



FINAL

September 03, 2020

Clarification memo 1

Protocol

Version 1.0

HVTN 136/HPTN 092

A phase 1 dose-escalation clinical trial to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of the monoclonal antibody PGT121.414.LS administered alone and in combination with VRC07-523LS via intravenous or subcutaneous infusions in healthy, HIV-uninfected adult participants

DAIDS-ES ID 38634

IND #146153—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 Added IND number to the cover page..... 2

Item 2 Clarified throughout the protocol (in accordance with COVID-19 precautions):
 “Clinic Visits” 2

The changes described herein will be incorporated in the next version of Protocol HVTN 136/HPTN 092 if it undergoes full protocol amendment at a later time.

Item 1 Added IND number to the cover page

When the HVTN 136/HPTN 092 protocol was submitted to the FDA, the IND number had not yet been assigned. The IND number has been added to the cover page.

Added:

IND ~~TBD~~ 146153 HELD BY DAIDS

Item 2 Clarified throughout the protocol (in accordance with COVID-19 precautions): “Clinic Visits”

In accordance with COVID-19 precautions to maintain social distancing, certain “clinic visit” procedures and data collection may be performed remotely.

Throughout the protocol, “clinic visits” for data collection and procedures (scheduled and ad hoc) may be conducted by phone, text message, or email, or other electronic means. An in-person clinic visit is required only for physical exam, point-of-care testing, collecting biological samples, or administering study agents.

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 136/HPTN 092 are described below.

Date: September 03, 2020

Protocol version: Version 1.0

Protocol modification: Clarification memo 1

Item 1 Added IND number to the cover page

Item 2 Clarified throughout the protocol (in accordance with COVID-19 precautions):
“Clinic Visits”

Date: October 8, 2019

Protocol version: 1.0

Original protocol