

CLINICAL RESEARCH STRATEGY

SickKids 2030

LEADERSHIP MESSAGE



Ronald Cohn President & CEO



Stephen Scherer Chief of Research



Subbarao

Padmaja Subbarao Associate Chief, Clinical Research Better clinical research means better care for patients. Every study, every breakthrough, every advancement we pursue starts with the goal of improving the lives of patients and families. At SickKids, clinical research is at the heart of our mission, fueling progress and bringing new possibilities to the children and families who count on us.

More than 3,000 active clinical research studies take place across our hospital each year, a reflection of our longstanding commitment to discovery and continuous learning. With this new strategy, we are building on that strength to embed clinical research more deeply into the clinical setting.

The goal is simple: create a more integrated and coordinated research environment that partners with patients to deliver real-world impact through clinical research. By integrating clinical research across SickKids, investing in people and digital tools, advancing safety and quality, and partnering closer than ever before with patients, we will build up a learning health system that ensures every research question starts with patient needs and fuels innovation across our campus and beyond.

This Clinical Research Strategy was shaped by the insights of more than 500 people across our community, from patients and families to clinicians, researchers, staff and community members. Their input helped define a clear definition of how we want to conduct clinical research and the path forward, anchored by our core drivers: patient partnership, integration and impact.

Together, we will ask bolder questions, uncover more meaningful answers, and deliver care that is truly tailored to every child. This is how we will advance child health through world-class clinical research.

THE INFINITY LOOP: A SYMBOL OF CONTINUOUS DISCOVERY AND LEARNING

The infinity loop on the cover of this strategy captures the spirit of clinical research at SickKids. At its core, the loop is a powerful symbol of continuous discovery and learning. It represents the dynamic exchange between research and clinical care this strategy seeks to inspire, wherein research discoveries inform improved care, and real-world challenges spark new questions that drive further research.

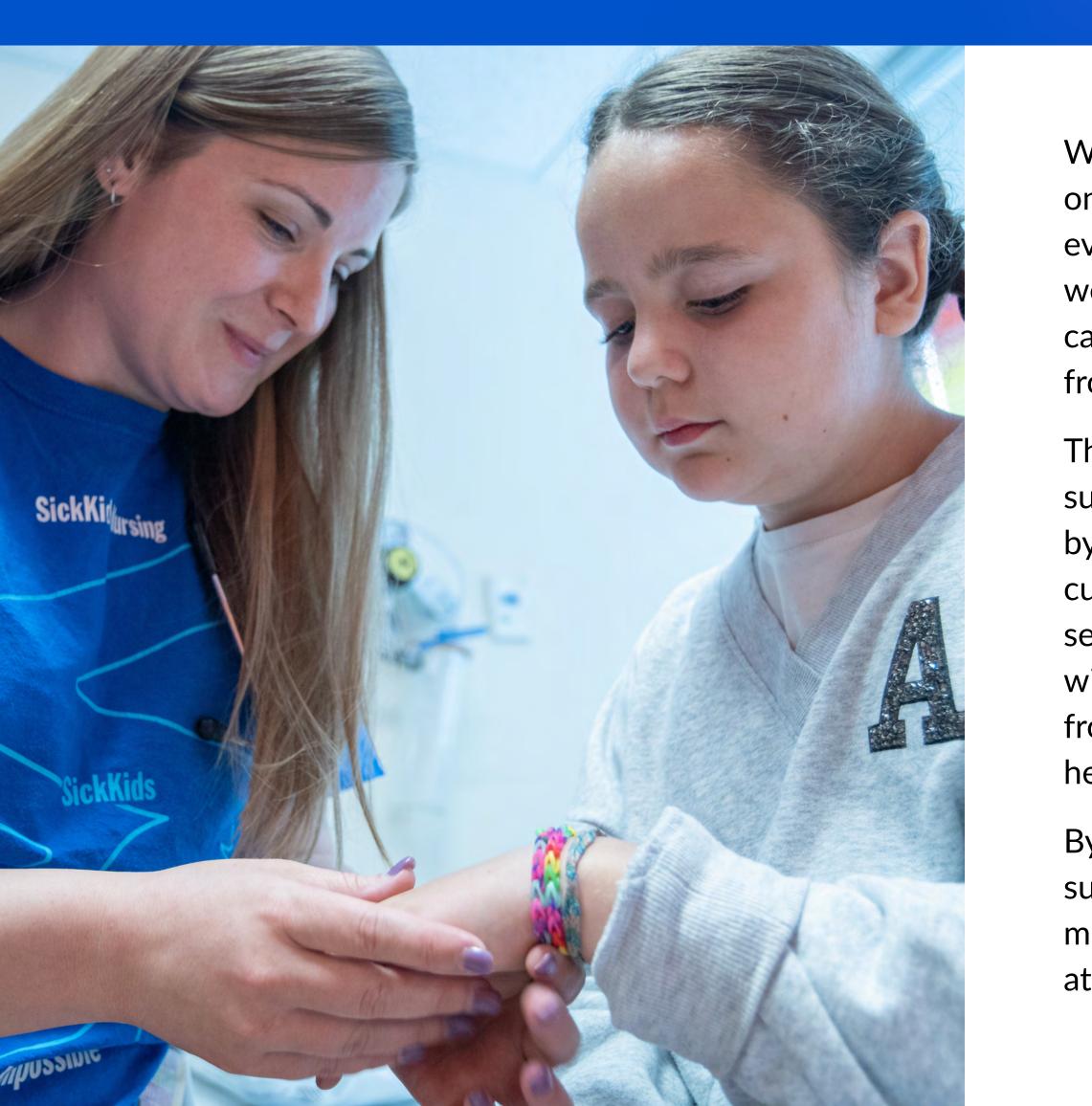
Woven into the loop are many interdependent threads. These threads represent the people, systems, and structures that make clinical research possible: researchers, clinicians, clinical research staff, patients and families, infrastructure and technology, and the processes and operations that support them. Together, they reflect the strength of an integrated approach to clinical research, one in which research and care are not siloed, but instead seamlessly embedded in the way we deliver care every day.

