

CLINICAL TRIALS TRAINING PLATFORM

Visit https://wecantrain.ca/home/vision-mission-values-goals/

2023-2024 Application Guidelines

https://wecantrain.ca/home/studentships-fellowships-and-internships/qualified-clinical-research-professionals/

Internships (*Practicum*) for Clinical (Trial) Research Professionals

Academic or Healthcare Institutions, Research Centers or Institutes, Regional or District Health Authorities, Hospitals, Non-for-Profit or Community Organizations, referred as "Institutions"

For Clinical (Trial) Research Professionals (CRP*) who are guided by one or more aspects of the principles of Good Clinical Practice (GCP) and have backgrounds in health sciences, nursing, pharmacy, medical technology, health record management, statistics, education, or other areas.

* A CRP may be an individual who is employed and/or involved in any aspect of conduct of clinical research / trial protocol. Examples are: Administrator, clinical / data manager, clinical research pharmacist, clinical research assistant / associate, clinical research / trial coordinator, clinical trial manager, Clinical Trial Educator, quality assurance manager, clinical trial regulatory affairs manager, research nurse, study coordinators and research assistants

At this time, an overall yearly allocation of 16 Internship Awards across Canada, up to a value of \$10,000 each (\$160,000)

Partnering:

BC (n=6), MB (n=2), NB (n=4), NS (n=4)



Under development: AB, SK, ON, QC, Nfld & Lab

Competition timeline: Applications are invited BETWEEN September 2023 to March 2024.

- **Rolling Review Process:** The Applications will be reviewed regularly by the partnering CTTP Managers, Nominated Principal Applicants and partnering funding provincial organizations, and subject to the availably of funds.
- Announcements: Notice of Awards will be sent after monthly review, until the end of March 2024, subject to availability if funds.
- Duration: Option 1, over one year, the funding is to support secondment salary for <u>virtual</u> engagement (e-Learning and e-Mentoring). The number of hours of protected time for the Applicant to be involved in clinical trial activities (ex. 1 day per week, that needs to be justified in the application see below) is to be documented from a faculty, a clinical trial department or unit (CTU). Such a group needs to be from outside the own Institution of the Applicant. The Institution can be from within the same province of the Applicant.

NOTE: Relative to the budget justification, one cannot pre-define the duration of the practicum, since CRP as Applicants can be junior to senior Applicants which salary and benefits will be different, therefore the length of time to support secondment salary.

Option 2, over one year, the funding is to support <u>on-site visit and in-person exchange</u> at a selected Institution for a number of days/weeks (that needs to be justified in the application – see below).

- **Term:** The Internship must be completed by October 1st, 2024.
- **Funding amount:** Up to \$10,000 funded by partnering funding provincial organizations, to be paid to the Institution employing the Applicants. This internship award may be combined with other awards as an incentive, up to a combined maximum stipend allowed by the Institution, partnering co-funder(s) and the funding conditions of other awards held Applicant.

The full stipend will be transferred to the Institution where the Applicant is from by March 31st, 2024.

The host Institution will receive a \$1,000 stipend to cover administrative process from CANTRAIN.

- Use of funds: The following are allowable expenses: (i) Protection of Time (secondment salary); (ii) travel expenses; (iii) accommodation expenses; and (iv) per diem. This must be outlined in the use-of-fund budget justification.
- **Eligibility requirements: See above*.** Open to various group of highly qualified health research professionals who are involved in any aspect of conduct of clinical research / trial protocol, including the analysis of clinical trial samples and/or data analysis. At the time of funding, Applicants must be a Canadian resident or permanent resident or hold a valid Canadian work permit. For this competition, Applicants from private and for-profit organization are excluded.

NOTE: The program considers scientific excellence and aims to support the full and fair participation of all members of the clinical trial community through consideration of barriers experienced by underrepresented groups, with respect to EDI principles. (*https://cihr-irsc.gc.ca/e/52543.html*).

MandatoryIn addition to the time spent on the internship, the successful Applicant will be
required to complete part of the CANTRAIN Clinical Trials Training Program: (i) The
Orientation Level and (ii) the Mandatory Regulatory Compliance Level BEFORE the
start of the CRP Internship. Alongside the internship (over one year), the Applicant is
also to complete the (iii) Common Core Foundation Level and (iv) subsequent levels
based on the Applicant's expertise as a CRP. Those Levels are composed of
knowledge-based learning modules and competency/experiential-based mentorship
webinars.

