Medicine by Design

Convergent Working Groups

INTRODUCTION

For Medicine by Design, regenerative medicine represents the future of human health. Living therapies are one aspect of this, but more broadly the goal is to enable regenerative responses while minimizing degenerative responses or non-functional repair responses with the goal of better health through the lifespan.

With large-scale funding from the federal government’s [Canada First Research Excellence Fund](https://www.cfref-apogee.gc.ca/home-accueil-eng.aspx) (CFREF), Medicine by Design has amplified the University of Toronto’s (U of T) global leadership in regenerative medicine by integrating expertise across disciplines and the Toronto Academic Health Sciences Network (TAHSN) into new collaborations and investing deeply in them. Through direct investment of over $75 million into a portfolio of transformational research projects, training programs and the recruitment of new faculty, Medicine by Design has catalyzed new discoveries and is now advancing them toward patient impact.

**Regenerative medicine** uses stem cells to replace diseased tissues and organs, creating therapies in which cells are the biological product. Regenerative medicine can also mean triggering stem cells that are already present in the human body to repair damaged tissues (e.g. endogenous repair) or to modulate immune responses (e.g. immune engineering). Increasingly, regenerative medicine researchers are using a stem cell lens to identify critical interactions or defects that prepare the ground for disease, paving the way for new approaches to preventing disease before it starts.

Under its [Strategic Plan,](https://mbd.utoronto.ca/about/about-us/#vision) Medicine by Design has made three commitments to advance its mission to “*harness Toronto's extraordinary expertise across convergent disciplines and institutions to invent, develop, scale and implement living therapies that will transform healthcare for Canada and the world*” and to make Toronto “***a globally leading ecosystem for regenerative medicine innovation***”.

**Living therapies** are therapeutic products that build on a regenerative medicine approach to disease treatment and/or prevention and are inclusive of cell therapy, gene therapy as well as products that promote endogenous repair (e.g. biomaterials, small molecules, *in vivo* gene editing).

These commitments are:

1. Advance transformative research and early-stage translation in regenerative medicine;
2. Enable the commercialization of accessible, living therapies at-scale;
3. Prepare health systems, clinics and communities to implement living therapy innovations.

As Medicine by Design continues to advance the frontiers of regenerative medicine through the [Grand Questions Program](https://mbd.utoronto.ca/research/grand-questions-program/) and to bridge early-stage translation with the [Pivotal Experiment Fund](https://mbd.utoronto.ca/opportunities/pef/), we now need to define research priorities to guide the implementation of these commitments.

The **Call for Convergent Working Groups** aims to integrate convergent disciplines and experiences that are new to the regenerative medicine community together with those who have been involved with Medicine by Design for many years. It is also imperative that we incorporate industry partners, regional accelerators and the voice of the patients and communities we expect to serve and engage.

This funding call is seeking broad participation from U of T and TAHSN across multiple disciplines (spanning the physical and life sciences, medicine, engineering, and social sciences) and across the academic, private and not-for-profit sectors, in setting these research priorities for Medicine by Design.

The Call for Convergent Working Groups consists of two phases:

**Phase 1: Convergent Working Groups (CWG) and Position Papers**

Successful applicants will receive $25,000 of funding to convene a CWG of experts and stakeholders for a 1-2 day workshop addressing one of the identified research **themes** (described on page 3). Workshops are expected to include academic, industry, government and not-for-profit participants who will collectively articulate the nature of the research questions, how they could be tackled, and what intellectual resources are needed to make progress. Groups are expected to produce a **position paper with a call-to-action** as an output from the workshop.

The workshop will bring together a working group of ~25 participants from multiple disciplines (spanning the physical and life sciences, medicine, engineering and social sciences), institutions across TAHSN and sectors (e.g. academic, industry, government) both within Canada and internationally. Co-investigators and proposed participants must integrate principles of equity, diversity and inclusion (EDI) and consist of individuals at a mix of career stages, including Early Career Researchers.