Supporting the loop is the hands of two children, a reminder of why we do this work. Their hands represent inspiration and partnership, reflecting our shared commitment to improving health outcomes by working with and for children and families.

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OUR MISSION



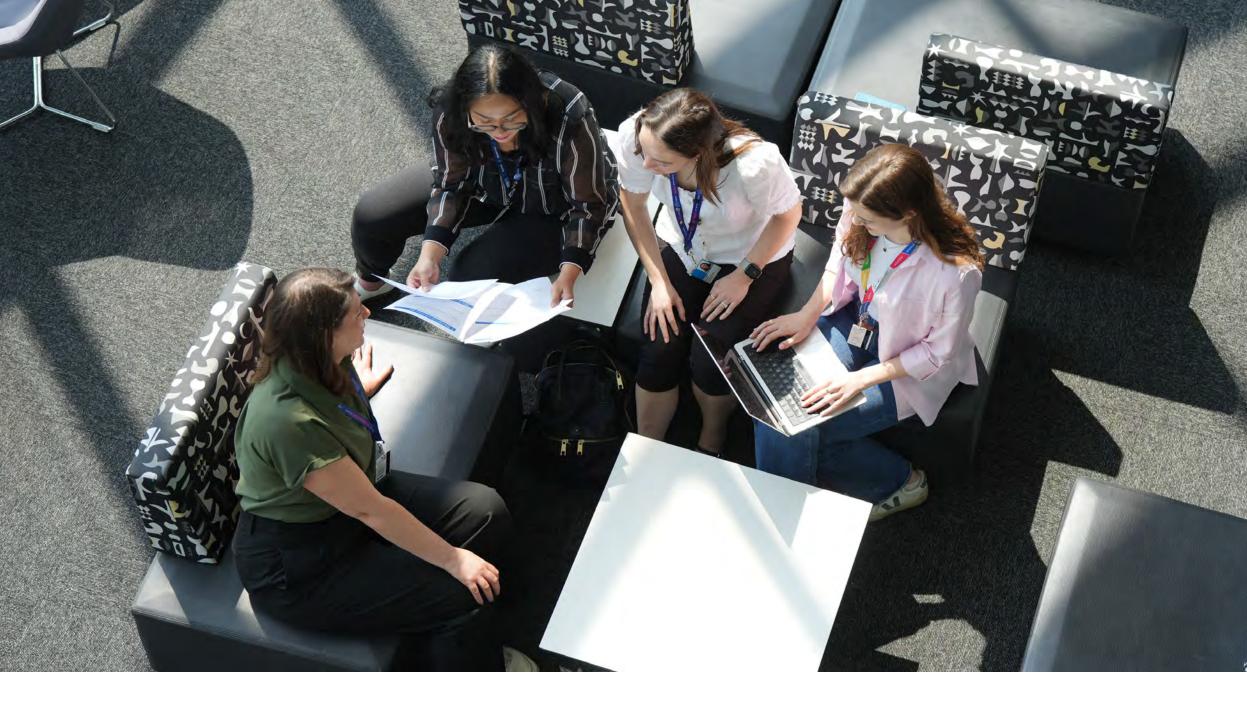
Advance child health through world-class clinical research