NOTE: Applicants will also be linked to provincial clinical trials programs, supports and services where applicable, to further help strengthen the provincial infrastructure, to further enable clinical trials and their professional development (ex. For BC Applicants: <u>Clinical Trials BC</u>.

Intended tangible At the end of the funding period, the successful Applicant will have:

- Obtained the certified training in (i) Good Clinical Practice (ICH-GCP), (ii) Health Canada Division 5 and (iii) TCPS-2, as required for mandatory regulatory compliance modules;
 - Acquired further knowledge of the regulations and practices around clinical trials, based on the modular curriculum provided through CANTRAIN and co-funders clinical trials programs when applicable (cited above), and
 - Participated in either individual or group mentoring experiences required by CANTRAIN;

Application checklist The application must include the items listed below that shall be filled-up in the portal or uploaded via the portal on-line. No more than 2 pages in length for each item.

- 1) Personal statement from the Applicant;
- Letter of support <u>SIGNED</u> by the Department Head or Direct Supervisor (Requirement: Must be on the Applicant's <u>home</u> Institution Letterhead)
- 3) Curriculum Vitae: CV <u>or</u> CCV;

outcomes and

expectations

- 4) Description of the proposed internship;
- 5) Letter of invitation/support <u>SIGNED</u> by the Institution leadership that will host and be accountable for welcoming you (the Applicant). The welcoming site must have been in operation for at least 3 years and which includes clinical research / trials expertise. (Requirement: The letter must be on the <u>host</u> Institution Letterhead)

NOTE: If you have difficulties in identifying a welcoming site, communicate by Email (<u>https://wecantrain.ca/home/contact-us-internship/</u>) with CANTRAIN to discuss a list of welcoming sites which have been in operation for at least 3 years and which includes clinical research / trials expertise.

Document Format: • PDF format (the only authorized format); • 8 1/2 in x 11 in (216 mm x 279 mm), i.e. "Letter" size;

- · All margins: Minimum 2 cm;
- Font: Times New Roman (12 points);
- · Single line spacing;
- Inscribed in the header of each of the above 5 sections:
 - Last name of the Applicant,
 - First name of the Applicant,

Name of the Institution from where the Applicant is applying from.

APPLICATION DETAILS:

NOTE: CANTRAIN values your trust and it is committed to the responsible management of your personal information. This CANTRAIN Privacy Policy describes how we collect, use, and share personal information received from this application (https://wecantrain.ca/privacy-policy/). By providing personal information, your CV/CVV or any other information to CANTRAIN, you agree to this Privacy Policy.

- 1) **Personal statement from the Applicant.** An opportunity to complement your CV. Requirement are to include the following elements. No more than two (2) pages.
 - i. Briefly describe how your project and internship is related to your current work as a Clinical Research Professional (CRP) or Early Career Researcher (ECR):
 - ii. Briefly describe why the Clinical Trial Training Programs (CTTP) you selected is of interest to you and how you expect to benefit from this training experience:
 - iii. Describe your current training environment and supervisory support:
 - iv. Describe your professional, academic and extracurricular experiences/achievements and how they will contribute to your training success
 - v. Outline your career goals and describe how the award would help to support your pursuit of these goals
 - vi. **If applicable,** reflect on barriers that you as a member of an underrepresented group in science or research have experienced thus far and ways that you have sought to overcome these barriers. Describe how would the present internship award support you to overcome barriers relative to equity, diversity, inclusion, and accessibility (EDIA) / IDEA ?

Our funding partners are committed to developing capacity for the conduct of clinical trials across the province. Through this internship program we're interested in supporting both Applicants who are currently working in trials and need more training and experience, as well as Applicants who are looking to work in clinical trials, but need (more) training and experience to take on tasks in the conduct of trials in order to meet the regulatory requirements and sponsor expectations.

