Information Type: ViiV Healthcare Epidemiology **Protocol Amendment** v1.0

Title:	A Prospective Observational Cohort Study to Monitor and Compare the Occurrence of Hypersensitivity Reaction and Hepatotoxicity in Patients Receiving Dolutegravir (with and without Abacavir) or other Integrase Inhibitors (with or without Abacavir).
Compound Number:	GSK1349572 (Tivicay), GSK2619619 (GSK1349572+GR109714+GI265235, Triumeq), GSK3365791 (GSK1349572+GSK1329758, Juluca), GSK 3515864 (GSK1349572+GR109714, D3)
Development Phase	III - IV
Effective Date:	06-OCT-2017

Subject: Dolutegravir, Integrase Inhibitors, hypersensitivity reaction, hepatotoxicity

PROTOCOL AMENDMENT

"A Prospective Observational Cohort Study to Monitor and Compare the Occurrence of Hypersensitivity Reaction and Hepatotoxicity in Patients Receiving Dolutegravir (with and without Abacavir) or other Integrase Inhibitors (with or without Abacavir), Study # 201177 is a post authorization safety study (PASS), currently included in the Tivicay™ (Dolutegravir) and Triumeq™ (DTG+ABC+3TC) risk management plans. With the development of DTG-based two-drug (2 DR) regimens, this study will be part of the risk management plans for DTG+Rilpivirine (Juluca) and DTG+3TC . This protocol amendment reflects the inclusion of other DTG based regimen as an additional group.

Currently the following groups are being monitored and compared for hypersensitivity reaction (HSR), hepatotoxicity and skin rash:

A. Patients that start DTG and ABC based ARV regimen [as Triumeq™, the fixed dose combination of DTG+ABC+3TC]
B. Patients that start DTG based ARV regimen [as Tivicay™] without ABC
C. Patients that start other integrase inhibitor based regimen (RAL and EGV) and with ABC
D. Patients that start other integrase inhibitor based regimen (RAL and EGV) but without ABC

In order to include patients on other DTG based regimens, including Juluca and DTG+3TC, a fifth group (group E) will be added that will capture all other DTG users:

E. Patients that start any other DTG based ARV regimen [including DTG as monotherapy or two-drug regimens]

Beginning with the annual report to be delivered by the end of 2018 (Report #4), Group E will be added to the summary tables that report the outcomes of HSR, hepatotoxicity and skin rash. For HSR cases, each specific DTG drug combination from Group E will be reported. In order to capture as many patients as possible who would currently satisfy the inclusion criteria, data for Group E will be collected immediately following approval of this protocol amendment.