Eligible expenses for Phase 1 funding include travel, accommodation, meals and workshop facilitation and logistical/technical support.

Medicine by Design will provide assistance with introductions to potential participants and some event logistics as needed to bring a broad set of stakeholders to the table for purposeful conversations that will strengthen Canada as a globally leading ecosystem for regenerative medicine innovation.

**Phase 2:** **Pilot Program**

Working groups funded in Phase 1 are eligible to apply **for additional research funding** **of up to $200,000** for one-year (funding period: April 1, 2023 – March 31, 2024) to address a specific research question identified by the CWG.

The details of the Pilot Program will be released in the fall of 2023.

MEDICINE BY DESIGN’S STRATEGIC COMMITMENTS AND CONVERGENT WORKING GROUP THEMES

1. ***Advance transformative research and early-stage translation* *in regenerative medicine***
   1. Leveraging new technology platforms (e.g., AI-driven design of experiment, robotic self-driving labs, immune engineering, gene editing, synthetic biology, precision medicine) to accelerate the discovery and early-stage translation of engineered, bespoke living therapeutics.
   2. Enabling the development of regenerative medicine technologies and living therapies for faster, better recovery from organ failure, severe infections and/or cancer.
   3. Strategies that support maternal and children’s health. For example: (i) exploring the role of biological inheritance (e.g., epigenetics, intergenerational factors) in health and disease and the implications for new approaches to regenerative medicine (e.g., therapeutic modulation of the epigenome); (ii) novel regenerative medicine-based approaches to infertility and/or addressing perinatal complications.
2. ***Enable the commercialization of accessible living therapies at-scale***
   1. Innovative biomanufacturing strategies (e.g., on-chip/microfluidics, biosensors, vector-free manufacturing strategies, automation, machine learning) to drive technological breakthroughs that will enable affordability and accessibility of living therapies.
   2. Policy frameworks to support the delivery and wide-spread uptake of regenerative medicine innovations and to ensure a constructive impact on the local bioinnovation ecosystem.
   3. Novel business models and/or frameworks for the payment, distribution and delivery of regenerative medicine therapies that take into consideration the nature of these complex products compared to conventional pharmaceuticals.
3. ***Prepare health systems, clinics, and communities to implement living therapy innovations*** 
   1. Frameworks for engaging diverse communities (inclusive of Indigenous and other equity-seeking populations) and integrating culturally sensitive, patient perspectives to explore disparities, gaps and needs. Ensure that regenerative medicine research is conducted considering equity and inclusion (e.g., conditions that predominantly affect equity-seeking populations are considered). Enhance ethical access and accountability (e.g., health disparities research seed funds).
   2. Needs assessment (e.g., regulatory support, correlative study suites, dedicated beds, nursing and data management) for clinical trials of new living therapies and for their adoption into the health system.
   3. Methodologies for evaluating the cost-effectiveness of regenerative medicine therapies (e.g., cost-effectiveness of regenerative medicine therapies; patient preferences). For example: Lifecycle Health Technology Management (HTM) frameworks that can be deployed to guide the process of evidence generation early in the R&D process. Proposed frameworks could support the development of high value technologies by capturing and evaluating data on clinical evidence, patient preferences, social impact and economic value propositions prior to regulatory approval.

CONVERGENT WORKING GROUPS FEATURES AND OUTCOMES

CWGare expected to align with Medicine by Design’s strategic commitments and vision to make Toronto “***a globally leading ecosystem for regenerative medicine innovation****”.*

CWG proposals will feature the following:

* Outline the core elements of an ambitious, multidisciplinary theme and a range of possible research questions for consideration;
* Identify priorities and sectoral experts, facilitate introductions and build a diverse community of interest around the chosen theme;
* Build on programs that are already globally-leading and where gaps may be filled through recruitment of new faculty or through collaboration with globally leading groups outside of Toronto;
* **Produce a Position Paper that:** 
  + Identifies both research gaps and gaps in representation, including expertise and communities (e.g., who is not at the table and should be).
  + Includes a Call to Action, with both short-term (within two years) and long-term (more than five years) plans. Some calls may envision the recruitment of a small cadre of postdoctoral fellows to tackle a pertinent research question, while others may outline a multi-year, multi-million-dollar research and development program. Medicine by Design will strive to support these action plans to the extent it can via Phase 2 (Pilot Program).