- vii. Define your level of experience in clinical trials:
 - a. I am currently working in health research and/or clinical research and do not have the training and experience to work in regulated clinical trials; **or**
 - b. I am currently working in clinical trials and looking to enhance my experience/skills in at least one of the following areas: (select all that apply)
 - 1. monitoring trials,
 - 2. quality management,
 - 3. decentralized trials,
 - 4. culturally safe trials,
 - 5. vulnerable populations,
 - 6. institutional sponsored or investigator led trials

- 7. Phase I trial conduct.8. Other (please describe)
- viii. Please provide us with a short paragraph describing the experience/ intended outputs you wish to gain through this internship and how this particular placement will help you achieve your goals.
- 2) Letter of support <u>SIGNED</u> by the Department Head or Direct Supervisor. Requirement: This letter should include the elements listed below. No more than two (2) pages.
 - i. In what capacity you know the Applicant and how long as the Applicant worked at the institution?
 - ii. In what capacity the Applicant will benefit from this internship / practicum / protection of time?
 - iii. Applicant's performance and experience, strengths/weaknesses;
 - iv. How will this experience contribute to the career or individual growth of the Applicant;
 - v. Describe the training environment at your institution for the Applicant and how your current training environment supports the Applicant's proposed project and personal goals;
 - vi. Provide justification of the projected use of funding define the specifics relate to protected time when applicable;

3) Curriculum Vitae: CV or CCV. Make sure your CV include:

- i. Degrees;
- ii. All relevant clinical research activities, for example the number of various clinical trials in which you have participated;
- List of publications, presentations, abstracts (poster versus oral presentations at local, provincial, national, international venues), the establishment of dataset(s), intellectual property, commercialization activities/participation in start-ups.
- iv. If a CCV* from <u>https://ccv-cvc.ca/</u>

*Funding Source (select): CIHR CV

*CV Type (select): Biosketch

NOTE: If you have alternative achievements in addition to traditional academic achievements, please list and describe them (up to 2 additional pages' space in the submission portal). Visit: Declarations of Research Assessment (DORA; <u>https://sfdora.org/</u>).

- 4) **Description of the proposed internship.** Requirement: The project description much include the elements listed below. No more than 2 pages in length.
 - i. Enumerate and briefly elaborate your practicum goals / objectives;
 - ii. Impact and Expected Outcomes. Elaborate expected results, deliverables and dissemination plan for your proposed project;
 - iii. Feasibility and timelines. Demonstrate scientific and technical feasibility of additional skill development during the internship (e.g., recruitment of patients, acquisition of data, biostatistics, access to necessary equipment, etc.). Identify potential limitations and describe mitigation strategies. Describe timelines and milestones. Where the proposed project relies on existing resources (e.g., databases, established research infrastructure, equipment), describe the availability of these resources at the hosting institution where you will conduct the internship;
 - iv. Define your role during the internship at the welcoming / host Institution;

i.

- 5) Letter of invitation/support <u>SIGNED</u> by the leadership of the Institution that will host and be accountable for welcoming the Applicant. Examples: Director of the site, Clinical Department or Clinical Trial (Research) Unit (CTU) of the welcoming Institution. The welcoming site must have been in operation for at least 3 years and which includes clinical research / trials expertise. Requirement: The letter must be on the host institution Letterhead and no more than 2 pages in length.
 - Provide details about the site, Clinical Department or CTU welcoming the Applicant.
 - What type of trials do you conduct;
 - What type of training do you provide with your own personal;
 - ii. This letter must include the name and contact information of the hosting supervisor-mentor;
 - iii. The site, Clinical Department or CTU must have a minimum 3 years of active clinical trials' operations;

NOTE: If you have difficulties in identifying a welcoming site, communicate by E-mail (<u>CRPinternships@wecantrain.ca</u>) with CANTRAIN to discuss a list of welcoming sites which have been in operation for at least 3 years and which includes clinical research / trials expertise.

PLEASE NOTE: Applications and supporting documentations written in French are allowed 25% more space.

A CONFIRMATION OF RECEIPT. An E-mail will be sent within 48 hours of the application submission. A separate email will be sent upon receipt of both letters of support / letters of references. If a CONFIRMATION OF RECEIPT email is NOT received, the onus is on the individual submitting the application to follow-up with <u>CRPinternships@wecantrain.ca</u> to ensure that the parts were received. We want to ensure that all applications submitted are received; we appreciate your assistance with this process.

If you have any questions about the submission process, the application portal, and required documents related to the application for CANTRAIN, please contact us <u>here</u>.

ONLINE submission portal: <u>https://wecantrain.ca/account</u>

The Applicant can ONLY submit one APPLICATION to one Clinical Trials Training Platform (CTTP)

NOTE: Applicants and their host institutions will be required to complete two post-internship reports: (i) One within 30 days of completing the internship and (ii) a survey one year later. The provincial funding partners may require additional reporting in later years.