MICYRN

better health for mothers and children

MICYRN

ANNUAL REPORT

Catalyzing advances in maternal and child healthcare by connecting minds and removing barriers to high-quality health research

22/23

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Message from the Scientific Director

Thierry Lacaze-Masmonteil, MD, PhD

The secret of change is to focus all your energy not on fighting the old but on building the new.

Socrates

With recent funding and efforts well underway to transform the clinical trials landscape in Canada, MICYRN is in an excellent position to help shape the future of maternal-child research infrastructure. If MICYRN were a garden, 2022 was about planting seeds, tending to early sprouts, and carefully nurturing the exciting growth ahead.

Expanding upon previous years' efforts, MICYRN has further grown its core team and its capacity to support our community with an expansion of our consultation and Academic Research Organization (ARO) services, including our Cross Institutional Monitoring Program. We were pleased to collaborate on the successful CIHR award for the Pediatric Outcome imProvement through COordination of Research Networks (POPCORN). MICYRN became the coordinating centre for this important initiative, which is making headway in streamlining multicentre projects across the country.

MICYRN was delighted to be awarded both CTU and Network statuses with the Accelerating Clinical Trials (ACT-AEC) Consortium. We remain eager to be the voice for maternal and pediatric research and look forward to promoting our community via this national collaboration.

In anticipation to the launch of the Rare Diseases (RD) High-Cost Drugs

Strategy, 2022 was also the year for MICYRN to strengthen relationships with CORD and RD research networks; advocate for a RD clinical research infrastructure; formalize collaboration with national and international partners; and consolidate resource planning.

I anticipate another exciting and engaging year ahead for MICYRN and hope you will share in my excitement as you read about our accomplishments in this report. We are committed to the hard work in front of us and, to this end, I would like to acknowledge and express my gratitude to:

- our internal MICYRN team for their dedication, nimbleness and collaborative spirit;
- the MICYRN Board of Directors, for their wisdom and guidance;
- the MICYRN Clinical Trials Consortium and all of our network partners for their excellent and ongoing contributions to our organization;
- the MICYRN Research Institutes and Organizations Forum for their financial and leadership contributions;
- the granting agencies and other partners for their generous financial support;
- and most importantly, the patients and families who participate in research every day, without whom our work would not be possible.

I look forward to our continued work toward our shared vision of *Better Health for Mothers and Children*!

MICYRN Board of Directors

Jason Berman, MD, FRCPC, FAAP	Chair
Soren Gantt, MD, PhD, MPH	Vice Chair
Sandra Davidge, PhD, FCAHS	Past Chair

Darryl Adamko, MD, FRCPC
Quynh Doan, MDCM, FRCPC(C), MHSc, PhD
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Padmaja Subbarao, MD MSc (Epid)
Suzanne Tough, MSc, PhD

It has been a privilege and a pleasure to serve as chair of the MICYRN Board of Directors this past year. The Board has been proud to support the expansion of MICYRN's activities, including the establishment of new collaborations and engaging as key partners on several successful large national grant applications. MICYRN has become the go to source for pediatric and perinatal clinical trials in Canada and we have welcomed new talent on the MICYRN team to support this work. The Board looks forward to continuing to empower MICYRN to deliver on its goals as a CRO/ARO and realize the potential of these funded initiatives to improve clinical trial access for children, youth and pregnant persons with the ultimate purpose of enhanced health and quality of life.

Jason Berman, Chair

MICYRN Team

Leadership

Stephen Barbazuk	Executive Director
Thierry Lacaze-Masmonteil	Scientific Director
Karin Kushniruk	Associate Director, Clinical Trials (2023)
Breanne Stewart	Associate Director, Clinical Trials (2022)

Project Operations

Munaza Jamil	Clinical Trials Monitoring Lead (2023)
Sarah Ahira	Clinical Research Project Manager
Olga Arsovska	Clinical Research Project Manager
Jessica Lee	Clinical Research Project Manager (2022)
Andrea Linares	Clinical Research Project Manager
Breanne Stewart	Clinical Research Project Manager (2023)
Wenli Xie	Clinical Research Project Manager
Lori Anderson	Regulatory Affairs
Kate Guzzo-Foliaro	Research Assistant

