



Update

Newsletter Date

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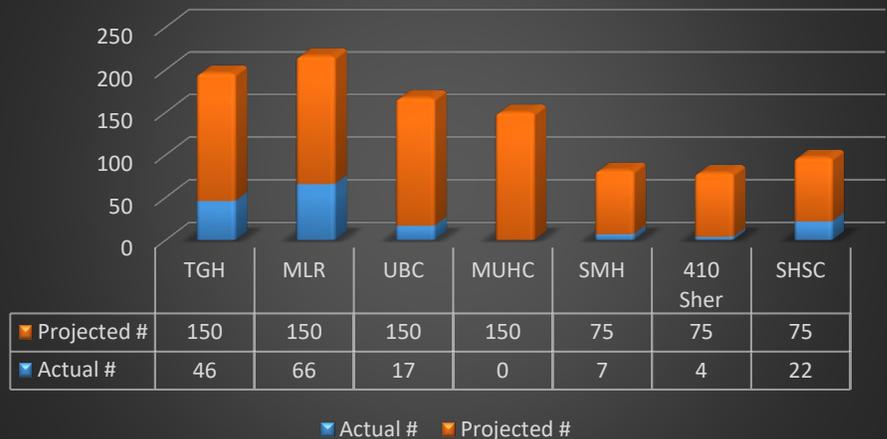
Study Update

First participant first visit was October 10, 2019. To date 131 participants are enrolled across Canada. 6 out of 7 sites have been activated to begin enrollment! The Montreal site should be activated this month.

CHANGE HIV Overall Enrollment



CHANGE HIV Site Enrollment



COVID-19 Effect



Due to the COVID-19 Pandemic, all non-essential research stopped which included the CHANGE study. As a result, a site letter was sent out putting participant visits and recruitment on hold. As of mid-July remote visits where possible started via telephone interviews. Currently there are some sites that are able to conduct in-person visits but most visits are being conducted remotely where possible, with participants getting their stipends at their next clinic visit. Full study activities including recruitment has resumed as per each site's activities

Amendment

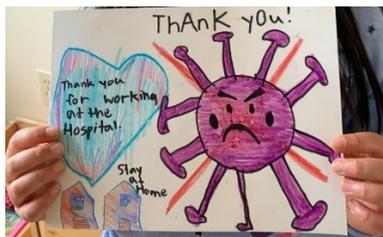
With increased virtual visits and working remotely becoming the "new norm" in research, an amendment to the CHANGE protocol is required to accommodate and prepare for this new model. Should there be another wave, virtual consents need to be outlined as well as the ability to monitor or audit research data remotely. The REDCap database utilized for the CHANGE study has the capability to send study questionnaires to participants remotely which they can complete in the comfort of their own home. This allows for a mixed structure model where onsite visits are only reserved for assessments that cannot be conducted remotely. An amendment outlining these changes has been submitted for approval.

COVID-19 Sub-Study

In light of the COVID-19 pandemic, a small survey was sent to the CAB to find out how people were coping at this time. Based on the responses received it became evident that PLWHIV could be affected in ways different from the general population, therefore a substudy was designed in collaboration with the Canadian Co-infection Cohort (Dr. Marina Klein) to explore the effects of COVID-19 on PLWH.

- The study will consist of 3 visits over a 12-month period (baseline, 6 months and 12 months). Questions will focus on COVID-19 symptoms, routine HIV/HCV care, emotions, and satisfaction with virtual care.
- In addition, research blood samples will be tested for COVID-19 antibodies. These samples will be batch tested at the end of the study or until a validated antibody test is identified, if not already identified at the end of the study.

THANK YOU



The CHANGE HIV team recognizes and appreciates the dedication on the part of all investigators and research staff who are working tirelessly to maintain critical research operations to follow participants during this difficult time.