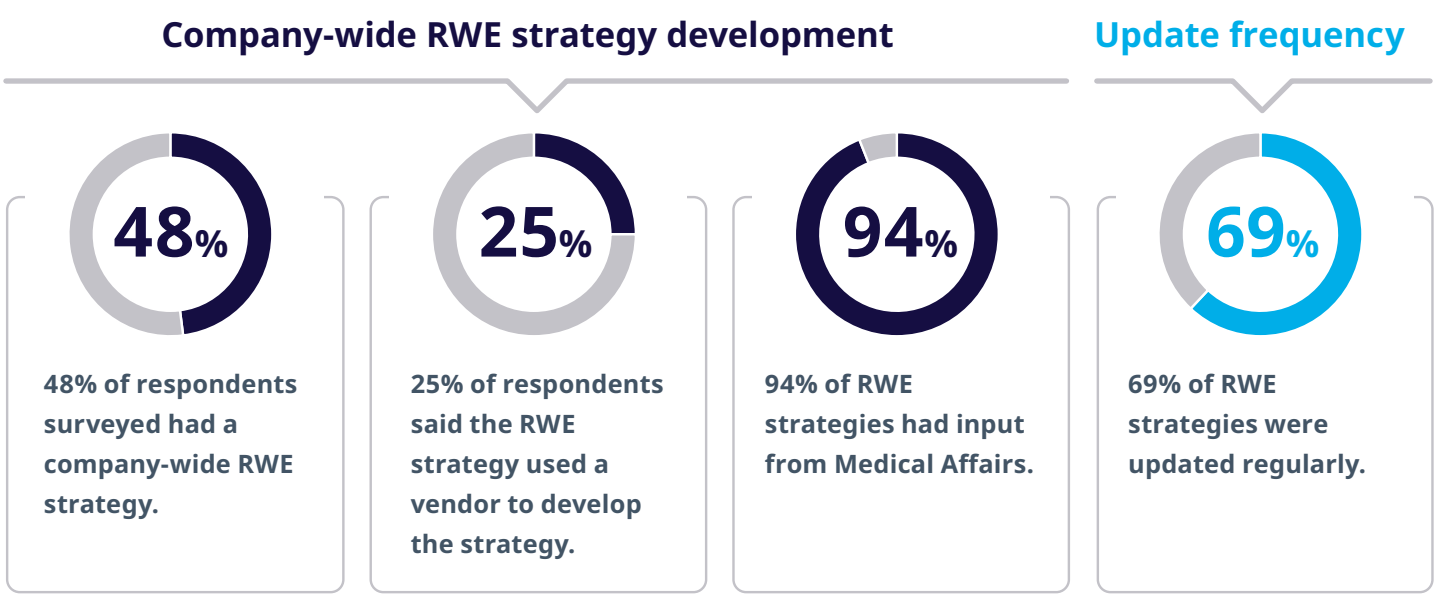
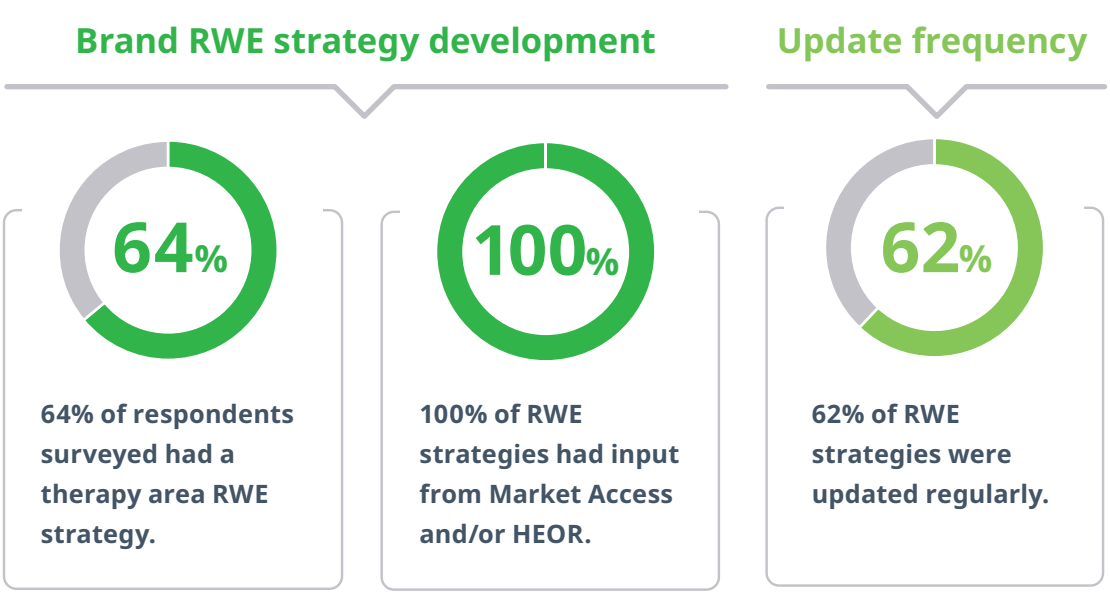