We strive to provide the best possible patient care today while constantly innovating on how to do better tomorrow. As clinical research grows increasingly complex, we must evolve alongside it. To move from scientific discovery to real-world implementation, we need to help clinical researchers bridge the gap between discovery research and care. Achieving this requires sustained collaboration and unwavering commitment from researchers, health-care providers, leaders and staff across our enterprise.

This strategy aims to ignite a cultural shift, strengthening how we provide oversight, support and connect research across SickKids. It sharpens our focus on integration by bringing together teams from across the institute to address needs and gaps in current systems, infrastructure and technology, and workforce development. It also sets the stage for our Precision Child Health movement and advances SickKids 2030, with a central focus on partnering with patients so that they can participate in, benefit from, and help shape clinical research as part of a continuously improving learning health system.

By accelerating the translation of research findings in clinical practice, we can make sure every study is more patient-oriented, inclusive and impactful. So clinical research moves faster, reaches further, and becomes an even stronger driver for our patients at SickKids and beyond.





HOW WE DEFINE CLINICAL RESEARCH

Clinical research has the goal of improving paediatric health and preventing illness through the study of individuals, cohorts, health systems and populations in Canada and around the world.

Clinical research spans the full continuum—from discovery bench research on human tissues or samples, to evaluating treatments through clinical trials, and implementing solutions within health systems to improve care. Clinical research aims to generate evidence that directly informs patient care and health outcomes.

Clinical research encompasses a continuum of three domains that involve human participants:



Observational Studies

Study associations between exposures and health outcomes at the individual or group level



Interventional Clinical Trials

Evaluate the safety and efficacy of treatments or other interventions



Population Health Research

Study how social determinants, health systems, and policies influence health outcomes at the population level

In addition to aligning with our Hospital Values, this strategy is guided by the following core drivers:





HOW WE GOT HERE



~535

total leaders, staff and community members engaged to develop strategy



~30

Patients and family members



~300

Clinical research staff and community members





focus group sessions including:



10

internal & external reports and consultations



~25

Clinical research Principal Investigators



~180

Physicians and clinical leaders

INSPIRATION FROM OUR COMMUNITY

OBSERVATIONAL STUDIES

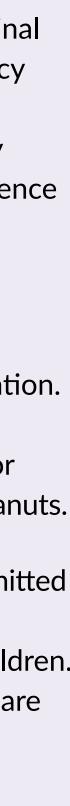
Priya & Nindu

While working at a Toronto hospital, Nindu transitioned from health-care professional to clinical research participant when she accepted an invitation to join the Canadian Healthy Infant Longitudinal Development (CHILD) cohort at SickKids while attending a pregnancy clinic. Motivated to help others through research participation, she enthusiastically participated in this multi-centre observational study that has followed participants from mid-pregnancy through adolescence to better understand child development and health.

Studies like CHILD collect multi-dimensional data from genetics to environmental factors across a participant's life to help identify risk factors that promote a healthy childhood and inform disease prevention. When her daughter Priya showed signs of an allergy, the study team confirmed she was anaphylactic to nuts—a life-changing discovery for their Sri Lankan family, whose cuisine often features cashews and peanuts.

Now a teen, Priya remains in the study. She and her mother are committed to advancing long-term research, especially for underrepresented communities. "There's little research on South Asian women and children. Participating in clinical research is critical to understanding who we are and building an inclusive understanding of health."

One small but meaningful tradition continues: Each year, Priya receives a birthday card from the study, a reminder that her involvement is part of something bigger, helping improve outcomes for children like her.



