

Venture Navigator, Integrated Management Platform to Accelerate Clinical Trials (IMPACT) Life Sciences Innovation Hub

The Integrated Management Plan to Accelerate Clinical Trials (IMPACT) is a program designed to facilitate the efficient conduct of high-quality clinical trials through an integrated, multi-step process.

The Life Sciences Innovation Hub (LSI Hub) at the University of Calgary is a one-of-a-kind facility located within University Research Park. The LSI Hub offers access to space (office, wet and dry labs, prototype maker space), entrepreneurial and business development programming, mentorship, and technical expertise for research-intensive startups and developing companies.

NATURE OF THE WORK

The Venture Navigator (“Navigator”) will functionally report to the Executive Director of the Integrated **Management Platform to Accelerate Clinical Trials (IMPACT)** Program and administratively to the Director, Economic Development, Life Sciences Innovation Hub.

This is a full-time position that requires approximately 37.5 hours per week, usually Monday to Friday. Overtime is a possibility, depending on project deadlines. Travel to clinical research sites may be required. Navigators are the primary contact for life science Ventures in the IMPACT program. Each Navigator will directly assist several Ventures at one time.

The successful applicant will act as a mentor and advisor to Ventures, must be self-motivated, and have advanced knowledge related to the conduct of phase I through III clinical trials. Additional responsibilities may include business, regulatory, database, or educational support, based on the skills and aptitude of the Navigator. Navigators are recognized as technical experts and scientific contributors. They must manage Ventures and any research projects; adapting plans and priorities to meet service challenges. They must apply their technical and functional knowledge to the design of projects. They must interpret and apply, using their own discretion, any compliance or scientific requirements for projects. They must also work closely with other experts on the IMPACT team and expert consultants, as well as Ventures to facilitate regulatory and other requirements. Navigators must also freely share their knowledge and skills with the IMPACT team and may assist other Navigators on their projects as needed. They must possess excellent interpersonal and communication skills, be highly flexible, multi-task, and effectively work independently in a fast-paced, changing environment with frequent tight deadlines.

PRIMARY PURPOSE OF THE POSITION

To guide Ventures through Clinical Trials process, including:

- linking Ventures with Principal Investigators (PIs) and key opinion leaders (KOLs)
- assisting with designing research and regulatory plans to facilitate market approval of new health technologies. This may include assessing and conducting a gap analysis of existing resources assisting Ventures in developing a product research pathway that aligns with regulatory guidance that the Venture receives
- developing clinical trial protocols

- facilitating ethics approvals
- aiding and coordinating research milestones with processes required for Health Canada and other regulatory agency submissions
- ensuring timely contract execution
- liaising with the Calgary Centre for Clinical Research (CCCR) to develop budgets for clinical trials
- working with other research resources at the University of Calgary
- working with the PIs and coordinators to successfully conduct clinical trials
- liaising with the Clinical Research Unit (CRU) to establish case report forms, secure data collection, and quality assurance metrics for clinical trials, including developing methods for data tracking and trial management activities
- working with internal and external regulatory consultants to ensure project milestones are aligned
- assisting Ventures with knowledge translation activities that include scientific publications and other forms of communication, and
- other duties required for the successful development, conduct, and translation of clinical trials

The Navigator must be able to perform these tasks on time, at times with minimal guidance, and in collaboration with all of the IMPACT team members.

QUALIFICATIONS/EXPERTISE:

- Navigators must have at least 3 years of experience in clinical research project coordination, broad experience in data collection systems, and in-depth knowledge of clinical research best practices.
- Must be certified in Good Clinical Practice guidelines and experienced in Investigator-initiated and/or Industry-sponsored clinical trials.
- Must have a solid understanding of clinical trial design, case report form construction, clinical trial management, and extensive experience with electronic data capture systems and custom software.
- The ability to adapt quickly to changes or new approaches in each project is a requirement. Certification in the Society of Clinical Research Associates (SOCRA) is desired.

KEY ACCOUNTABILITIES/TASKS AND DUTIES:

The Navigator will work on all aspects of clinical project management and execution. They will also work with other technical staff, physicians, researchers, senior healthcare administrators, and government staff. This position requires work on various projects with different deadlines throughout the year.

Responsibilities include independent project development, management, and execution. Navigators must make decisions that require developing new options to solve complex problems, including in ambiguous situations. They must be able to explain difficult concepts and influence others to adopt a different point of view when appropriate.

The Navigator must be highly organized and able to complete the various duties based on fluctuating position requirements. The successful applicant must have excellent communication skills, be able and willing to exercise judgment within established guidelines, be a strong team player, and be willing to

develop creative solutions to the various challenges posed.

This position requires work on various projects with different deadlines throughout the year. The applicant must be self-motivated, be able to acquire new skills, be flexible with multiple projects and duties, and accomplish the various tasks in a team environment.

Interested applicants are asked to forward their **resumes and cover letters** to hr@innovatecalgary.com. Alternatively, resumes may be mailed to: HR, Innovate Calgary, 3655 36 Street NW, Calgary, AB, T2L 1Y8.

We thank all applicants for their interest; however, only those persons for whom we need further information, or are being considered for an interview will be contacted.

Application deadline: End of Day **December 1, 2021**

Innovate Calgary is an equal opportunity organization committed to building and fostering a fair and inclusive community that values diversity and encourages respect for all. We welcome applicants across any race, colour, religion, sex, sexual orientation, gender identity, national origin, disability, protected veteran status, Indigenous status, or any other legally-protected factors. We recognize the value of identifying and removing barriers for any applicants interested in participating in our programs.