Business Operations

Christine Oriel	Research Network Administrator
Andrea Rudy	Engagement Associate
Yunna Bystrova	Administrative Assistant (2023)
Heather Muir	Administrative Assistant (2022)
Annabelle Pangilinan	Administrative Assistant (2023)

Member Organizations

Alberta Children's Hospital Research Institute

IWK Health Centre

Schulich Medicine & Dentistry

BC Children's Hospital Research Institute

Laurentian University / Université Laurentienne

SickKids Research Institute

Lunenfeld-Tanenbaum Research Institute
Sinai Health System

Bloorview Research Institute

Sunnybrook Research Institute

McMaster University
Department of Pediatrics

The Children's Hospital Research Institute of Manitoba

Centre de recherche CHU de Québec Université Laval

Memorial University

Université de Sherbrooke

CHEO Research Institute / Institut de recherche

University of Saskatchewan College of Medicine
Department of Pediatrics
medicine.usask.ca

Children's Health Research Institute

Queen's University

women & children's health research institute

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

Institut de recherche Centre universitaire de santé McGill
Research Institute McGill University Health Centre

Women's Health Research Institute at BC Women's

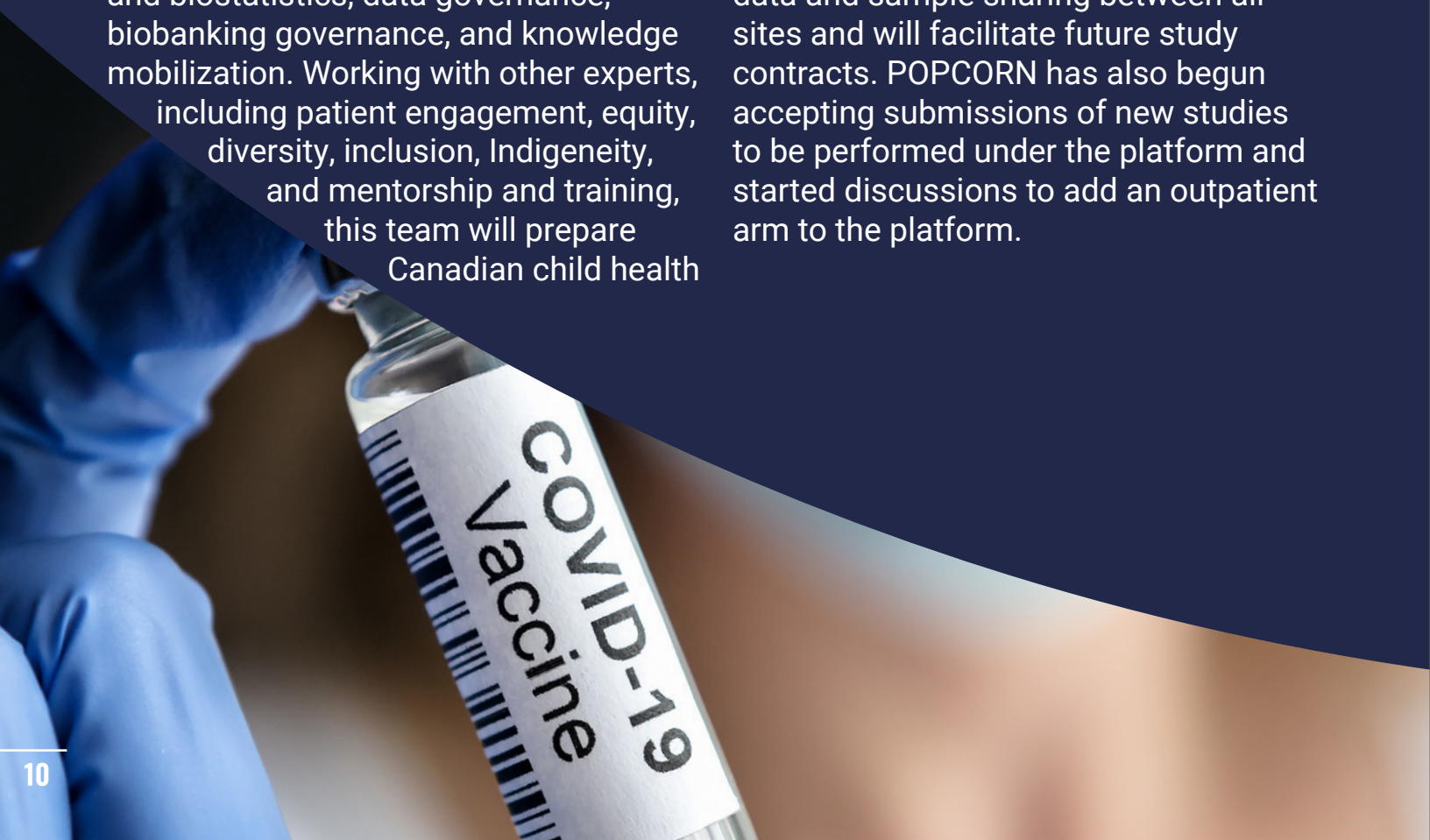
Member Representatives

Representative	Organization
Susa Benseler	Alberta Children's Hospital Research Institute
Quynh Doan	BC Children's Hospital Research Institute
Bruno Piedboeuf	Centre de recherche du CHU de Québec — Université Laval
Jason Berman	Children's Hospital of Eastern Ontario Research Institute
Victor Han	Children's Health Research Institute
Terry Klassen	Children's Hospital Research Institute of Manitoba
Jacques Michaud	CHU Ste-Justine
Evdokia Anagnostou	Holland Bloorview
Tom Chau	Holland Bloorview
Frank MacMaster	IWK Health Centre
Douglas Sinclair	IWK Health Centre
(Vacant)	Laurentian University
Stephen Lye	Lunenfeld-Tannenbaum Research Institute
Roger Chafe	Memorial University
Paul Moorehead	Memorial University
Katherine Morrison	McMaster University
Jagdeep Walia	Queen's University, Dept of Pediatrics
Indra Gupta	Research Institute of the McGill University Health Centre
Craig Campbell	Schulich School Medicine and Dentistry, Dept of Pediatrics
Stephen Scherer	Sick Kids Research Institute
Nir Melamed	Sunnybrook Health Sciences Centre
Frédéric Dallaire	Université de Sherbrooke
Darryl Adamko	University of Saskatchewan
Sandra Davidge	Women and Children's Health Research Institute
