# CTN Study Reporting Template

## CTN STUDY REPORTING TEMPLATE

### STUDY INFORMATION

| CTN or CTNPT Study #:324 | Date: June 11, 2024 |
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Study Title/Name:
A multicenter, randomized controlled trial of the efficacy, safety and immunogenicity of the 9-valent human papillomavirus (HPV) vaccination in preventing recurrence of high-grade anal dysplasia in HIV-positive men who have sex with men (MSM)

*Sub-study of the HPV-SAVE Study: HPV and HPV Vaccine Evaluation in men who have sex with men*

Principal Investigator(s): Dr. Irving Salit & Dr. Troy Grennan

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### 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?):

The study has started recruiting since May 2023 and recruitment still ongoing. No SAEs at the moment.

### 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:

**During the period of April 1st, 2023 to March 31st, 2024, CTN funds have been used for:**

- Research Assistants: $12,589.35
- Criminal record clearance fee for staff: $28
- Research supplies: $544.23
- Study website: $60.00

As of Mar. 31st, 2024, the balance of this grant after commitment/obligation is **$ 1,809.49**.

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### 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.

N/A

3a. Has the CTN been acknowledged in all publications connected to this study? ☐ Yes ☐ No (if no, describe why)

N/A

4. Please provide details of any publications, presentations, and abstract submissions that are planned for the upcoming year:

N/A

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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:

N/A

## COLLABORATIONS

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

Currently working on amending protocol V5.0 (to make a protocol V6.0)

Enrollment status:
UHN has 8 participants recruited
UBC has 11 participants recruited

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:

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### 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):

Date First Patient is Enrolled: 25-May-2023
Number of Evaluable Subjects Enrolled: 19/180
Date 50% Enrollment is Complete: March 2025
Date Enrollment is Complete: August 2026
Date all Patient Visits are Complete: End of 2029
Target Congress/Meeting Date:2029
Target date for manuscript submission to MSD: 2030

### STUDY IMPACT

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

This study will allow us to analyze the potential role played by the HPV vaccine in the overall management of HIV + MSM. The role of the HPV vaccine in secondary prevention of anal pre-cancer (i.e. anal HSIL or HGAIN) has only been examined in one small Dutch study, and otherwise has not been examined in a systematic, prospective way. Our study will contribute to a currently-sparse literature. Furthermore, this study will provide more information on the vaccine's potential in reducing anal HPV carriage, which is important as well be cause chronic carriage is associated with anal cancer.

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