

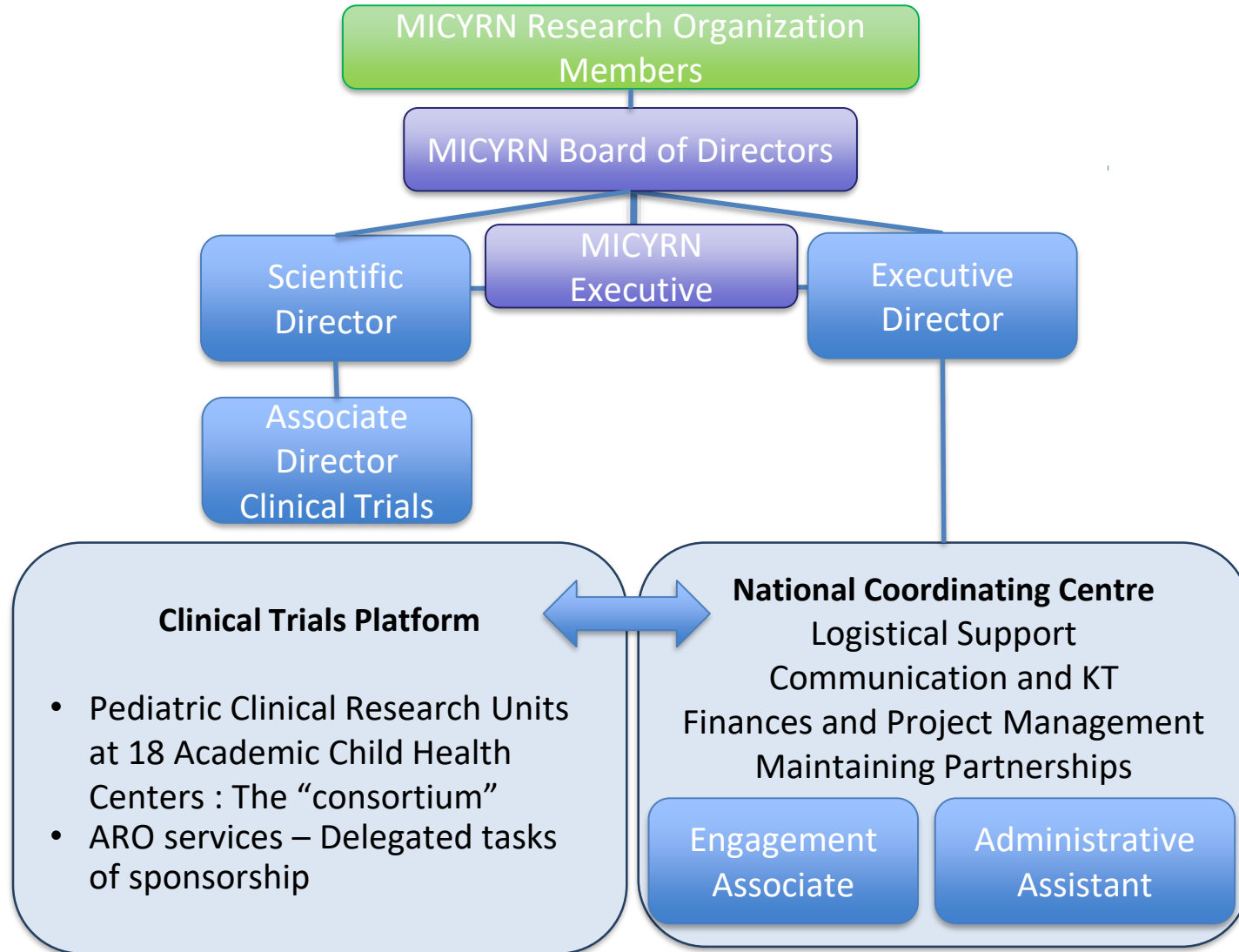
MICYRN - Streamlining Maternal/Child Health Research

Paediatric Grand Rounds June 22, 2022



A national maternal/child health research network

- Established in 2006
- Linking all of the 18 child and the three of the largest maternal health research organizations in Canada
- Incorporated non-profit, registered charity 2011
- BOD, executive team, with coordinating centre in BC
- Funded by RIs, Foundations and Departments (also supplemented by CIHR and Genome Canada via Rare Diseases Network, Canadian Childhood Cannabinoid Clinical Trials Network, some fee-for-service support agreements with other organizations).

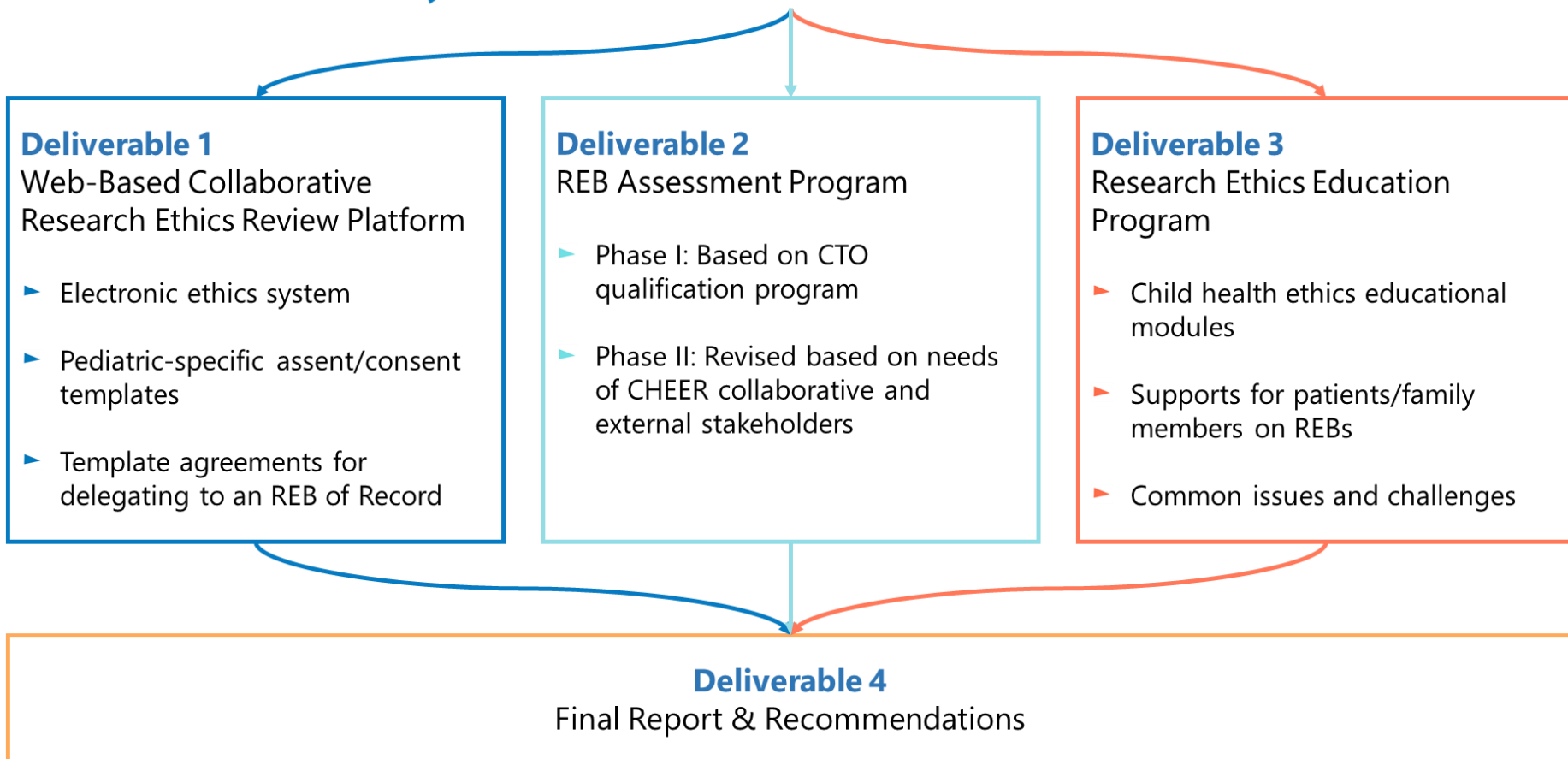


Advocacy and National Partnerships

- **Maternal/Child and Youth Health Research Director Council** – national voice and direction, collaborative opportunities, COVID-19 challenges/approaches, large funding opportunities
- **Paediatric Chairs of Canada (PCC)** – Clinician Scientist Training Program - resident research – annual meeting
- **Children’s Healthcare Canada (CHC)** – clinical investigation unit partnerships with hospitals, research embedded in hospitals
- **Health Canada: OPPI**– coordinated advocacy (CPS, PCC, CHC, C17) and consultation
 - Agile Regulation – Modernizing Pediatric Clinical Trials Regulations
 - Pediatric Drug Action Plan (CMAJ Open, 2022, 194:E678)
 - National Strategy on High-Cost drugs for Rare Diseases – a pledge for a national infrastructure

CHEER

- ▶ Cross-province streamlined ethics review process for multi-site studies
- ▶ Goal: Achieve a single ethics review for child health studies in Canada



National Collaborations

- Canadian National Perinatal Research Meeting (CNPRM) 2022 and 2023
- Health Research Training Platform (ENRICH, Dr. Susan Samuel)
- The Canadian Collaborative for Childhood Cannabinoid Therapeutics Network
- MICYRN and Child Bright partnering for renewal (CIHR SPOR network – chronic diseases): Lessons learned from Child Bright #1
- Rare Diseases (Institute of Genetics, IHDCYH, HC, and CORD):
 - Rare Diseases: Models & Mechanisms Network (RDMM)
 - National Infrastructure to support CT in the rare disease space
 - Establishing a network of centres of excellence following models in other jurisdictions

National Pediatric Clinical Trials Infrastructure

Tactics to improve Canadian child health through increased access to high-quality clinical trials supported by an efficient, safe, and family-centered national infrastructure.

1. Support the development of **clinical trials unit (CTU) capability** across the research organizations (e.g. national CTU capability database, delegated sponsorship tasks)
