

Congratulations!!

McGill (RVH) randomized their first patient.

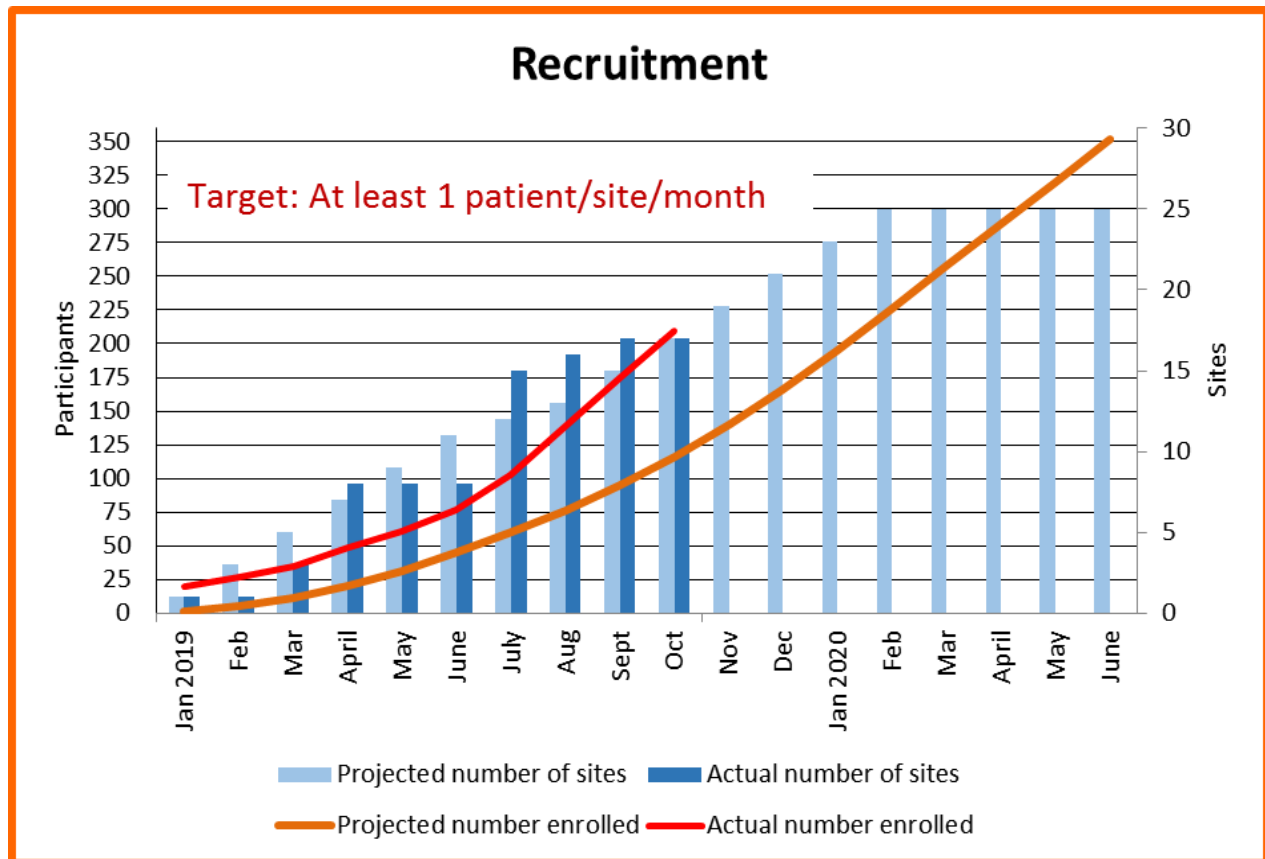
We are at 220 patients enrolled!

We thank you all for your excellent work!



Our TOP 3 Enrolling Sites for October 2019:

- ① CIUSSS de l'Estrie - CHUS: 13
- ② Ottawa General: 6
- ③ Juravinski Hospital and St-Joseph's Healthcare: 3



No Objection Letter received for amendment no. 3

We received the NOL from Health Canada for amendment no. 3 of the LOVIT research protocol (protocol version 5, 19-SEP-2019). The letter has been sent to all sites on November 7, 2019. Please print the letter and file it in your regulatory binder.

