

# COVAXHIV AIM 1: COVID-19 vaccine immunogenicity in people living with HIV (CTN 328)

Wednesday, March 8, 2023

COVID-19 Immunity Task Force Scientific Meeting

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University of British Columbia and Centre for Health Evaluation and Outcome Sciences

*on behalf of the COVAXHIV CTN 328 study team*



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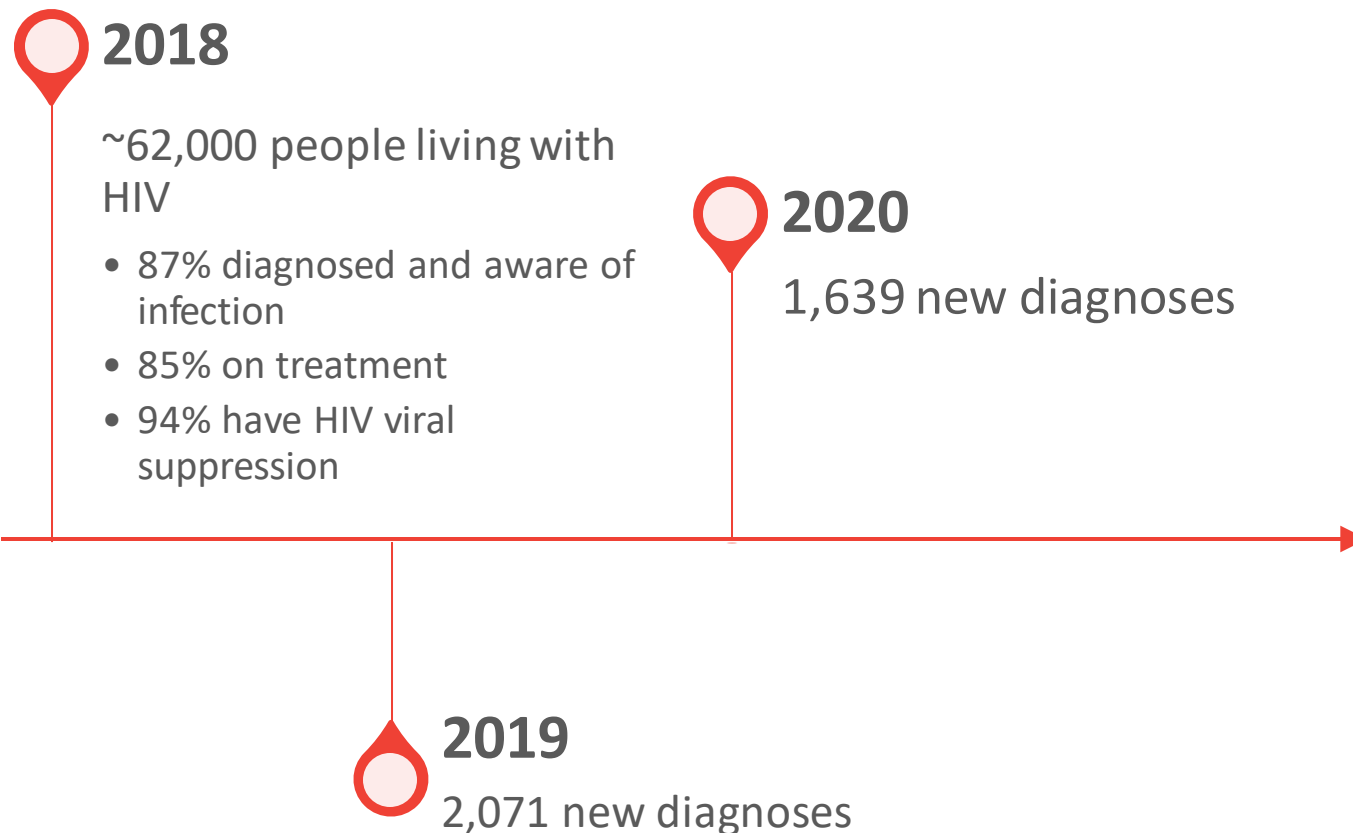


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## People living with HIV in Canada

30% are immune non-responders, i.e., undetectable HIV viral load but abnormal CD4 T cell counts (<350 cells/mm<sup>3</sup>)

Many face challenges due to social determinants of health including lower incomes, unemployment, sexual orientation, gender, and racism



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# Why is it important to study COVID-19 vaccination among people living with HIV?

PLWH display poor immunogenicity to common vaccines influenza, pneumococcal, meningococcal and Hepatitis A and B vaccines, especially with low CD 4 T cell counts (<200 cells/mm<sup>3</sup>)/viremia

Other intersecting vulnerabilities increase risk of COVID-19 acquisition and outcomes

## PLWH understudied in COVID-19 vaccine clinical trials:

normal CD4 T cell counts (>500 cells/mm<sup>3</sup>) and few comorbidities  
data were excluded from primary publications

not generalizable to the broader spectrum of PLWH

**COVID-19 vaccines are safe for people living with HIV**

- The COVID-19 vaccines under development or approved by regulators are believed to be safe for most people, including people living with HIV. There is therefore no reason why people living with HIV should not take the vaccine when offered it.
- COVID-19 vaccines bring the same benefits to people living with HIV as they bring to all individuals and communities—prevention of severe disease due to SARS-CoV-2 and potentially reduced transmission of the SARS-CoV-2 virus.
- People living with HIV should continue to take effective antiretroviral therapy.
- Even after vaccination, people should continue to take preventive measures against the SARS-CoV-2 virus.