2. Develop multicentre **trial guidance tools and resources** (e.g. trials checklists, contracts lawyer network, support for trials submissions to Health Canada)
3. Build expertise as the **“single-point” of contact** for clinical trials to for the investigator community and industry (expertise pool of investigators, specialty research networks and industry centres of excellence)

National Pediatric Clinical Trials Infrastructure

Tactics to improve Canadian child health through increased access to high-quality clinical trials supported by an efficient, safe, and family-centered national infrastructure.

4. Work with **Health Canada** on key guidance issues to better support sponsors of clinical trials
5. Support development of **research ethics harmonization** for multijurisdictional studies
6. Global collaborations: pan-European (c4c) and US (i-ACT) clinical trial networks



Removing Barriers

- Through partnerships with academia, MICYRN is assisting international and national investigators in the planning, development, and execution of non-oncology, multi-centre, maternal/child health clinical trials
- Centralized national infrastructure
- Academic Research Organization (ARO)-like function

ARO Service Goals

- Improve access, quality, efficiency, timelines, and cost effectiveness for maternal/child health clinical trials
- Streamlining processes to bring better medicines and therapies to mothers and children in Canada



ARO Services

Pre-Award Services (In-kind)

Consultation (Regulatory and Budget)

Scientific Depth and Protocol Optimization

Project Planning

Letters of Support

Expert Groups

[Home](#)

[Questionnaire](#)

[Update Submitted Details](#)

[View All Experts](#)

[Clinical Experts](#)

[Methodology Experts](#)

[Original Contacts](#)

[Statistics](#)

ARO Services

Post-Award Services (Cost Recovery)

