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Medicine by Design

Strategic Plan 2022-2027

FOREWORD

Regenerative medicine will revolutionize the future of human health and fundamentally change the way we think about disease. Rather than merely treating symptoms and slowing disease progression, regenerative medicine will cure intractable chronic diseases. Regenerative medicine will enable dysfunctional organs to repair themselves, reverse damage caused by aging, and engineer tissues to resist infections or cancer.

Unparalleled in Canada, Toronto is home to one of the strongest regenerative medicine communities in the world, with the University of Toronto and its affiliated hospitals supporting the ground breaking work of noted pioneers in stem cell biology, immunology, bioengineering, transplant surgery, oncology and health policy. The Canada First Research Excellence Fund's (CFREF) unprecedented \$114M investment to establish Medicine by Design in 2015 represented a bold initiative to leverage Toronto's unique strengths in regenerative medicine and propel Canada to the forefront of the field.

This strategic plan outlines our commitment to build on this strong foundation to not just innovate, but innovate at scale—capturing the unique opportunity afforded by Toronto's regenerative medicine community to create an end-to-end innovation ecosystem that: bridges people and perspectives from across all sectors and disciplines; integrates transformative discovery and translation with biomanufacturing and clinical implementation; and, ultimately, brings economic and health benefits to all who live in Canada.

The development of this strategic plan was a collaborative, evidence-based process involving benchmarking of global comparators, interviews and small group discussions with international, Canadian and local stakeholders from academia, industry, government and the not-for-profit sector, as well as continued guidance from Medicine by Design's leadership, Strategic Planning Committee, Executive Leadership Team, Scientific Advisory Board and Executive Committee.

A strategic plan is a statement of aspirations. This plan articulates Medicine by Design's aspiration to serve as a convergence hub for a world class regenerative medicine innovation ecosystem in Toronto and outlines guidance on a collaborative approach to bringing this vision to life.

Medicine by Design would like to acknowledge Shift Health for their expertise and support in guiding us through the strategic planning process.



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REFLECTING ON THE PAST

Medicine by Design was established in 2015, through an unprecedented investment of \$114M from the Canada First Research Excellence Fund (CFREF). Over the last seven years, Medicine by Design has sharpened the peaks of excellence and pushed the frontiers of regenerative medicine through large-scale investments in transformative, interdisciplinary research projects and the recruitment of world-class faculty and trainees.

By fostering convergence across the city's leading centres and supporting high-risk/high-reward research, Medicine by Design has built on Toronto's legacy in regenerative medicine—from the discovery of stem cells to the cloning of T-cell receptor genes—to solidify the field as one of the most prolific areas of research at the University of Toronto and its affiliated hospitals. Indeed, in terms of publications related to the field of regenerative medicine, the University of Toronto is ranked 4th among global universities (see table below), and 1st among Canadian institutions.

Affiliations	# of Regenerative Medicine Publications ¹
Harvard University	23,928
Universite de Paris	10,229
University of Pennsylvania	9,126
University of Toronto	8,195
University College London	8,193
Stanford University	8,086
Johns Hopkins University	7,844
Shanghai Jiao Tong University	7,821
University of Pittsburgh	7,347
University of Michigan	7,093

¹ Data Source: Clarivate Analytics Web of Science and InCites; Date accessed: 6/27/2022; Limitations: limited to document types: Articles, Review articles, Conference Proceedings, Books, and Book Chapters.



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Reflecting on this strong foundation, Medicine by Design has identified clear opportunities to refocus its efforts and amplify its impact going forward by:

- Placing a greater emphasis on the tangible solutions that leverage Toronto's global research excellence in regenerative medicine, including living therapies;
- Closing an identified gap in early-stage translation by providing product development support and greater collaboration with industry, investors and commercialization entities;
- Building on its distinguishing strength in fostering convergence by broadening its portfolio to include disciplines such as health economics, public policy and bioethics;
- Engaging with vulnerable populations to co-create solutions that enhance accessibility and affordability and mitigate concerns related to health equity;
- Instilling an entrepreneurial, interdisciplinary culture within its training and professional development programs to reflect the scientific, clinical, social and economic complexities of creating novel living therapies; and
- Leveraging the extraordinary expertise and resources of the Toronto Academic Health Sciences Network (TAHSN) to accelerate the application of regenerative medicine in the clinic.