Lori Brotto	Women's Health Research Institute

POPCORN

Over the last year, MICYRN has successfully acted as a coordinating centre to launch the Canadian Institutes of Health Research (CIHR) funded platform: Pediatric Outcome imProvement through COordination of Research Networks (POPCORN) with Dr. Caroline Quach-Thanh as NPI. POPCORN's main goal is to establish a unified research structure that is able to comprehensively answer important child health questions, starting with COVID-19. POPCORN brings together leaders from eight areas of expertise: infectious diseases, inpatient medicine, emergency medicine, critical care, epidemiology and biostatistics, data governance, biobanking governance, and knowledge mobilization. Working with other experts, including patient engagement, equity, diversity, inclusion, Indigeneity, and mentorship and training, this team will prepare Canadian child health researchers and their networks to respond rapidly to the current and future pandemics, as well as other child health-related issues of importance. Currently, there are 16 participating sites across Canada with local research teams assisting on specific projects under the POPCORN platform.

Over the last year, the network has established infrastructure and governance structure; strengthened the relationship with existing networks; created a website; built a comprehensive database; and successfully signed a contract with the 16 sites that allows data and sample sharing between all sites and will facilitate future study contracts. POPCORN has also begun accepting submissions of new studies to be performed under the platform and started discussions to add an outpatient arm to the platform.



POPCORN's Achievements

1. Launch of the COVID-19 Prospective Cohort Study in 2023
2. POPCORN Biobank, which includes five decentralized biobanks
3. Multiple administrative health data studies
4. COVID-19 seroepidemiology in children Using Retrieved POPCORN site Leftover Samples (CURNLS)

MICYRN has played a major role in POPCORN's success, including providing project management and administrative support to complete tasks such as grant writing, contract execution, protocol review, database build and launch, communications, collaboration between pillars and committees, and coordination with participating sites. MICYRN will continue to act as POPCORN's coordinating centre in the coming year and beyond, should the network be refunded in the future.

