IMPaCT

Accroître la capacité à conduire des essais cliniques avec les personnes enceintes et les enfants

Increasing capacity for Maternal and Paediatric Clinical Trials

# SUMMIT REPORT

## JUNE 24, 2023


**PRESENTED BY :**
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# LAUREN KELLY

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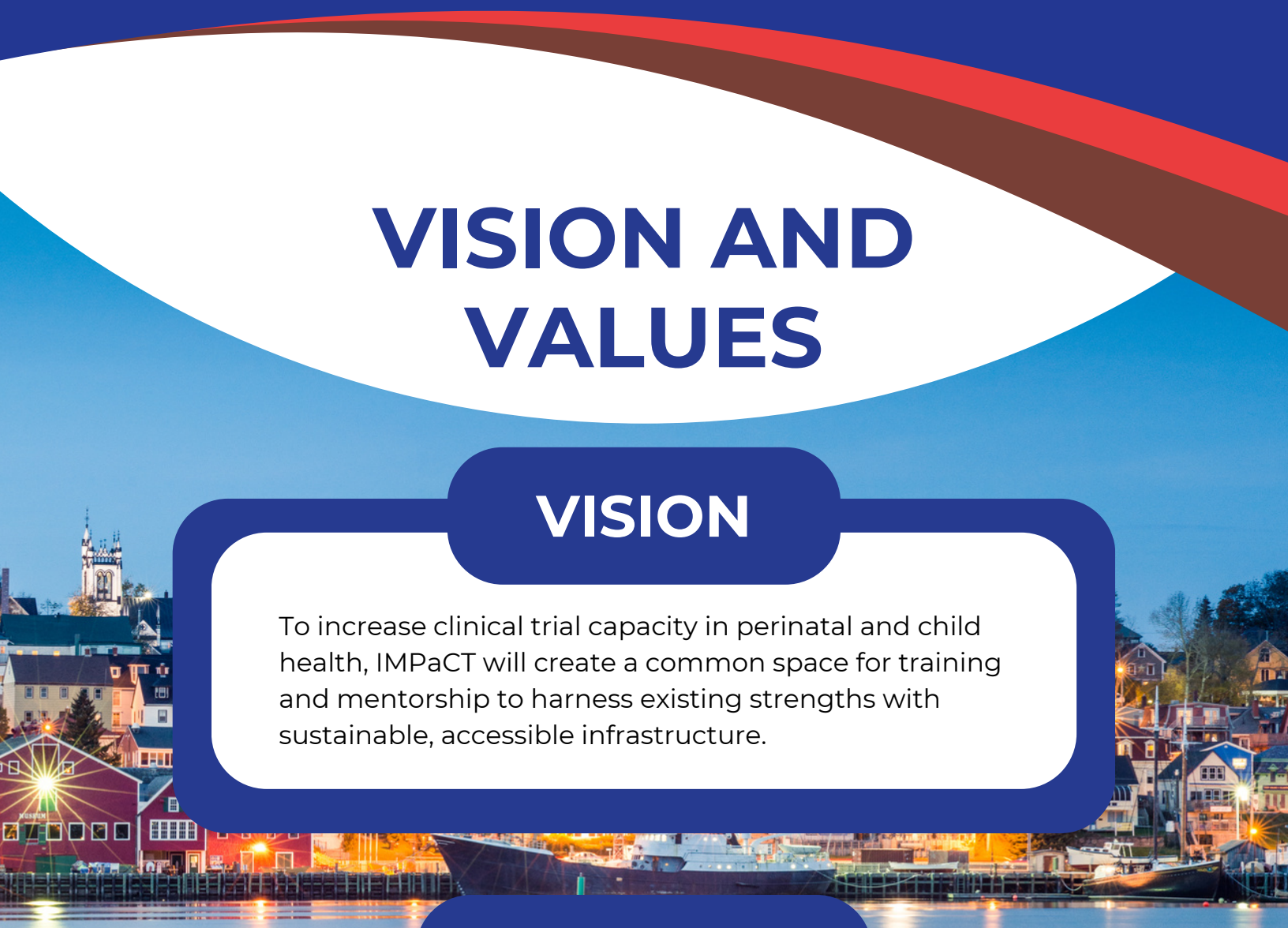
Increasing Capacity for Maternal and Paediatric Clinical Trials (IMPaCT) was funded in December of 2022 to create an immersive training program for clinical trials in perinatal and child health. On June 24th, **37 collaborators from 23 organizations assembled in Halifax, Nova Scotia to attend the IMPaCT strategy meeting and summit.**

We thank our presenters Drs. Catherine Walsh, Charlotte Moore-Hepburn, Thierry Lacaze-Masmontiel and Dawn Richards. We also thank the youth presenters Kate Stevens, Georgia Simkin, Trinity Lowthian and Zahra Alidina.