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.

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).

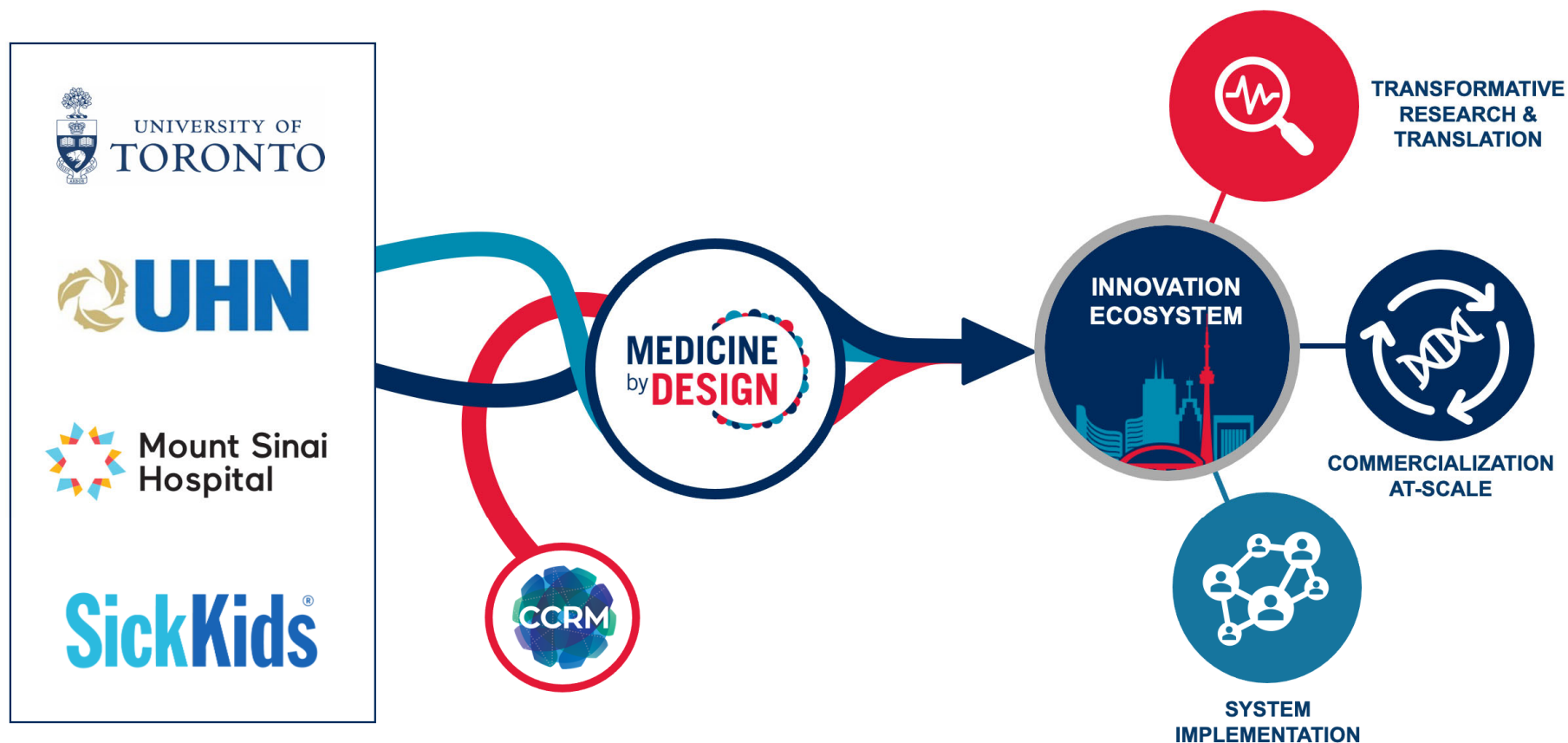


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Looking to the Future

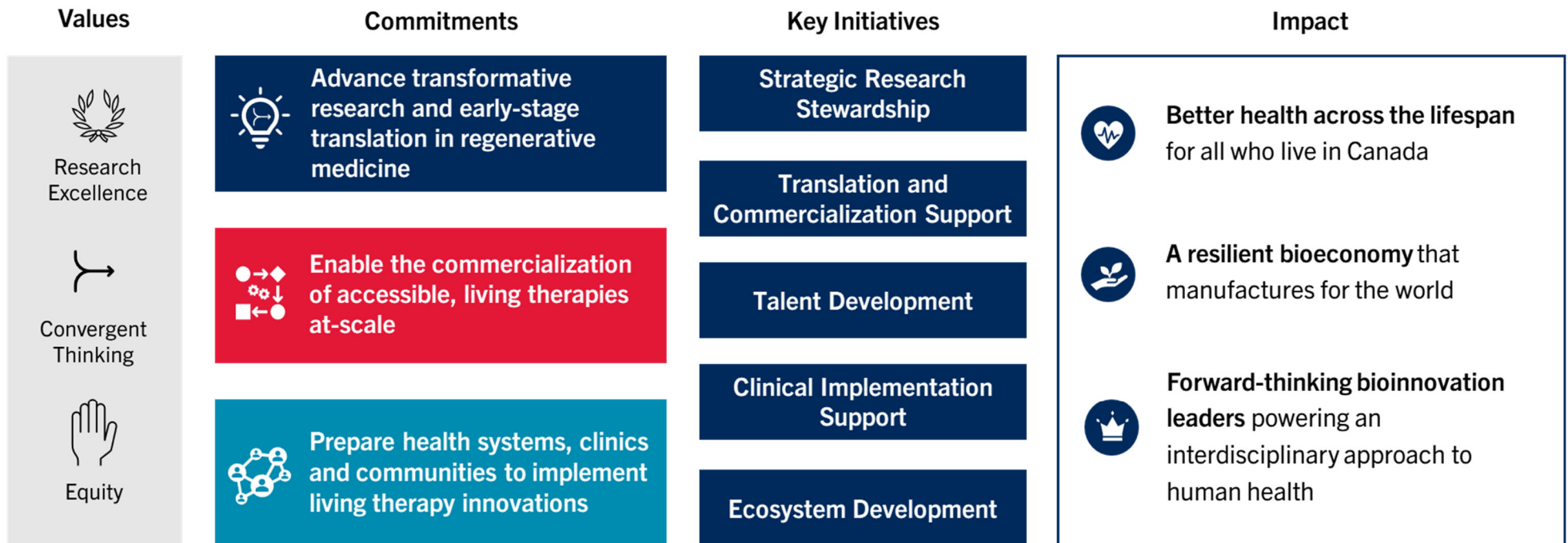
Medicine by Design will serve as a convergence hub that amplifies the impact of individual centres through strategic collaboration—unlocking Toronto's potential as a globally recognized regenerative medicine innovation



2022-2027 STRATEGY SNAPSHOT

VISION: Toronto is a globally leading ecosystem for regenerative medicine innovation.

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.



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VALUES



Research Excellence

Transformative regenerative medicine innovation is rooted in world class research in engineering, medicine, and physical and social sciences.



Convergent Thinking

Interdisciplinary, multi-stakeholder, cross-sector collaborations are critical to tackling regenerative medicine's most pressing challenges.



Equity

Overcoming the clinical, social and economic barriers that hinder the adoption of living therapies in all communities is fundamental to unlocking the promise of regenerative medicine.



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COMMITMENT 1: Advance transformative research and early-stage translation in regenerative medicine

Goal 1.1 Curate, fund and nurture convergent, high-risk, transformative research focused on addressing the scientific, clinical, social, and economic challenges in regenerative medicine.

Goal 1.2 Advance the translation of promising research by supporting investible opportunities in navigating the complexities of early product development, venture creation and clinical trials.

Goal 1.3 Prepare the next generation of regenerative medicine leaders to meet the evolving needs of the bioeconomy by arming them with the diverse perspectives, skills and knowhow required to translate research insights into real world solutions.



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COMMITMENT 2: Enable the commercialization of accessible, living therapies at-scale

Goal 2.1 Shepherd promising innovations through commercialization

by offering funding and expertise for technology validation, market assessment and venture scale-up.

Goal 2.2 Connect Medicine by Design innovators with an international network

of commercialization partners, investors, clinical key opinion leaders and receptor industries to enable production at scale.

Goal 2.3 Support innovation in biomanufacturing

to drive technological breakthroughs that enable the production of affordable and accessible living therapies.



