



PREGTRIAL QUARTERLY NEWSLETTER

OCTOBER 2026 - ISSUE #4

PREGTRIAL IN-PERSON MEETING

OCT
26
2026

Thomson House, McGill University, Montreal

Registration now closed. Thank you!

The PregTrial in-person meeting "*From Inclusion to Implementation*" brings together knowledge holders from across Canada to develop consensus-based tools for including pregnant and lactating individuals in clinical research.



Agenda and details
www.pregtrial.ca



Hotel
Omni Mont-Royal



Getting there
3650 McTavish St.



Questions?
pregtrial@rimuhc.ca

THIS ISSUE AT A GLANCE

- Our team submitted a CIHR Project Grant for PregTrial-TWO, with results expected in January 2027.
- Dr. Natalie Dayan presented the PregTrial Rapid Response Consultation Service (RRCS) at the ACT2 meeting in Edmonton.
- A manuscript led by Rose Mwangi reframing the exclusion of pregnant and lactating individuals from clinical trials as an implementation gap has been submitted to SAGE's Women's Health.
- INCLUDE-HER is officially underway, with new team members, two inaugural team meetings, and governance frameworks in progress.

Progress & Milestones

PregTrial-TWO submitted to CIHR: We have submitted a CIHR Project Grant application for PregTrial-TWO, which aims to improve informed and equitable participation of pregnant and lactating individuals in clinical trials through better consent processes and decision-support tools. Its objectives are to:

1. Refine and finalize our web-based ICF toolkit with people with lived experience and the CanReview consent team
2. Co-develop the first patient decision aid for pregnant and lactating individuals considering trial participation
3. Pilot both tools in four Canadian trials: Sleep-Disordered Breathing in Pregnancy, CALM, RESET-Postpartum, and SNAP Canada

This work also lays the foundation for INCLUDE-HER, our new network for cardiometabolic clinical trials in women. INCLUDE-HER aims to develop and scale up best practices in sex-based trial design, and the ICF toolkit offers a natural starting point. Many of the consent issues it addresses, such as pregnancy during a trial or participation of women of reproductive age, are just as relevant to cardiometabolic trials. RESET-Postpartum, a cardiometabolic trial in the postpartum period, already bridges both initiatives.

Together, PregTrial-TWO and INCLUDE-HER move us toward more inclusive trial design for women across the reproductive lifespan. Results for PregTrial-TWO are expected in January 2027.

Manuscript submitted to Women's Health: Our team has submitted a manuscript to SAGE's Women's Health journal, led by postdoctoral fellow Rose Mwangi. It is titled "From Ethical Consensus to Real-World Applications: Reframing Exclusion of Pregnant and Lactating Women from Clinical Trials as an Implementation Gap." Using the Consolidated Framework for Implementation Research (CFIR), the paper maps barriers to inclusion across the clinical research system, including:

- regulatory ambiguity and misaligned incentives
- risk-averse institutional cultures and fragmented accountability
- gaps in investigator training and confidence, and participant concerns

It also examines how responsibility for inclusion is shared across regulators, sponsors, investigators, REBs, and clinicians. The manuscript reflects the work of more than 30 authors and PregTrial collaborators. We are grateful to our collaborators at MICYRN, IMPaCT, and SOGC, and to our patient partners, whose insights helped shape this work. We look forward to sharing the article once published.



OTHER TEAM UPDATES

ICF Toolkit update: Our investigator and REB survey on the feasibility and readiness to adopt an Informed Consent Form (ICF) toolkit closed on September 25th. Thank you to everyone who took part! Findings from the survey and our focus groups will inform refinements to the toolkit prototype. Meeting attendees will also work directly with the toolkit on October 26.

Welcome and welcome back!

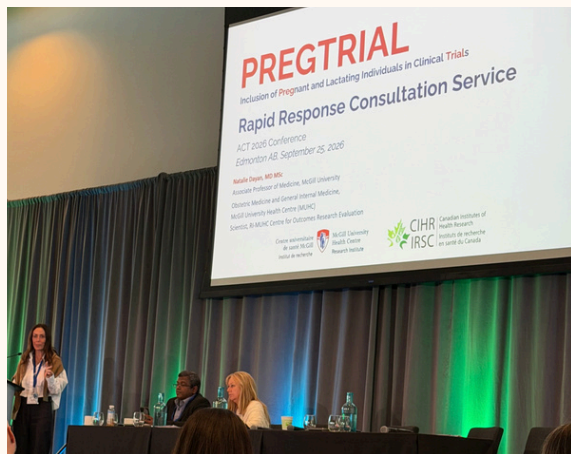
- Sandeep Vanamala joins INCLUDE-HER as Project Manager. He brings valued experience in project management in health research systems. Welcome Sandeep!
- Aiyu Liu joins INCLUDE-HER as Research Associate, bringing her expertise in maternal health and research with pregnant individuals. Welcome Aiyu!
- Welcome back to Gabe Shapiro, who is working on cardiovascular disease research. We're happy to have Gabe back from paternity leave!

RECENT AND UPCOMING TALKS

UPCOMING TALKS

November 5, 2026, CTO Conference (Toronto, ON):

Dr. Dayan will join the panel "Building a Safer and More Inclusive Clinical Trials Ecosystem," discussing opportunities to advance equity, inclusion, safety, and representation across the research ecosystem.



RECENT TALKS

September 25, 2026, ACT2 Conference (Edmonton, AB):

Dr. Dayan presented the PregTrial Rapid Response Consultation Service. More details can be found at our website: [RRCS](https://www.pregtrial.ca)

October 7, 2026, Partnership Women's Health Research (PWHR) Seminar Series (Online):

Dr. Dayan spoke about PregTrial & the exclusion of women in clinical research on the panel "Closing the Inclusion Gap: Progress and Innovation in Pregnancy Research".

STAY CONNECTED

Stay in touch with the PREGTRIAL team - contact us or visit our website for updates



pregtrial@rimuhc.ca



www.pregtrial.ca