Program Overview update - Version: 1.2 (Nov 29, 2023):

Added on page 13 - **How does the time release funding for HQP employed at public sector organizations correlate with the required time commitments for these participants in the program?**

Added on page 13 - **What does it mean if an HQP employed at a public sector organization earns an hourly wage that is of lesser or greater value than the time release funding?**

Added on page 14 - **The illustrative example ("correlating the time release funding, for public sector HQP, to the required time commitments for these participants") references a hypothetical 50-week work-year (2 weeks of vacation), yet I take more vacation time than this. How does this impact the time release funding?**

Added on page 15 - **What happens when I take vacation time during the program, or if I need to take an extended leave of absence for another reason?**

Program Overview update - Version: 1.1 (Nov 27, 2023):

Added on page 8 - **How will the future trial leaders collaborate with postdoctoral fellows in the program through the development of a pragmatic trial protocol?**

Added on page 8 - **What are some example projects for the public sector HQP employed by HDRN Canada member organizations that will expand HDRN Canada's capacity to support pragmatic trials research, particularly multi-regional trials?**

Added on page 10 - **How will the public sector HQP employed by HDRN Canada member organizations engage in a project that furthers HDRN Canada's ability to support pragmatic trials research?**

Added on page 12 - **For the trainee streams engaged in experiential project-based learning, what is the anticipated breakdown of a participant's time on these projects, in relation to the routine asynchronous engagement within a learning management system?**

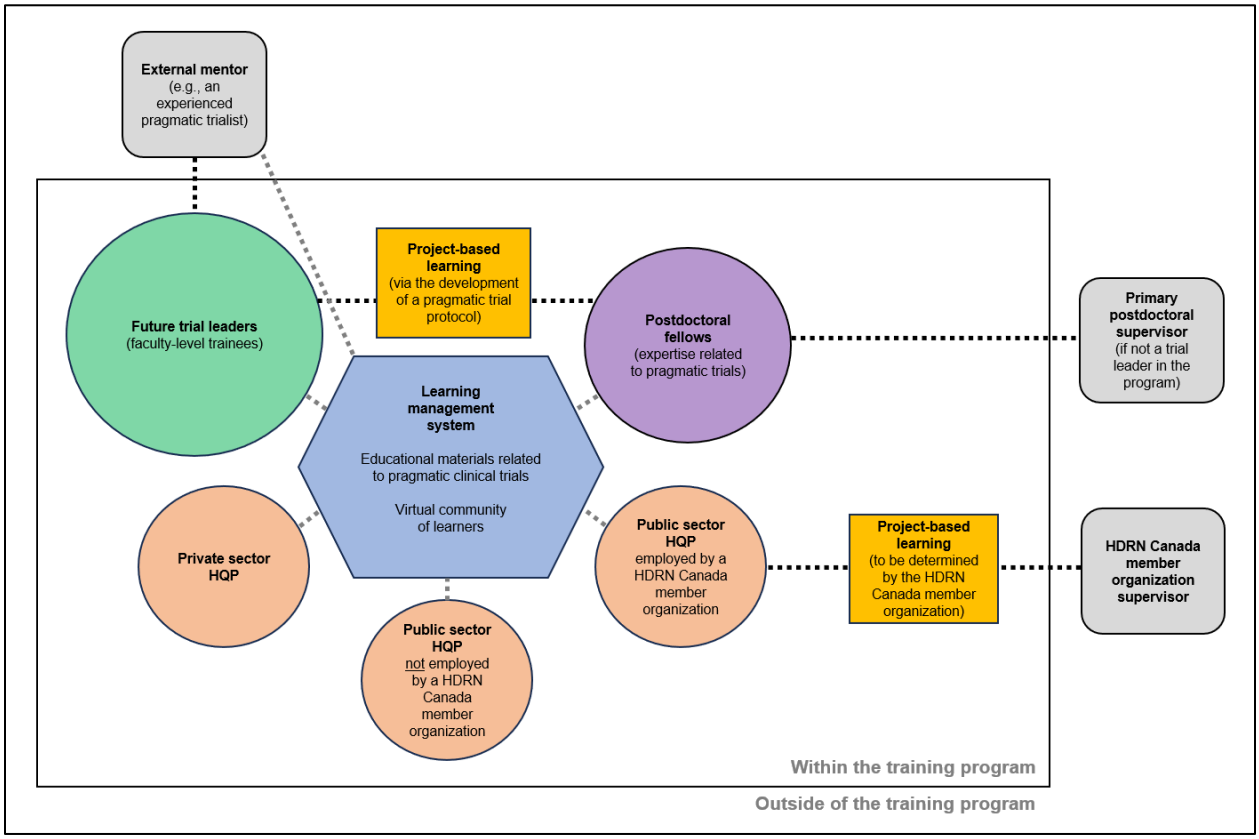
Added on page 14 - **How will participants be evaluated?**

HDRN CANADA PRAGMATIC TRIALS TRAINING PROGRAM OVERVIEW:

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 (HQP).

