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Research Internship Insights Series | Policy Brief

EQUITY IN CANADIAN MENTAL HEALTH TRIALS

HOW CANADA'S MOST INFLUENTIAL PSYCHIATRIC MEDICATION TRIALS RECORD RACE, ETHNICITY, SEX, GENDER, AND INDIGENOUS IDENTITY, AND WHAT POLICY CAN DO TO CLOSE THE GAP.

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Executive Summary

Three factors shape Canada's mental-health treatment evidence base: who enrolls in clinical trials, how researchers record participant backgrounds, and who governs the resulting data. In Canada, 26.5% of the population identifies as a visible minority, and the Constitution recognizes Indigenous self-determination (1). When Canadian trials report equity, diversity, inclusion, and accessibility (EDIA) inconsistently, the evidence may not fully reflect the populations these treatments are intended to serve.

This brief examines diversity reporting in the five most cited randomized controlled trials (RCTs) of pharmacotherapy for mental disorders run at Canadian sites between 2016 and 2026 (2 to 6). The pattern is consistent. International funders and industry sponsors require race and ethnicity reporting, but the trials use United States classification systems that do not match Canada's population. Smaller Canadian-only trials report demographics inconsistently or not at all. None of the five trials separate sex from gender, reference Indigenous data sovereignty, or conduct intersectional analysis.

The brief recommends five policy options. First, require PROGRESS-Plus minimum demographic reporting at the final grant reporting stage for all Canadian Institutes of Health Research (CIHR) funded trials. Second, require Canadian trial registries to capture structured demographic fields at the protocol stage. Third, require Ownership, Control, Access, and Possession (OCAP) compliance and Indigenous community partnership for any trial enrolling Indigenous participants. Fourth, require Canadian psychiatric and medical journals to adopt the CONSORT-Equity reporting extension. Fifth, invest in Canadian-specific demographic taxonomies for clinical research that align with Statistics Canada and Indigenous self-identification categories.

Context

a. Why diversity reporting in mental-health trials matters

Canada's clinical-trial evidence base informs prescribing decisions across the public health system. When trials skip race, ethnicity, language, or migration history, clinicians and patients lose visibility into whether the evidence reflects newcomer and racialized populations. The point matters most in psychiatry. Drug-metabolizing enzymes such as CYP2D6 and CYP2C19 vary across ancestral populations, and that variation shapes both efficacy and side-effect profiles for antidepressants, antipsychotics, and mood stabilizers (7,8).

Demographic visibility also shapes trust. When newcomer, racialized, and Indigenous communities do not see themselves in the evidence behind a recommended treatment, informed consent suffers and clinical trust erodes. In a Canadian context where mental-health service inequities are well documented, the gap matters.

b. The Canadian policy framework

Canada has built equity-oriented research policies that point in the right direction. The Canadian Institutes of Health Research (CIHR) Sex and Gender Based Analysis Plus (SGBA+) policy, formalized in 2019, requires applicants to integrate sex, gender, and other identity factors into research design (9). The Tri-Council Policy Statement (TCPS2) Chapter 9 sets ethical obligations for research involving First Nations, Inuit, and Métis peoples, including community engagement and culturally appropriate data governance (10). The Tri-Agency Equity, Diversity and Inclusion Action Plan (2018) commits the federal research funders to systemic change in research practice (11).

Together, these frameworks signal a strong national commitment to equity and inclusive research governance. However, their implementation remains concentrated at the proposal and funding stage. Current policies do not require structured demographic reporting at the trial publication or grant-completion stage. The result is a system that articulates equity at the start and enforces it unevenly at the end.

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What is Happening

To examine how the most influential Canadian mental-health pharmacotherapy RCTs report diversity, the five highest-cited Canadian-site RCTs of pharmacological agents for DSM-5 mental disorders published between 2016 and 2026 were identified. The analysis focused on how trials reported demographic and equity-related variables, including race, ethnicity, sex, gender, Indigenous identity, and other social determinants relevant to equitable mental-health research. The five trials, listed in descending order of citations, are summarized below.