# VISION AND VALUES



## VISION

To increase clinical trial capacity in perinatal and child health, IMPaCT will create a common space for training and mentorship to harness existing strengths with sustainable, accessible infrastructure.

## VALUES

1. **Collaboration and inclusivity:** We believe that involving patients and caregivers in clinical trial teams will result in better outcomes
2. **Innovation:** We strive to be leaders in perinatal and child health clinical trials in adaptive methods and integrating new technologies
3. **Education and mentorship:** We are committed to providing open-access training and targeted immersive opportunities to increase capacity
4. **Participant safety**: We prioritize the quality and ethical conduct of clinical trials involving term and preterm infants, pregnant and lactating people, children and families with a focus on building trust

# STRATEGIC PLANNING MEETING RECAP

## HALIFAX, NOVA SCOTIA
## MAY 24, 2023

**Session one**
The way forward: Setting goals and metrics for the IMPaCT training platform.

**Session two**
Co-creating a curriculum to train the next generation in perinatal and child health trials.

**Session three**
Creating impact: effective advocacy to increase capacity for child health research in Canada.

**Session four**
Demystifying the process of engaging youth in trials.

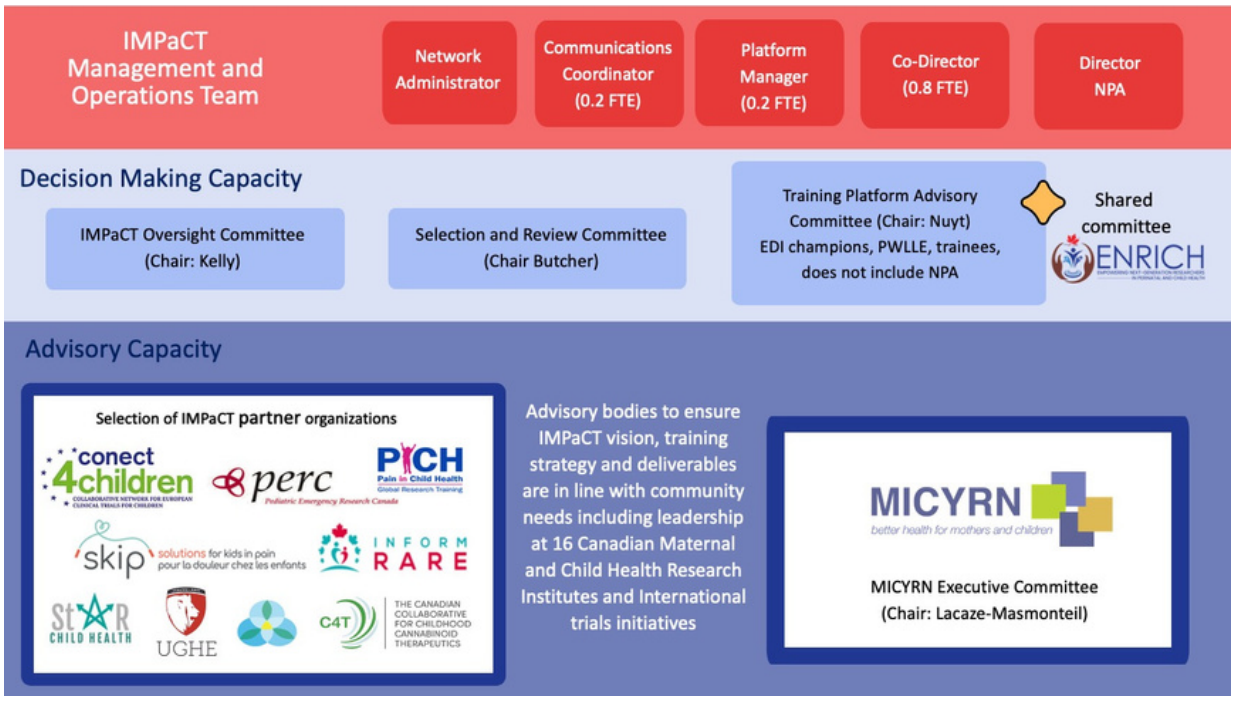
Session one:

# THE WAY FORWARD: SETTING GOALS AND METRICS FOR THE IMPACT TRAINING PLATFORM

The objectives of this session we to:

1. Introduce IMPaCT
2. Highlight the roles and responsibilities for mentors, partners and trainees
3. Discuss what are the goals and objectives for IMPaCT

## IMPACT ORGANIZATION CHART



# IMPACT OVERVIEW

IMPaCT is a one year immersive learning experiences with assigned mentors and deliverables.

