APPLICATION FORM – FUTURE TRIAL LEADERS:

Pragmatic clinical trials are often embedded in routine care and involve the analysis of routinely collected data (e.g., health registries, electronic medical records, and administrative data). Done well, pragmatic trials yield valid generalizable results faster than explanatory ("traditional") clinical trials and can be completed at a fraction of the cost.

The **HDRN Canada Pragmatic Trials Training Program** is a Clinical Trials Training Platform funded by the Canadian Institutes of Health Research (CIHR). Coordinated by the Schulich School of Medicine & Dentistry at Western University and embedded within HDRN Canada, this two-year virtual pan-Canadian program will provide training to advanced learners across three streams: (1) future trial leaders, (2) postdoctoral fellows, and (3) highly qualified personnel.

Eligibility: Future trial leaders must have a faculty appointment at a Canadian academic institution that is eligible to receive funding from CIHR. Applicants (i.e., faculty-level trainees) should not have led a major pragmatic trial in the past and be motivated to lead the development of what will be their first large-scale pragmatic trial protocol.

Application deadline: Applications will be accepted until Friday, December 22, 2023 (5:00 PM Eastern time). Results will be announced via e-mail in February 2024.

Program duration: April 15, 2024 – March 31, 2026 (2 years).

Description: Acknowledging that faculty-level trainees are advanced learners with various obligations, this training program is entirely virtual and largely asynchronous in nature. At minimum, future trial leaders must be able to engage with tasks related to the program on a bi-weekly basis (i.e., 8 hours over a two-week period, ~4 hours per week).

To facilitate project-based learning, future trial leaders will collaborate with postdoctoral fellows in the program through the development of a pragmatic trial protocol. These fellows may have expertise including but not limited to epidemiology, biostatistics, research ethics, and implementation science, and they will lend their expertise to the trial leader's protocol. (It must be understood that fellows in the program may have primary supervisors, and corresponding obligations, outside of the program.) Throughout the program, trial leaders will reflect and present on obstacles and solutions encountered during the development of their protocols.

With the goal of creating a community of learners, attendance at monthly, one-hour virtual meetings will be required as well as routine asynchronous engagement (e.g., reflections on educational content) within a learning management system.

When possible, future trial leaders will identify an external mentor (e.g., an experienced pragmatic trialist) who can provide guidance to the applicant throughout their involvement in the program. For the benefit of all trainees, the applicant will request that this mentor also commits to supplying relevant educational materials (e.g., lecture slides, recorded presentations) to the training program.

Funding: Future trial leaders will receive up to $30,000 (transferred to their host institution) to facilitate project-based learning through the development of a pragmatic trial protocol.

Experiential learning activities that may require funding during protocol development include but are not limited to: engagement with patients and other partners in the refinement of research questions and strategies for intervention delivery (e.g., facilitating meetings, assessing current practice via surveys or qualitative interviews), data access requests (e.g., service charges, administrative fees, secure research environment costs), analyses of routinely collected data to inform trial design (e.g., use of analytical services), and media support to develop trial resources (e.g., patient-facing materials, a study website).

Acknowledging that these services may not be readily available in the future trial leaders local environment, trial leaders may be eligible to receive project-based training through the Pragmatic Trials Stream of the Accelerating Randomized Trials (ART) Platform (Schulich School of Medicine & Dentistry, Western University). As an alternative to the self-directed use of the funding by the trial leader, the ART Platform will use this funding to facilitate experiential learning for the trial leader through the development of their pragmatic trial protocol.

All trial leaders will provide routine reports describing the progress of their protocol as well as the necessary financial documentation to track the use of the funding (particularly if they are using the funding outside of the ART Platform). Note that this funding cannot serve as salary support for the trial leader, and it cannot be used to support ongoing research activities.

Program offerings:

- Participants will have access to a learning management system with educational materials focused on pragmatic clinical trials (e.g., trials examining interventions that can be evaluated in routine care settings, with large diverse samples of patients, which produce generalizable evidence that informs real-world decision making).
- As a first time offering, the program will seek routine feedback from participants and adapt to help meet their learning objectives. Acknowledging the various obligations of participants, this largely asynchronous virtual program will facilitate experiential project-based learning opportunities and foster the development of a vibrant community of learners.
- Participants will have access to a pan-Canadian network of HDRN Canada member organizations that have committed to providing further training and career advancement opportunities.
- Participants will have access to the Wabishki Bizhiko Skaanj Learning Pathway, and other related training, to enhance their knowledge and awareness of racial biases, Indigenous voices and stories, the impact of colonization on Indigenous health, and culturally safe health research practices.

