

DATA QUALITY CONSIDERATIONS WHEN COLLECTING REAL-WORLD DATA WITHIN A PATIENT SUPPORT PROGRAM

Obtaining high-quality real-world data (RWD) has been identified as critical by Canadian HTA and regulatory bodies when assessing real-world evidence (RWE) for healthcare decision making.

As noted in the CADTH [Guidance for Reporting Real-World Evidence](#)¹, “... the generation of RWE requires many complex decisions and can vary largely in quality, thus, reaching appropriate conclusions from RWE requires transparent reporting and careful interpretation of the RWD source, study design, and methods.”

To support the generation of high-quality PSP data, an accelerated design sprint was conducted on **building a patient support program data quality program**. Five themes were identified, with details listed under each theme, which should be considered by stakeholders when planning to collect data within a PSP.

Key data quality areas to consider when collecting RWD within a PSP

Area 1: Integrate a data quality plan in the initial PSP design.

- Identify data points, sources, and methods that will be most feasible.
- Create a data governance plan, including data management practices and policies that apply to how data is gathered, stored, processed, accessed and disposed of.
- Consider PSP elements that are managed internally vs. outsourced, and the implications on the ability to control critical data quality elements.
- Include data quality plans in the PSP vendor contract, including alignment on data quality objectives, processes, metrics, data access, training records, regular data quality review meetings and costs.
- Use automation and standardization as much as possible to increase data quality.
- Co-create with public payers, private insurers, HTA and other key external stakeholders.

Area 2: Define data quality roles and responsibilities.

- Define manufacturer, vendor, and third-party roles (e.g., data controller responsible for data access, governance and consent; data analyst responsible for testing and monitoring the data).
- Create clear accountability and engagement on data quality.

Area 3: Train PSP staff who are collecting the data.

- Training needs to be provided for all PSP staff collecting and entering the data (e.g., head office and field nursing staff).
- Document training records and schedules (e.g., annually).

Area 4: Manage PSP vendor ongoing on data quality.

- Establish a Service Level Agreement (SLA) for data quality including a data plan, resources and training.
- Hold regular meetings between the manufacturer and the vendor to review data quality metrics. Collect input from both parties on issues and opportunities, accountability, and collaboration to improve data quality and efficiencies.

Area 5: Monitor data quality ongoing.

- Test the data regularly (e.g., control reports on a schedule) to enable the timely identification and correction of errors.
- Perform formal data audits.
- Run regular analysis reporting to ensure data is as expected.