Trial 1. Solanezumab for mild Alzheimer's disease (Honig et al.) (1,039 citations)
Year: 2018· Sample size: n = 2,129· Disorder: Dementia / Alzheimer's. Funding: Industry (Eli Lilly)· Canadian site(s): Western University

Diversity reporting: Phase 3, double-blind, placebo-controlled, multinational. Sex reported. The trial collected race and ethnicity to meet United States industry-sponsored Phase 3 expectations, but the Canadian site did not report demographics in Statistics Canada categories. Indigenous identity, religion, sexual orientation, gender identity, and intersectional variables were not reported (2).

Trial 2. MDMA-assisted therapy for severe PTSD (Mitchell et al.) (931 citations)
Year: 2021· Sample size: n = 90· Disorder: Post-traumatic stress disorder. Funding: Private foundation (MAPS / MAPS PBC)· Canadian site(s): BC Centre on Substance Use, University of Toronto

Diversity reporting: Phase 3, double-blind, placebo-controlled, multi-site (United States, Canada, Israel). The trial reported race using United States Office of Management and Budget (OMB) categories: White 76.7%, Multiple races 8.9%, Asian 7.8%, American Indian or Alaska Native 3.3%, Black or African American 2.2%, Native Hawaiian or another Pacific Islander 0%, with 10% identifying as Hispanic or Latino. Sex reported as binary. Canadian Indigenous identity (First Nations, Inuit, Métis) were not separately reported. OCAP principles not referenced. Religion and intersectional analysis not reported (3).

Trial 3. Esketamine nasal spray for treatment-resistant depression (TRANSFORM-1, Fedgchin et al.) (583 citations)
Year: 2019· Sample size: n = 346· Disorder: Treatment-resistant major depression. Funding: Industry (Janssen)· Canadian site(s): University of Ottawa, University of Toronto

Diversity reporting: Phase 3, double-blind, active-controlled, multinational. The trial reported race using United States categories: White 76.6%, Other 8.8%, not reported 7.3%, Black or African American 5.6%, Asian 1.5%, Multiple 0.3%. Sex reported as binary (70.5% female). Employment status reported. Indigenous identity, religion, sexual orientation, gender identity, and intersectional analysis were not reported (4).

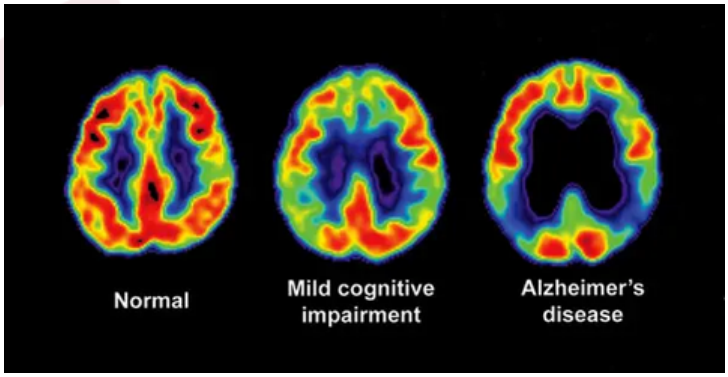
Trial 4. Ketamine infusions for treatment-resistant depression (Phillips et al.) (400 citations)
Year: 2019· Sample size: n = 41· Disorder: Treatment-resistant major depression. Funding: Foundation (Royal Ottawa Foundation, University of Ottawa Brain and Mind Institute)· Canadian site(s): Royal Ottawa Mental Health Research Institute (single-site)

Diversity reporting: Single-site, randomized, double-blind, crossover. Sex reported. Race and ethnicity not reported in publicly available abstract or summary materials.
The study fits the profile of smaller Canadian-only single-site trials, where demographic reporting is weakest (5).