Intended outcomes: At the conclusion of this two-year virtual training program, future trial leaders will have expanded their understanding of pragmatism in clinical trials and advanced a large-scale pragmatic trial protocol. Trial leaders will have strengthened their networks through engagement with other trial leaders, postdoctoral fellows, and highly qualified personnel in the program. A certificate will be provided upon successful completion of the program.

Applicant evaluation criteria: With the goal of training future trial leaders who are committed to experiential learning and mentorship, a pan-Canadian selection committee will assess the following: the applicants (1) research training and experience, (2) ability and capacity to provide virtual within-program mentorship, (3) need for specific training in pragmatic trials, (4) proposed pragmatic trial concept (e.g., originality, feasibility, and potential impact).

If you have any questions or concerns, contact the Program Manager (Taylor McLinden) at taylor.mclinden@hdrn.ca.

Applicants must review the program overview document prior to submitting their application.

APPLICATION FORM – FUTURE TRIAL LEADERS:

Contact information

Name: _____ Preferred name (optional): _____

Position/title: _____ Organization: _____

Street address: _____ City/town: _____

Province: _____ Postal code: _____

E-mail: _____ Phone: _____

Citizenship status (check one)

☐ Canadian citizen

☐ Canadian permanent resident Country of citizenship: _____

☐ Canadian work permit Country of citizenship: _____

☐ Other Specify: _____

Self-declarations (optional)*

* Although self-declarations are encouraged, non-responses will have no consequences. This information will only be viewed by program staff and may be used in aggregate for anonymized reporting purposes.

Gender:

☐ Agender ☐ Bi-gender/multi-gender ☐ Gender-fluid ☐ Gender Queer

☐ Man ☐ Non-binary ☐ Questioning ☐ Transgender

☐ Two-spirit ☐ Woman

☐ Gender not specified Specify: _____

☐ Prefer not to answer

Do you identify as a person with a disability?

☐ Yes ☐ No ☐ Prefer not to answer

Do you identify as an Indigenous person (e.g., First Nations, Inuit, and/or Métis)?

☐ Yes ☐ No ☐ Prefer not to answer

Which categories best describe you? Check all that apply.

☐ Black ☐ East Asian ☐ Latin American ☐ Middle Eastern

☐ South Asian ☐ Southeast Asian ☐ White

☐ Other Specify: _____

☐ Prefer not to answer

Curriculum planning

What is your primary area of expertise? Check one (the most relevant).

☐ Epidemiology ☐ Biostatistics ☐ Clinical research ☐ Privacy, ethics, regulations

☐ Implementation science ☐ Inclusion, Diversity, Equity, and Accessibility

☐ Indigenous rights and data sovereignty

☐ Other Specify: _____

Which area do you wish to learn more about? Check one (the most relevant).

☐ Epidemiology ☐ Biostatistics ☐ Clinical research ☐ Privacy, ethics, regulations

☐ Implementation science ☐ Inclusion, Diversity, Equity, and Accessibility

☐ Indigenous rights and data sovereignty

☐ Other Specify: _____

Have you previously completed any training modules in the Wabishki Bizhiko Skaanj Learning Pathway? Check all that apply.

☐ Supporting Each Other's Journey: Land Acknowledgment Learning Series

☐ KAIROS Blanket Exercise

☐ San'yas Indigenous Cultural Safety Training

☐ Indigenous Research Ethics and Protocols

☐ Knowledge Keepers in Research

☐ The First Nations Principles of OCAP Training

☐ Cultural Competency Knowledge Bundle

☐ Other Specify: _____

Statement of interest (maximum 3000 characters with spaces)

Applicants must outline their academic background, current research focus, and expectations regarding how this training program will support their career trajectory.

- The goal is for faculty-level trainees to lead the development of their first large-scale pragmatic trial protocol. Therefore, if you have already led a small-scale pragmatic trial in the past, discuss what you intend to gain through your involvement in this program.

The applicant should comment on their interest, experience, and capacity to provide project-based mentorship to postdoctoral fellows in the training program, particularly in a virtual environment.

- It must be understood that postdoctoral fellows in the program may have primary supervisors and other obligations outside of the program. However, if a fellow directly under your primary supervision is applying to the program as well, indicate their name and provide a description of your pre-existing mentorship relationship with them.

Funding preferences (check one)

Eligibility for future trial leaders to receive project-based training through the Pragmatic Trials Stream of the ART Platform (Schulich School of Medicine & Dentistry, Western University) will be assessed after acceptance into the program.

