CTN Study Reporting Template

CTN STUDY REPORTING TEMPLATE

STUDY INFORMATION

CTN or CTNPT Study #: 031	Date: 07 May 2024
Study Title/Name: Vedolizumab treatment in antiretroviral drug treated chronic HIV infection (HAVARTI)	
Principal Investigator(s): Drs. Cameron and McGuinty	
Phone: 613-737-8899, ext. 78923	E-mail: bcameron@ohri.ca

STUDY PROGRESS

1. Please describe study progress during the period of 01 April 2023 to 31 March 2024 (for example, have you met your enrolment targets, have there been any SAEs?):

Study contract is extended until December 2025 to add one more participant to the study. The 10th Patient is in screening. No SAEs. Recovery of OHRI CIU capacity and HIV clinic population from COVID-19 Effects.

CTN FUNDING

2. Is the CTN providing funding? ☐ Yes ☒ No (if no, proceed to Question 3)

2a. Are the study financial statements attached? ☐ Yes ☐ No (if no, describe why)

2b. Please describe how the funds provided by the CTN have been used to date and justify why the release of the next instalment is required:

KNOWLEDGE TRANSLATION ACTIVITIES

3. Please provide a list of publications, presentations, and conference submission details over the past year (may be provided in a separate attachment). If available, please include the Digital Object Identifiers (DOIs) for publications.

There have been no activities in the past year.

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3a. Has the CTN been acknowledged in all publications connected to this study? ☒ Yes ☐ No (if no, describe why)
4. Please provide details of any publications, presentations, and abstract submissions that are planned for the upcoming year: 1. Update on last (10th) case- high dose Vedolizumab regarding outcome of ATI 2. Evaluation of Vedolizumab PK and effect on serum creatinine during the infusion period, compared with prior and later period. 3. Analysis 4. Dose/PK/PD relationships with PVL Kinetics in ATI

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5. Please provide details on other knowledge translation activities, such as media interviews, webinars, articles in newsletters, community presentations, etc. over the last year:

The CAHR clinical track plenary summarized this trial (see attached slides) as one of Canada's HIV cure trials.

COLLABORATIONS

6. Please describe activities conducted with partners and collaborators over the last year:

There have been no activities in the past year.

6a. Have there been any new collaborators, partners, or external funders (not listed in the original submission documents) over the past year? ☐ Yes ☒ No

If yes, please name them here:

STUDY ACTIVITIES FOR UPCOMING YEAR

7. Please describe the study plans over the next year(s) (include the end date of the study, both last participant, last visit date, and estimated date of completing the final manuscript):

Manuscript estimated date 2024

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STUDY IMPACT

8. Please describe the anticipated impact and significance of this study:

This trial will create (has created) a design platform for HIV cure research. This platform will permit both pharma and investigator driven trials to have comparable methods for between trial comparisons of candidate “cure” intervention.

Please use this space to provide any further details you need to report: