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

Morning Plenary

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)

Panel 1: International Frameworks, Developments, and Expertise
Moderator: Dr. Natalie Dayan, McGill University
8:50am – *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 – attendance by Zoom) (20 mins)
9:10am – *TBD, FDA/EMA representative (20 mins)*
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)
9:50 - Panel 1 Question Period (15 minutes)

10:05 Refreshments break (15 mins)

Panel 2: Insights from Canadian Initiatives in Clinical Trials in Reproductive-Aged Pregnant and Lactating Women
Moderator: Dr. Anick Bérard, Université de Montréal

10:20am – *Updates on PregTrial: time for implementation* (Natalie Dayan; Rose Mwangi, McGill University) (20 mins)
10:40am – *Maternal–Child Trials Network: putting the "M" in MICYRN* (Thierry Lacaze-Masmonteuil, Cumming School of Medicine, University of Calgary) (20 mins)

11:00am – *Training future generations in maternal and pediatric clinical trials: update on IMPaCT* (Lauren Kelly, University of Manitoba) (20 mins)
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. Deveraux, McMaster University) (20 mins)
11:40 - Panel 2 Questions (20 minutes)

Session 3: Keynote Address
Moderator: Dr. Natalie Dayan, McGill University
12:00pm – *From Protection to Inclusion: Rethinking Research Ethics for Pregnant and Lactating Participants* (Jonathan Kimmelman, McGill University) (45mins, 15 min Q&A)

1:00pm – ***Networking Lunch (60 mins)***

Afternoon Workshops

Session 4: Consensus-Building Breakout Group Workshops
Moderator: Dr. Rose Mwangi, McGill University (Post-doctoral Fellow) 2:00pm – Concurrent group workshop sessions (75 min)

- **Workshop A**: Pregnancy-specific informed consent form toolkit consensus
- **Workshop B**: Infrastructure needs (REB harmonization / hub, training, patient networks)

3:45pm – ***Break (30 mins)***
3:15pm – Report-backs and consensus discussion (90 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

- Summary of consensus points and priority actions
- Post-meeting working group commitments and member assignments
- Timeline for deliverable completion:
  - Consensus report (1 month)
  - ICF template finalization and publicization (3 months)
  - Canadian implementation guidance document (6 months)

5:15pm – Adjourn