

# LEADS Trial

*Liberation from mechanical ventilation using Extubation Advisor Decision Support:  
The multicentre (LEADS) Pilot Trial*

*Karen Burns  
Andrew Seely*

Canadian Critical Care Trials Group  
(CCCTG)

LEADS Trial  
Extubation Advisor



RFA 3 – Canadian Biotech/RCTs

ACT  
AEC Accelerating  
Clinical Trials  
Accélérer les  
Essais Cliniques

CIHR  
IRSC Canadian Institutes of  
Health Research  
Instituts de recherche  
en santé du Canada

# Evaluating Canadian Biotech with RCTs

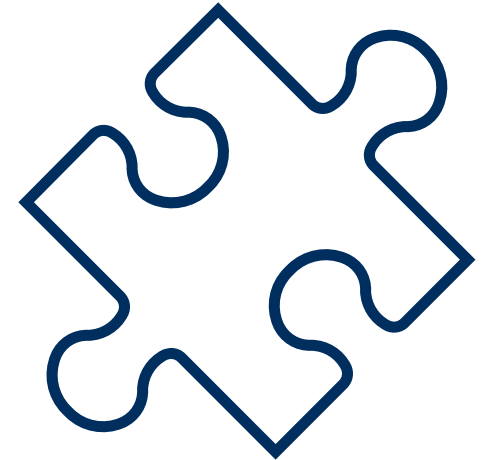
- Therapeutic Monitoring Systems Inc
  - [www.therapeuticmonitoring.com](http://www.therapeuticmonitoring.com)
- In(ter)vention: Extubation Advisor
  - Clinical Decision Support Software Tool



Therapeutic  
Monitoring  
Systems

# Research Question

- Can we recruit ventilated critically ill adults at multiple centres?
- Can we feasibly maintain **protocol adherence?**



# Design

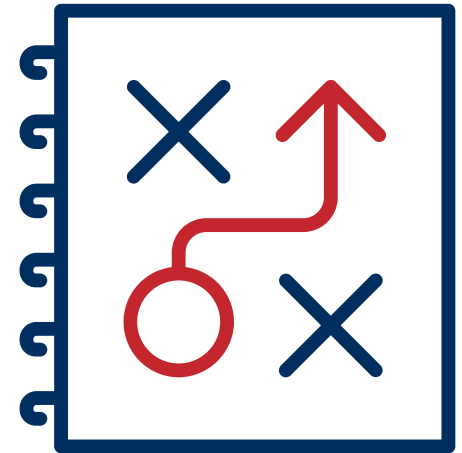
Multicentre pragmatic vanguard open-label feasibility pilot RCT of EA tool

Patients: randomized (1:1) to intervention (EA tool) or control (standard care)

Aim: 100 patients across >10 centres over 10 months

SBTs (Spontaneous Breathing Trials): All patients - SBTs as per standard of care

Intervention: EA report generated for each SBT to assist extubation decision-making



# Timeline



# Updates

Sites	Location	Lead Site PI	Ethics	Contracts	Launch	Enrolled
Unity Health	Toronto	K Burns	✓	✓	Apr 22	5
TOH (2 sites: General/Civic)	Ottawa	A Tran	✓	✓	May 27 / Jun 15	12 / 7
Kingston	Kingston	D Maslove	✓	✓	Jun 24	2
QCH	Ottawa	A Iyengar	✓	✓	Sep 25	0
CHUM	Montreal	E Charbonney	✓	✓		
Royal Alexandra	Edmonton	J Kutsogiannis	✓ (pending Admin approval)	✓		
St Boniface	Winnipeg	O Mooney	✓ Pending institutional	Internal review		
HSC Winnipeg	Winnipeg	A Mendelson	✓ Pending institutional	Internal review		
Queen Elizabeth II	Halifax	E. Tan	submitting	✓		
CHUS	Sherbrooke	F Lamontagne		Sent		
IUCPQ	Quebec City	F Lellouche	submitting	Sent		
Sunnybrook	Toronto	D Scales	submitting	Sent		
Hôtel-Dieu de Lévis	Lévis	P Archambault	submitting	Sent		
Hôpital de l'Enfant-Jésus	Quebec City	A Turgeon	submitting	Sent		

Thank you! Merci!



Accelerating  
Clinical Trials  
Accélérer les  
Essais Cliniques



CIHR  
IRSC

Canadian Institutes of  
Health Research  
Instituts de recherche  
en santé du Canada