AIDS

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What is the immune response to COVID-19 vaccines among people living with HIV?

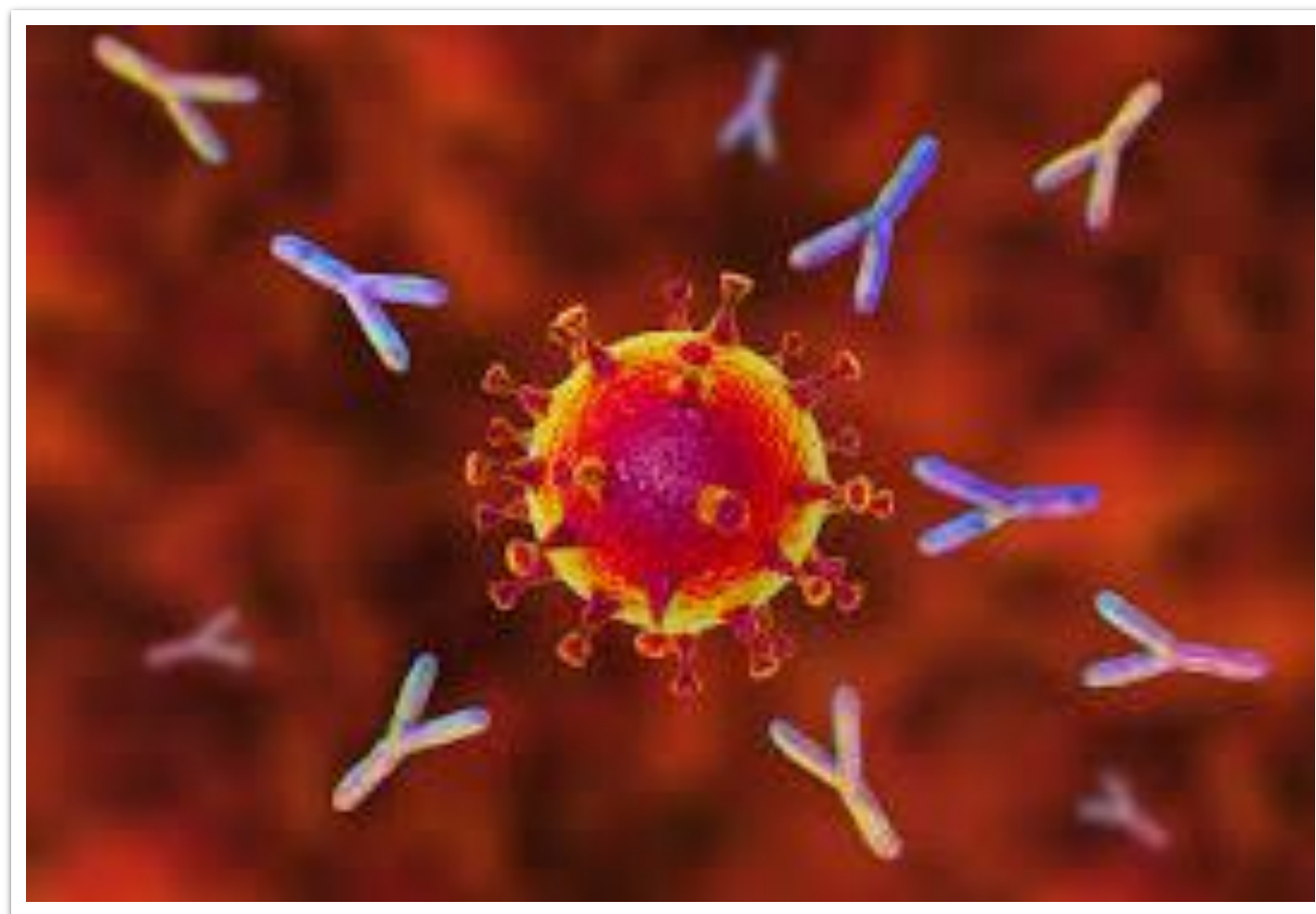


Photo credit: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/antibodies.html>



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# Visits completed to date

Site	Visit 1	Visit 2 + Visit 1/2	Visit 3 + Visit 1/3	Visit 4	V5	V6	B1	B6	B12
	Pre- vaccine	4 weeks after dose 1	3 months after dose 2	6 months after dose 2	12 months after dose 2	15 months after dose 2	4 Weeks after dose 3	6 months after dose 3 OR prior to dose 4	12 months after dose 3 OR 4 weeks after dose 4
<b>Montreal</b>	14	28	102	81	15	2	56	32	22
<b>Ottawa</b>	14	97	78	30	2		57	20	13
<b>Toronto</b>	5	12	63	54	9	4	17	41	25
<b>Vancouver</b>	66	97	96	62			88	82	65
<b>Study Total</b>	99	234	339	227	26	6	218	175	125