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COMMITMENT 3: Prepare health systems, clinics and communities to implement living therapy innovations

Goal 3.1 Engage with diverse communities to explore unmet needs and disparities in regenerative medicine to ensure our research ultimately serves all end-users.

Goal 3.2 Integrate health system and patient perspectives in the design, development and clinical implementation of living therapies to enhance downstream accessibility and adoption of innovations.

Goal 3.3 Develop policy positions that embolden the Toronto regenerative medicine ecosystem and accelerate the uptake of regenerative medicine innovation.



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KEY INITIATIVES

Key Initiative	Activities	Anticipated Outputs
Strategic Research Stewardship (See Research Priorities section for additional detail)	<ul style="list-style-type: none"> Curate and fund high-risk, transformational research aligned with the prioritized opportunities identified by the ecosystem (e.g., Grand Questions program; Convergent Ideas Awards). 	<ul style="list-style-type: none"> Strategically allocated research budget aligned with Medicine by Design's research priorities.
	<ul style="list-style-type: none"> Engage diverse stakeholders and communities through working groups and roundtables to systematically define bold research questions and prioritize opportunities to address Medicine by Design's 10-year goals. 	<ul style="list-style-type: none"> Evidence-based, consensus-driven landmark research programs aligned with Medicine by Design's Vision, Mission and Commitments.
	<ul style="list-style-type: none"> Establish and operate a world-class design studio consisting of core facilities, research labs and idea-generation spaces with virtual and physical features supported by experienced, in-house support personnel. 	<ul style="list-style-type: none"> Deeper partnership among stakeholders and across disciplines to advance convergence-driven regenerative medicine solutions.
Translation and Commercialization Support	<ul style="list-style-type: none"> Offer best-in-class product development and hands-on project management support to drive the translation of regenerative medicine research into living therapies (e.g., product development roadmaps; pivotal experiment design). 	<ul style="list-style-type: none"> Feasible, validated product concepts and prototypes. Accelerated translation of transformative innovations.
	<ul style="list-style-type: none"> Advance product and venture concepts through expert advice (e.g., intellectual property strategists, regulatory and manufacturing consultants), mentorship (e.g., Entrepreneurs-In-Residence) and seed funding (e.g., expanded Pivotal Experiment Fund). 	<ul style="list-style-type: none"> Made-in-Toronto investible regenerative medicine R&D portfolios.
	<ul style="list-style-type: none"> Enable access to risk capital to scale new ventures through an established international network of commercialization partners, industry and investors. 	<ul style="list-style-type: none"> Made-in-Toronto regenerative medicine companies that commit to staying and growing in Canada.



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Key Initiative	Activities	Anticipated Outputs
Talent Development	<ul style="list-style-type: none"> Develop comprehensive, interdisciplinary regenerative medicine-focused training, mentorship and professional development programs. 	<ul style="list-style-type: none"> Leading regenerative medicine specialists with a convergent mindset that build long-term careers in Toronto.
	<ul style="list-style-type: none"> Establish international trainee internships, International Doctoral Clusters and other vehicles to attract global talent to Toronto. 	
	<ul style="list-style-type: none"> Enrich Equity, Diversity and Inclusion (EDI) in the regenerative medicine community through targeted talent recruitment at the faculty and trainee level and retention initiatives (e.g., Healthy and Inclusive Labs program; training and research opportunities for vulnerable communities). 	<ul style="list-style-type: none"> Greater representation of equity-deserving communities in the Toronto regenerative medicine ecosystem.
Clinical Implementation Support	<ul style="list-style-type: none"> Contribute to the recruitment of world-class clinician scientists to lead clinical trials for living therapies (e.g., with expertise in cell therapy, in vivo gene editing, precision child health). 	<ul style="list-style-type: none"> Globally leading clinician scientists that build long-term careers in Toronto.
	<ul style="list-style-type: none"> Offer clinical trial research operations and data management support for living therapies aligned with opportunities prioritized by a Clinical Implementation Working Group. 	<ul style="list-style-type: none"> Greater number of living therapy clinical trials conducted in Toronto. Better collection of Real-World Evidence (RWE) to inform adoption of living therapies.
	<ul style="list-style-type: none"> Develop lifecycle health technology management (HTM) frameworks incorporating RWE. 	<ul style="list-style-type: none"> Modernized early-stage HTM frameworks to better inform trial design, reimbursement and funding decisions for living therapies.



