

# CLINICAL TRIAL REGISTRATION AND RESULTS DISCLOSURE POLICY – 2023 MONITORING

## EXECUTIVE SUMMARY

### What is the Canadian Institutes of Health Research (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 requires transparency and public disclosure of CIHR-funded clinical trial results. CIHR monitors 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 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 CIHR.

### How was the policy monitored for the 2023 monitoring cycle, and what did we learn?

Given the long timelines associated with clinical trial start-up and recognizing the gradual nature of research culture change, in this second cycle of policy monitoring, CIHR maintained focus on improving response rates to monitoring efforts.

**The 2023 monitoring cycle included grants flagged as clinical trials with a funding start date between January 1, 2022 and December 31, 2023.** Similar to the first monitoring cycle, a compliance report (a questionnaire evaluating each requirement of the policy) was sent to all Nominated Principal Investigators<sup>1</sup> (NPIs) of CIHR-funded clinical trials to evaluate policy compliance. **Results show that:**

**308** 

CIHR funded  
clinical trials  
in 2022 and 2023

**99%**

of Nominated  
Principal Investigators  
responded to the  
compliance report



**68.3%**

of respondents  
had reached the step of  
registering their clinical trial  
in a publicly available registry



**96.7%**

of respondents  
haven't yet  
published results



- ❑ CIHR funded 308 clinical trials in 2022 and 2023.
- ❑ Compliance reports were received for 305 of the 308 clinical trials, a 99% response rate, over the course of the monitoring cycle (including follow-up and escalation).
- ❑ 207 (67.2%) NPIs<sup>2</sup> 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 the early stages of trial start-up and working towards registration.
- ❑ Four studies reported publications; three were publications of trial results (studies were ongoing prior to monitoring), one was a protocol publication, and all other respondents had not yet reached the publication stage.

Although 31.5% (96) of respondents had not reached the registration step by the final reporting deadline, many of these studies had achieved milestones which precede trial registration, such as having applied for research ethics board and regulatory approval or awaiting approval from the registry. Furthermore, registration rates were higher in trials funded in 2022 (80.6%) than those funded in 2023 (55.2%), indicating that compliance with this reporting element is increasingly achieved with time.

Few studies were sufficiently underway to report on results. Of the four studies that reported publications, three had begun prior to receiving CIHR funding in 2022, aligning with the anticipated lengthy timelines for trial completion.

In this second year of monitoring, success in executing a coordinated, efficient, and thorough data collection effort can largely be attributed to the implementation of lessons learned from the first year of monitoring. Despite doubling the number of trials monitored, a significant improvement in the response rate was observed, which provided a good overview of the current progress of trials funded by CIHR in 2022 and 2023.

**We would like to thank the researchers and their institutions for their timely responses.**

## WHAT'S NEXT?

As part of its ongoing efforts to promote a research culture of open science, CIHR continues to engage with the 1% of NPIs who did not submit the compliance report to identify barriers and work collaboratively towards compliance and/or moving ahead with processes to pause eligibility for future funding until compliance is achieved. General information about the policy continues to be communicated with partners, stakeholders, and the public. CIHR will continue to assess compliance and report on these results annually.



## FOR ADDITIONAL INFORMATION, PLEASE CONTACT

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1. CIHR terminology for the lead Principal Investigator and grant holder
2. Two (2) additional respondents answered "yes" to the question of trial registration but did not use a WHO-approved registry and are excluded from the number reported herein.