UTOPIAN Primary Care Trials Group – Session 9 *Minutes*

Wednesday, November 18th, 2020 from 4:00 p.m. to 5:00 p.m., Zoom teleconference

Attendance:

Andrew Pinto (AP) – Chair
Aashka Bhatt (AB)
Giles Pereira (GP)
Rahim Moineddin (RM)
Braden Gregory O'Neill (BGO)
Michelle Greiver (MG)
Sumeet Kalia (SK)
Noah Ivers (NI)
Noah Crampton (NC)
Chris Meaney (CM)
Joanna King (JK)
Peter Selby (PS)
Eva Grunfeld (EG)
Ross Upshur (RU)
Sheila Dunn (SD)
Rosemarie Lall (RL)
Michale Farkouh (MF)
Luca Pisterzi (LP)
Deepti Pasricha (DP)
Carolyn Steele Gray (CSG)
Tony D'Urzo

Regrets:

Payal Agarwal (PA)
Marjan Moeinedin (MM)
Donatus Mutasingwa (DM)
Abhimanyu Sud (AS)
Jennifer Rayner (JR)
Ann Burchell (AB)
Stephanie Terenzi (ST)
Tara Kiran (TK)

Item	Topic	Minutes	Action	Responsible
1	Introductions (Andrew Pinto)	• Andrew Pinto introduced those present on the phone.		
2	Review and approval of June 18, 2020 draft meeting minutes (All)	• Minutes of the previous meeting were approved by those present.	Approved	All

3	Discussion topic #1: Site Preparation to Support Clinical Trails (Andrew Pinto)	**1. Objectives of Primary Care Trials Groups**: a) To support primary care providers who conceive an intervention (emerging from real-world clinical work) to test it rigorously using an RCT design as PI b) To support primary care providers be thoughtful site investigators for RCTs c) To build a community of practice, and ultimately create more efficient and effective research **2. Site Readiness and Preparedness:** • Responsibilities that a PI has to a Site Investigators: o Include SI as member of study team o Include SI on grant(s), which may involve adding the SI to existing grants o Include SI in discussions around study design, analysis and interpretation of results o Invite SI to be co-author on paper(s) o Identify study resources available to site investigators, including staff and documents o Reach out and visit site and meet with staff – e.g. sponsor introductory lunch • Responsibilities of a Site Investigator: o Confirm the study is relevant and applicable to primary care, and meets the policies of the DFCM (e.g. relationship to industry) o Champion the study at the site, including approaching site leadership + colleagues to confirm involvement o Manage REB at site if applicable, with the support of the PI and study staff o Manage Research Contracts at site if applicable, with the support of the PI and study staff o Manage Cost Centres/financial details at site if applicable, with the support of the PI and study staff o Advertise study to participants and support recruitment (e.g., posters, emails, use of EMR to identify potential participants) o Contribute to interpretation of results o Contribute to editing paper, meeting ICMJE criteria for authorship **3. Checklist:** □ Site Investigator identified: Requires each site to be aware of the interests, availability and experience of each potential SI: □ Qualified Investigator Undertaking Form and Protocol Agreement signed □ CVs (signed) and licenses as required □ REB identified and forms available: requires knowledge of each REB process, incld. CTO □ Staff and HR policies (where applicable)		

		□ Training for TCPS2, GCP, Health Canada Division 5 □ Contracts (where applicable) □ Medical directive/Delegated act process & establish delegation log □ Finances (e.g., research cost centre) □ Recruitment processes: posters, emails, staff, on-site, pre-authorization to be contacted □ Process to communication about the trail to the site □ Data storage & consent documentation □ Site Initiation Visit □ Drug storage: standard operating procedures, temp, monitoring, logs □ Insurance □ Process to address any new identified health concerns, crisis management		
4	Discussion Topic #2: Clinical Trials: A Journey to Translate Discovery and Evidence into Changes in Clinical Practice (Dr. Michael Farkouh)	**Role of a Primary Care Clinical Trials Network:** o Ask good questions generated form clinical practice and you will end with reliable answers that will inform your practice o Medical students, residents and colleagues often bring the best questions to the table-work with colleagues across the hospital/university and beyond o An RCT is a journey-it will generate new questions and inspire new collaborations o Include Sub Studies of mechanism including engagement of the basic and translational scientists that will lead to the next generation of trials o Work together with Outcomes Research groups-they will generate hypotheses that need to be tested and allow for long-term follow-up **Role of a Primary Care Clinical Trials Network:** o Focus on your questions: DIVERSE POPULATION WITH UNIVERSAL COVERAGE o Prevention, Prevention, Prevention o Longitudinal Follow-up of Trial Cohorts o Partners in our novel, specialty trials with a Permanent Member status on Steering Committees o Federate with QI initiatives o Participate in mechanistic sub studies: biorepository (blood and genomics, imaging)		
Meeting adjourned at 5:00 p.m.				
Next meeting: December 3, 2020; 4:00 p.m.-5:00 p.m. (virtual)				