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Key Initiative	Activities	Anticipated Outputs
Ecosystem Development	<ul style="list-style-type: none"> Partner with social scientists, health economists and representatives from vulnerable communities to define policy initiatives aimed at improving health equity and nurturing a favourable adoption environment for novel living therapies. 	<ul style="list-style-type: none"> Stakeholder-driven policy tools for engaging decision makers on adopting regenerative medicine innovations.
	<ul style="list-style-type: none"> Execute marketing, business development and public relations initiatives to attract international research and commercialization partners and funders to support Medicine by Design and its spin-offs. 	<ul style="list-style-type: none"> Toronto is recognized globally as a hub for regenerative medicine innovation. Foreign direct investment in the Toronto ecosystem.
	<ul style="list-style-type: none"> Develop an international events portfolio to enable networking and knowledge sharing across the ecosystem (e.g., Global Research Summits; Summer by Design). 	<ul style="list-style-type: none"> A highly engaged and informed community of diverse stakeholders committed to advancing Medicine by Design's Vision.



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STRATEGIC RESEARCH STEWARDSHIP

Toronto's world-class research infrastructure and expertise are foundational to Medicine by Design's Vision of transforming the city into a globally leading ecosystem for regenerative medicine innovation. The University of Toronto and its affiliated hospitals together form a global powerhouse in fundamental and clinical research. Our community's size and concentration of expertise across a range of disciplines and clinical specialties make it one of the world's leading academic health science centres.

While Toronto has established exceptional research programs across a variety of life sciences fields, regenerative medicine is an area of distinction for the city—with a storied history of landmark discoveries and the continued momentum fueled by the investment of \$114M of CFREF funding into research, faculty recruitment and training. Building on this foundation, Medicine by Design will nurture the development of a Toronto-wide research enterprise advancing basic, translational and clinical research aligned with Medicine by Design's Values:



Research Excellence

Medicine by Design's success is enabled by the leading-edge research of the academics and clinicians of the University of Toronto and affiliated hospitals. Medicine by Design will assemble teams of **world-class** researchers in areas where Toronto is a **global leader** to advance **bold, transformative research** that addresses **unmet clinical needs**.



Convergent Thinking

Medicine by Design appreciates that living therapy innovation requires a truly interdisciplinary approach that brings together disparate types of expertise in a meaningful way from project inception to execution. As such, Medicine by Design will prioritize research that **converges thinking across different research disciplines and sectors** including stem cell and developmental biology, engineering and data science, medicine and community health, social science and health economics.



Equity

Recognizing that the health equity challenges increasingly informing healthcare decisions are heightened for relatively expensive and complex living therapies, Medicine by Design will prioritize research that anticipates and **actively addresses the scientific, clinical, social and/or economic barriers that hinder access** to novel living therapies. Meaningful engagement and partnership with the communities, clinicians and policymakers who understand many of these barriers firsthand will be critical to the success of Medicine by Design-enabled research.



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Research Priorities

Regenerative medicine is the future of human health—broadly aiming to enable regenerative tissue responses while minimizing degenerative responses or non-functional repair responses. Through a series of consultations with its Scientific Advisory Board (SAB) and Strategic Planning Committee (SPC) and considerations of emerging trends, unmet needs and local strengths, Medicine by Design has identified six draft Research Priorities to organize the requisite follow-on consultations with key opinion leaders and local experts. These priorities are aligned with Medicine by Design’s values and build on existing pillars of excellence.

The process for advancing these Research Priorities is described in the ‘Implementation Considerations’ section. A key feature of the implementation plan is to integrate convergent disciplines and experiences that are new to the regenerative medicine community, while also incorporating the voice of the patients and communities we expect to serve. The next step is to curate the requisite interdisciplinary teams and focus on tangible, measurable, achievable, near- and long-term outcomes. Medicine by Design continues to engage its partners in critical discussions with a view to identifying 10-year goals and grounding the vision in ambitious, yet feasible research programs.

