# RWE for Providers

MEDLIOR™
HEALTH OUTCOMES RESEARCH

## Key Messages

- Real World Evidence (RWE) is derived from real world sources such as insurance claims databases, patient registries, electronic medical records, and administrative data.
- RWE may enhance patient-provider decision-making and, ultimately, improve patient care and health outcomes.
- Clinical advisors are essential to RWE research, including consultation on the objectives, interpretation and dissemination of findings.

## Introduction

Real World Evidence (RWE) is evidence that has been obtained from the analysis of real-world data (RWD).[1] RWD are data that have been obtained outside of a conventional randomized controlled trial (RCT) setting and include prospective observational studies, retrospective studies, and observational registries, such as insurance claims databases, patient registries, electronic medical records, and administrative data.[2] With increasing attention being paid to translational bench-to-bedside research, insights gathered from RWE studies represent a logical complement to RCT evidence and offer numerous benefits to decision-makers, providers, and, of course, patients. This paper explores the collaborative role of clinical advisors (e.g., healthcare providers) in RWE studies.

## What can RWE do?

While RCTs are essential for establishing the efficacy and safety of treatments, robust RWE studies can provide information on real-world safety, effectiveness, and utilization of specific treatments, as well as patient outcomes.[3] Because RWE studies utilize health system data with diverse demographics of patients, many of whom have complications and/or comorbidities, RWE studies provide a more representative picture of patient outcomes in a routine clinical setting. As a result, RWE can be used to fill gaps in research that are often difficult or unfeasible to address with an RCT. Additionally, RWE can guide research initiatives that are meaningful to everyday health care practice. Both of these attributes of RWE can contribute to improving the care of individual patients.

Although research involving RWD has been gaining momentum in recent years, it is important to note that there are limitations to how the data can be used, particularly in Canada, where data are not captured in a standardized manner across jurisdictions. However, efforts to create research data infrastructure that can support multi-province RWE studies are currently underway,[4,5] and the number and quality of RWD sources in Canada is continuously increasing.

## The Clinical Advisor Role

A well-designed RWE study requires a methodologically rigorous approach and typically involves a collaboration between biostatisticians, epidemiologists, and clinical experts. Healthcare provider involvement and partnership in RWE research is recommended by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the International Society for Pharmacoepidemiology (IPSE) Special Task Force on RWE in healthcare decision-making. The task force specifically recommends physician involvement in study design, choice of clinically meaningful outcome measures, and dissemination strategies.[1]

The role of the clinical advisor in an RWE research study would center around providing clinical expertise and validating assumptions, processes, and clinical decisions. Figure 1 demonstrates a high-level flow of work in RWE research projects and the key areas where clinical advisor input is needed. For example, in the early discovery and development stages of the project, clinical advisors could help to formulate research questions that are most relevant to routine clinical practice. Afterwards, the ethics application process and data analysis stages would be completed by the research team with expertise in epidemiology, advanced biostatistics, and data linkage. After the data analysis stage is completed, clinical advisors could provide meaningful and accurate interpretation of the results and the clinical significance of the research findings.

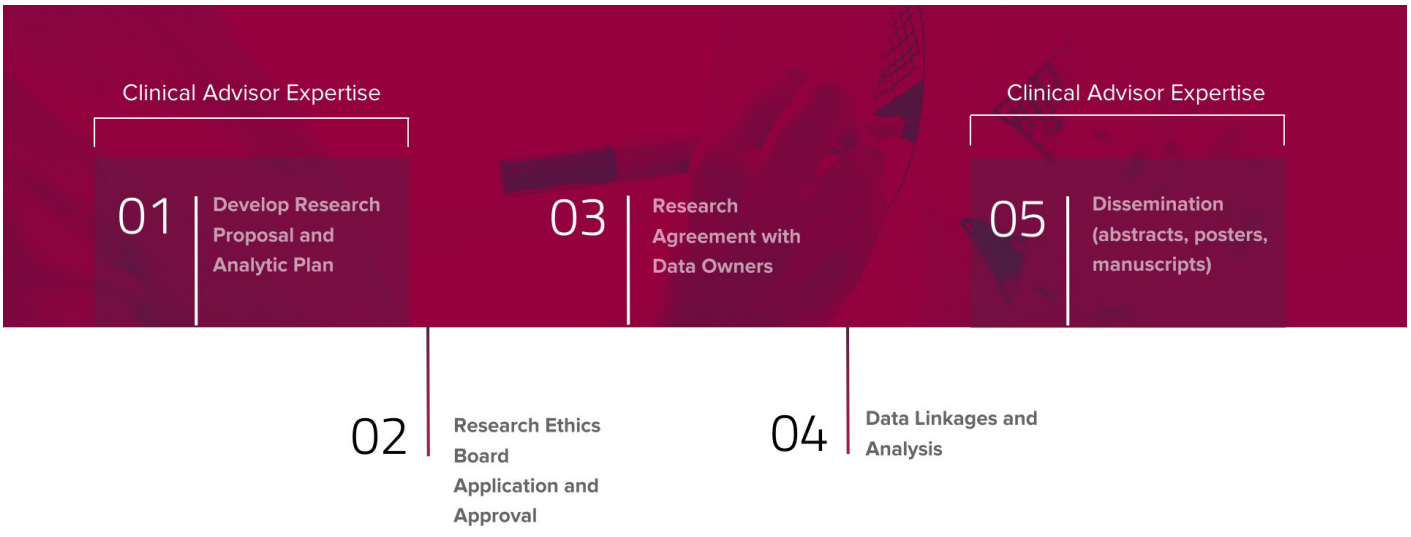


Figure 1: The RWE Research Process

## Medlior RWE Research

Medlior recently published the results of an RWE study that examined patterns of disease modifying therapy (DMT) use among patients with multiple sclerosis (MS) in Alberta.[6] The study linked six sources of administrative data from the Alberta provincial health system and included 2,864 patients diagnosed with MS. The study found that patients taking oral or infusion DMT (as opposed to an injectable DMT) were more likely to adhere to their treatment regimen. Furthermore, medication adherence was found to be associated with a significantly reduced utilization of health services, including fewer ambulatory care visits, physician claims, and hospitalizations. These findings on DMT use in MS were previously unknown and could inform treatment decisions for patients with MS in Canada.

The Medlior team values the expertise provided by our partnerships with clinical advisors on our RWE research studies. Medlior also supports clinical and academic research initiatives with expertise that includes but is not limited to: grant/funding preparation, medical writing support, data management (data cleaning/linkage), complex statistical analysis, and interpretation of findings.

## Conclusions

Effective decision-making in healthcare relies on a combination of good procedural practices, as well as methodologically-sound science and appropriate interpretation of evidence.[1] As such, involving healthcare providers as clinical advisors in the design and interpretation of RWE studies is essential.

## References

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