Montreal (Chronic Viral Illness Service—Dr C Costiniuk)

Ottawa (The Ottawa Hospital Immunodeficiency Clinic—Dr C Cooper)

Toronto (University Health Network—Dr S Walmsley)





Vancouver (St Paul's Hospital—Dr M Hull)

# Select Publications to date

Open access

Protocol








## BMJ Open CTN 328: immunogenicity outcomes in people living with HIV in Canada following vaccination for COVID-19 (HIV-COV): protocol for an observational cohort study

Cecilia T Costiniuk <sup>1</sup>, Joel Singer,<sup>2,3</sup> Marc-André Langlois,<sup>4</sup> Iva Kulic,<sup>2</sup> Judy Needham <sup>2</sup>, Ann Burchell,<sup>5,6</sup> Mohammad-Ali Jenabian,<sup>7</sup> Sharon Walmsley,<sup>8</sup> Mario Ostrowski,<sup>9,10</sup> Collin Kovacs,<sup>11</sup> Darrell Tan,<sup>12,13</sup> Marianne Harris,<sup>14</sup> Mark Hull,<sup>14</sup> Zabrina Brumme,<sup>14,15</sup> Mark Brockman,<sup>14,15</sup> Shari Margolese,<sup>16</sup> Enrico Mandarino,<sup>16</sup> Jonathan B Angel,<sup>17</sup> Jean-Pierre Routy <sup>18</sup>, Aslam H Anis,<sup>2,3</sup> Curtis Cooper <sup>19</sup>



Article

## SARS-CoV-2 Vaccine-Induced T-Cell Response after Three Doses in People Living with HIV on Antiretroviral Therapy Compared to Seronegative Controls (CTN 328 COVAXHIV Study)

Yulia Alexandrova <sup>1,2</sup>, Alexis Yero <sup>1</sup> , Ralph-Sydney Mboumba Bouassa <sup>1,2</sup> , Eve Comeau <sup>1</sup>, Suzanne Samarani <sup>2</sup>, Zabrina L. Brumme <sup>3,4</sup> , Mark Hull <sup>4,5</sup>, Angela M. Crawley <sup>6,7,8,9</sup> , Marc-André Langlois <sup>7,9</sup> , Jonathan B. Angel <sup>6,7,9,10</sup>, Curtis L. Cooper <sup>6,10</sup>, Judy Needham <sup>11</sup>, Terry Lee <sup>11</sup>, Joel Singer <sup>11</sup>, Aslam H. Anis <sup>11</sup>, Cecilia T. Costiniuk <sup>2,12</sup>  and Mohammad-Ali Jenabian <sup>1,\*</sup> 

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## COVID-19 vaccine immunogenicity in people with HIV

Cecilia T. Costiniuk<sup>a,b,c</sup>, Joel Singer<sup>d,e,f</sup>, Terry Lee<sup>e,f</sup>, Marc-André Langlois<sup>g</sup>, Corey Arnold<sup>g</sup>, Yannick Galipeau<sup>g</sup>, Judy Needham<sup>e,f</sup>, Iva Kulic<sup>e,f</sup>, Mohammad-Ali Jenabian<sup>i</sup>, Ann N. Burchell<sup>h</sup>, Hasina Shamji<sup>j,k</sup>, Catharine Chambers<sup>h</sup>, Sharon Walmsley<sup>l</sup>, Mario Ostrowski<sup>m</sup>, Colin Kovacs<sup>n</sup>, Darrell H.S. Tan<sup>l,o,p</sup>, Marianne Harris<sup>q</sup>, Mark Hull<sup>q</sup>, Zabrina L. Brumme<sup>j,q</sup>, Hope R. Lapointe<sup>q</sup>, Mark A. Brockman<sup>j,q,r</sup>, Shari Margolese<sup>e</sup>, Enrico Mandarino<sup>e</sup>, Suzanne Samarani<sup>a</sup>, Branka Vulesevic<sup>e,s</sup>, Bertrand Lebouché<sup>a,b,t,u</sup>, Jonathan B. Angel<sup>g,s</sup>, Jean-Pierre Routy<sup>a,b,v</sup>, Curtis L. Cooper<sup>s</sup>, Aslam H. Anis<sup>d,e,f</sup>, for the COVAXHIV Study Group

SARS-CoV-2 live virus neutralization after four COVID-19 vaccine doses in people with HIV receiving suppressive ART. Cheung P, Lapointe H Sang Y... Brumme Z. AIDS 2023



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# Lessons learned: Adaptive funding designs

- Networks can leverage research infrastructure and funds to support pandemic-related research before official study funding received
- Methodologists may be challenged by powering of studies
- Keep enrolment criteria as broad as possible to maximize recruitment and ensure study power
- REBs must accept more generic, less focused protocols
- Funding agencies must accept more open-ended designs



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- CIHR Canadian HIV Trials Network CTN 328



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