Research Vision (What Medicine by Design aims to achieve through the research it enables)	Enabling endogenous regenerative responses and minimizing degeneration to improve health across the lifespan.					
Research Priorities (Areas of unmet need aligned with Medicine by Design’s Values; illustrative examples provided)	Platform Technologies Applying synthetic biology, gene editing and immunotherapy to engineer bespoke living therapeutics	Organ Rejuvenation Building new organs from stem cells and novel regenerative biomaterials	Maternal and Children's Health Supporting mothers and children with infertility or perinatal complications	Accelerated Recovery Enabling faster, better recovery from organ failure, severe infections and cancer	Biomanufacturing Developing innovative biomanufacturing strategies to produce living therapies at scale	Adoption Enabling adoption of cost-effective and accessible living therapies



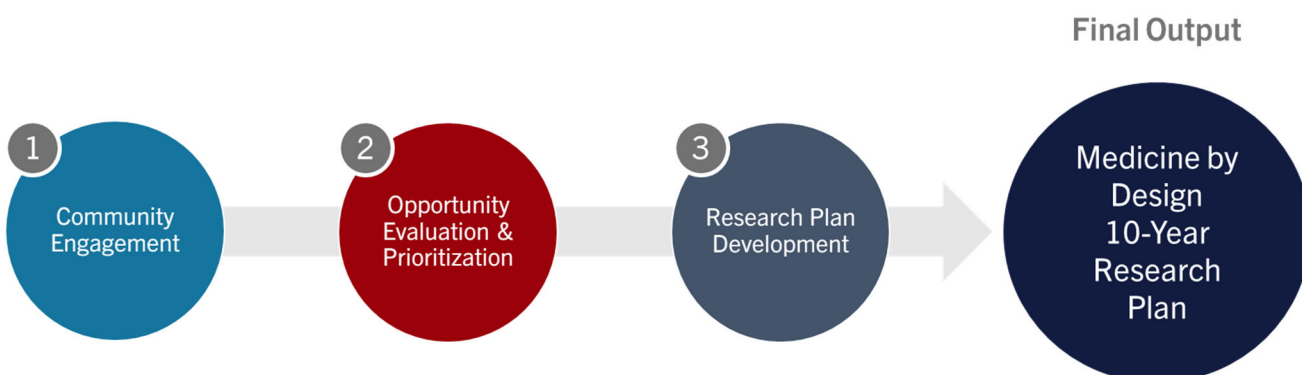
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IMPLEMENTATION CONSIDERATIONS

Bringing the Research Vision to Life

Medicine by Design's refreshed strategy creates an opportunity to implement a novel model for collaborative research planning that embodies its values of Research Excellence, Convergent Thinking and Equity. This approach will allow Medicine by Design to engage a broader spectrum of stakeholders and incorporate areas of expertise and experiences that have not traditionally been reflected in regenerative medicine research. Key steps of this approach will include:



1. Community Engagement

Building on the foundational thinking outlined in the 'Strategic Research Stewardship' section, Medicine by Design will issue a call for Convergent Working Groups (CWG) that can more fully define the Research Priorities. CWGs will be comprised of world-class researchers and thought leaders in a variety of areas of relevance to each Priority, spanning the relevant disciplines and sectors, locally, nationally and internationally. CWGs will come together to:

- Explore the key research, commercialization and implementation challenges and opportunities that can be addressed through regenerative medicine;
- Identify priorities and sectoral experts, facilitate introductions and build a diverse community of interest around each Research Priority; and
- Produce a white paper that outlines current research gaps and identifies short-term and long-term calls to action to address these gaps and that may form the basis of Landmark Research Programs.



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2. Opportunity Evaluation and Prioritization

Working in close collaboration with the SAB and SPC, Medicine by Design will analyze and build on the outputs of CWGs to:

- Assess scientific merit, novelty, feasibility, potential impact and alignment with Medicine by Design's Vision, Mission and Values;
- Identify synergies across the recommendations of the CWGs that may inform cross-cutting initiatives;
- Identify bold, yet feasible, 10-year goals that can be achieved through sustained and substantive funding and effort over the next decade;
- Develop a high-level preliminary proposal of Landmark Research Programs and complementary initiatives focused on achieving the 10-year goals through collaboration across the ecosystem.

3. Research Plan Development

Medicine by Design will present the preliminary proposal to the Executive Committee for validation and feedback, before developing a research plan that outlines:

- **Bold and Transformative 10-Year Goals** that can only be accomplished through the convergence of Toronto's world-class experts from different disciplines;
- **Landmark Research Programs** and projects to fulfill these Goals, including key objectives, timelines and resource requirements; and
- **Potential Sources of Funding**, including organizations that may not have been historically engaged by Medicine by Design (e.g. organizations with missions aligned with particular Research Foci or 10-Year Goal).