Therefore, applicants are not bound to this preliminary selection and all trial leaders will be able to explore which option they prefer (self-directed vs. ART Platform) during the initial stages of the program.

☐ **OPTION 1 –** At the time of applying, it is my preference that the funding be transferred to my institution (that is eligible to receive funding from CIHR) to allow for the self-directed facilitation of project-based learning through the development of my pragmatic trial protocol.

☐ **OPTION 2 –** At the time of applying, it is my preference to receive project-based training through the Pragmatic Trials Stream of the ART Platform through the development of my pragmatic trial protocol.

(Only complete one of the two "project description" sections below.)

OPTION 1 – Project description (maximum 3000 characters with spaces)

***Potential* self-directed use of funding:** To the best of your ability, describe how you would employ the funding to facilitate project-based learning through the development of a pragmatic trial protocol. Further, to the extent it is possible, describe the hypothetical research question, intervention (to be randomized), setting (locations, study population), outcome(s), and the routinely collected data source(s). Speak to areas where pragmatism could be introduced into your trials design (see here for a list of pragmatic design elements).

OPTION 2 – Project description (maximum 3000 characters with spaces)

Potential **use of the ART Platform:** For program staff to begin determining whether the ART Platform can potentially facilitate experiential learning for the trial leader through the development of their pragmatic trial protocol, describe the hypothetical research question, intervention (to be randomized), setting (locations, study population), outcome(s), and routinely collected data source(s). Speak to areas where pragmatism could be introduced into your trials design (see here for a list of pragmatic design elements).

External mentor (maximum 1500 characters with spaces)

If possible, identify an external mentor (e.g., an experienced pragmatic trialist) who can provide guidance to you during your involvement in the training program. Provide the name, affiliation, and e-mail of the external mentor. Briefly describe the mentor's relevant expertise, your experience with them (if any), and confirm that you have discussed this program with them. (Note that program staff will contact the external mentors of all successful applicants.)

Alternatively, if you cannot identify a mentor at this time, describe an ideal mentorship pairing (e.g., *"Someone with experience leading pragmatic trials in ___ setting, in the following clinical area ___, who has a background leveraging routinely collected data in ___ region…"*)

- Note that the inability to name a mentor at the time of applying will not reduce your likelihood of being accepted into the program. If you are accepted, program staff will work with you to find a suitable mentor.

☐ **If a mentor is identified above –** For the benefit of all trainees, I have requested that this mentor also commits to supplying relevant educational materials (e.g., lecture slides, recorded presentations) to the training program.

Conflict of interest declaration (maximum 1500 characters with spaces)

☐ I have an actual, perceived, or potential conflict of interest that may relate to my involvement in this training program and I have described it below.

☐ I do not have an actual, perceived, or potential conflict of interest that may relate to my involvement in this training program.

APPLICATION CHECKLIST – FUTURE TRIAL LEADERS:

☐ Completed application form *(this document)*

☐ Curriculum Vitae (CV)

Declaration

I, the applicant, certify that I have read the program overview document and that the information provided in this application is correct and complete. I understand that submission of this signed application permits the HDRN Canada Pragmatic Trials Training Program to request and/or confirm any information necessary to support my application and that submission of any false statements or documents will result in withdrawal of consideration for admission to the program.

If accepted into the program, I commit to:

☐ Engaging with tasks related to the program on a bi-weekly basis (i.e., for a minimum of 8 hours over a two-week period, ~4 hours per week).

☐ Seeking out mentorship (e.g., from an experienced pragmatic trialist) throughout my involvement in the program and, in collaboration with program staff, ensuring this mentor supplies relevant educational materials (e.g., lecture slides, recorded presentations) to the program.

☐ Collaborating with postdoctoral fellows in the program through the development of my pragmatic trial protocol, even if those fellows are not under my primary supervision outside of the program.

☐ Reflecting and presenting on obstacles and solutions encountered during the development of my trial protocol.

☐ Attending 80% of the monthly, one-hour virtual meetings and routine asynchronous engagement (e.g., reflections on educational content) within a learning management system.

☐ Providing any necessary financial documentation to program staff, in a timely manner, for the purposes of CIHR reporting.

Name: _____

Date: _____

Signature: _____

**Note that the application form may lock (preventing further editing) after it is saved with a digital signature.*

Deadline: Friday, December 22, 2023 (5:00 PM Eastern time)
Submit the completed application form and CV as one combined package (i.e., a merged PDF) to pragmatic.training@uwo.ca with the subject line: *Trial leader application*