- Assigned 1-3 mentors (including youth and parents)
- Complete a RCT protocol deliverable
- Elevator pitch during the summit
- Modules with live discussions on extended topics on RISE LMS
- In-person mentoring
- Mock peer-review
- Leadership training opportunities available
- Immersive learning opportunities w/ ongoing clinical trials and partners

We have fifteen (15) salary awards available each year for 2 years, for a total of thirty (30) trainees from April 2024 to March 2026.

6 PhD awards $35,000
6 Postdoctoral awards $50,000
18 Early career awards $70,000

IMPaCT includes three key activities:

# TERMS OF REFERENCE

**MENTORS**

·Discuss expectations, support onboarding and integration of mentees
·Meet regularly (e.g. monthly, minimum 2x per year) to review progress
·Coordinate experiential learning opportunities for mentees
·Attend the annual IMPaCT summit
·Invitations to develop and create modules, webinars
·Participate in a mock peer-review panel and elevator pitch competition
·Optional: participation in selection committee

**PARTNERS**

·IMPaCT partners are offered travel awards to send someone from their organization to learn about clinical trials and network at the SUMMIT
·Partners conditions of acceptance include offering immersive learning opportunities for salary awardees

**SALARY AWARDED TRAINEES & ECRs**

·Discuss a realistic learning plan and schedule meetings with mentor(s)
·Fulfill project tasks and responsibilities assigned by mentor(s)
·Attend all relevant project meetings as advised by mentor(s)
·Attend the annual IMPaCT summit
·Participate in the elevator pitch competition
·Participate in a mock peer-review panel
·Complete the applicable training modules on RiSE LMS
·Complete feedback form at the end of term

# GOALS AND OBJECTIVES

**Capacity:**

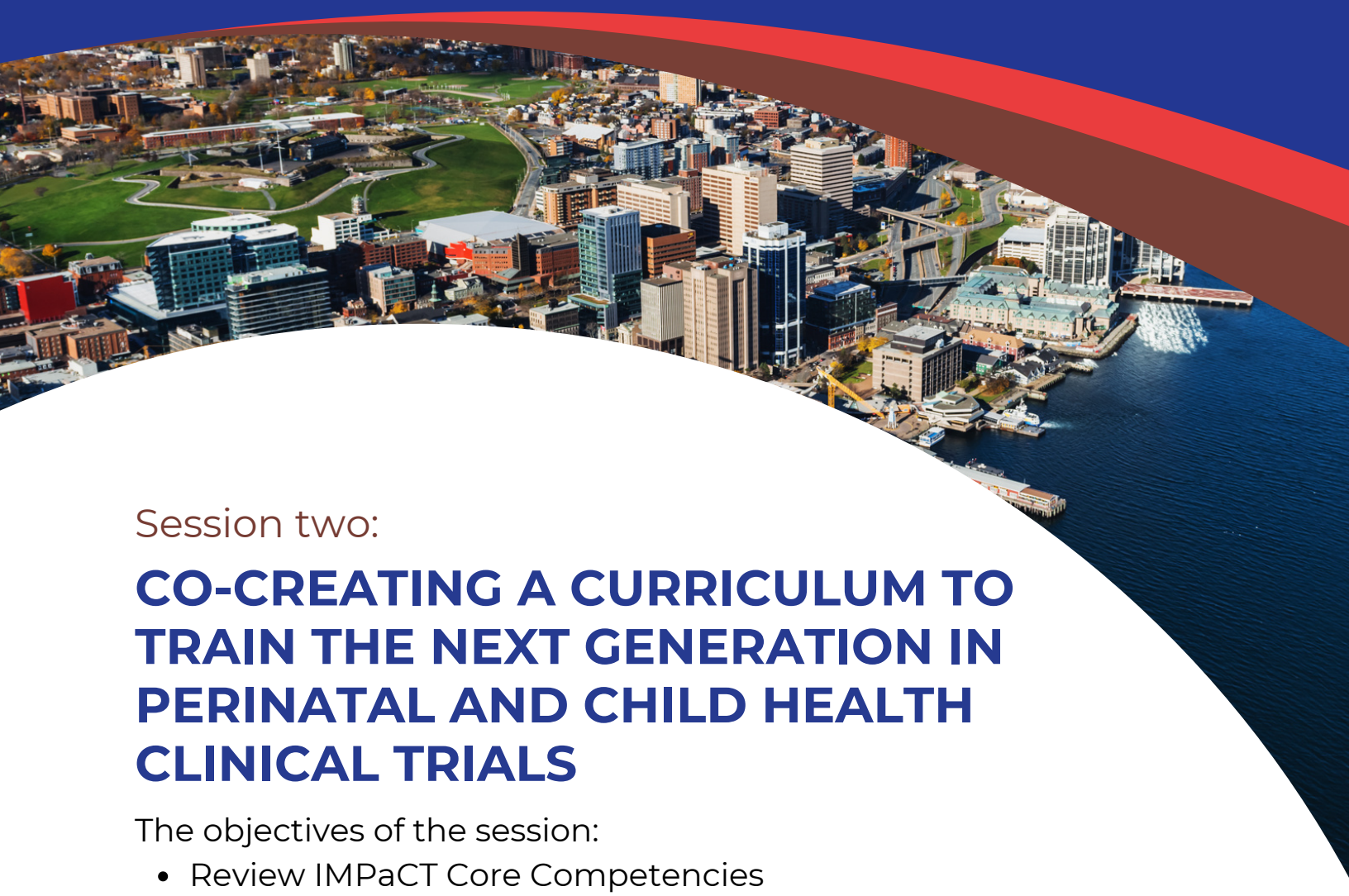
- Broaden the reach and scope of the training program.
- Streaming processes in terms of building capacity for operating procures, tools and resources for trialists within pediatric and maternal trials across the country.
- Create consistency, enhance quality, and decrease some of the barriers to trials that are done in traditionally underrepresented places like rural community hospitals.