Trial 5. Gantenerumab and solanezumab in dominantly inherited Alzheimer's disease (DIAN-TU, Salloway et al.) (361 citations)
Year: 2021· Sample size: n = 194· Disorder: Dominantly inherited Alzheimer's disease. Funding: NIH-affiliated DIAN-TU consortium with industry partners (Roche, Eli Lilly)· Canadian site(s): McGill University, Sunnybrook Health Sciences Centre, University of British Columbia, University of Toronto

Diversity reporting: Phase 2/3, randomized, multinational. Sex reported (40-58% female across arms). Genetic mutation type (APP, PS1, PS2) and APOE4 status reported. Race and ethnicity not reported in the baseline demographics table. Indigenous identity, religion, sexual orientation, gender identity, and intersectional analysis were not reported (6).

Diversity reporting differs sharply across the five trials. The next section summarizes the patterns and what they mean for Canadian psychiatric care.



Key Observations

First, three of the five trials reported participants' race or ethnicity, but all relied on United States classification frameworks rather than Canadian standards (6). None of the five studies used Statistics Canada classifications for visible minorities or identified Indigenous Peoples using Canadian categories, limiting comparisons between trial participants and Canada's population.

Second, all five trials report sex. None reports gender. None separates sex (a biological attribute) from gender (a social attribute). The conflation persists despite CIHR's Sex and Gender Based Analysis Plus (SGBA+) policy, in force since 2019, which expects research to integrate both (9). In psychiatric pharmacotherapy, treatment-seeking, adherence patterns, and outcome reporting can be shaped by gender- related social factors, making this distinction clinically and analytically important (12).

Third, no trial referenced Indigenous data sovereignty or the Ownership, Control, Access, and Possession (OCAP) principles set by the First Nations Information Governance Centre (13). The Phase 3 MDMA-PTSD trial enrolled three participants under the United States Census term American Indian or Alaska Native (3.3% of the sample). The publication described no Indigenous community partnership, no separate Indigenous outcome reporting, and no governance under Canadian Indigenous data sovereignty frameworks (3). No trial in the set demonstrated evidence of co-design or governance collaborations with First Nations, Inuit, or Métis communities. The gap between Canadian policy aspiration and trial-level practice is widest here.

Fourth, none of the five trials reported religion, sexual orientation, gender identity, occupation, or intersectional analysis. These dimensions shape newcomer mental-health care: religious and ethnocultural identity drives treatment engagement, occupational status drives functional outcomes, and intersecting disadvantages compound treatment barriers (14)(15). The absence of these variables reflects broader limitations in current clinical-trial reporting standards, where equity-related demographic dimensions are often treated as optional rather than essential components of evidence generation.

Fifth, trial scale and funding source appear to influence the depth of demographic reporting. The two trials with the most comprehensive reporting of race and ethnicity were both multinational, multi-site, Phase 3 studies (the MDMA-PTSD and TRANSFORM-1 trials), whereas the single-site Canadian ketamine trial (Phillips et al., 2019) did not report participants' race or ethnicity in its publicly available report. This pattern suggests that multinational trials may be more likely to adopt standardized demographic reporting practices than studies conducted solely within Canada, although the reasons for this difference require further investigation.

Pathways Forward

For policymakers and funders

Canadian clinical-trial reporting requirements should more closely align with Canada's demographic realities, equity commitments, and Indigenous governance frameworks.

One policy option is to require PROGRESS-Plus minimum demographic reporting at the final grant reporting stage for all CIHR funded clinical trials, not only at the application stage (16). Expected fields would include place of residence, race or ethnicity, occupation, gender and sex, religion, education, socioeconomic status, social capital, age, disability, and sexual orientation or gender identity. The current SGBA+ policy operates as a grant-application question. Extending SGBA+ to mandatory reporting requirement would help address the gap between equity-oriented research design and final trial reporting practices.

Canadian clinical-trial reporting requirements should more closely align with Canada's demographic realities, equity commitments, and Indigenous governance frameworks.

A second option is to require Canadian trial registries, including Canadian-led ClinicalTrials.gov registrations, to capture structured demographic fields at protocol registration. Required fields would include race, ethnicity, gender identity, Indigenous identity, and language. This approach mirrors the prospective demographic collection rules applied to trials registered in the United States. This change would normalize equity reporting from study inception, instead of bolting it on after results are in.