Figure 3



Many brands developed their RWE strategy too late in the product life cycle which can limit the impact of the evidence

At the brand-level, respondents acknowledged the importance of RWE to their overall strategy. However, despite this, many brands developed their plans late (after the Phase III study) in the product development cycle. Large companies were more likely to proactively develop strategies during or prior to the conduct of Phase III studies, but many mid-size companies developed their RWE strategies during the product regulatory or payer submission stages, or in some cases at- or post-launch.

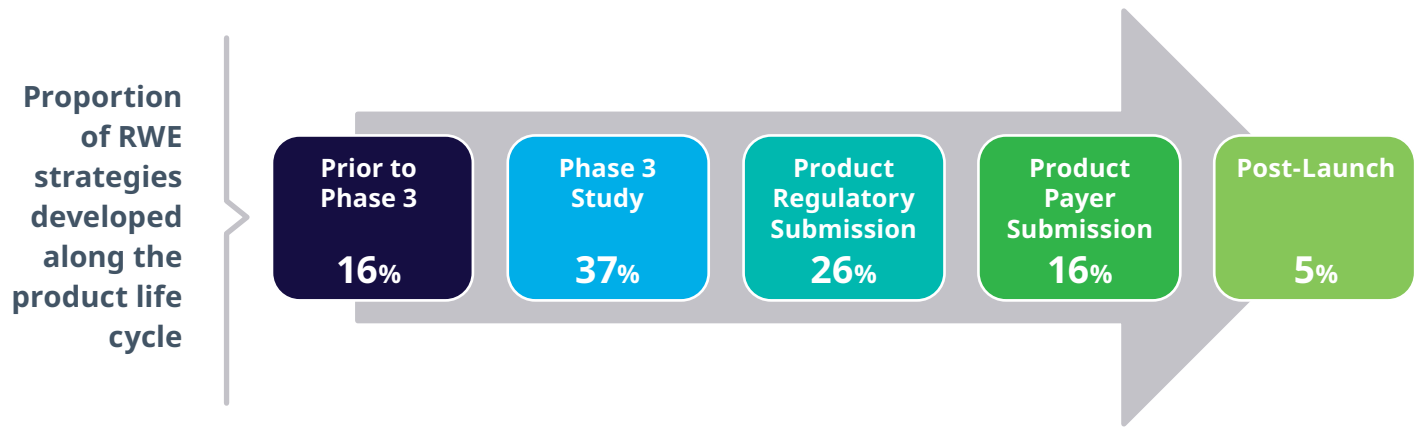
The best practice for brands is to plan for RWE requirements early, ideally prior to conducting Phase III studies, and to include all cross-functional partners in the planning. Deadlines for market access submissions are strict and delays to planning and executing studies can lead to sub-optimal RWE generation due to budget, timeline, or availability constraints. Delays can also limit companies from effectively utilizing the full scope of RWD sources, since some studies can take up to 18 months to complete.

It is essential that RWE strategies are developed early so that evidence required to support the market access strategy and payer submissions can be effectively generated and can address the evidence gaps from clinical trials for decision-making by clinicians and patients.

During Phase III studies, where local resources are typically limited to Medical Affairs, it is essential that these resources work with their global medical, access, and evidence generation teams to ensure Canadian representation in global RWE strategy.

Local RWE plans should be developed as soon as the local cross-functional commercialization team is in place.

