Final

July 7, 2022

Clarification Memo 2

Protocol

Version 1.0

HVTN 140 / HPTN 101

A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, and pharmacokinetics of PGDM1400LS alone and in combination with VRC07-523LS and PGT121.414.LS in healthy, HIV-uninfected adult participants

DAIDS-ES ID 38723

IND #154188—HELD BY DAIDS

HIV Vaccine Trials Network (HVTN) and HIV Prevention Trials Network (HPTN)
Clinical Research Site (CRS) filing instructions

Please distribute this clarification memo to all appropriate staff members, and file with your protocol documents. Consult your local Institutional Review Board (IRB)/Ethics Committee (EC) regarding submission requirements for clarification memos (CMs).

List of changes

Added text is shown in **bold underline** and deleted text is shown with ~~strikethrough~~.

Item 1 Corrected in Letter of Amendment 1 dated February 24, 2022, and Clarification Memo 1 dated March 28, 2022: date of original protocol

The date of the original protocol listed in the modifications was corrected from June 23, 2020 to June 23, 2021.

A Protocol modification history in Letter of Amendment 1 and Clarification memo 1

Revised text:

Date: June 23, 202~~0~~**1**

Protocol version: 1.0
Protocol modification: not applicable

Original protocol

B Protocol Signature Page in Letter of Amendment 1

Revised text is shown below, and the corrected page is appended.

DAIDS Protocol Number: HVTN 140/HPTN 101

DAIDS Protocol Version: Version 1.0

Protocol Date: June 23, 202~~0~~**1**

Protocol Signature Page for Letter of Amendment 1

A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, and pharmacokinetics of PGDM1400LS alone and in combination with VRC07-523LS and PGT121.414.LS in healthy, HIV-uninfected adult participants

I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable U.S. Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies

Investigator of Record Name (print)	Investigator of Record Signature	Date

DAIDS Protocol Number: HVTN 140/HPTN 101

DAIDS Protocol Version: Version 1.0

Protocol Date: June 23, 2021

Protocol modification history

Protocol modifications are made via clarification memos, letters of amendment, or full protocol amendments. The version history of, and modifications to, Protocol HVTN 140 / HPTN 101 are described below.

Date: July 7, 2022

Protocol version: Version 1.0
Protocol modification: Clarification Memo 2

Item 1 Corrected in Letter of Amendment 1 dated February 24, 2022, and Clarification Memo 1 dated March 28, 2022: date of original protocol

Date: March 28, 2022

Protocol version: Version 1.0
Protocol modification: Clarification Memo 1

Item 1 Corrected in Appendix G, *Laboratory procedures for Part B*: CBC/differential and Chemistry panel added to visit 2

Date: February 24, 2022

Protocol version: Version 1.0
Protocol modification: Letter of Amendment 1

Item 1 Added in Section 1, *Overview*: HPTN Leadership and Operations Center

Item 2 Updated in Section 1.1, *Protocol Team*: team members

Item 3 Added in Section 8.3.3.3, *PGT121.414.LS fixed-dose intravenous infusion* preparation: information regarding storage times and temperatures

Item 4 Corrected in Appendix F, *Laboratory procedures for Part A*: Ab reaction maximum blood volume in footnote 13

Item 5 Corrected in Appendix G, *Laboratory procedures for Part B*: formatting

Item 6 Corrected in Appendix F, *Laboratory procedures for Part A* and Appendix G, *Laboratory procedures for Part B*: visit number referenced in footnote 7

Item 7 Corrected in Appendix I, *Procedures at HVTN CRS for Part B*: remote documentation of diary in footnote 3

Item 8 Added in Section 8.4.1, *General considerations for subcutaneous infusion study product administration*: reference to HVTN140/HPTN101 Study-Specific Procedures (SSP) manual) for additional details on anatomic locations for infusions

Item 9 Revised in Section 8.3.1.1, *Thawing instructions*: PGDM1400LS vial storage time conditions

Date: June 23, 2021

Protocol version: 1.0
Protocol modification: not applicable

Original protocol