ARO Services

MICYRN continued to expand the suite of Academic Research Organization (ARO) services offered and focused largely on Consultation and Letters of Support, Project Management, Monitoring, and support towards Health Canada Regulatory Submissions.

Services Offered

- Consultation Services
- Study Design & Protocol Optimization
- Project Planning
- Protocol Development
- Health Canada Regulatory Submissions
- Harmonized Ethics Consultation and Submissions
- Letters of Support
- Contracts Facilitation
- Monitoring
- Safety and Adverse Event Reporting
- Data Management
- Project Management
- Drug Procurement and Placebo Development

Intake Form

As MICYRN has expanded its range of ARO support for delegated sponsorship tasks within Canada, the organization's insurance requirements were reviewed to ensure adequate mitigation to risk exposure is in place for this growing area of support to our investigator community. Historically, with the sponsorship responsibilities remaining with the university/research institute, the risk exposure to MICYRN in supporting sponsored tasks via a Service Level Agreement with the Institution-Sponsor was deemed low. An insurance review conducted in 2022, however, highlighted the requirement that the organization increase its corporate liability insurance coverage from $1M to $5M to ensure adequate coverage for ARO services.

For the first time, MICYRN is taking full sponsorship responsibility (as a stand-alone organization) for an internationally led and sponsored trial involving five participating Canadian sites. As the International Sponsor was unable to acquire insurance in Canada on their own – which would have prevented Canadian site participation – MICYRN explored Canadian sponsorship for this trial and in this arrangement will be responsible for the Canadian contribution to the study. For MICYRN to become the Canadian sponsor of an internationally led study, a legal review of an international service level agreement was conducted and a Clinical Trial Agreement between the Internal Sponsor and MICYRN was executed. The acquisition of adequate liability and errors/omissions insurance over and above the current organizational policy will be purchased. Expenses associated with functioning as the Canadian Sponsor for this particular trial, including additional legal and insurance costs, are borne by the International Sponsor. Building on the acquired knowledge, MICYRN is prepared to assume sponsorship responsibilities for additional international trials in the near future. Investigators who are interested in learning more about MICYRN's ARO Services suite may contact us via our Intake Form.

25

Pre-award consults and letters of support

6

Presentations about MICYRN given

15

Projects utilizing ARO services

International Collaborations

MICYRN co-chairs the Enpr-EMA International Collaborations working group (members: US, EU, UK, Canada, Australia, Japan). The European Network for Pediatric Research (Enpr-EMA) is housed at the EMA (Amsterdam) and MICYRN is a member of its Coordinating Group. This working group finalized two manuscripts ready for publications entitled, *Regulatory Requirements for Drug Trials Across Six Jurisdictions and Special Considerations for Trials with Children – Clinical trials application review and approval;* and *Requirements for Drug Trials Across Six Jurisdictions and Special Considerations for Trials with Children – Research ethics review and approval.*

MICYRN continues to strengthen its partnership with conect4children (C4C), I-ACT, and the Pediatric Clinical Trial Network with one publication in 2022: *Pediatric Clinical Trial Networks: Role in Accelerating Development of Therapeutics in Children* (Therapeutic Innovation & Regulatory Science 2022;56:934-47) and one manuscript yet to be submitted (*Harmonizing quality improvement metrics across global trial networks to advance paediatric clinical trials delivery*).

Site Standard Survey and Interviews

To gather regional information on the minimum set of site standards required for participation in pediatric clinical trials from the industry sponsor and Clinical Research Organization (CRO) perspective, the working group disseminated a survey and received 42 global responses.

MICYRN conducted follow-up interviews with industry partners to discuss the barriers and potential solutions to multijurisdictional pediatric clinical trials. These results were presented at the Enpr-EMA/c4c meeting in Amsterdam in October 2022. Since then, two new working groups were established to further advance the definition of quality criteria, map the existing standards, to ultimately implement the recommend quality criteria and standards identified. MICYRN remains heavily involved in each of these working groups.