Figure 4



RWE in Canada relies on traditional sources of RWD with a slower uptake of more innovative methodologies

Most respondents used RWE for payer submissions and medical communications. While the use of RWE is well established in life sciences, it has generally been limited to specific applications in Canada. This is due, in part, to variability in the underlying data as well as the methodologies used for analysis. Upcoming industry guidelines from CADTH and PAAB on the use of RWD/RWE will support more transparent and consistent reporting which may expand the use of RWE for regulatory and commercial purposes.[3,6] Guidelines will also put the onus on pharmaceutical companies to conduct high-quality RWE studies that meet these new standards.

Despite the evolving landscape of RWE use in Canada, many survey respondents suggested that using RWE to support payer submissions and medical communications will continue to be the primary uses of RWE in the future. Companies need to remain forward-thinking and plan for expanded use of RWE to ensure early approvals and quick access of new medications to the patients that companies are trying to serve.

RWE is often generated by companies using traditional RWD sources (such as provincial and national administrative data and pharmaceutical claims datasets) despite the breadth of available RWD. Data from patient support programs, with clinical data from electronic health records (EHRs) or registries was used less frequently. Adoption of innovative RWD/RWE sources and methodologies such as natural language processing, mobile phone health application data, and social media data has been slow and was not often used.

Most companies were also using traditional study methodologies, including retrospective chart and database reviews. Few companies had expanded their RWE capabilities to leverage innovative methodologies such as artificial intelligence and machine learning (AI/ML). These technologies have widened the scope of possibilities for RWE because they can be used to process large, complex, raw data sources, which has been described previously by IQVIA.[7] Innovative methodologies can also support the generation of evidence for rare or complex diseases which have a greater onus on data collection that may not be feasible through traditional methodologies.[8] Companies will need to have a dynamic and strategic approach to RWE generation, including the use of newer data sources and methodologies, to effectively leverage this evidence for their commercial requirements.

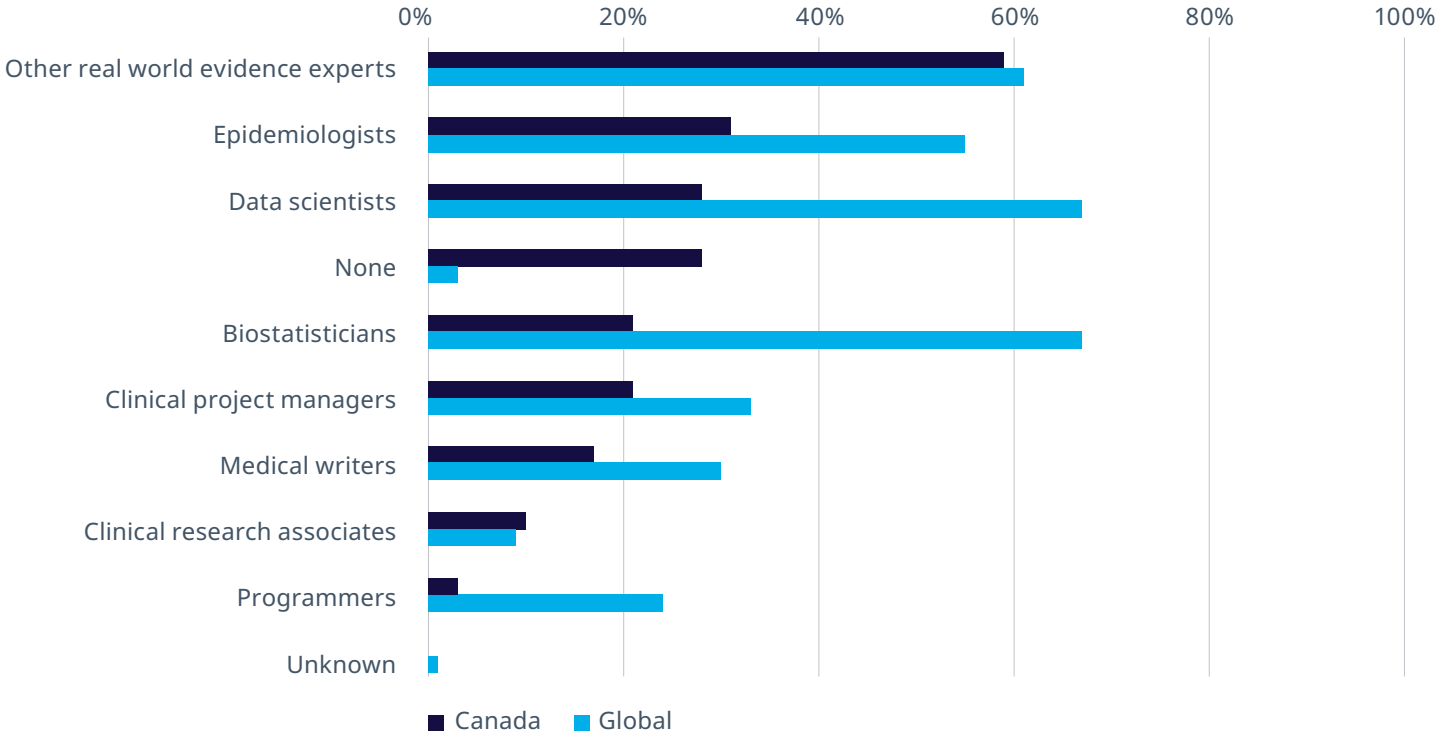
Most companies did not have the full range of RWE capabilities essential to undertake studies