INSPIRATION FROM OUR COMMUNITY

INTERVENTIONAL CLINICAL TRIALS

Ben

When Ben was diagnosed with Duchenne muscular dystrophy at just 3.5 years old, his family faced an uncertain path. But everything changed from the moment they were introduced to the team behind a clinical trial that Ben participated in— they no longer felt alone

The study team ensured a patient and family centered care experience by supporting Ben and his family, coordinating appointments, anticipating needs, and guiding them through every step of their research participation journey.

For Ben's parents, Amanda and Brodie, what stood out most was how the team not only provided care through the study, but also championed their son, opening doors to potential treatments and opportunities they may not have otherwise had.

"They were always pushing for what's next," says Brodie. "When you're dealing with a diagnosis like Duchenne, it means everything to know that you have a team in your corner—so you can focus on just being parents."

To this day, the study team remains a trusted part of the family's circle of care. "Every visit, we feel supported, seen and cared for, not just as patients, but as people," says Amanda. At SickKids, clinical trials are not just about research. They offer hope, delivered with the same compassion that defines every patient experience.



INSPIRATION FROM OUR COMMUNITY

POPULATION HEALTH RESEARCH

Advancing global health equity

Stunted growth affects an estimated 148 million children under five years old globally, often linked to challenges in health, nutrition, and early development.

The Exemplars in Stunting project, led by Dr. Zulfiqar Bhutta at the SickKids Centre for Global Child Health, used mixed methods and multidimensional decomposition analysis to explore drivers of stunting improvement in 10 low- and middle-income countries.

Working closely with an interdisciplinary team and local partners, the study underscores how direct and indirect interventions, like clean water access, girls' education, empowerment, accessible maternal and child health services, and malaria control, can improve child outcomes by addressing the social determinants of health as well as health system bottlenecks.

"At home in Toronto and around the world, poor health outcomes are clustered among the most disadvantaged communities," says Dr. Bhutta. "Through such population health assessments, we can move research to policy and close health equity gaps."

SickKids[®] 2030

CLINICAL RESEARCH STRATEGY

Healthier Children. A Better World.



Commit to Patients & Families as Partners

- Enable patients and families to guide research design and priority setting
- Increase equitable participation of patients, families and communities in research
- Improve the connection between clinical care and clinical research
- Facilitate research dissemination and integration into patient care to maximize benefit



Advance Safety, Quality & Accountability

- Establish an institution-wide approach to management and oversight • Enhance operations to uphold and continuously improve regulatory, ethical and compliance standards
- Elevate robust monitoring and auditing mechanisms
- Deliver education and training to build expertise in responsible clinical research practices

Enable a Seamless Clinical Research Ecosystem

- Enhance operational support, simplify processes and promote clarity throughout the clinical research lifecycle
- Foster collaborative partnerships with service providers for workflow, financial and capacity planning
- Plan and invest in integrated infrastructure, services and space to support clinical research activities



Adopt Innovative Digital Solutions

- Expand technology to support the research study lifecycle and strengthen compliance, risk monitoring and oversight
- Enhance and broaden patient-facing digital tools to enhance engagement and participation
- Invest in digital systems to support decentralized trials and advanced research methods
- Leverage electronic medical record systems to enable seamless research and care integration

Core Drivers — Patient Partnership — Integration

As leaders in child health, we partner locally and globally to improve the health of children through the integration of care, research and education.

Collaboration Compassion Integrity





Develop & Support a Skilled Clinical Research Workforce

- Partner to attract and retain top clinical research talent
- Broaden research mentorship, training and credentialing opportunities across roles and career stages
- Foster and incentivize a collaborative culture for discovery and research-care integration
- Streamline the clinical research appointment and evaluation process
- Build a cohesive clinical research community

Ensure Sustained Impact of Clinical Research

- Promote the integration of implementation science into planning, design and execution
- Increase access to interventions and innovations
- Advance advocacy efforts with regulatory bodies
- Build a national and international presence to champion paediatric discovery and innovation
- Measure our impact on patient outcomes, scientific advancement and organizational performance

Impact

Inclusion

Innovation

Excellence









COMMIT TO PATIENTS & FAMILIES AS PARTNERS

Our objectives:

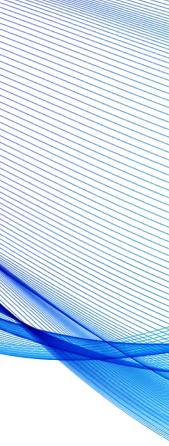
- to maximize benefit

How can we partner with patients and families across the clinical research lifecycle?