Leveraging Expertise

Medicine by Design's renewed strategy will require the inclusion of additional and a broad range of expertise, either in-house or through partnership. These areas of expertise include:

- Product development and commercialization (e.g. intellectual property strategy, company creation and scale-out strategy)
- Innovative biomanufacturing
- Clinical trial design and implementation science
- Community outreach and engagement including Indigenous ways of knowing and doing
- Health system and innovation policy
- International partnerships
- Public relations

Measuring Impact

Medicine by Design will assess the success of its new strategy according to the following metrics.



COMMITMENT 1: Advance transformative research and early-stage translation in regenerative medicine

- \$ Value of new funding (e.g., government, philanthropy etc.) secured for Medicine by Design's Landmark Research Programs
- # New regenerative medicine-focused researchers and clinicians recruited to Toronto
- # Medicine by Design-affiliated, large-scale transformative regenerative medicine research projects and living therapy clinical trials in Toronto
- # Convergence-based publications in top journals



COMMITMENT 2: Enable the commercialization of accessible, living therapies at-scale

- # Validated product concepts, prototypes and/or biomanufacturing solutions developed by Medicine by Design-supported research teams
- # New strategic industry partnerships
- # Regenerative medicine companies spinning out of Medicine by Design-funded projects
- \$ Value of third-party investment secured to advance development and commercialization of Medicine by Design-enabled innovations and/or ventures



COMMITMENT 3: Prepare health systems, clinics, and communities to implement living therapy innovations

- # End-users (e.g. patients, commercial stakeholders) contributing to the design and execution of Medicine by Design projects
- # Regional community stakeholders (e.g. local government bodies; healthcare centres) partnering with Medicine by Design on implementation initiatives; size of populations served by regional community stakeholder partners
- # Living therapy clinical trials initiated in Toronto
- Quantitative or qualitative impact (e.g. health, clinical, socioeconomic) of the implementation of Medicine by Design-enabled innovations



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Advancing the Strategy

Medicine by Design will stage the implementation of key elements of its renewed strategy according to the following timelines.

Initiative	Task	Timeline		
		2022	2023	2024+
Medicine by Design Strategy	Finalize and approve 2022-2027 Strategic Plan			
	Determine refreshed governance structure			
	Approval for Medicine by Design transition funding (2024-26)			
	Develop and execute on Team Toronto fundraising campaign (philanthropy, government)			
Strategic Research Stewardship	Facilitate CWGs to generate white papers that address key research questions and gaps for each of the six Research Priorities			
	Work with the SAB and SPC to review CWG recommendations and develop a Research Plan with 10-year Research Goals for approval by the Executive Committee			
	Establish and operate a world-class design studio			
Translation and Commercialization Support	Develop an industry engagement plan			
	Implement product and venture support (e.g. access to IP strategists, regulatory consultants, Entrepreneurs-in-Residence, and seed funding)			
	Establish partnerships with industry and investors to enable access to risk capital to scale new ventures			
Talent Development	Develop a faculty recruitment strategy			
	Develop and implement a comprehensive regenerative medicine training program			
	Establish international trainee internships, International Doctoral clusters and other vehicles to attract global talent to Toronto			
Clinical Implementation Support	Launch clinical trial and data management support and HTM frameworks for for living therapies			
Ecosystem Development	Forge partnerships with external groups (e.g., social scientists, health economists, representatives from vulnerable communities)			
	Execute marketing, business development and public relations initiatives to attract partners and funders to support Medicine by Design and the spin-offs it supports			
	Develop an international events portfolio to enable networking and knowledge sharing across the ecosystem			



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IMPACT

Medicine by Design's refreshed strategy positions the organization to unlock Toronto's potential as a globally leading ecosystem for regenerative medicine innovation. By serving as a convergence hub that strategically engages partners from the University of Toronto and its affiliated hospitals to build large-scale, interdisciplinary teams focused on tackling the most complex scientific, clinical, social, and economic challenges related to the development and implementation of living therapies, Medicine by Design will drive:



Better health across the lifespan for all who live in Canada



A resilient bioeconomy that manufactures for the world



Forward-thinking bioinnovation leaders powering an interdisciplinary approach to human health



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