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



HQP = highly qualified personnel. HDRN Canada = Health Data Research Network Canada (member organizations).

This diagram illustrates the collaborative, mentorship, and experiential learning aspects of the HDRN Canada Pragmatic Trials Training Program.

All participants will have access to a learning management system.

- Participants will have the opportunity to access educational materials and network with other trainees from all streams.

Future trial leaders will receive external mentorship (e.g., from an experienced pragmatic trialist).

- For the benefit of all participants, external mentors will also contribute educational materials to a learning management system.

Future trial leaders will facilitate experiential learning through collaborations with postdoctoral fellows in the program through the development of a pragmatic trial protocol.

- In the situation when a fellow's primary supervisor is not a trial leader in the program, it must be understood by **trial leaders** that **fellows** will be involved in other work directed by their **primary postdoctoral supervisor** outside of the program.

Public sector HQP employed by HDRN Canada member organizations will engage, when possible, in projects, i.e., a project that furthers HDRN Canada's ability to support pragmatic trials research (e.g., reducing barriers for analyses of routinely collected data, particularly multi-regional data, that informs trial design and execution).

- Mentorship on **projects** within HDRN Canada member organizations will come from **supervisor(s) at the HDRN Canada member organization**.

Private sector HQP and public sector HQP not employed by HDRN Canada member organizations will access a learning management system where they can view educational materials and network with other trainees.

- These HQP will not necessarily engage in a project-based learning experience. However, such opportunities can be discussed after acceptance into the program on a case-by-case basis.

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

The HDRN Canada Pragmatic Trials Training Program believes Inclusion, Diversity, Equity, and Accessibility (IDEA) is key to fostering a respectful, innovative, and pioneering learning environment. The program's commitment to IDEA ensures participants will benefit from the full range of skills, perspectives, cultural backgrounds, and experiences needed to learn about the design, implementation, and management of pragmatic trials.

The activities of the HDRN Canada Pragmatic Trials Training Program are taking place on the traditional and ancestral territories of First Nations, Inuit, and Métis Peoples across Canada.

GENERAL INFORMATION:

What are pragmatic clinical trials?

Pragmatic clinical trials are a type of experimental study used to evaluate the effectiveness of interventions, often by randomizing the intervention (e.g., a treatment) under study. These trials are typically conducted in routine care settings with the aim of providing evidence that is applicable to real-world clinical care. Pragmatic trials are often contrasted with explanatory or "traditional" clinical trials, which typically focus on establishing the efficacy of an intervention under ideal conditions. Characteristics of pragmatic trials may include:

- *Real-world settings*: Pragmatic trials are conducted in diverse settings, such as clinics, hospitals, and primary care facilities to reflect the variability and complexities of routine practice.
- *Broad inclusion criteria:* Pragmatic trials often have less strict eligibility criteria compared to explanatory trials, allowing for a wider range of patients to participate. This helps to ensure that the study results are generalizable to a broader population.
- *Flexible interventions:* Interventions in pragmatic trials are typically designed to mimic how they would be used in routine care, rather than being highly controlled or standardized. This means that providers may have some flexibility in how they deliver the intervention under study.
- *Patient-centered outcomes:* Pragmatic trials often prioritize outcomes that matter to patients, such as reductions in hospitalizations, rather than focusing solely on surrogate markers or biomarkers.
- *Larger sample sizes:* To detect meaningful differences in clinical outcomes, pragmatic trials often involve larger numbers of participants than explanatory trials. This is often made possible by using routinely collected data (e.g., health registries, electronic medical records, and administrative data) at various stages of the trial.
- *Longer follow-up:* The use of routinely collected data enables pragmatic trials to have longer follow-up periods to assess the effects and sustainability of interventions.

Pragmatic clinical trials are important for bridging the gap between highly controlled clinical research and actual practice. Using randomization, they provide valuable insights into how treatments and interventions perform in diverse settings and populations. Trial results are typically highly generalizable and readily translatable into healthcare policy and clinical care.

What topics may be covered in this training program?

Participants will learn about designing, implementing, and managing pragmatic trials alongside best practices in clinical trial reporting and standards. Topics that may be covered include but may not be limited to:

Design and analysis:

- Randomization unit: Individual vs. cluster randomization, level of the intervention (e.g., an intervention may be delivered by a healthcare provider, but the randomization unit may be a hospital).