A third option is to require any clinical trial enrolling Indigenous participants to document OCAP compliance, community partnership, and, where indicated, separate Indigenous outcome reporting, as a condition of research ethics board approval. This implements the substance of TCPS2 Chapter 9 at the trial conduct level rather than only at the grant review level (10). Several trials reviewed in this brief enrolled participants identified through United States Indigenous categories without documented Indigenous governance arrangements. A Canadian trial-level requirement would close that gap.

A fourth option is to require Canadian psychiatric and medical journals to adopt the CONSORT-Equity 2017 reporting extension as a submission standard (17). Editorial checklists that prompt authors to report equity-relevant baseline data, or to justify any omission, would change publication norms. This change may be especially important for smaller Canadian-only trials, where demographic reporting was least comprehensive.

A fifth option is to invest in Canadian-specific demographic taxonomies for clinical research, building from Statistics Canada Census visible-minority categories and First Nations, Inuit, and Métis self-identification frameworks. Developing standardized Canadian demographic reporting categories would improve comparability between clinical-trial populations and the broader Canadian population, reducing reliance on United States classification systems that may not fully reflect Canadian demographic contexts.

For the public, advocacy, and the settlement sector

Patients, families, community advocates, and immigrant-serving organizations can help advance more equitable mental-health research by participating in research partnerships, identifying community priorities, advocating for inclusive recruitment, and requesting clearer reporting of participant demographics. Clinicians can also consider whether the evidence supporting a psychiatric treatment reflects the diversity of the populations expected to receive it, including newcomer, racialized, and Indigenous communities. However, the primary responsibility for collecting and reporting demographic information rests with researchers, funders, regulators, research institutions, and journals. When this information is absent from clinical-trial publications, patients, clinicians, and community organizations may still raise concerns and advocate for greater transparency, but they cannot independently determine whether the evidence is representative or applicable to the communities they serve.

However, the primary responsibility for collecting and reporting demographic information rests with researchers, funders, regulators, research institutions, and journals.

The organizations operating within the immigrant-serving sector are particularly well positioned to translate this evidence gap into policy and advocacy discussions. Their role may include supporting community education, identifying barriers newcomers face in accessing mental-health services, and contributing newcomer perspectives to broader conversations on equitable healthcare and research inclusion.

Through partnerships with healthcare providers, researchers, and public institutions, settlement organizations can also help highlight the importance of culturally and demographically representative mental-health evidence in Canada's healthcare system. Greater transparency in clinical-trial reporting is not only a research issue; it is also connected to public trust, equitable care, and confidence that mental-health evidence reflects the diversity of the populations it is intended to serve.

Closing the Gap

Improving demographic reporting is essential to determining whether psychiatric treatment evidence is relevant to Canada's diverse population. Canada needs a consistent national framework that requires researchers to collect, analyze, and report demographic information using categories appropriate to the Canadian context. Such a framework should distinguish sex from gender, support meaningful inclusion of immigrant, racialized, and Indigenous populations, and respect Indigenous data-governance principles. Clearer standards would strengthen research transparency, help identify gaps in representation, and support more equitable mental-health policy and clinical decision-making.

Canadian policy frameworks have set the right direction. CIHR SGBA+, TCPS2 Chapter 9, and the Tri-Agency EDI Action Plan all point the right way. The next step is to translate those commitments into requirements that operate at the trial level: at registration, during conduct, at publication, and at grant completion. More than one in four Canadian residents identifies as a visible minority. The Constitution protects Indigenous self-determination. Doctors prescribe psychiatric medications across the full diversity of the Canadian population. Closing this reporting gap is an ethical obligation.

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TIES Centre for Immigrant Research (TCIR) is a community-based research centre that generates evidence that informs policies, programs, and practices to strengthen immigrant settlement, integration, and community well-being across Canada. Our work is organized around three interconnected areas:

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