PregTrial 2026 In-Person Meeting - Draft Agenda

From Inclusion to Implementation: Building Consensus and Advancing Guidelines for Pregnant and Lactating People in Clinical Trials

Monday, October 26, 2026 | Montréal Quebec | Thomson House, Mcgill University

GENERAL OBJECTIVES AND OUTCOMES:

1) Review ethical principles and frameworks relating to the inclusion of pregnant and lactating individuals in clinical trials
2) Discuss Canada-specific barriers and facilitators in the implementation of ethical frameworks supporting enhanced inclusion of pregnant and lactating individuals in clinical trials
3) Develop consensus through the application of a draft informed consent toolkit facilitating inclusion of pregnant and lactating individuals in clinical trials

OUTPUTS AND DELIVERABLES:

1) Stakeholder-informed pregnancy-specific informed consent form toolkit
2) Manuscript of proceedings of meeting
3) Development of an engaged network focused on inclusive clinical trials for women/individuals across the reproductive lifespan

Meeting Schedule

8:00am – Breakfast and registration

8:30am – Opening address, land acknowledgment, and introductions - Natalie Dayan (5 mins)

8:35am –*Patient Partner Talk* (10 mins, 5 min Q&A) (Margaret Loniewska)

<u>Panel 1: Ethical Principles and International Frameworks</u>
Moderator: Dr. Emily McDonald (to be confirmed), McGill University

8:50am – *Research ethics 101* (Jonathan Kimmelman) (20 mins)
Learning objectives -

- Describe key ethical principles guiding the design of clinical trials
- Evaluate the ethical considerations of including vulnerable groups in clinical trials
- Apply these principles to the inclusion of pregnant and lactating individuals in clinical trials

9:10am – *Health Canada perspective and updates on the International Council of Harmonization E21 document: priority areas for adaptation and rapid implementation in Canada.* (Lindsay Patrick, Health Canada) (20 mins)
Learning objectives -

- Describe the ICH-E21 guidelines and their relevance to the inclusion of pregnant and lactating individuals in clinical trials
- Identify approach for implementing ICH-E21 that meets the needs of the Canadian research community

9:30am – *A Review of Disease-Specific and Agnostic Toolkits as part of the WHO Task Force on Inclusion of Pregnant and Breastfeeding Women in Clinical Trials* (Martina Penazzatto WHO) (20 min)
Learning objectives -

- Define the objectives of the WHO task force on inclusion of pregnant and lactating women in clinical trials
- Compare disease-specific and disease-agnostic toolkits for pregnant and lactating women inclusion
- Propose strategies for international uptake in view of local guidelines and ICH-E21 WHO recommendations

9:50 - Panel 1 Question Period (15 minutes)

10:05 Refreshments break (15 mins)

<u>Panel 2: Insights from Canadian Initiatives to enhance representation of Reproductive-Aged Pregnant and Lactating Women in Clinical Trials</u>
Moderator: Dr. Anick Bérard, Université de Montréal

10:20am – *Updates on PregTrial: time for implementation* (Natalie Dayan; Rose Mwangi, McGill University) (20 mins)
Learning objectives -

- Summarize the current state of the PregTrial initiative and its key outputs to date
- Identify opportunities for implementation of PregTrial tools and frameworks in Canadian clinical research settings
- Outline next steps for national scale-up of PregTrial recommendations

10:40am – *Maternal–Child Trials Network: putting the "M" in MICYRN* (Thierry Lacaze-Masmonteuil, MICYRN) (20 mins)
Learning objectives -

- Describe the development of a Canada-wide Maternal-Child Trials Network within MICYRN
- Identify how a dedicated maternal-child trials network can address gaps in representation of pregnant and lactating individuals in clinical research
- Discuss opportunities for collaboration between MICYRN and other Canadian clinical trial initiatives

11:00am – *Training future generations in maternal and pediatric clinical trials: update on IMPaCT* (Lauren Kelly, University of Manitoba, IMPaCT) (20 mins)
Learning objectives -

- Describe the IMPaCT training program and its objectives for building capacity in maternal and pediatric clinical trials
- Identify strategies for integrating pregnant and lactating participants into the training of the next generation of clinical trialists
- Evaluate the role of education and training in advancing equitable representation in clinical research

11:20am – *Accelerating Clinical Trials in Canada: how a national network can be leveraged to move the needle forward on inclusion of under-represented groups* (P.J. Devereaux, McMaster University/ ACT) (20 mins)
Learning objectives -

- Describe the structure and mandate of the Accelerating Clinical Trials (ACT) national network
- Identify how national trial networks can be leveraged to improve inclusion of under-represented groups including pregnant and lactating individuals
- Evaluate the potential of coordinated national infrastructure to accelerate implementation of the guidelines discussed in panel 1

11:40 - Panel 2 Questions (20 minutes)

<u>Session 3: Keynote Address</u>
Moderator: Dr. Natalie Dayan, McGill University
12:00pm – *"Words Matter: The Ethics of Misclassifying Pregnant Participants as Vulnerable in Clinical Trials"* (Dr. Stephanie Morain, Johns Hopkins University) (45mins, 15 min Q&A)
Learning objectives -

- Explain how the classification of pregnant individuals as "vulnerable" in research ethics frameworks has historically shaped their exclusion from clinical trials
- Critically evaluate the ethical implications of misclassification and its downstream effects on evidence generation for pregnant populations
- Apply an ethics-informed lens to the language and framing used in trial protocols and informed consent documents involving pregnant participants

1:00pm – ***Networking Lunch (45 mins)***

Afternoon Workshops

<u>Session 4: Consensus-Building Breakout Group Workshops</u>
Moderators: Dr. Rose Mwangi, McGill University (Post-doctoral Fellow); Dr. Natalie Dayan – Concurrent group workshop sessions

1:45-1:55 Amy Choi presents the draft PregTrial ICF toolkit
1:55-2:05 Emily Doerksen presents RRCS as "buddy implementation strategy" for ICF toolkit

2:05-2:15 Rose Mwangi presents workshop scenario and objectives

2:15 - 3:15 Workshop

• Application of a pregnancy-specific informed consent form toolkit to a research scenario requiring inclusion of pregnant and lactating people in trials

3:15pm – *Break (20 mins)* with refreshments

3:35pm – Report-backs and consensus discussion (70 min)

• Each workshop group presents (5-10 min each)
• Facilitated discussion to identify consensus points
• Nominal group voting on priority areas/actions

4:45pm – Closing Remarks and Commitments

- Group consensus
- Summary of consensus points and priority actions
- Post-meeting working group commitments and member assignments

5:15pm – Adjourn wine and cheese