- Randomization strategy and justification: Cluster-randomized, stepped-wedge, cross-over, factorial, adaptive; choice and construction of a comparator group (e.g., active or usual care); choosing a statistically efficient design and ensuring the design is fit-for purpose (see PRECIS-2).
- Randomization method: Simple, covariate-constrained, minimization, pair matched, stratified; randomization schedule for cluster-randomized trials with multiple cluster-periods.
- Blinding and allocation concealment: Who is blinded (e.g., the patient, the provider, the outcome assessor), when does blinding happen; justifications for blinding; ensuring blinding is maintained through time.
- Endpoints and outcomes: Considerations regarding the outcome distribution (i.e., time to event [including recurrent events, competing risks], binary, continuous, ordinal, count); single vs. composite; cost effectiveness; patient-reported and patient-important outcomes.
- Sample size considerations: Intraclass correlation, unequal cluster sizes, multiple cluster periods, adjustment for small samples (i.e., <30 clusters), treatment-effect heterogeneity, novel trial designs, and planning for sub-group and stratified analyses.
- Analysis: Unit of analysis (individual-level; cluster-level), covariate adjustment, heterogeneous treatment effects; handling missing data.
- Bias: Assessment of selection bias, measurement error/misclassification, residual confounding, and other threats to validity.

Data sources, variables, quality, and linkage: Data for pragmatic trials, including but not limited to baseline characteristics and outcomes, can come from existing routinely collected data sources such as linked provincial administrative health data, disease and healthcare registries, e-health records, and surveillance systems. Topics may include:

- Linking data across systems, regions, and networks; how to assess data quality; how to select and define outcome measures; database coding; and how to conduct validation studies and complete privacy impact assessments.
- Ethical and legal aspects of aggregating data across networks while maintaining privacy rules, how to link externally collected trial datasets to administrative data, and opportunities for data collection outside of the routinely collected data.
- The First Nations principles of OCAP: standing for ownership, control, access, and possession, OCAP is a tool to support strong information governance on the path to First Nations data sovereignty.

Implementation science and trial conduct: Participants will learn about the importance of designing simple, scalable interventions for broad implementation. They will learn about implementation frameworks, theories, and models. Implementation plans ensure successful intervention uptake and help determine the need for a pilot phase. Topics may include:

- How to assess current practice patterns (via surveys and/or routinely collected data analyses), perform qualitative studies to understand potential barriers to intervention uptake, prepare trial roll-out strategies informed by evidence-based implementation

strategies, develop monitoring protocols to assess fidelity, and how to measure and assess implementation outcomes.
- Privacy compliance, quality assurance, contracts, and budgets.

Partner buy-in and public/patient engagement: Participants will learn about the importance of engaging and communicating with diverse partners to cultivate a research-ready community (where partners may include healthcare organizations, providers, administrators, and public, patient, and family advisory councils). Topics may include:

- How to liaise with key partners using audience-adapted materials and how to seek feedback through various channels.
- How to create educational websites and brief videos tailored to key partner groups, and how to appropriately use social media to promote the trial and provide updates on recruitment, progress, and knowledge translation.

Research ethics and regulations: Existing ethical frameworks were developed primarily in the context of explanatory clinical trials, where the efficacy and safety of interventions for market approval is usually tested in trials of individually randomized patients. In contrast, pragmatic trials of usual-care interventions are often delivered by healthcare staff, using existing data collected in routine care, and these elements can present challenges to existing ethical and regulatory frameworks. Topics may include:

- How randomization, intervention delivery, and existing data collection at the level of the patient, health provider, or health system raises fundamental questions about the process of informed consent, the nature of research participation, and ethical protections.
- In the absence of internationally accepted ethical guidelines, researchers and ethics committees may have no common standard to guide appropriate practices in pragmatic trials. This can lead to variability in ethics reviews across regions. (Contributors to this training program have played leadership roles in advancing a responsible ethical framework for conducting these trials, including developing the first international ethics guidelines for cluster-randomized trials).
- Potential ethical considerations unique to pragmatic trials and appropriate modifications to traditional screening, recruitment, and consent models (e.g., e-consent, integrated consent, short form consent), the role of local partners, and how to prepare submissions for research ethics boards.
- Equipoise for routine care interventions (e.g., completing a literature review before a trial to demonstrate there is genuine uncertainty within the research community about the effectiveness of the interventions being compared), community engagement and patient-centered outcomes (e.g., demonstrating that the study's potential results will be meaningful to participants and that they align with their preferences and values), data security, confidentiality, and post-trial data access (e.g., data repositories).

Inclusion, Diversity, Equity, and Accessibility (IDEA): By design, pragmatic trials are highly inclusive, as typically all patients who would receive the intervention in practice will be included in the trial. These trials also enable the inclusion of patients and community-based centres in

remote locations, which are often excluded from explanatory trials due to a lack of dedicated research staff.

Participants in the program will consider the following overarching questions in the context of data and its use within a pragmatic trial: (1) Who is the data collected by? (2) For whom and for what purpose is the data being collected? and (3) Who benefits from the data collection?

Indigenous rights: 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.

How does this training program compare to the other CIHR-funded Clinical Trials Training Platforms?

Currently, the HDRN Canada Pragmatic Trials Training Program is the only CIHR-funded training platform that focuses specifically on pragmatic clinical trials. While more general ("traditional") clinical trials educational materials will be available in a learning management system, participants in this program will focus on novel and evolving aspects related to pragmatically evaluating interventions in real-world settings.