Study Start Up Repository

For investigators embarking on multicentre projects, the detailed requirements and processes to conduct clinical research at a particular site/ institutional is not always easily accessible and at times is non-existent. This lack of readily available information contributes to investigators' reluctance to participate in trials, and creates delays in study start up. Our colleague, Ashton Chugh, from the University of Calgary Department of Pediatrics, worked with MICYRN as a clinical trial navigator to create and populate a database containing the local requirements and details at each of MICYRN's member sites. The database includes site intake processes, local ethics requirements (including institution-specific forms), the contract process, vendor start up (i.e., pharmacy, lab, diagnostic imaging, and other), as well as information about operational, institutional, and administrative approvals. We encourage our members to visit the database and contact MICYRN should they require further information about start up processes at their participating sites.

ACT Canada and IMPACT

Accelerating Clinical Trials (ACT) (NPI PJ Deveraux, PHRI) was established to *accelerate, optimize, and facilitate the conduct, implementation, and results translation from high-quality, high-impact randomized controlled trials to improve health in Canada and around the world.* The consortium was awarded $39M from CIHR as part of the Federal Government's Biomanufacturing and Life Science Strategy – Clinical Trial Fund. In its dual role as one of 11 Clinical Trial Units (CTUs) and one of 28 Research Networks, MICYRN will receive core funding to support cross-institutional activities such as data science, contracts and agreements, quality assurance and monitoring, trial unit management, and other ARO services. MICYRN also co-chairs the ACT Consortium Contracts Committee.

MICYRN is partnering with the CIHR-funded ($4.9M) Clinical Trials Training Program Increasing Capacity for Maternal and Paediatric Clinical Trials (IMPaCT) NPI: Dr Lauren Kelly, University of Manitoba.

Promoting Research Integration Within Clinical Care

The Health Professionals Research Engagement Project is a 3-phase Quality Improvement initiative jointly launched by MICYRN and BC Children's Hospital Research Institute (BCCHR). Traditionally, there is a disconnect between research and clinical care in the Canadian health system, and hospital point of care staff are

often minimally engaged in clinical research. Unfortunately, this lack of integration between research and clinical care creates significant barriers for researchers to conduct high-quality, efficient research. As one of the major pediatric academic health centres in Canada, BC Children's Hospital is seeking ways to improve local

research infrastructures that would lead to better research and care. Point of care staff engagement in research is identified as a top priority, as they play a key role in delivering quality research in the institution.

Work on the Quality Improvement initiative started in early 2022, led by a clinical trial navigator (Kelly Sandhu in 2022 and Falla Jin in 2023) supported by both MICYRN and BCCHR. During phases 1 and 2, focus groups with multiple stakeholders (point of care staff, educators, leadership, patient partners, etc.) were conducted to identify barriers for point of care staff engagement with research. An education video was subsequently created to raise research awareness. Currently, the initiative has moved to phase 3 where the impact of the video is being evaluated by the large staff members at BC Children's Hospital, using a pretest-posttest survey design. Data collection is underway and the final results will be presented in the coming year. The collaboration between MICYRN and BCCHR highlights the shared interests in creating better research infrastructure and improving care through research. We hope this project will set an example for integrating health professionals in research and fostering a positive research culture for other pediatric health care centres.

Health Research Training Platform

The Health Research Training Platform ENRICH (Empowering Next-generation Researchers in perinatal and Child Health, NPA: Dr. Susan Samuel, University of Calgary) was funded by CIHR in February 2022. The successful Canadian Child Health Clinical Scientist Program (CCHCSP), which MICYRN has partnered with for many years, has now transitioned to ENRICH. The ENRICH and MICYRN leadership teams have explored the possibility of the ENRICH program nesting within the MICYRN governance structure and operational financial processes. Both parties see value in this symbiotic relationship in that organizational integration of the national training program supports MICYRN's training mandate and is beneficial to the stakeholders of the ENRICH program from a long-term sustainability perspective.