To advance world-class clinical research, we will actively partner with patients and families in shaping the questions we ask and the solutions we seek. We will integrate research and care to enhance accessibility, reduce burden on patients, and boost engagement and participation in clinical research.

• Enable patients and families to guide research design and priority setting • Increase equitable participation of patients, families and communities in research • Improve the connection between clinical care and clinical research • Facilitate research dissemination and integration into patient care

> By applying patient-centred frameworks and models, we will prioritize patients' needs, preferences and experiences. This approach aims to supports equitable and inclusive representation, and outcomes that are meaningful across diverse communities. We will close the gap between research and care by supporting the translation of fundamental discoveries into clinical settings and continue learning from bedside experiences to inform and drive new research.





ADVANCE SAFETY, QUALITY & ACCOUNTABILITY

Our objectives:

- Establish an institution-wide approach to management and oversight
- Enhance operations to uphold and continuously improve regulatory, ethical and compliance standards
- Elevate robust monitoring and auditing mechanisms
- Deliver education and training to build expertise in responsible clinical research practices

How can we continuously advance our clinical research practices and standards?

We will break barriers between the Hospital and Research Institute, strengthening cohesion across the organization through a unified and enterprise-wide vision for clinical research. To support this shift, we will establish new management and oversight mechanisms for regulatory, operational and scientific oversight that are responsive and reflective of our community's evolving needs.

With strategic oversight, robust auditing and monitoring, and smarter operational systems, we will continue to uphold and continuously improve our regulatory, ethical and compliance standards. With greater education and training, we can help clinical research teams continue building the skills and expertise needed to conduct research that is high-quality, responsible and safe.



DEVELOP & SUPPORT A SKILLED CLINICAL RESEARCH WORKFORCE

Our objectives:

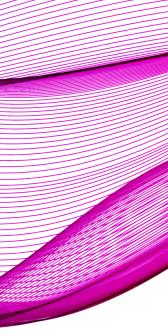
- Partner to attract and retain top clinical research talent
- Broaden research mentorship, training and credentialing opportunities across roles and career stages
- Foster and incentivize a collab and research-care integration
- Streamline the clinical research appointment and evaluation process
- Build a cohesive clinical research community

How will we empower those involved in clinical research?

Empowering our people means creating meaningful opportunities for growth, fostering a culture of collaboration, and removing barriers to getting things done. Partnership between Hospital and Research Institute leadership will enable a stronger and more supported workforce where multidisciplinary teams can thrive and bring bold ideas to drive meaningful change for patients and families.

• Foster and incentivize a collaborative culture for discovery

Bolstered by our operational investments, we will streamline clinical research appointments to grow capacity for research across our community and enhance ways to nurture talent, improve support for research staff, and create new opportunities for continuous development.



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ENABLE A SEAMLESS CLINICAL RESEARCH ECOSYSTEM

Our objectives:

