

Non-Binding Summary of Key Terms – For discussion purposes only

ViiV is committed to supporting high-quality independent research to improve the unmet needs of people living with HIV and who could benefit from PrEP. Our investigator-sponsored research (“ISR”) program provides funding and/or drug supply for studies conducted by third-parties. An ISR is a type of Study where the Investigator and their Sponsoring Institution are responsible for the design, implementation, sponsorship, and conduct of the study, including compliance with applicable law and regulation.

This Term Sheet is for discussion purposes only and serves to clarify ViiV’s key expectations in providing funding for an ISR. ViiV has prepared these Key Terms based to be balanced, reasonable, and meet the needs of both parties. Negotiating ISR Agreements requires significant resources and can delay study timelines. **ViiV strongly encourages Investigators to review these Key Terms with their Institutional Sponsor and contracts managers before submitting an ISR research proposal to ViiV. These Key Terms will need to be accepted in their entirety for ViiV to progress with funding.**

This document is not a binding agreement or letter of intent between the Parties. Any transaction between the Parties will be subject to the negotiation, execution and delivery of definitive agreement(s) satisfactory to the Parties and receipt of any other approvals and conditions once the ISR is approved by ViiV after the completion of all required scientific and medical reviews. Until such a definitive agreement is executed by each Party, any Party may determine not to proceed with the proposed transaction at any time and for any reason.

This document and its terms are confidential, and no Party shall disclose to a third-party (other than such party’s legal advisors) the existence of this document or its terms without the prior written consent of all Parties.

I. GENERAL TERMS	
1.1. “Sponsor”	<p>[Third Party Legal Name] [Third Party Legal Entity Address]</p> <p>The Sponsor is defined as the Institution or Sponsor Investigator.</p>
1.2. “ViiV”	<p>[ViiV Legal Entity Name] [ViiV Legal Entity Address]</p> <p>SPONSOR and ViiV collectively referred to as “Parties” or in the singular “Party”.</p>
1.3. “Study”	<p>SPONSOR wishes to undertake the Study and ViiV wishes to provide SPONSOR with support in respect of such Study.</p>
1.4. Summary	<p>The Parties agree to enter into an Agreement for an Investigator-sponsored study (the “Agreement”) under which ViiV will provide SPONSOR with financial support in respect of the aforementioned Study.</p>

II. KEY DEFINITIONS	
2.1. Confidential Information	“Confidential Information” means all information, data and materials concerning the arrangements contemplated by this Agreement or the technical, business or other affairs of one Party or its Affiliates that it discloses to the other Party or the other Party obtains pursuant to or in connection with the Study or this Agreement and which (i) is marked “confidential”, or (ii) a reasonable person would recognise is confidential or proprietary given its nature or the circumstances of disclosure including, without limitation, Know How and any safety information or data relating to the Investigational Medicinal Product.
2.2. Data	“Data” means all work, clinical and other data of experimentation and testing that are generated in the Study, including data recorded in the Study database before or on the date of database freeze. Data may be individual patient level or aggregated in a report, manuscript or publication.
2.3. Intellectual Property Rights	“Intellectual Property Rights” means patents, trademarks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to extract information or prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them
2.4. Results	“Results” means the results of the Study including, without limitation, all Data and any reports generated under this Agreement, Know How and Intellectual Property Rights generated, identified or first reduced to practice or writing in the course of the Study or the performance of obligations under this Agreement
III. PRINCIPAL INVESTIGATOR, SPONSOR OBLIGATIONS	
3.1. Principal Investigator	Sponsor represents that it is entitled to procure, and Sponsor will procure the services of [Investigator Name] to act as Principal Investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.
3.2. Performance	Sponsor shall procure the performance of obligations allocated to Principal Investigator, Participating Institutions and Other Investigators set out in this Agreement. The Sponsor, through the Principal Investigator, will be responsible for the creation and development of the Protocol. Sponsor shall ensure that it's and the Principal Investigator's ability to perform their obligations under this Agreement are not adversely affected by the conduct of other studies.
IV. STUDY GOVERNANCE	
4.1. Timelines	The Parties agree that adherence to the Timelines set out in the Agreement is critical to the success of the Study. Failure to meet a Timeline shall constitute a material breach of this Agreement for which ViiV may terminate this Agreement except where SPONSOR's failure is due solely to the act or omission of ViiV. Any amendments to Timelines must be agreed in writing and signed by both Parties.