PROCESS AND TIMELINE

Research funding for the CWG program will include two phases. Successful applicants to Phase 1 of the competition will have access to up to $25,000 towards convening a CWG for a workshop held between December 2022 and February 2023 (most likely in 2023). The objective of these CWG will be to produce a position paper with a call-to-action. Teams are eligible for up to $200,000 of seed funding in Phase 2 to execute on this project over the period of April 1, 2023, to March 31, 2024.

Before submitting a proposal for Phase 1, prospective applicants must email [awards.mbd@utoronto.ca](mailto:awards.mbd@utoronto.ca) to schedule a meeting with Medicine by Design leadership to discuss the proposal idea. The proposal form for Phase 1 can be found in this package and is to be submitted with all required documents by **October 5, 2022**.

**Key dates:**

|  |  |  |
| --- | --- | --- |
| Milestone | Who | Dates |
| Phase 1 CWG proposals due | Applicants | October 5, 2022 |
| Phase 1 proposals reviewed  Successful proposals awarded Phase 1 funding | Expert Review Panel | October - November 2022 |
| **Phase 1 Funding Period (to hold workshop): December 2022 – February 2023**  1-2 day workshops are held with cross-sectoral participants. | | |
| Summary of workshop outputs, draft position paper and Phase 2 funding project plan due | Applicants | March 15, 2023 |
| Position paper due | Applicants | June 30, 2023 |
| **Phase 2 Funding Period: April 1, 2023 – March 31, 2024** | | |

# \* Expert Review Panel will consist of members of Medicine by Design’s Scientific Advisory Board and international experts on the proposed research topic(s).

# ELIGIBILITY

Applicants

Only one application will be accepted from each lead investigator, who will act as the coordinator of the workshop. Additional co-investigators will constitute the core organizational team. Some groups may wish to designate a logistics coordinator as a point-of-contact. Medicine by Design encourages proposals led by Early Career Researchers as well as investigators new to the Medicine by Design community (e.g., those who are new to the regenerative medicine field, or who have not previously led a Medicine by Design-funded project and/or received funding from Medicine by Design).

Lead investigators must have a faculty appointment at the University of Toronto and be eligible to hold tri-council funding.

# EQUITY, DIVERSITY, AND INCLUSION

The University of Toronto recognizes that diversity is essential to the creation of a vibrant intellectual community that allows our researchers to maximize their creativity and their contributions. Medicine by Design is therefore strongly committed to diversity in research and especially welcomes applications from racialized persons/persons of colour, women, Indigenous/Aboriginal Peoples of North America, persons with disabilities, LGBTQ2S+ persons, and others who may contribute to the further diversification of ideas. CWGs are also asked to describe how the team composition addresses EDI principles and how their work will integrate considerations of sex/gender and diversity.

Medicine by Design

Convergent Working Groups

# Proposal

# INSTRUCTIONS

Before submitting a proposal for Phase 1, prospective applicants must email [awards.mbd@utoronto.ca](mailto:awards.mbd@utoronto.ca) to schedule a meeting with Medicine by Design leadership to discuss the proposal idea.

**APPLICATION PACKAGE**

Email the completed application package to [awards.mbd@utoronto.ca](mailto:awards.mbd@utoronto.ca)by**5 pm on October 5, 2022.** Notification of receipt will be sent within one business day.

The application package contains 2 documents:

1. **Proposal**
   * Complete the following Microsoft Word template and convert to a PDF document for submission
   * Formatting requirements: Arial size 11 font, with 1-inch (2.54 cm) margins, single spacing.

1. **CV document**
   * Attach a **single PDF file with CVs** of all lead and co-investigators.
   * CVs can be in any format (e.g. CIHR Biosketch), but each CV must be less than 8 pages.

**MY RESEARCH APPLICATION (MRA)**

The lead investigator on the RFA must register in My Research Application (MRA) at <http://aws.utoronto.ca/services/my-research-mr/> and submit the RFA document via this portal, in addition to sending them directly to Medicine by Design, by the deadline above. This will help Medicine by Design with the reporting/tracking to CFREF and ensures that the correct departmental or divisional approvals are in place. If you do not already have an account with MRA, please contact RAISE Help at 416-946-5000 or [raise@utoronto.ca](mailto:%E2%80%AFraise@utoronto.ca) as soon as possible to initiate this process. The program name in MRA for this competition is “MbD Convergent Working Groups”.

Medicine by Design

Convergent Working Groups

PROPOSAL

**Project Title:**

**Lead Investigator:**

**Co-Investigators (Core Organizing Team Members):**

**Which Convergent Working Groups (CWG) Theme are you addressing?** (Please check only one)

*Please note that applications that do not address a theme from the list below or re-write one of the listed themes may be considered nonresponsive.*

*Applicants uncertain as to whether their intended project meets the requirements of this RFA are encouraged to contact Michael Sefton (*[*michael.sefton@utoronto.ca*](mailto:michael.sefton@utoronto.ca)*) or Allison Brown (*[*allisonl.brown@utoronto.ca*](mailto:allisonl.brown@utoronto.ca)*).*

***Advance transformative research and early-stage translation in regenerative medicine***

☐ Leveraging new technology platforms to accelerate discovery and early-stage translation of engineered, bespoke living therapeutics

☐ Enabling faster, better recovery from organ failure, severe infections and/or cancer

☐ Strategies that support maternal and children’s health

***Enable the commercialization of accessible living therapies at-scale***

☐ Innovative biomanufacturing strategies to drive technological breakthroughs that will enable affordability and accessibility of living therapies

☐ Policy frameworks to support the delivery and widespread uptake of regenerative medicine innovations and to ensure a constructive impact on the local bioinnovation ecosystem

☐ Novel business models and/or frameworks for the payment, distribution and delivery of regenerative medicine therapies

***Preparing health systems, clinics, and communities to implement living therapy innovations***

☐ Frameworks for engaging diverse communities (inclusive of Indigenous and other equity-seeking populations) and integrating culturally sensitive, patient perspectives to explore disparities, gaps and needs

☐ Needs assessment for clinical trials of new living therapies and their adoption into the health system

☐ Methodologies for evaluating the cost-effectiveness of regenerative medicine therapies

# EXECUTIVE SUMMARY

Provide a summary of your working group concept in lay terms including key stakeholders to be involved and the impact of convening this CWG. For successful proposals, this summary may be used in press releases/website content.

*(Maximum 1/2 page)*

# SECTION 1: WORKING GROUP CONCEPT

*CWG**are expected to align with Medicine by Design’s strategic commitments and vision to make Toronto “****a globally leading ecosystem for regenerative medicine innovation****”.*

*CWG proposals will feature the following:*

* *Outline the core elements of an ambitious, multidisciplinary theme and a range of possible research questions for consideration;*
* *Identify priorities and sectoral experts, facilitate introductions and build a diverse community of interest around the chosen theme;*
* *Build on programs that are already globally-leading and where gaps may be filled through recruitment of new faculty or through collaboration with globally leading groups outside of Toronto;*
* *Host a 1-2 day in person workshop that convenes the CWG to address one of the identified research themes (described on page 3);*
* ***Produce a Position Paper that:*** 
  + *Identifies both research gaps and gaps in representation, including expertise and communities (e.g., who is not at the table and should be).*
  + *Includes a Call to Action, with both short-term and long-term plans. Some calls may envision the recruitment of a small cadre of postdoctoral fellows to tackle a pertinent research question, while others may outline a multi-year, multi-million-dollar research and development program. Medicine by Design will strive to support these action plans to the extent it can via Phase 2 (Pilot Program).*