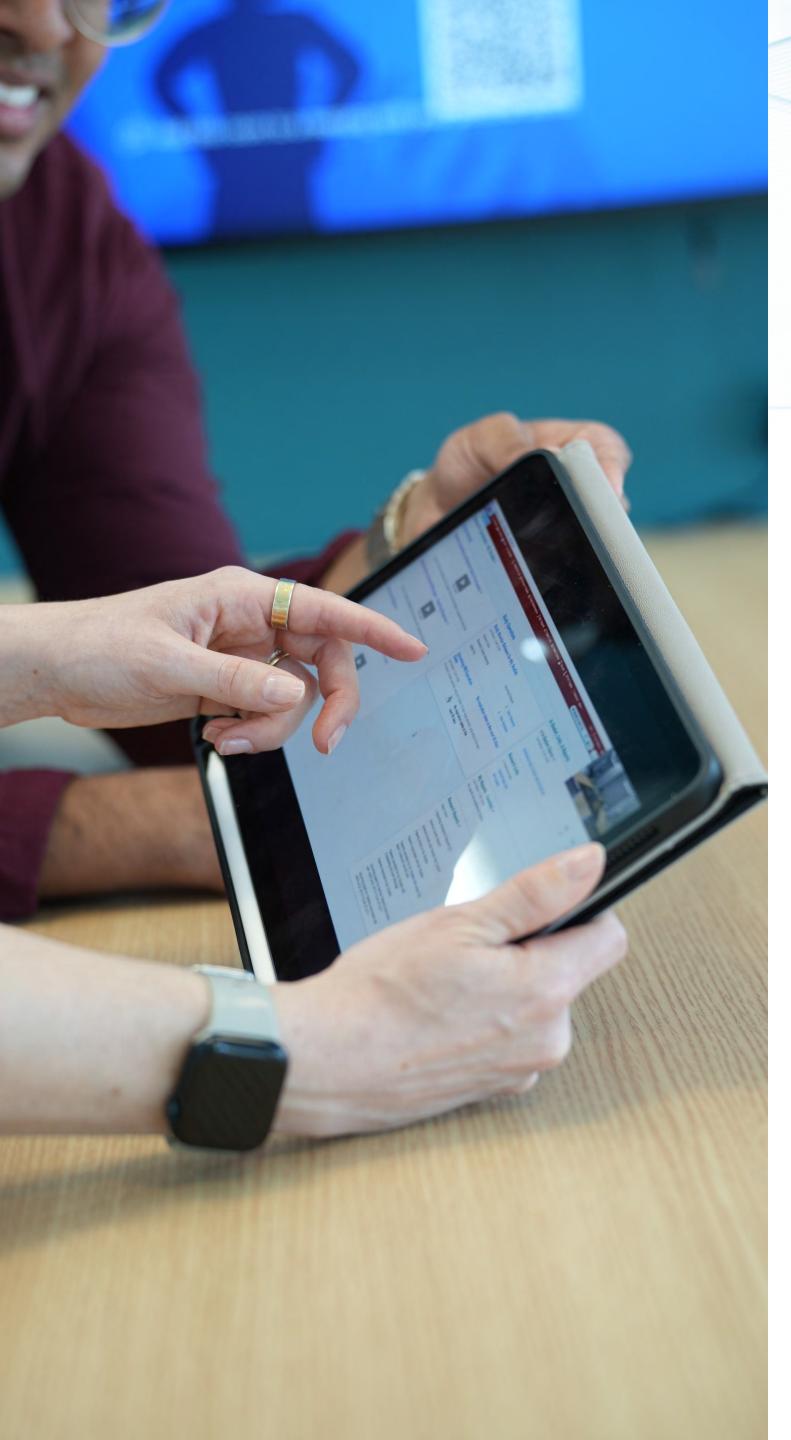
- Enhance operational support, simplify processes and promote clarity throughout the clinical research lifecycle
- Foster collaborative partnerships with service providers for workflow, financial and capacity planning
- Plan and invest in integrated infrastructure, services and space to support clinical research activities

How can we create an integrated and efficient clinical research ecosystem?

A truly seamless ecosystem empowers researchers to focus on what matters most: discovery, collaboration and impact. Clear, coordinated processes and strong operational support are the backbone of this vision, including reducing friction, clarifying roles, and unifying teams around our shared mission.

With intention and investment, we will embed research into clinical workflows. We will also integrate new infrastructure to align clinical expertise, staffing, and care delivery processes with the resources needed to support and advance clinical research priorities. Recognizing that clinical research is increasingly part of how we deliver innovative care every day, we will work with internal service and care providers to facilitate improved research-care integration.





ADOPT INNOVATIVE DIGITAL SOLUTIONS

Our objectives:

- and participation
- research and care integration

How can technology elevate clinical research across our institution?

More than a tool, technology is a catalyst for connection, efficiency and progress, touching every aspect of the clinical research lifecycle. Integrated digital solutions can unlock new pathways to participation, elevate patient experiences, and enable new ways of working that support research-care integration. Beyond streamlining operational workflows and increasing efficiency, modernized systems will allow us to think beyond traditional trial designs, opening the door to decentralized trial models and

• Expand technology to support the research study lifecycle and strengthen compliance, risk monitoring and oversight

• Enhance and broaden patient-facing digital tools to enhance engagement

• Invest in digital systems to support decentralized trials and advanced research methods • Leverage electronic medical record systems to enable seamless

> advanced research methods like remote monitoring and telemedicine, so research meets patients where they are.

