

UTOPIAN Clinical Research Group Meeting – *Minutes*

Wednesday, November 24th, 2021, from 4:00 p.m. to 5:00 p.m., Zoom teleconference

Item	Topic	Minutes	Action	Responsible
1	Introductions (Andrew Pinto)	<ul style="list-style-type: none"> Andrew Pinto introduced those present via Zoom and on the phone 		
2	Review and approval of October 28, 2021, draft meeting minutes (All)	<ul style="list-style-type: none"> Minutes of the previous meeting were approved by those present 	Approved	All
3	Sharing the experience of working with Clinical trials (Peter Selby)	<ul style="list-style-type: none"> Implementing Pragmatic Trials: <ul style="list-style-type: none"> Clinical Trials Types: <ul style="list-style-type: none"> Prevention Screening Diagnostic Treatment Behavioural Quality of Life Patient-Oriented Research Clinical Trial Designs (Regulated and unregulated trials) <ul style="list-style-type: none"> Randomized Controlled Cohort Feasibility/Pilot Case Control Quasi-experimental Multi-arm multi-stage Cross-sectional Regulated/Nonregulated Hybrid Design types Hybrid Study Design (Curran et al, 2012) <ul style="list-style-type: none"> An effectiveness-implementation hybrid design takes a dual focus a priori in assessing clinical effectiveness and implementation <ol style="list-style-type: none"> Testing effects of a clinical intervention on relevant outcomes whiles observing and gathering information on implementation Dual testing of clinical and implementation interventions/strategies Testing of an implementation strategy while observing and gathering information on the 		

		<p>clinical intervention's impact on relevant outcomes</p> <ul style="list-style-type: none">• Example of a published RCT:<ul style="list-style-type: none">○ STOP Program Trial Details<ul style="list-style-type: none">▪ Objective: To increase access to smoking cessation interventions for smokers across Ontario▪ Design: pragmatic, open-label▪ Intervention: Nicotine Replacement Therapy (NRT) and behavioural support▪ Population: Treatment seeking smokers across Ontario▪ Methods:<ul style="list-style-type: none">▪ Direct to patient▪ Pharmacy (n=98)▪ Public Health Units (n = 36)▪ Primary Care Clinics:<ul style="list-style-type: none">– Family Health Teams (n = 153)– Community Health Centres (n = 61)– Nurse Practitioner Led Clinics (n = 18)▪ Addiction Agencies (n = 58)																							
4	Plan for the CRG Lecture Series in 2022 (Andrew)	<ul style="list-style-type: none">• Goal:<ul style="list-style-type: none">○ To enhance learning and capacity building• Approach:<ul style="list-style-type: none">○ 6 short sessions during Jan to Jun, 2022 recorded and posted online <table><thead><tr><th>Topic</th><th>Proposed speaker</th><th>Date</th></tr></thead><tbody><tr><td>1. Intro to RCTs and overview of types of RCTs</td><td>Andrew</td><td>Jan 27</td></tr><tr><td>2. Patient engagement in primary care trials</td><td>Michelle / Andrew</td><td>Feb 24</td></tr><tr><td>3. Recruitment + data collection</td><td>Aisha? Shivani/Joe?</td><td>Mar 24</td></tr><tr><td>4. Sample size calculation and data analysis</td><td>Rahim / Chris</td><td>Apr 28</td></tr><tr><td>5. DSMB + Ethics</td><td>Ross?</td><td>May 26</td></tr><tr><td>6. Health Canada/FDA requirements for clinical trials (eg, handling IPs)</td><td>Nav?</td><td>Jun 30</td></tr></tbody></table> <ul style="list-style-type: none">• Suggestions:<ul style="list-style-type: none">○ Eva G: Include a session on the use of administrative health data to support clinical trials either through identifying eligible patients or to measure outcomes. Cluster trials can often be used in order to potentially not have to get individual patient consent.	Topic	Proposed speaker	Date	1. Intro to RCTs and overview of types of RCTs	Andrew	Jan 27	2. Patient engagement in primary care trials	Michelle / Andrew	Feb 24	3. Recruitment + data collection	Aisha? Shivani/Joe?	Mar 24	4. Sample size calculation and data analysis	Rahim / Chris	Apr 28	5. DSMB + Ethics	Ross?	May 26	6. Health Canada/FDA requirements for clinical trials (eg, handling IPs)	Nav?	Jun 30		
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5	Status of Clinical Trials (Andrew/Jamie)	<ul style="list-style-type: none">• SARTAN-AD:<ul style="list-style-type: none">○ Looks at the hypertensive medications proving protective benefits in slowing down Alzheimer's disease (and mild to moderate cognitive decline)○ 16 patient referrals sent○ Resuming chart reviews using the updated eligibility criteria																							