1. **CWG Theme**

*(Maximum 2 pages)*

1. What will be the key focus of this CWG and how will it build on and/or fill gaps in existing globally leading, interdisciplinary programs within this theme? Describe the significance of the theme.
2. How does the proposed CWG align with Medicine by Design’s mission and vision to make Toronto “a globally leading ecosystem for regenerative medicine innovation”?
3. Describe the current state of knowledge, including barriers and challenges, related to the theme that you plan to address with this working group.
4. Identify the goal(s) and aims of the workshop, as well as the potential research questions to be discussed during the workshop. Describe how the proposed CWG will incorporate SGBA+/diversity and inclusion in the research area and the call to action.
5. Outline the expected impact of this CWG. Describe plans to continue the discussions and collaborations established in the CWG beyond this workshop.
6. ***Knowledge Mobilization***

*(Maximum 1 page)*

1. How will the position paper and any additional outputs from the workshop be disseminated to non-academic stakeholders and knowledge users from industry, the public sector, or civil society, both locally as well as across Canada and internationally?
2. How will the workshop outputs be used to benefit the regenerative medicine community and healthcare in Canada?

# SECTION 2: TEAM DESIGN

*Each team should consist of the following:*

* *One* ***Lead Investigator*** *acting as the working group coordinator - this individual must have a U of T faculty appointment and will hold the $25,000 in Phase 1 funding;*
* ***Co-Investigators*** *who make up the core organizational team – co-investigators are not required to have a U of T faculty appointment;*
* *A* ***Logistics Coordinator*** *who will handle the logistics of the workshop and will serve as the point-of-contact for Medicine by Design to follow up on the progress and details of the event. The logistics coordinator may be one of the investigators or may be someone who does not have a faculty appointment.*
* *A starting list of potential invitees from multiple disciplines (spanning the physical and life sciences, medicine, engineering, and social sciences), institutions across TAHSN and sectors (e.g. academic, industry, government)* *both within Canada and internationally.*

*Proposals led by investigators new to the Medicine by Design community (e.g., those who are new to the regenerative medicine field or who have not previously led a Medicine-by-Design-funded project and/or received funding from Medicine by Design) and early career investigators are encouraged.*

*(Maximum 1 page, excluding tables)*

1. What groups, expertise, and experiences will be brought to the table in order to address research questions and challenges in the chosen CWG theme? Broadly outline the sectors, and/or communities that will be invited to participate in the CWG. Identify those who have been traditionally omitted and why their inclusion in the CWG is crucial to advancing the field of regenerative medicine and its community. If co-investigators do not have a University of Toronto faculty appointment, highlight the rationale for their inclusion.
2. Describe how equity, diversity, and inclusion (EDI) considerations were addressed in assembling the CWG. Describe processes used to engage a broad and diverse group of team members and proposed participants, including those from under-represented groups, and/or describe how the team incorporates expertise in EDI. Please **do not**disclose demographic information about team members.
3. In the tables below, list all the core team members involved in this project. Proposed participants must include of individuals at a mix of career stages.

LEAD INVESTIGATOR:

|  |  |
| --- | --- |
| Lead investigator Name: | E-mail Address: |
| Department & Institution: | |

CO-INVESTIGATORS (CORE ORGANIZING TEAM):

Please add rows as needed.

|  |  |  |
| --- | --- | --- |
| Name | Position & Institution | Email |
| 1. |  |  |
| 2. |  |  |

LOGISTICS COORDINATOR

|  |  |  |
| --- | --- | --- |
| Name | Position & Institution | Email |
| 1. |  |  |

PRELIMINARY LIST OF POTENTIAL INVITEES TO THE CWG WORKSHOP:

Please add rows as needed. Please list no more than 10 individuals. (Workshop should host on the order of 20-30 participants.)