V. DATA REPORTING AND COMMUNICATION	
5.1. Reporting	<p>SPONSOR and Principal Investigator shall, at [monthly/quarterly] intervals, provide ViiV with a report detailing the progress of the Study including the initiation of study site(s) and study subject recruitment, as well as supplies of IMP, as applicable.</p> <p>The Principal Investigator and ViiV shall meet at [monthly/quarterly] intervals either virtually, through teleconferences or at SPONSOR'S premises or at such other times and venues as the Parties may mutually agree. at these meetings the principal investigator shall update ViiV on the progress of the study including SPONSOR'S adherence to the timelines as agreed in this agreement.</p>
5.2. Data	<p>SPONSOR will collect the Data from the Study Site(s) and all Participating Institutions and provide the Data, suitably anonymised to ViiV in a timeframe as is agreed in writing with ViiV after such Data is recorded in the Study database after database freeze or at such time that the Principal Investigator or Other Investigator provides the Data from the Study to a third party, whichever is the earliest date. The Data will be provided in such format as ViiV may reasonably request.</p> <p>ViiV may perform analysis of such Data as ViiV deems appropriate and ViiV may use such Data and analyses as it wishes, which shall include, without limitation, disclosure to any third parties to the extent that they may be assisting ViiV with any analysis, subject to that third party agreeing to keep such Data and analyses confidential.</p>
5.3. Commercial Exclusivity	<p>SPONSOR shall not and shall procure that the Participating Institutions shall not, give access to the Data to any commercial organisation other than ViiV (or ViiV's nominees) during the term of this Agreement and for a period of five (5) years from the date of completion of the Study without the prior written consent of ViiV.</p>
5.4. Final Report	<p>Within ninety (90) days of completion of the Study (whether prematurely or otherwise), SPONSOR and the Principal Investigator shall provide ViiV with a report of the Study (which may be in form of a draft manuscript) detailing the methodology, Results and containing an analysis of the Data and drawing appropriate conclusions (the "Final Report").</p>
VI. PUBLICATION	
6.1.	<p>SPONSOR and Principal Investigator may publish or disclose the Results of the Study; provided, that (a) a copy of any proposed disclosure, including any publication, abstract, oral presentation, or poster that reports all or parts (interim or final) of the results of the study or study progress, is given to ViiV for review at least ninety (90) days prior to the date of submission for publication (including abstracts) or of public disclosure; (b) if required by ViiV, any reference to the Confidential Information of ViiV is deleted; and (c) if an invention is contained in the disclosure, sponsor and/or principal investigator defer publication or disclosure for up to an additional ninety (90) days from the time ViiV notifies SPONSOR and/or Principal Investigator that ViiV desires patent application(s) to be filed on any such invention. SPONSOR and Principal Investigator will ensure that any publication or public disclosure of the results of the study proposed by other investigators is made in accordance with this Clause.</p>

6.2.	SPONSOR agrees to publicly disclose a summary of the Protocol prior to the commencement of the Study and the Results summary within twelve (12) months after the conclusion of the Study at all Study Site(s) by posting such information in publicly accessible, worldwide registers, which posting shall include the name of the SPONSOR and the names of the Principal Investigator, the Other Investigators, and the Participating Institutions involved in the study.
VII. INTELLECTUAL PROPERTY	
7.1. Inventions	<p>SPONSOR and Principal Investigator agree that Inventions that incorporate, are based on, refer to or relate to Confidential Information of ViiV or the IMP (including inventions that generically encompass within its scope the manufacture, form, formulation or use of the IMP, inventions relating to a new use of the IMP, the use of the IMP in combination with other agents, and inventions relating to drugs in the same class as the IMP), or that involve identification or use of biomarkers related to the safety, efficacy, or use of the IMP (collectively, “IMP Inventions”) will be the sole and exclusive property of ViiV.</p> <p>Inventions that are not IMP Inventions (the “Other Inventions”) shall be owned in accordance with inventorship as determined under relevant Patent Law</p>
7.2. License Grants	<p>SPONSOR and Principal Investigator each grant to ViiV a non-exclusive, fully paid-up, perpetual, world-wide, royalty-free license to use Other Inventions for all purposes, with the right to grant sublicenses under such license to ViiV’s Affiliates and development and marketing collaborators.</p> <p>Ownership of all Data shall vest in SPONSOR. SPONSOR hereby grants to ViiV a non-exclusive, indefinite, fully paid-up, worldwide, royalty-free licence (with the right to sub-license to any Affiliate and to any person working for, or on behalf of, ViiV or any Affiliate, but only for the purpose of carrying out that work, and otherwise without the right to sub-license) to use the Data for any purpose in accordance with this Agreement.</p>
7.3. Option Rights	<p>SPONSOR grants ViiV a first option to obtain an exclusive perpetual, worldwide, sublicensable license to SPONSOR’s, Principal Investigator’s, Study Personnel’s or any Study Site’s or Other Investigator’s, interest in any Other Inventions, on reasonable financial terms to be negotiated in good faith, to make, use and sell (or otherwise research, develop or commercialize) those inventions or any products that are covered by patent rights that claim or include those inventions. ViiV’s option may be exercised with respect to any Other Invention at any time during a period of one hundred eighty (180) days (the “Option Period”) after the full written disclosure to ViiV of each such Other Invention by notice in writing from ViiV to SPONSOR. Upon ViiV’s exercise of its option with regard to any particular Other Invention, SPONSOR and ViiV will negotiate in good faith in an attempt to reach a license agreement satisfactory to all Parties (the “Negotiation Period”). Unless extended by the written mutual consent of the Parties, the Option Period and the Negotiation Period shall not exceed twelve (12) months in the aggregate. If ViiV fails to exercise an option during an Option Period or the Parties fail to conclude an exclusive or non-exclusive license to any Other Invention within the applicable Negotiation Period, SPONSOR shall have no further obligation to GSK under this Agreement with regard to SPONSOR’s interest in such Other Inventions; provided, however, that the non-exclusive license granted to ViiV will remain in full force and effect.</p>

