

# ADDRESSING TRUST AND BIAS ISSUES WHEN COLLECTING REAL-WORLD DATA WITHIN A PATIENT SUPPORT PROGRAM

Trust and bias were identified as the top issues by Canadian HTA and payers with RWE studies using PSP data.

## What are trust and bias issues with data?

**Trust**, as it pertains to data, includes data integrity, audibility, and the ability to validate. As per NICE, “concerns about the integrity and trustworthiness of the resulting evidence (i.e., resulting from data dredging or cherry-picking) need to be addressed.”

**Bias**, as it pertains to data, includes selection, missing data, and publication biases. As per NICE, a primary bias of concern is when “people studied are not representative of the target population.”

Table 1: Checklist to address trust and bias issues at PSP data collection

	Trust	Bias
Area 1: Study Design	<ul style="list-style-type: none"> <li><input type="checkbox"/> Did you register the study?</li> <li><input type="checkbox"/> Were any 3rd parties involved in the study design?</li> <li><input type="checkbox"/> Were any HTA/payers involved in the study design?</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Which patients are being directed to the PSP?</li> <li><input type="checkbox"/> What are the patient eligibility requirements to be included in the PSP?</li> <li><input type="checkbox"/> Are all patients on drug included in the PSP?</li> <li><input type="checkbox"/> Was consent obtained to enable the use of all patient data in aggregate results?</li> <li><input type="checkbox"/> What are the patient requirements to be included in the study?</li> <li><input type="checkbox"/> Will the study results be published regardless of the outcome?</li> </ul>
Area 2: Data Source	<p><b>Data provenance details:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> How was the data collected by the PSP infrastructure? And over what time period?</li> </ul> <p><b>PSP data governance process:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Who is the data controller of the PSP data?</li> <li><input type="checkbox"/> Is there a data dictionary?</li> <li><input type="checkbox"/> Are there quality assurance and data management processes for the PSP data?</li> <li><input type="checkbox"/> Have there been audits of the data to ensure its integrity?</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> What is the coverage of the data? PSP population vs. total patient population; geography, age, gender, etc.</li> <li><input type="checkbox"/> How does the PSP population compare to the RCT population?</li> <li><input type="checkbox"/> Are there quality assurance processes for the data? And associated metrics?</li> </ul>
Area 3: Data Quality	<ul style="list-style-type: none"> <li><input type="checkbox"/> What are the data governance results for missing data and data accuracy?</li> <li><input type="checkbox"/> Was any of the PSP data validated with another source? I.e., Key fields.</li> <li><input type="checkbox"/> Were there author statements to confirm the data integrity?</li> <li><input type="checkbox"/> Were there any third-party data quality assessments?</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Based on the level of data accuracy and completeness (missing data), how were the results impacted? Did this result in bias?</li> <li><input type="checkbox"/> Overall, how are the results biased or not (what are the limitations of the results)?</li> </ul>