**Sustainability:**

- Plan to continue the program past the three years.
- Generate performance metrics so that we can hopefully be refunded at the end of the 3 years.
- IMPaCT will work with learning content that already exists and hopefully embed some trial specific content into it.

**Mentorship:**

- IMPaCT should go above the standardized mentorship and be adapted to the needs of the trainees.
- Curate mentors with a variety of backgrounds and areas of expertise.
- Create a college of mentors across Canada so there is a sharing of thoughts and resources in a pan-Canadian perspective.



Session two:

# CO-CREATING A CURRICULUM TO TRAIN THE NEXT GENERATION IN PERINATAL AND CHILD HEALTH CLINICAL TRIALS

The objectives of the session:

- Review IMPaCT Core Competencies
- Review format, timelines and compensation for curriculum development
- Discussion on core vs extended topics, and in-person sessions at the summit

## IMPaCT core competencies

**1. Scientific skills to design rigorous, ethical and innovative clinical trials**

**Trial Design**

- ☐ Trial design
- ☐ Ethics in clinical trials
- ☐ Innovative methods
- ☐ Patient and family engagement
- ☐ Qualitative methods
- ☐ Equity, diversity, inclusion and anti-racism (EDIAR)

**2. Clinical and operational skills to run efficient and regulatory compliant trials**

**Operations**

- ☐ Trial management and budgets
- ☐ Regulations and GCP
- ☐ Placebos and blinding
- ☐ Quality control and monitoring
- ☐ Data management and reporting
- ☐ Operational considerations for integrating trials into clinical care

**3. Transferable skills to foster professional development and increase trial impact**

**Communication**

- ☐ Grant writing
- ☐ Communication
- ☐ Team building
- ☐ Knowledge translation
- ☐ Advocacy and government relations
- ☐ International partnerships

**Considerations for pregnant people, children, EDI-AR and family engagement are embeded throughout.**

# CURRICULUM OVERVIEW

**Core topics** that everyone should know. Will be required for salary awarded learners. Will be separated into  modules that feature population specific considerations for pregnancy and pediatric (preterm neonates through adolescents).

**Extended topics** might not be relevant to everyone.
Will include a combination of deliverables:

- Relevant topics that may not be applicable to all clinical trials within a population.
- Deeper dive into a single topic
- Co-hosted topics with other clinical trial training platforms
- Open access monthly webinars with resources
- Exclusive Q&A for IMPaCT trainees and ECRs with experts

During this session 10 small groups were provided a list of topics and came to a consensus as a group on which suggested topics were core or extended topics. Groups were encouraged to suggest new topics.

Following the Halifax meeting a survey was distributed to all impact mentors and partners to determine the priority of topics and comprehensiveness of IMPaCT Curriculum.