VIII. LIABILITIES AND INDEMNITY	
8.1. ViiV's Indemnification Obligation	ViiV will indemnify, defend and hold harmless SPONSOR, its trustees, directors, officers, employees (including Principal Investigator), Participating Institutions and Other Investigators, and any other third parties engaged at their direction, (collectively, the "SPONSOR Indemnitees") against any third party claims, including reasonable attorney's fees for defending those claims (each, a "Claim") to the extent a Claim arises out of or relates to the negligent manufacture of the IMP. ViiV's obligations under this Clause 13.1 will not apply to the extent that a Claim arises out of or relates to (a) a SPONSOR Indemnitee's (i) negligence, gross negligence or willful misconduct, (ii) failure to adhere to the terms of the Protocol, this Agreement or any written instructions from ViiV or its designee, or (iii) failure to conduct the Study in accordance with Applicable Laws; or (b) any materials, equipment or drug products used in the Study that are not manufactured or provided by ViiV.
8.2. Sponsor's Indemnification Obligation	<p>SPONSOR will indemnify, defend, and hold harmless ViiV, its directors, officers, employees and agents (collectively, the "ViiV Indemnitees") against any Claim to the extent such Claim arises out of or relates to (a) the performance of the Study; or (b) any SPONSOR Indemnitee's (i) negligence, gross negligence or willful misconduct, (ii) failure to adhere to the terms of the Protocol, this Agreement, or any written instructions from ViiV or its designee, or (iii) failure to conduct the Study in accordance with Applicable Laws; in each case to the extent permitted by Applicable Laws.</p> <p>SPONSOR will indemnify ViiV for all losses resulting from any Security Breach due to negligence or wilful misconduct by SPONSOR, its agents, its Affiliates, or any vendor retained by SPONSOR, including but not limited to, legal damages, government penalties, and/or mitigation expenses.</p>
IX. TERMINATION	
9.1. Termination by ViiV for Convenience	ViiV may terminate this Agreement at any time without cause by providing thirty days (30) prior written notice to SPONSOR.
9.2. Termination for Failure to Progress	ViiV may terminate this Agreement where ViiV determines in its sole opinion (at all times acting reasonably) that significant progress has not been made in relation to the Study whether in respect of recruitment, adherence to the Timelines or otherwise
9.3. Termination for ABAC Violation	ViiV shall be entitled to terminate this Agreement immediately on written notice to SPONSOR if SPONSOR fails to perform its obligations in accordance with the Anti-Bribery and Corruption Clause. SPONSOR shall have no claim against ViiV for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause

Timelines and study enrollment are critical to ViiV's decision to support an ISR. Adherence to the Timelines set out in the Agreement is critical to the success of the Study. Likewise, ViiV disburses funding based on the achievement of key milestones, such as contract execution, IRB approval, enrollment, and publication. Failure to meet a Timeline constitutes a material breach of Agreement for which ViiV may terminate any Agreement. Amendments to Timelines must be agreed in writing and signed by both Parties.

The Tables below demonstrate the timeline and funding milestones that will be captured in the Agreement.

TIMELINES

Milestone	Target Date (month/year)
Final Protocol approved by IRB/Ethics or equivalent Sponsor approving body	
Study Authorisation submission	
Study Authorisation approval	
Ethics Committee submission	
Ethics Committee approval	
First Subject, First Visit	
Last Subject, First Visit	
Last Subject, Last Visit	
Database Freeze	
Final Report (or draft manuscript) delivered to ViiV in accordance with the Communication of Data Clause	
Manuscript in accordance with the Publication Clause submitted for publication within 18 months of Study completion at all Study Site(s)	

FINANCIAL ARRANGEMENTS

	Milestone	Payment [€/\$/£/CAD\$]	Target Date (QQYYYY)
01.	Upon receipt by ViiV of the final and fully executed Agreement		
02.	Upon receipt by ViiV of (i) all required documentation demonstrating regulatory and IRB approval, and (ii) confirmation that the summary Protocol has been posted on clinicaltrials.gov or other public register in accordance with the Agreement		
03.	Upon ViiV's receipt of documentation that Sponsor has enrolled 25% of the X total Study enrollment (X Subjects)		
04.	Upon ViiV's receipt of documentation that Sponsor has enrolled 50% of the X total Study enrollment (X Subjects)		
05.	Upon ViiV's receipt of documentation that Sponsor has enrolled 75% of the X total Study enrollment (X Subjects)		
06.	Upon ViiV's receipt of documentation that Sponsor has enrolled 100% of the X total Study enrollment		
08.	Upon confirmation of submission of an Abstract/Poster of Interim or Final data results submitted to a congress		
09.	Upon documentation of the following: (i) a Manuscript (Primary Endpoints) submitted for publication WITHIN 18 MONTHS of Last Subject, Last Visit or Analysis Complete, and (ii) confirmation that Final Results Summary has been posted to an appropriate public register*.		
	TOTAL	[€/\$/£/CAD\$]	