This training program will not focus on a particular disease or content area but rather, there will be an expanded focus on the use of existing data sources in trials, including health registries, electronic medical records, and administrative data. This is one of the reasons why this training program is embedded within HDRN Canada.

Pragmatic trials involve innovative study design choices. (See here for a list of pragmatic design elements that can be introduced into a trials design.) In addition to the rapid evolutions observed in the explanatory clinical trials space, there are many novel pragmatic trial-specific elements to consider as well, including but not limited to multi-regional participant recruitment and data access (with specific considerations around Inclusion, Diversity, Equity, and Accessibility, as well as Indigenous data sovereignty), altered consent procedures and novel ethical considerations, biostatistical and epidemiologic methods complexities, and intricacies of implementing and maintaining interventions in routine care settings.

Lastly, unlike several of the other Clinical Trials Training Platforms, this program focuses solely on advanced learners (e.g., faculty-level trainees, postdoctoral fellows, and HQP in the workforce).

Has this training program been offered before?

No. The program will launch for the first time in April 2024 and run for two years. Therefore, participants should be prepared for the realities that come with a first-time offering. In light of this, the program will seek routine feedback from participants and adapt to help meet their learning objectives.

What is the language of instruction for this program?

The language of instruction for the program will be English. Therefore, to fully engage with the educational materials and other participants, all applicants must have an adequate level of proficiency in English.

How will the future trial leaders collaborate with postdoctoral fellows in the program through the development of a pragmatic trial protocol?

Using the information provided in the application forms, program staff will connect future trial leaders and postdoctoral fellows in the program based on shared interests and complementary expertise. (Note: If a future trial leader applies to the program with a postdoctoral fellow who is already under their direct supervision outside of the program, and both are accepted, they can further their collaboration within the program, if they so choose.)

While the program will provide visibility to participants in terms of where potential pairings may exist (e.g., a future trial leader may propose a trial that has novel ethical or analytical considerations, lending to potential pairings with a research ethics fellow or a biostatistician fellow), it will be up to the participants to formalize suitable arrangements with each other.

Throughout the program, future trial leaders and their collaborating fellows will be responsible for operationalizing their experiential learning through the development of a pragmatic trial protocol. i.e., It is anticipated that participants will engage with each other, and this will require initiative from the future trial leader and collaborating fellows that results in routine correspondence and meetings. (Note: If the trial leader is using their funding to receive project-based training through the Pragmatic Trials Stream of the ART Platform, the platform may be able to provide administrative supports as well.)

As indicated, future trial leaders and fellows will reflect and present on obstacles and solutions encountered during the development of their protocols and this will serve as a means of tracking progress throughout the program.

Lastly, it is possible that a given trial leader may not be matched with a fellow in the program. This may happen due to an imbalanced number of trainees across each stream. Also, if agreed upon, an individual trial leader with additional interest and capacity may decide to collaborate with multiple fellows in the program. This reflects the reality that future trial leaders and postdoctoral fellows are advanced learners with various obligations, and there may not be a one-size-fits-all experiential learning arrangement for all participants.

What are some example projects for the public sector HQP employed by HDRN Canada member organizations that will expand HDRN Canada's capacity to support pragmatic trials research, particularly multi-regional trials?

In no particular order, the following are examples of topics/projects that could further HDRN Canada's ability to support pragmatic trials research (e.g., reducing barriers for analyses of routinely collected data, particularly multi-regional data, that informs trial design and execution). The process through which such projects are developed, the timeline for the work, and the

output of the projects, will vary. The examples below and the relevant areas of expertise are not meant to be exhaustive.

- Comparing and documenting the consent and privacy considerations within individual provinces/territories relating to the conduct of multi-regional pragmatic trials.
    - From the lens of conducting multi-regional trials, this project could build upon the "Privacy Legislation by Province or Territory" section of HDRN Canada's Data Access Support Hub (DASH). Specifically, this work could be expanded to build out the specific trial-related requirements on a region-by-region basis.
        - e.g., How can de-identified data be shared between individual provinces/territories for trial planning/execution purposes? Can this de-identified data be shared at the individual-level or at a summary-level? What permissions are required to share these data, and what does this approval process look like for trialists interested in using multi-regional de-identified data?
        - e.g., Approaches to coordinate research ethics board approvals across multiple provinces/territories and guidelines to ensure consent language is appropriate for multiple regions.
    - *Relevant areas of expertise: e.g., research ethics, privacy, legal*
- Developing approaches for the use of routinely collected data to corroborate ("adjudicate") outcomes captured by primary data collection within trials.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics*
- Developing approaches for the use of routinely collected data to monitor adherence to the randomly-assigned intervention.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics*
- Developing approaches for the use of routinely collected data to monitor outcomes (e.g., health services utilization, use of other downstream interventions, occurrence of morbidity or mortality), including unanticipated safety concerns or signals in the trial.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics*
- Developing approaches for the use of routinely collected data to monitor and optimize participant enrolment in trials.
    - e.g., Use of administrative data to identify the location of potentially eligible participants. Comparing the number of potentially eligible participants in an area to the number of participants ultimately enrolling in a trial.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics, research ethics*
- Developing post-trial approaches for comparing characteristics of the study participants to those who were eligible to enroll but did not.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics, research ethics*
- To support trial planning including power and sample size calculations, developing approaches for the use of routinely collected data to understand current practice patterns, baseline characteristics, and outcome event rates.
    - *Relevant areas of expertise: e.g., epidemiology, biostatistics*