For Quebec sites: The NOL has been sent to the central REB. We had already received approval for protocol version 5. Please make sure your ICFs are modified and sent to your "Bureau de soutien à l'éthique". Once approved, please send us your approved ICFs and approval.

For the Ontario sites (under CTO): The NOL has been sent to CTO. This was a requirement to obtain the REB approval. A new version of the ICFs will be sent to you once we get REB approval.

For sites outside Quebec and Ontario: Please submit the NOL with your amendment of protocol version 5 and the updated ICFs to your REB. Make sure to send us your approved ICFs and approval.

Training on the use of StatStrip glucometers

We thank the people who participated in the training session on the use of the StatStrip glucometer on November 7, 2019. Please send your training log to:
marie-helene.masse3@usherbrooke.ca and
julie.menard.ciusse-chus@ssss.gouv.qc.ca

New versions of the CRFs, Operations Manual, and Pharmacy Manual

Version 6 of the CRFs, and version 4 the Operations Manual and Pharmacy Manual have been sent to all sites on November 13, 2019. Please note that Question 23.1 on Form 4.3 must be revised only for patients randomized since Septembre 20, 2019 who received insulin.

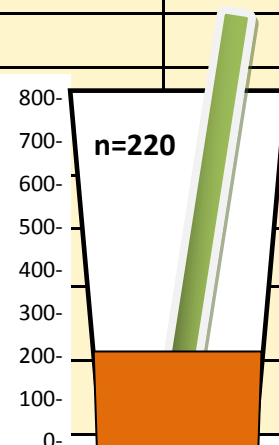
Please let us know if you have any questions about the changes

Interim Analysis

An interim analysis will be conducted when 250 participants will have completed the study. We anticipate that the interim analysis will take place in the early New Year. Please ensure that all data are entered so that the interim analysis will not be delayed.

THE NEXT ROUND OF PAYMENTS IS PLANNED ON DECEMBER 1st, 2019.

Sites	Ethics Process started	Ethics Submitted	Final Ethics Approval	Agreement Executed	SIV	Activated	# Patients Enrolled
CIUSSS de l'Estrie - CHUS			👍	👍	26-SEP-2019	👍	102
Kingston HSC			👍	👍	07-FEB-2019	27-FEB-2019	19
IUCPQ			👍	👍	28-FEB-2019	01-MAR-2019	5
CISSS Chaudière-Appalaches			👍	👍	02-APR-2019	05-APR-2019	15
CHUM			👍	👍	03-APR-2019	05-APR-2019	9
Juravinski Hospital			👍	👍	09-APR-2019	17-APR-2019	22
Maisonneuve-Rosemont			👍	👍	09-APR-2019	17-APR-2019	2
Hamilton General Hospital			👍	👍	10-APR-2019	26-APR-2019	2
McGill (RVH)			👍	👍	18-APR-2019	09-JUL-2019	1
McGill (MGH)			👍	👍	18-APR-2019	09-JUL-2019	
Trois-Rivières (CIUSSS MCQ)			👍	👍	23-MAY-2019	15-JUL-2019	4
Ottawa General Hospital			👍	👍	03-JUIL-2019	17-JUL-2019	21
Ottawa Civic Hospital			👍	👍	03-JUIL-2019	17-JUL-2019	9
University of Alberta			👍	👍	28-MAY-2019	17-JUL-2019	3
Hôpital Sacré-Cœur			👍	👍	08-JUIL-2019	26-JUL-2019	3
St. Joseph's Healthcare			👍	👍	18-JUN-2019	23-AUG-2019	3
Sunnybrook HSC			👍	👍	21-JUN-2019	12-SEP-2019	
Victoria (VIHA)			👍	👍	13-SEP-2019		
Mount Sinai Hospital			👍		18-NOV-2019		
CHU de Quebec - Univ. Laval			👍	👍	16-DEC-2019		
Apollo Hospital, Chennai, India		👍			20-JAN-2020		
Regina General Hospital		👍		👍			
St. Michael's Hospital		👍					
Royal Alexandra Hospital		👍		👍			
Raymond Poincaré University Hospital, France		👍					
Auckland City Hospital, New Zealand		👍					
London HSC	👍						
Niagara Health Hospital	👍						



DO NOT HESITATE TO CONTACT US FOR ANY INFORMATION OR HELP

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