Only half of the companies surveyed had some RWE resources for studies in Canada, either locally or globally, but most lacked the full range of specific skill sets required to conduct these types of studies (epidemiologists, data scientists, biostatisticians, medical writers). RWE strategies and project execution were said to be a joint effort between corporate Market Access, Medical Affairs, and specialized RWE teams (where available). Most companies always or often relied on external partners to access, collect, or manage RWD. Some larger companies played more active roles in other aspects of RWE studies such as protocol development, biostatistics, and scientific communication.

Companies should continuously invest in RWE skills and capabilities. The future CADTH and PAAB guidelines will allow for broader use of RWE but the standards to which the studies must be executed will be higher. This may impact the cost-effectiveness of RWE if companies must make substantial upgrades to internal skills and capabilities to conduct studies to the degree required by these agencies. Continuously investing in RWE will facilitate a smoother transition to – and faster uptake of – different RWD and study types to fully maximize the use of this evidence source. Internal RWE skills and capabilities can also support evidence generation initiatives because of a deep understanding of how RWE can meet their company or product needs, as well as by establishing relationships with expert RWE vendors that can support those goals.

Though most companies involved Market Access, HEOR, Medical Affairs, and specialized RWE units in their RWE strategies and generation, very few companies included wider cross-functional partners in strategy development. Cross-functional input is critical to ensure the evidence generated will meet the objectives of the market access strategy and the specific demands for RWE in the Canadian context.

Figure 5 Capabilities for RWE in Canada (N = 29) and globally (N = 33):