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Position & Organization | Email | Expertise |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| 4. |  |  |  |
| 5. |  |  |  |

## SUPPORTING DOCUMENTATION

1. Attach a single PDF file with CVs for all lead and co-investigators listed above. CVs can be in any format (e.g., CIHR Biosketch), but each CV must be less than 8 pages.

SECTION 3: BUDGET

*Successful teams will receive up to $25,000 of funding to convene a Working Group of experts and stakeholders for a 1-2 day workshop. Eligible expenses include accommodations and travel for invited speakers, as well as costs associated with holding the workshop such as venues, catering, and logistics/technical support.*

*All expenses must follow CFREF eligibility guidelines. Please see the CFREF Financial Administration Guide at* [*http://www.cfref-apogee.gc.ca/program-programme/admin\_guide-guide\_administration-eng.aspx*](http://www.cfref-apogee.gc.ca/program-programme/admin_guide-guide_administration-eng.aspx)

*(No page limit)*

* + 1. Complete the budget table below with projected expenses. The budget does not have to be detailed and can be a rough outline of cost estimates.

|  |  |
| --- | --- |
| **BUDGET ITEM** | **AMOUNT (CAD)** |
| **WORKSHOP HOSTING EXPENSES** | |
|  |  |
| **TRAVEL EXPENSES (BRINGING INVITEES TO THE WORKSHOP)** | |
|  |  |
| **OTHER** | |
|  |  |
| **TOTAL** | $ |

1. Provide a budget justification for each line item above.

# CONVERGENT WORKING GROUP REVIEW CRITERIA

The proposal will be reviewed according to the following criteria:

**SECTION 1: WORKING GROUP CONCEPT**

1. **CWG Theme**

* The proposed CWG:
  + aligns with Medicine by Design’s strategic vision to make Toronto “a globally leading ecosystem for regenerative medicine innovation” and addresses one of the identified research themes.
  + describes the current state of knowledge, including barriers and challenges, related to the theme.
  + defines core elements of an ambitious, multidisciplinary theme and a range of possible research questions for consideration
  + builds upon programs that are already globally-leading and/or fills critical gaps through collaboration with globally leading experts/groups outside of Toronto.
  + identifies goals and aims for the workshop that incorporate SGBA+/diversity and inclusion in the research area and the call to action.
* The impact of the CWG extends beyond the planned workshop to continue these discussions and collaborations into the future.

1. **Knowledge Mobilization**

* The team has a well-defined plan to disseminate CWG outputs, inclusive of the position paper, to both academic and non-academic stakeholders and knowledge users from industry, the public sector, or civil society, both locally as well as across Canada and internationally.
* The CWG proposal has reach beyond academia and benefits the regenerative medicine community and healthcare in Canada.

**SECTION 2: TEAM DESIGN**

* Team of co-investigators and proposed participants is:
  + multidisciplinary, multi-institutional and multi-sectoral with investigators and other participants at a mix of career stages.
  + has diverse expertise and experience and is well equipped to tackle the objectives of the CWG theme.
  + new or different from existing Medicine by Design-funded research teams.
* Proposal identifies the specific sectors and/or communities that will be invited to participate in the CWG workshop.
* Project teams took equity, diversity and inclusion (EDI) into consideration when assembling the proposed CWG team:
  + Applicant has identified processes to engage a broad and diverse group of individuals and communities in the design and execution of the workshop.
  + Involvement of underrepresented communities is described
* Preliminary list of proposed participants and proposed workshop design is reflective of EDI considerations

**SECTION 3: BUDGET**

* The team has proposed a suitable budget to cover expenses that will bring in speakers and cover costs associated with holding the workshop such as venues, catering, and logistics/technical support.