		<ul style="list-style-type: none"> • PCSAR-EDU (Primary Care Severe Asthma Registry and Education project) <ul style="list-style-type: none"> ○ Currently in Phase 1 of 4, which involves developing a severe asthma (SA) registry in primary care ○ Phases 2-4 involve developing an education program that addresses patient- and provider-identified barriers to SA management and EMR data capture. This program will be piloted at UTOPIAN sites in Phase 3 • Advanced Care Planning (ACP): <ul style="list-style-type: none"> ○ Site visits are complete, and participant follow ups are anticipated to be complete by November 2021. Currently in the data cleaning phase and preparing materials to share findings back to patients, care partners and clinicians • SPIDER: <ul style="list-style-type: none"> ○ Actively recruiting , including pilot testing through POPLAR Networks; unintended consequence was the additional REBs required; in context with CPSO for a possible integration of SPIDER QI in CPSO's Practice Improvement Plan initiative • ANTICIPATE: <ul style="list-style-type: none"> ○ A cluster RCT that aims to test proactive outreach and bio-psycho-social support for elderly patients with a) chronic conditions b) serious mental illness, or c) poverty during COVID and the ongoing restrictions on primary care. ○ Received REB Approvals from St. Michael's and UofT • MEDOTATE: <ul style="list-style-type: none"> ○ Testing the impact of a (virtual) meditation intervention on people living with chronic pain and depression (total sample = 160) ○ Interest from pain clinics at Sinai, WCH and TRI ○ 29 patients participating 		
6	POPLAR Clinical Research (Andrew)	<ul style="list-style-type: none"> • Andrew Pinto and Dee Mangin serve as the co-chairs of POPLAR's Clinical Research Working Group • The work is moving along and in many ways learning from the work done in this group, the UTOPIAN Clinical Research Group and the work done at McMaster • A lot of the other networks do not have as much clinical research capacity or experience • Slowly developing a community of practice to share knowledge across POPLAR 		
7	Discussion: Project Intake Review Process (Andrew Pinto)	<ul style="list-style-type: none"> • UTOPIAN Project Request Review Process: <ul style="list-style-type: none"> ○ Someone who is interested in doing work with UTOPIAN or POPLAR, fills out and submits an online form which provides project details (i.e. the research question, project purpose, the request) 		

		<ul style="list-style-type: none"> ○ Tom Rylett (UTOPIAN Project Manager) receives the form and briefly reviews ○ For clinical research projects, the form will go to Jamie for review. ○ Jamie will bring it to a discussion with Andrew and the Research Officers within the Clinical Research Group for review and feedback. ○ If feasible, it would be suggested that the project be presented at UTOPIAN's Scientific Advisory Committee (SAC) meeting • Suggestions: <ul style="list-style-type: none"> ○ Would it make more sense for the Jamie to bring all clinical research project requests to this meeting, the UTOPIAN Clinical Research Group, to review the science and determine feasibility, before sending it off to UTOPIAN SAC? <ul style="list-style-type: none"> ▪ Eva G: Should it go first to SAC for review (is this relevant, does it fit our values, etc) and then to the Clinical Research Group for assessment of the feasibility and review of procedures and how to improve those 		
Meeting adjourned at 5:00 p.m.				
Next meeting: December 15, 2021; 4:00 p.m.-5:00 p.m. (virtual)				