- Developing approaches for the use of routinely collected data to identify and subsequently contact eligible participants (e.g., employment of case-finding or other identification algorithms, followed by participant outreach).
    - *Relevant areas of expertise: e.g., research ethics, privacy, legal, epidemiology, biostatistics*
- Developing approaches to study the long-term impacts of the trial results on changes in real-world practice patterns in the post-trial period.
    - *Relevant areas of expertise: e.g., research ethics, privacy, legal, epidemiology, biostatistics*

How will the public sector HQP employed by HDRN Canada member organizations engage in a project that furthers HDRN Canada's ability to support pragmatic trials research?

Using the information provided in the application forms, program staff will connect with HDRN Canada HQP in the program to refine their project ideas and, if appropriate, connect HDRN Canada HQP with each other based on shared interests and objectives. e.g., It is possible that some projects may require a multi-regional focus from the outset and HQP from several HDRN Canada member organizations may wish to work together on shared objectives. It is also understood that some member organizations are distributed across a given province or territory (e.g., ICES has various sites across Ontario). As such, there may be a desire to connect HDRN Canada HQP from multiple sites within the same region (e.g., Ontario) to collaborate on complementary projects.

While the program will provide visibility to participants in terms of where potential pairings may exist (e.g., various staff working in the privacy space may wish to work together on a multi-regional framework, various epidemiologists/statisticians may wish to work together on multi-regional analytical considerations), it will be up to the participants to formalize suitable arrangements with each other.

Throughout the program, HDRN Canada HQP will be responsible for operationalizing their experiential learning projects. i.e., It is anticipated that participants will engage with each other, and this will require initiative from the HDRN Canada HQP that results in routine correspondence and meetings.

As indicated, HDRN Canada HQP will reflect and present on obstacles and solutions encountered during their projects and this will serve as a means of tracking progress throughout the program.

Lastly, it is understood that not all HDRN Canada HQP or their member organizations will have the same interest and/or capacity to engage in project-based learning; there may not be a one-size-fits-all experiential learning arrangement for all participants. e.g., It is possible that a given HDRN Canada HQP may be based at a smaller site that does not have the capacity to involve themselves in a project. However, HDRN Canada HQP at these sites may wish to collaborate with a larger site, in another region, on a project of interest to them. The premise is that strengthening expertise, systems, and processes in one region will ultimately serve to move the entire network towards this goal. In other words, each HDRN Canada HQP is not expected to

lead a separate project and collaboration will be key to the success of the experiential learning projects.

Why are public sector HQP employed by HDRN Canada member organizations being asked to engage in an experiential project-based learning experience?

Pragmatic trials are often embedded in routine care and, thus, can leverage routinely collected data (e.g., health registries, electronic medical records, and administrative data). HDRN Canada is a distributed pan-Canadian network that supports multi-regional data access for transformative and world-leading health data use, working to shape a data future that better supports health and health equity. HDRN Canada supports researchers in accessing multi-regional data housed in data centres across the country through its Data Access Support Hub (DASH).

Therefore, the training program is formally embedded within HDRN Canada and one of its goals is to expand HDRN Canada's capacity to support pragmatic trials research, particularly multi-regional trials. To help meet this goal, there is a targeted need for HQP employed by HDRN Canada member organizations to expand their ability to support pragmatic trials research (e.g., reducing barriers for analyses of routinely collected data, particularly multi-regional data, that informs trial design and execution).

Unlike other public sector organizations that employ HQP, and unlike private sector organizations, the direct relationship between this training program and HDRN Canada member organizations permits the facilitation of potential project-based learning experiences. It would be more challenging to prescribe or support such projects for HQP at other employers, particularly those in the private sector, within this program.

Can public sector HQP outside of HDRN Canada member organizations, or private sector HQP, get involved in project-based learning experiences?

The program acknowledges that HQP from, for example, other public sector organizations (e.g., clinical trial organizations, clinical trial units) may also be well situated to engage in projects that expand their organization's ability to support pragmatic trials research. However, due to the breadth of host organizations employing these public sector HQP (outside of HDRN Canada), this will not be assessed at the time of application. As mentioned, the engagement of public sector HQP from outside HDRN Canada in project-based learning experiences will be discussed after acceptance into the program on a case-by-case basis.