Session three:

# CREATING IMPACT: EFFECTIVE ADVOCACY TO INCREASE CAPACITY FOR CHILD HEALTH RESEARCH IN CANADA

The objectives of the session:

- Creating impact Policy, Politics and Pediatric Drugs: A Case Study
- Worked Canadian advocacy example: Rare disease and high cost drugs
- Open discussion on collective and sustained advocacy for perinatal and pediatric clinical trials

How to make change

- Set an audacious goal and make it good
- Make lots of friends
- Know your audience
- Be persistent
- Get lucky!

# CREATING IMPACT: A CASE STUDY

It is important to remember that children are NOT ‘small adults’. Infants, young children, and children with anatomic / sensory / neurodevelopmental difference require pediatric-appropriate formulations for safe administration and effective dosing.

**Children deserve the same regulatory protections associated with commercially-prepared drug formulations.** However, children are ‘therapeutic orphans’. Modern drug regulatory frameworks were stimulated by pediatric tragedies, and early regulatory initiatives had unintended consequences for children and youth.

At present, Canada does not mandate the submission of pediatric data, even when pediatric use of a drug can be reasonably expected or anticipated. **Up to 80% of all medications currently prescribed in Canadian pediatric hospitals are “off-label”.** “Off-label” therapy compromises not only safety, but also access to evidence-based drug therapy.

Over the last two decades, leading international regulators have actively sought to address these challenges. For example, in the US a “Pediatric Rule” was established, which requires submission of pediatric data for drugs and biologics to be reviewed by expert standing Pediatric Review Committee (PeRC).

The goal was to develop and implement Pediatric Regulations in Canada that mandate the submission and review of pediatric data when pediatric use of a drug is expected or anticipated.

After years of advocacy, **Health Canada's Pediatric Drug Action Plan was developed in 2020.** With policy guidance launch in the Fall of 2023, and gazette 1 publication pending.

# RARE DISEASES HIGH COST DRUG STRATEGY

**The problem:**

- Rare disease is not “rare” in children
- Pediatric patients in Canada have experienced longstanding regulatory neglect
- Children and youth in Canada are often victims of a “postal code lottery”
- Drugs are only one element of rare disease care
- Robust HTAs are essential both to protect the sustainability of our health care system and to ensure appropriate access to high value medications
- Children often require specialized formulations to ensure appropriate dosing, safe administration and tolerability
- Rare disease registries are an important and feasible tool to generate Real World Evidence
- Stable investment in pediatric clinical trials infrastructure is needed to generate necessary pediatric data and to attract clinical trials in Canada
- Pediatric expertise is essential to forward a child-centre national rare disease strategy

**The proposed solution:**

To Establish a Canadian Maternal/Child Health Clinical Trial Infrastructure to Support Canada’s National Strategy on High-Cost Drugs for Rare Diseases
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.

Session four:

# DEMYSTIFYING THE PROCESS OF ENGAGING YOUTH IN CLINICAL TRIALS

The objectives of the session:

- Select examples of youth engagement
  - CommuniKIDS
  - C4T youth advisors
  - KIDSCAN
- Youth partner involvement in clinical trials
- Youth-facilitated small discussion on barriers and facilitators to involving youth in trials

KidsCan

C4T

THE CANADIAN COLLABORATIVE FOR CHILDHOOD CANNABINOID THERAPEUTICS

# YOUTH ENGAGEMENT IN CLINICAL TRIALS

**KidsCAN:**
KidsCan is the official pediatric advisory group for research related to MICYRN. Prior to KidsCan, there were no groups operating on a national level that included youth as advisors in research. **KidsCan offers Canadian researchers access to a unique consultation service to support their research.** YPREG members also act as ambassadors to raise awareness of the importance of youth involvement in research.

Important to note that Youth involvement is not a “tick-box” and consults should include some kind of follow-up to ensure youths opinions are heard. **Ideally youth are involved in all phases of research.**

**What You Should Know?**

- Youth partners give “insider information” for knowledge translation to the pediatric population
- Involving youth in the planning stages is crucial to ensure the study is beneficial to patients
- Using alternative methods to contact youth besides social media
- What is important to youth may be different than what is important to a researcher
- Provide learning opportunities to youth partners

Learn more about the KidsCAN Young Persons Research Advisory Group here: micyrn.ca/ypag

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# THANK YOU

The take away goals from the summit for IMPaCT are clear:

- Become known internationally as a leader in maternal and pediatric trials
- Make trials more patient and family centered
- Establish a network of experienced (mentors), early-career researchers and clinicians
- Coordinate clinical trials training with other existing platforms to ensure harmonization
- Increase the number of confident and competent clinical trialists in perinatal and child health across the country

In the next three years we will work hard to achieve them together!

## CONTACT US :


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