Through strategic investment, digital infrastructure and patient-facing tools will become a foundation for innovation and increased research participation, supporting safer studies, smarter data use, and a more responsive research ecosystem that keeps pace with the rapidly evolving clinical research landscape.





ENSURE SUSTAINED IMPACT OF CLINICAL RESEARCH

Our objectives:

- Increase access to interventions and innovations
- Advance advocacy efforts with regulatory bodies
- and innovation
- and organizational performance

How can we ensure clinical research at SickKids has a lasting impact?

We're closing the gap between discovery and delivery by encouraging implementation science into the full lifecycle of research, to develop sustainable and transformative healthcare solutions that create lasting impact. We will work with other paediatric centres and partners across the healthcare system to advocate for systems and policies that accelerate access to paediatric innovations, guided by a deep understanding of the communities we serve.

Promote the integration of implementation science into planning, design and execution

• Build a national and international presence to champion paediatric discovery

• Measure our impact on patient outcomes, scientific advancement

As we strengthen our presence on the international stage, we will champion research that is not only scientifically rigorous but also patient-informed and context-aware, extending our expertise through a global health lens. By evaluating the performance of our clinical research, we can ensure we deliver enduring impact on knowledge and health outcomes of children and youth.



SickKids 2030

OUR STRATEGY IN THE YOUTH VOICE Developed in collaboration with the SickKids Children's Council



Include Patients and Families Along Every Step

Include patients and families throughout the clinical research process. Make it easy to inform and be part of clinical research. Ensure clinical research leads to answers that improve the lives of youth everywhere.

Keep Clinical Research Safe and Honest

Make sure clinical research is done in a way that is fair, honest, and easy to understand. Help teams follow the rules, keep everyone safe, and be responsible for the work they do.



Make it Easier to Do Great **Clinical Research**

Give clinical research teams the tools, space and support they need. Fix the tricky parts so that clinical research is easy to do. Make clinical research more of a part of what the hospital does every day.

Put smart tools to keep clinical research safe, organized, and easy to follow. Use helpful technology so patients and families can be part of clinical research, ask questions, and learn what is happening.

Core Drivers — Patient Partnership — Integration

As leaders in child health, we partner locally and globally to improve the health of children through the integration of care, research and education.

Compassion

Integrity

Collaboration







Support the People that Make **Clinical Research Happen**

Help doctors, nurses, researchers and staff deliver innovative clinical care and research to benefit patients. Make SickKids a great place for discovery and learning through clinical research.



Use Tech to Make Clinical Research Better



Make a Difference **That Lasts**

Make sure clinical research helps patients feel better and live healthier lives. Share what we learn so other hospitals and kids around the world can benefit too.

Impact

Inclusion

Innovation

Excellence







SickKids 2030

DIAGNOSE FASTER. TREAT SMARTER. PREDICT BETTER. Healthier Children. A Better World.



ALIGNMENT TO SICKKIDS 2030

Our clinical research strategy aligns with SickKids 2030 by strengthening clinical research to drive scientific and clinical excellence, while ensuring that patients and families can inform, participate in, and benefit from discovery research, translation, and clinical care. This strategy touches all strategic directions of SickKids 2030 and is critical to advancing the Precision Child Health movement.



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Strategy Advisors

Abhinav Bhatnagar Jelena Djurkic Hannah Neufeld This strategy is the result of an institution-wide effort to reimagine the future of clinical research at SickKids. We are deeply grateful to our Senior Leadership team, whose thoughtful leadership and willingness to ask bold questions and consider new possibilities was critical in developing our first enterprise-wide strategy dedicated to clinical research.

We thank the clinical leaders, department heads and program heads who contributed across all clinical departments and research programs. Their insights were instrumental in ensuring that the integration of research and care is meaningfully embedded throughout the strategy. We also acknowledge clinical researchers and the research community for identifying key structural and operational barriers and helping shape practical, forward-looking solutions to address them. Thank you for your shared expertise across all domains of clinical research and for being open to sharing your aspirations, challenges, and ideas.

Finally, we thank the broader SickKids community: more than 500 individuals, including research coordinators, clinical operations teams, administrative staff, and patients and families, who contributed their perspectives and experiences. We are especially grateful to the families who reflected on and shared their journeys as part of this strategy document. Your voices and stories remind us that clinical research is not separate from care; it is an essential part of how SickKids delivers care every day.