Cross Institutional Monitoring Program

Launched at the request of the MICYRN Consortium in the summer of 2022, the Cross Institutional Monitoring Program (CIMP) enables MICYRN member organizations to build local quality assurance capacity while leveraging cost effective monitoring approaches for multicentre, regulated clinical trials in the maternal-child health space.

The Cross Institutional Monitoring Program is led by an experienced lead monitor and is supported by MICYRN leadership and a pan-Canadian monitoring Steering Committee.

The program identified individuals nominated from within the MICYRN member research organizations and hosted its first virtual training session in June, 2022. Those who completed the training have become part of the Site Based Monitors resource pool to draw on for the program.

The program provides mentoring and oversight from the lead monitor as well as a monitoring toolkit, specific to maternal-child health to ensure standardized quality assurance processes.

As of April 2023, the program has:

1 1 active project

11 11 site-based monitors across eight member sites

+> Several trials on the horizon due to open September 2023

Monitoring Program Objectives

- Ensure the protection of participants
- Verify compliance with ICH GCP and Health Canada Division 5 Regulations
- Validate and verify quality of data generated
- Support study teams to build local capacity for quality assurance
- Provide support for Health Canada audit and inspection activities

C4T

Canadian Collaborative for Childhood Cannabinoid Therapeutics

MICYRN has supported the Canadian Collaborative for Childhood Cannabinoid Therapeutics (Lauren Kelly, Director and Principal Applicant, University of Manitoba) in grant application, contracts facilitation, and trial management. MICYRN also supported the C4T Executive team and day-to-day administrative activities.

In addition, MICYRN has provided trial management services to C4T for two Health Canada regulated clinical trials: CAN-CHA (dose-finding study in adolescents with chronic headaches) and CAN-PONC (symptoms management study in pediatric oncology), including trial start-up package preparation, regulatory approval attainment and site readiness support.