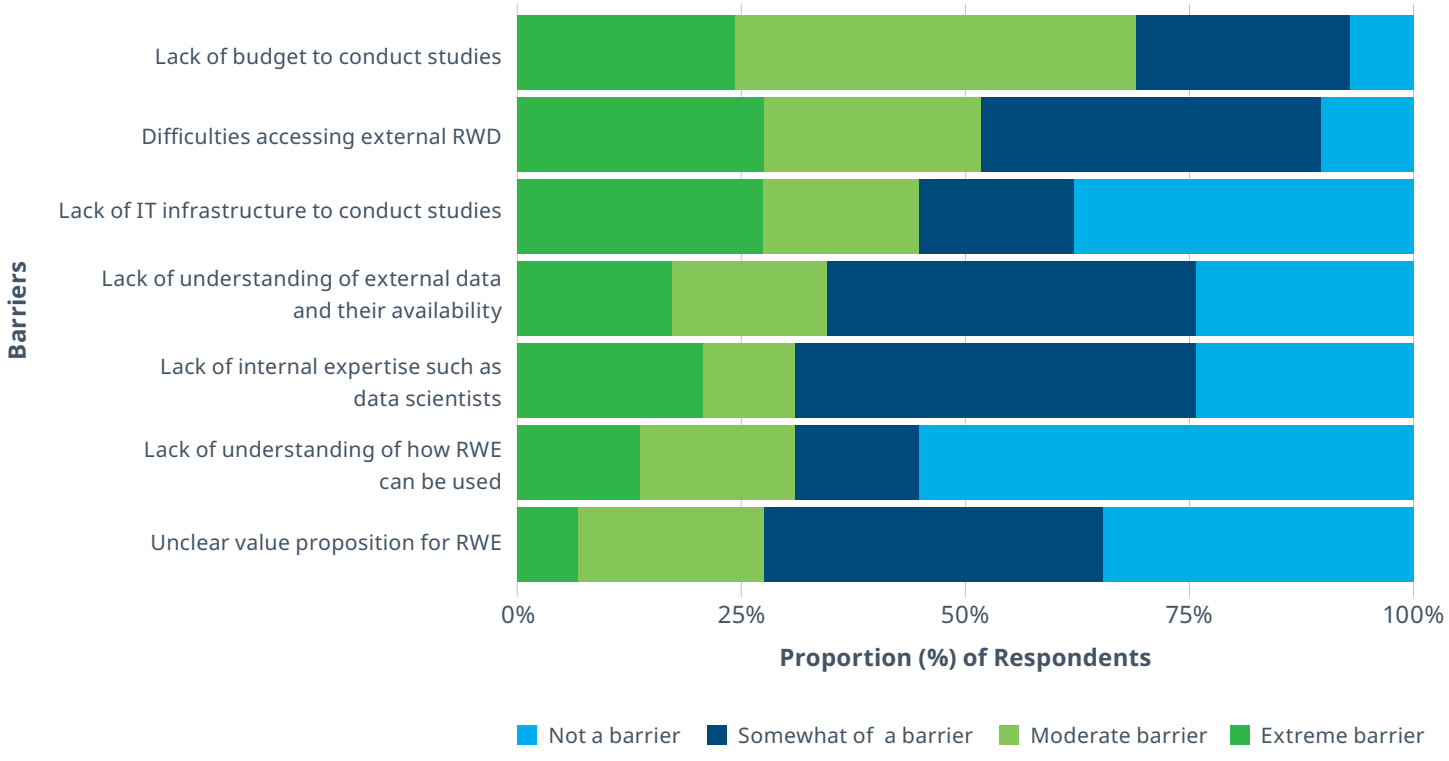
Companies face many barriers to generating RWE in the current research landscape which will become more complex as guidelines are released and emphasis on RWE increases

Companies understood the value proposition of RWE but identified the main challenges to conducting RWE studies as being budget constraints and limited resources/experience to engage with the external research environment. Respondents also cited difficulties accessing external RWD, and that administrative burdens and unclear rules and regulations are barriers to conducting studies.

Budget constraints were seen by respondents as a key challenge in fulfilling RWE plans. As the industry landscape evolves to incorporate more RWE, companies will need to plan earlier to ensure sufficient budget is assigned to their evidence generation needs. This finding further underpins the need for strategic RWE plans to be developed early in the product lifecycle to ensure the best evidence can be generated within defined timelines and budgets. Companies should work from their global plans and budget to ensure that studies are aligned across countries to create synergies in evidence generation needs and ensure that any evidence gaps are planned for in future studies.

Other key challenges for fulfilling RWE strategic plans included difficulty accessing RWD and a lack of technological infrastructure and experience to support studies. Outsourcing RWE needs, particularly around data access, to partners with this expertise is a best practice and can support companies in meeting their RWE generation goals. RWE is a complex area that is quickly evolving and leveraging experts in the field can ensure that timelines and expectations are met, the highest quality data is generated, and that studies adhere to industry standards.

Figure 6 Proportion of barriers to generating RWE among Canadian pharmaceutical companies (N=29)



Conclusions

RWE is growing in importance and its value is widely accepted across Canada and globally to support healthcare decision making. Companies need to develop RWE strategies to meet this evolving landscape and invest in the resources (human and technological) required to support the generation of RWE. RWE should be built into strategic thinking and operations within companies to support decision making. Focusing on growing internal capabilities and skill sets will allow companies to leverage RWE not only for market access initiatives, but also to support healthcare implementation and the patient therapeutic experience. The future of RWE is evolving and, for companies to benefit, they need to be planning early, investing in resources, using advanced approaches to RWE, and working with experts in the field.

The results of the survey can be found online at **https://www.iqvia.com/canada/rwebenchmarksurvey**

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