



May 22, 2019

Clarification Memo 1

Protocol

Version 1.0

HVTN 130/HPTN 089

A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of combinations of monoclonal antibodies PGT121, PGDM1400, 10-1074, and VRC07-523LS administered via intravenous infusion in healthy, HIV-uninfected adult participants

DAIDS-ES ID 38531

IND #143616—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.

List of changes

- Item 1 Corrected in Section 8.3.1.2, *PGT121 intravenous infusion preparation*, Section 8.3.4.2, *VRC07-523LS intravenous infusion preparation*, and Section 8.5, *Acquisition of study products: Typographical errors related to Sodium Chloride for Injection, 0.9% USP*..... 2

Item 2 Added to Title page: IND number 3

The changes described herein will be incorporated in the next version of Protocol HVTN 130/HPTN 089 if it undergoes full protocol amendment at a later time.

Item 1 Corrected in Section 8.3.1.2, *PGT121 intravenous infusion preparation*, Section 8.3.4.2, *VRC07-523LS intravenous infusion preparation*, and Section 8.5, *Acquisition of study products: Typographical errors related to Sodium Chloride for Injection, 0.9% USP***A** Section 8.3.1.2, *PGT121 intravenous infusion preparation***Previous:**

3. Using aseptic technique, add the withdrawn volume of PGT121 to the IV container with 100 mL of Sodium Chloride for Injection, 9.9% USP. **Record this as the study product preparation time. Assign a 4-hour expiration from this time.**

Changes tracked:

3. Using aseptic technique, add the withdrawn volume of PGT121 to the IV container with 100 mL of Sodium Chloride for Injection, ~~9.9%~~ 9.9% USP. **Record this as the study product preparation time. Assign a 4-hour expiration from this time.**

Revised:

3. Using aseptic technique, add the withdrawn volume of PGT121 to the IV container with 100 mL of Sodium Chloride for Injection, 0.9% USP. **Record this as the study product preparation time. Assign a 4-hour expiration from this time.**

B Section 8.3.4.2, *VRC07-523LS intravenous infusion preparation***Previous:**

4. Using aseptic technique, add the calculated volume of VRC07-523LS to the IV container with 100 mL of Sodium Chloride for Injection, 0.9 USP. **Record this as the study product preparation time.**

Changes tracked:

4. Using aseptic technique, add the calculated volume of VRC07-523LS to the IV container with 100 mL of Sodium Chloride for Injection, 0.9%~~0~~ USP. **Record this as the study product preparation time.**

Revised:

4. Using aseptic technique, add the calculated volume of VRC07-523LS to the IV container with 100 mL of Sodium Chloride for Injection, 0.9% USP. **Record this as the study product preparation time.**

C Section 8.5, Acquisition of study products**Previous:**

Filters, tubing, and 0.9% sodium chloride for injection will be locally sourced by the site. Please refer to the study product considerations section of the HVTN 130/HPTN 089 SSPs for product specific reference numbers.

Changes tracked:

Filters, tubing, and ~~0.9% s~~Sodium ~~e~~Chloride for ~~i~~Injection, **0.9% USP** will be locally sourced by the site. Please refer to the study product considerations section of the HVTN 130/HPTN 089 SSPs for product specific reference numbers.

Revised:

Filters, tubing, and Sodium Chloride for Injection, 0.9% USP will be locally sourced by the site. Please refer to the study product considerations section of the HVTN 130/HPTN 089 SSPs for product specific reference numbers.

Item 2 Added to Title page: IND number

Based on an email received from RSC dated May 8, 2019 we have updated the title page to include the IND number for this study (added text in **bold underline**).

Revised:

IND 143616 HELD BY DAIDS

Protocol modification history

Protocol modifications are made to HVTN-HPTN cross-network protocols via clarification memos, letters of amendment, or full protocol amendments. These protocols are modified and distributed according to the standard HVTN procedures as described in the HVTN Manual of Operations (MOP).

The version history of, and modifications to, Protocol HVTN 130/HPTN 089 are described below.

Date: May 22, 2019

Protocol version: Version 1.0

Protocol modification: Clarification Memo 1

Item 1 Corrected in Section 8.3.1.2, *PGT121 intravenous infusion preparation*, Section 8.3.4.2, *VRC07-523LS intravenous infusion preparation*, and Section 8.5, *Acquisition of study products*: Typographical errors related to Sodium Chloride for Injection, 0.9% USP

Item 2 Added to Title page: IND number

Date: April 04, 2019

Protocol version: Version 1.0

Protocol modification: NA

Original protocol