Similarly, it is not anticipated that private sector HQP (who will not receive time release funding) will have the capacity to engage in project-based learning. Although, as with non-HDRN Canada public sector HQP, this can be discussed on a case-by-case basis after acceptance into the program.

For the trainee streams engaged in experiential project-based learning, what is the anticipated breakdown of a participant's time on these projects, in relation to the routine asynchronous engagement within a learning management system?

Except for public sector HQP outside of HDRN Canada or private sector HQP, all other trainees will be involved, when possible, in a project-based learning experience. As the program progresses, the advancement of projects (i.e., a pragmatic trial protocol for future trial leaders and fellows; a project that furthers HDRN Canada's ability to support pragmatic trials research for HDRN Canada HQP) will be self-directed and the responsibility of the participants themselves.

A learning management system with educational materials focused on pragmatic clinical trials will exist to provide the core training to facilitate the initiation and advancement of projects. The system will also foster a community of learners, provide networking opportunities, and permit routine asynchronous engagement (e.g., reflections on educational content).

Acknowledging pan-Canadian trainees across all streams are advanced learners with various obligations, this training program is entirely virtual and largely asynchronous in nature. As outlined in the application forms, there is the expectation that:

- 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).
- Postdoctoral fellows must be able to engage with tasks related to the program on a bi-weekly basis (10 hours over a two-week period, ~5 hours per week).
- All HQP must be able to engage with tasks related to the program on a bi-weekly basis (6 hours over a two-week period, ~3 hours per week).

Within these time commitments, this program aims to amplify and complement the existing full-time activities of these pan-Canadian trainees. While developing general skills and knowledge related to pragmatic trials is a major focus of this program, another important goal is to amplify and support experiential learning activities.

Through project-based learning, this program will foster the creation and/or advancement of efficient systems and processes that researchers will ultimately need to complete pragmatic trials in Canada throughout their careers. This is why there is a focus on (1) pragmatic trial protocol development (which will inform robust funding applications, allowing for the completion of such trials in the future) and (2) HDRN Canada projects that will further the networks ability to support pragmatic trials research in the long-term.

In light of this, the amount of time these specific trainees will spend on asynchronous learning within a learning management system may fluctuate through time, with more time being spent on the core educational materials (e.g., reviewing lecture slides, videos, audio content) at the beginning of the program, with an increased focus on the trial protocols (for future trial leaders and fellows) and the HDRN Canada projects (for HDRN Canada HQP) through time. The amount of time a participant spends on the educational content will vary week-to-week, depending on their own schedules, educational backgrounds, and their interest in a given topic.

For public sector HQP outside of HDRN Canada or private sector HQP who do not ultimately collaborate on an experiential learning project, most of their time (apart from the monthly one-hour virtual meetings) will be spent asynchronously engaging with educational content and networking with other trainees within a learning management system.

Lastly, attendance at the monthly one-hour virtual meetings (for all trainee streams) is built into the required time commitments described in the application forms.

How does the time release funding for HQP employed at public sector organizations correlate with the required time commitments for these participants in the program?

To facilitate the involvement of public sector HQP, public sector organizations/employers will receive 150 hours of time release funding, per year, valued at a minimum of $50 per hour (i.e., each public sector employer will receive a minimum of $7,500 per year for each of their HQP in the program). This amount may be adjusted based on the number of successful public sector HQP applications.

At minimum, all HQP must be able to engage with tasks related to the program on a bi-weekly basis (6 hours over a two-week period, ~3 hours per week). Conceptually, the time release funding amount for public sector HQP was calculated under the following assumptions: i.e., if a given HQP spends 3 hours per week on training program tasks (for 50 weeks of the year, assuming 2 weeks of vacation time), this equates to 150 hours of time spent on tasks related to the program.

Ultimately, given the breadth of the public sector HQPs and the various host organizations, it is not possible to track the salary/compensation structures at each employer (e.g., benefits components to compensation). Further, it is not possible to consider other variables, including but not limited to cost recovery models, collective agreements, or annual salary increases. Therefore, the description that 150 hours of engagement per year (3 hours per week over the course of a 50-week work-year, valued at a minimum of $50 per hour) equates to a minimum of $7,500 is an illustrative example, and is not meant to map directly onto each participant's unique circumstances.

What does it mean if an HQP employed at a public sector organization earns an hourly wage that is of lesser or greater value than the time release funding?

From the perspective of the host organization/employer of a public sector HQP, it must be understood that employers will receive a minimum of $7,500 per year for each of their HQP in the program; see above for the assumptions used to calculate this amount. (Note: This amount may be adjusted based on the number of successful public sector HQP applications.)