Protocol Transition

Health Canada Regulatory Submissions

Harmonized Ethics Support

Monitoring

Contracts Facilitation

Safety and Adverse Event Reporting

Data Management

Project Management

Placebo Development and Drug Procurement



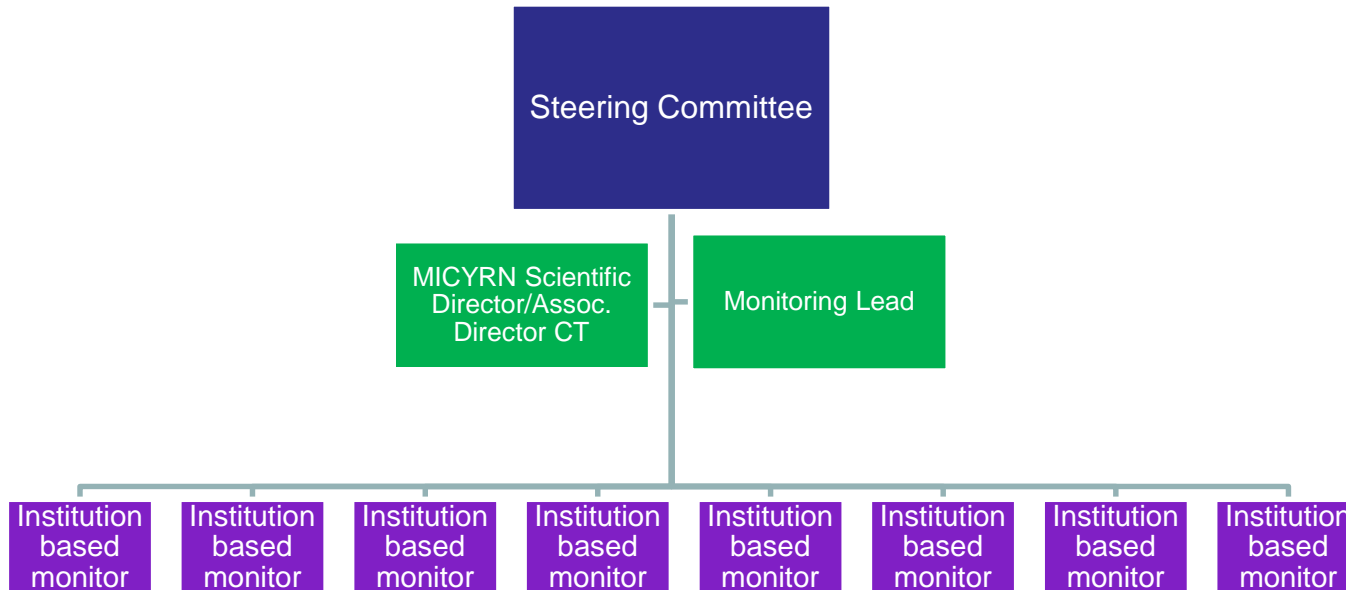
ARO Services

- **Health Canada Regulatory Submissions**
 - Expertise with over 15 years of experience
 - Clinical Trial Applications (Drugs)
 - Investigational Testing Authorizations (Devices)
 - Single Patient Studies
 - Average time for completion: 10-15 hours
 - MICYRN subsidized service (50%)



ARO Services

- **Monitoring and Quality Assurance**
 - Cross-institutional monitoring program



ARO Services: Accomplishments 2021

Consults
17

Regulatory Applications

- 7 CTAs
- 3 ITAs
- 2 SPS
- 2 training sessions

Project Support/ Management

- C4T Cannabis Trials
(2 Multi-Centre studies)
- 15 site PERC COVID
Study



POPcorn

Pediatric **O**utcome Im**P**rovement through **C**oordination of **R**esearch **N**etworks

Plateforme d'améli**O**ration des résultats **P**édiatriques par la **C**o**O**rdi**N**ation des réseaux de recherche

- To unite existing national networks in pediatric research under one coordinating umbrella to enhance responsiveness to emerging COVID-19-related issues, including unintended consequences of preventive measures.
- To establish a common national infrastructure for agile pediatric research to inform decision-making on any child health-related issue.
- To increase capacity at 16 pediatric research institution member sites and their regional partners.
- MICYRN serving as the collaboration/coordinating centre

Clinical Trial Sponsorship

- Increase the number of CTs that Canadian children can participate in
- Acquired clinical trial insurance
- Serve as the Canadian Regulatory Sponsor for investigator initiated clinical trials



Questions?

