

CIHR'S MONITORING OF **CLINICAL TRIALS** REGISTRATION AND DISCLOSURE – 2022

EXECUTIVE SUMMARY

What is CIHR's commitment?

In line with its [strategic priorities](#) to promote open science in the Canadian context and to contribute to global research excellence, CIHR formally signed onto the [WHO Joint Statement on public disclosure of results from clinical trials](#) in 2020. In signing-on to this statement, CIHR affirmed its commitment to reduce research waste by implementing a [policy guide](#) that promotes transparency and public disclosure of results for all CIHR-funded clinical trials. CIHR will monitor policy compliance annually for all [clinical trials](#) funded on or after January 1, 2022, and will publicly report aggregate data showing the degree of compliance with the policy requirements. Ultimately, non-compliance can result in withholding of new CIHR funding until compliance has been achieved.

Why monitor clinical trials?

Wasteful research practices such as the poor design and execution of research studies, a lack of transparency in the disclosure of study findings or non-publication of study results, limit the real-world impact of clinical and biomedical research. There are strong ethical and financial reasons to prevent waste in clinical trials research, particularly for a public granting agency like the Canadian Institutes of Health Research (CIHR).

How was the policy monitored in 2022, and what did we learn?

Given the long timelines associated with clinical trial start-up and recognizing the gradual nature of research culture change, the first year of monitoring focused on compliance with the trial registration requirement, an early step in the clinical trial lifecycle, with further enforcement planned as a future step. **A survey was sent to all Nominated Principal Investigators** (NPI, the lead investigator and grant holder) of CIHR-funded clinical trials with a funding start date between **January 1, 2022 - December 31, 2022**, to evaluate compliance with the policy.

Results show that:

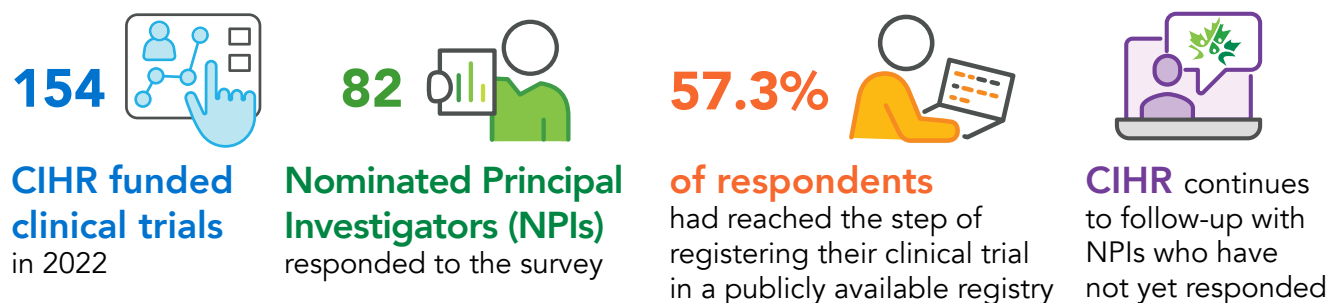


FIGURE 1. CIHR's Monitoring of Clinical Trials Registration and Disclosure – 2022



- ❑ CIHR funded 154 clinical trials in 2022.
- ❑ Of the 154 surveyed NPIs of these clinical trials, 82 responses were received by the survey cut-off date and evaluated.
- ❑ Of the 82 responses, 47 (57.3%) NPIs confirmed that they had registered their clinical trial in a publicly available, free to access, searchable clinical trial registry complying with [WHO's international agreed standards](#) before the first visit of the first participant. Others indicated they were in early stages of trial start-up and working towards registration.
- ❑ Of those studies that indicated that they had registered their trials, 3 studies had published trial findings. All other respondents had not yet reached the publication stage.
- ❑ CIHR is currently following-up with researchers who had not responded.

Although 43% (35) of survey respondents said they had not reached the registration step by the survey deadline, many of these studies had achieved some milestones which precede trial registration, such as having applied for research ethics board and regulatory approval, or awaiting approval from the registry. Few studies were sufficiently underway to share results. The studies that reported publishing results had begun prior to receiving CIHR funding in 2022, aligning with the anticipated lengthy timelines for trial start-up.

WHAT'S NEXT?

RESPONSE RATES to this first round of policy monitoring were low, pointing to a need to ensure additional communications with implicated researchers and their institutions. As part of its ongoing efforts to promote a research culture of open science, CIHR continues to engage with NPIs who did not respond to the survey to identify barriers and work collaboratively towards compliance. The general communication of the policy continues to be promoted to partners, stakeholders and the public. CIHR will continue to assess compliance and report on these results annually, and procedures linked to identifying deliberate non-compliance that could lead to future funding ineligibility will be implemented in subsequent monitoring cycles.

FOR ADDITIONAL INFORMATION, PLEASE CONTACT
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