As described, the funding is meant to facilitate public sector HQP involvement in the program (6 hours over a two-week period, ~3 hours per week). Ultimately, given the breadth of the public sector HQPs and the various host organizations, it is not possible to track the salary/compensation structures at each employer (e.g., benefits components to compensation). Further, it is not possible to consider other variables, including but not limited to cost recovery models, collective agreements, or annual salary increases. Therefore, the description that 150 hours of engagement per year (3 hours per week over the course of a 50-week work-year,

valued at a minimum of $50 per hour) equates to a minimum of $7,500 is an illustrative example, and is not meant to map directly onto each participant's unique circumstances.

i.e., An individual participant who earns less than the time release funding (e.g., less than $50 per hour – *final funding amount is to-be-determined*) will not necessarily earn more through their involvement in this program. In this case, where the time release funding is more than the employee's hourly wage, the additional funding will be retained by the employer and will be used to accommodate aspects that are not under the purview of the training program: e.g., benefits components to the compensation of their employee in the program, cost recovery models at their organization, collective agreements, and/or annual salary increases.

Similarly, an individual participant who earns more than the time release funding (e.g., more than $50 per hour – *final funding amount is to-be-determined*) should not earn less because of their involvement in the training program. If the employer approves of the applicant's involvement in the program, it must be understood that they are effectively subsidizing some of their employee's time as they engage with tasks related to the program.

The illustrative example ("correlating the time release funding, for public sector HQP, to the required time commitments for these participants") references a hypothetical 50-week work-year (2 weeks of vacation), yet I take more vacation time than this. How does this impact the time release funding?

As noted, the description that 150 hours of engagement per year (3 hours per week over the course of a 50-week work-year, valued at a minimum of $50 per hour) equates to a minimum of $7,500 is an illustrative example, and is not meant to map directly onto each participant's unique circumstances. Therefore, it follows that taking more vacation time than referenced in this example does not impact the amount of funding that is sent to the public sector HQPs employer.

Given the breadth of the public sector HQPs and the various host organizations, it is not possible to track the vacation time of each participant. Ultimately, each public sector employer will receive a minimum of $7,500 per year for each of their HQP in the program, regardless of all the other factors that may vary across the participants (e.g., amount of vacation time, the hourly wage of the employee) and/or their employer (e.g., benefits components to the compensation of employees, organizational cost recovery models, collective agreements, and/or annual salary increases).

How will participants be evaluated?

This training program is focused on advanced learners: faculty-level trainees (future trial leaders), postdoctoral fellows, and HQP in the workforce. Most participants will have completed extensive formal education and evaluation prior to enrolment. Therefore, this program is not focused on providing further formalized credentials. i.e., There are no plans to accredit this first offering of the program, nor will the program provide an "official transcript" to participants.

While a certificate will be provided upon successful completion of the program, this program will not place a strong emphasis on standardized testing of knowledge (e.g., exams, quizzes, assignments). The program will, however, monitor progress in the experiential learning tasks

and track engagement within a learning management system (e.g., reflections on the educational content).

As indicated, future trial leaders and collaborating fellows will reflect and present on obstacles and solutions encountered during the development of their trial protocols and this will serve as a means of tracking progress throughout the program. Similarly, HDRN Canada HQP will reflect and present on obstacles and solutions encountered during their projects, and this will also serve as a means of tracking progress.

For public sector HQP outside of HDRN Canada or private sector HQP who do not ultimately collaborate on an experiential learning project, it is important that these participants can go on to act as ambassadors for pragmatic trials within their host organizations. Therefore, routine asynchronous engagement (e.g., reflections on educational content) and networking with other trainees within a learning management system will take on a greater emphasis for these participants.

What happens when I take vacation time during the program, or if I need to take an extended leave of absence for another reason?

Acknowledging all trainees are advanced learners with various obligations, this training program is entirely virtual and largely asynchronous in nature. It is understood that all participants will take vacations and the amount of vacation time a person is entitled to, and the use of that time, is not under the purview of the program. It is expected that participants will self-manage their time and, upon returning to work, ensure they: e.g., (1) catch up on any applicable educational content and networking discussions within a learning management system, (2) continue advancing their experiential learning projects (if applicable), and (3) notify program staff with a brief explanation if they are anticipating not attending 80% of the monthly one-hour virtual meetings (due to vacation time).

There is the expectation that applicants to the training program will be able to meet the requirements of a two-year program (April 15, 2024 – March 31, 2026). Specifically, the program does have a large experiential learning component (especially for the future trial leaders and postdoctoral fellows, as well as the public sector HQP employed by HDRN Canada member organizations) which will follow a continuous two-year arc. The project-based learning opportunities (i.e., pragmatic trial protocols and the projects that further HDRN Canada's ability to support pragmatic trials research) will be initiated during year one and continue into year two. These timelines also reflect the funding availability and reporting timelines from the program's funder, CIHR.

For applicants who are interested but are unclear as to whether they can meet the requirements (e.g., due to a planned extended leave of absence), please note that the program plans to make many of the educational materials and other resources broadly available at a later date. Notably, there are no current plans to offer future intakes/enrolments for the program in this format (e.g., with associated funding and an emphasis on experiential learning), as the funding is not secured to do so.