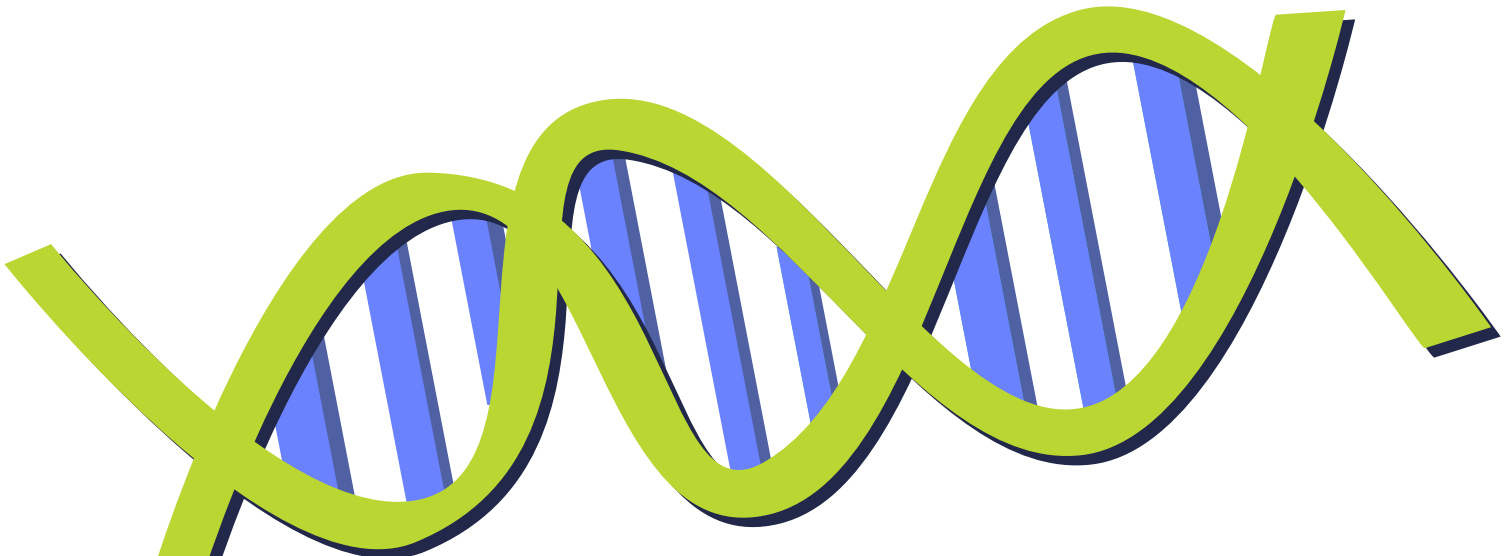
Rare Disease Advocacy with CORD

Advocacy efforts are underway for a Rare Diseases (RD) Clinical Trials Infrastructure (under the premises of the National Strategy on High-Cost Drugs for Rare Diseases). Triggered in January 2022 by preparatory consultations that took place under the auspices of Health Canada and involved CPS, RD researchers, and several RD research-intensive institutions, MICYRN wrote a proposal outlining the rationale for a national infrastructure with the following vision: *To create the sustained national coordination, expertise, and infrastructure necessary to ensure effective and novel therapeutics and interventions are available for children and their families with rare diseases (RD) in Canada; this coalition will generate the high-quality data to inform Health Canada and facilitate the decision-making process for access and pricing in high-cost RD drugs and enhance the overall cost effectiveness in the healthcare system.* The proposal was endorsed by the MICYRN BOD and the RI Directors in February 2022. It was shared with the HC Leadership involved in rolling out the Strategy. The pivotal role played by MICYRN in driving the RD

infrastructure cause was recognized at the CORD conference in June 2022. MICYRN was hailed as the potential vehicle for steering this vital initiative forward. Following the impactful CORD conference in November 2022 and in anticipation of the imminent launch of the National Strategy, along with research funding opportunities, MICYRN took proactive steps to engage researchers and representatives from patient organizations. MICYRN hosted a webinar in December 2022, providing a platform to discuss potential roles and mandates of a RD Clinical Research Network. Participants envisioned various categories of services and support that would be imperative should a national research infrastructure for RD clinical research activities receive funding.

Rare Diseases Models and Mechanisms

The network funding was renewed in 2022 for a third time ($2.5M, CIHR and Genome Canada). For the last eight years, RDMM has funded 118 connections between clinician scientists and researchers. MICYRN has provided administrative and communications support and will continue to provide this to the network. Christine Oriel, Research Network Administrator, has played a role in optimizing the application and review processes of the network, as well as providing support to RDMM's governance, steering and advisory committees.



CHILD-BRIGHT Network

MICYRN is collaborating with the SPOR CHILD-BRIGHT Network “phase two” (notice of award issued in April 2022) and the SPOR Innovative Pediatric Clinical Trials (IPCT) team (funded in 2018), to mobilize and apply the lessons-learned knowledge generated through the development, conduct, and execution of the 13 CHILD-BRIGHT 1.0 studies and the four IPCT studies.

MICYRN will gather data from project teams, patient-partners, and participants from both networks. Outputs of this work will provide the foundation to develop and implement a strategy to assist research communities on including patient-partners, healthcare practitioners, and participants and their families. Knowledge gained from this project is anticipated to generate research outputs to advocate for changes in national infrastructure models, with the aim to conduct more inclusive, patient-oriented, streamlined, efficient, and healthcare system-integrated research in children.

Financial Report

Sustainment of MICYRN's core operations continues to foster the rapid generation of added value to our members, and ultimately their maternal child health research investigators.

Financial Statements

Statement of Operations	2022/23*	2021/22	2020/21	2019/20
Revenue CAD$				
Member Contributions	406,000	437,500	320,000	350,000
Other Sources	649,333	286,508	135,474	67,067
TOTAL Revenue	**1,055,333**	**724,008**	**455,474**	**417,067**
Expenses CAD$				
Coordinating Centre Operations	123,524	36,386	26,604	24,751
Salary and Benefits	394,512	312,027	294,813	287,277
Conferences and Workshops	6,000	4,586	3,619	55,002
Platform Salary Support	552,333	221,555	92,892	68,811
TOTAL Expenses	**1,076,369**	**574,554**	**417,928**	**435,841**

***unaudited**

Estimated carry-forward to next fiscal year 2023/24: $407,000

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