However, it is understood that (1) not all leaves of absence may impact the experience of a given trainee in the same manner (e.g., leaves may vary in duration), and (2) not all leaves can be anticipated. Therefore, program staff are committed to accommodating participants whenever possible. i.e., In the case when an extended leave of absence is necessary, particularly a leave that may impact the experiential learning experiences for the participant and other collaborating trainees (i.e., trial protocol development involving future trial leaders and fellows; projects for HDRN Canada HQP that will expand HDRN Canada's capacity to support pragmatic trials research), program staff will work with impacted participants on a case-by-case basis. Similarly, extended leaves that may have an impact on funding eligibility (e.g., postdoctoral salary award top-up funding, time release funding for public sector HQP) will be discussed on a case-by-case basis.

How will you accommodate the required attendance at monthly, one-hour virtual meetings in the pan-Canadian context?

To accommodate time zones, these monthly meetings will be scheduled to start between 12:00 PM and 3:00 PM Eastern time; the exact day of the month is to-be-determined. Participants will be required to attend 80% of these meetings.

Will there be requirements and/or opportunities to attend in-person events?

There is no funding for in-person events for this training program. However, given that this program is embedded in HDRN Canada and has pan-Canadian partnerships with groups such as the ACT Canada Consortium and other Clinical Trials Training Platforms, there may be opportunities for participants to network in person. Such opportunities, while not guaranteed, will be announced to participants, when and if they arise.

What is the governance structure of this program?

HDRN Canada is a CIHR-funded pan-Canadian network focused on facilitating multi-regional studies (including, but not limited to, clinical trials) using routinely collected data. The training program is embedded within the governance structure of HDRN Canada; the nominated principal applicant and program manager are members of the HDRN Canada Leads Team and the ACT Canada Consortium/HDRN Canada Clinical Trials Working Group. The Leads Team receives input from the SPOR CDP Advisory Committee, as well as HDRN Canada working groups (e.g., Indigenous data, IDEA, and public engagement groups).

As a CIHR requirement, there is also a training program advisory committee that guides and monitors the progress of this program. Specifically, this committee advises on the design, implementation, and high-level operations of the program. As outlined by CIHR, the committee includes trainees, healthcare professionals, clinical research professionals, early career researchers, an IDEA champion, a person with lived/living experience, and an individual who self-identifies as Indigenous (First Nations, Inuit, and/or Métis).

The training program is coordinated by the Schulich School of Medicine & Dentistry at Western University in Ontario, Canada. The nominated principal applicant and program manager are also members of the Pragmatic Trials Scientific Advisory Committee at Western University, where the nominated principal applicant serves as an Associate Dean of Clinical Research and

the program manager is an Adjunct Research Professor in the Department of Epidemiology and Biostatistics. Further, the nominated principal applicant is a member of the ACT Canada Consortium Operating Committee and a Co-Chair of the Scientific Committee. The program manager is also a member of the ACT Canada Training Committee.

How are Inclusion, Diversity, Equity, and Accessibility (IDEA) considered in this program?

The training program grant was drafted with the input of HDRN Canada's IDEA team lead who is also a member of the training program advisory committee. There is funding from the grant devoted to supporting IDEA initiatives within this program. Further, this training program aligns with CIHR's goal of creating a more inclusive, diverse, equitable, and accessible Canadian research enterprise. The program staff endorse the statement that this is "essential to creating the excellent, innovative, and impactful research necessary to advance knowledge and understanding, and to respond to local, national, and global challenges."

How are Indigenous rights considered in this program?

The training program grant was drafted with the input of the Indigenous Peoples' Engagement and Research Council (IPERC) and program staff have seasonal check-ins with the IPERC. The program has a full-time Indigenous Cultural Competency Training Coordinator who is mentored by Indigenous Knowledge Keepers. The training program advisory committee also includes Indigenous representation and HDRN Canada has a team dedicated to Indigenous data in the context of pan-Canadian routinely collected data.

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.

If I am enrolled in another CIHR-funded Clinical Trials Training Platform, can I apply to this training program?

This program does not explicitly prohibit trainees participating in other platforms from applying to this program (albeit other platforms may have such restrictions). From the perspective of this program, the major barrier to involvement in multiple training programs are considerations around time commitments and funding.

For example, in this program, top-up salary awards for postdoctoral fellows may be combined with other awards, up to a combined maximum allowed by the host institution and/or the allowed maximum within the funding conditions of other salary awards currently held by the applicant. To maintain this funding, fellows must meet the requirements of this program (as outlined in the application form). Situations like these, and others that may impact future trial leaders and/or HQP trainees, may impact one's ability to be formally involved in multiple CIHR-funded training programs at the same time, many of which also provide financial support (with associated requirements to maintain that support).