

INNOVATE 2 REQUEST FOR PROPOSAL (RFP)

CABOTEGRAVIR LONG ACTING FOR PREVENTION

Application guide

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Application instructions

How to use the application guide

The application guide contains the information you will need to correctly submit a complete proposal. Understanding the application process and the ViiV Healthcare Investigator Sponsored Research (ISR) portal is critical to successfully submitting your application. We strongly encourage you to review the contents of this document carefully.

Use this application guide to understand:

- / The INNOVATE 2 Request for Proposals (RFP) research priority areas ('Areas of Interest')
- / How to use the ViiV Healthcare ISR external portal.
- / How to fill out the forms and submit study proposals online.
- / What information is required at each stage of the application proposal process.
- / How to complete the ViiV Healthcare budget tool.
- / Application, review, and notification process VH.RFP-admin@viivhealthcare.com

If you have any questions not addressed in this application guide, these can be directed to your local ViiV Healthcare medical contact or submitted to: VH.RFP-admin@viivhealthcare.com.

Purpose

"ViiV Healthcare is committed to supporting research efforts of HIV and Medical communities and is announcing a Request for Research Proposals for Investigator Sponsored Studies (ISS). This is your opportunity to apply for a research award from ViiV Healthcare to address the knowledge gaps and research priorities for the Cabotegravir Long Acting for Prevention (CAB LA for PrEP)"

Objective

We are seeking proposals for clinical research studies within specific areas of interest for Cabotegravir Long Acting for Prevention. See section below on [Research priority areas](#).

Successful proposals will receive financial support to undertake independent research through our ISS programme.

Research priority areas

The INNOVATE 2 RFP has three (3) research priority areas ('Areas of Interest') for scientific data on **Cabotegravir Long Acting for prevention**. If you have a concept that includes more than one priority area, please choose the most relevant area, and link the concept to this area. Concepts that address more than one priority area may be scored higher than proposals only addressing one priority area.

1	<p><u>Real-world use and impact on overall PrEP uptake and overall patient health in broad populations:</u></p> <p>Example research questions, but not limited to: Does offering CAB LA for PrEP to broad populations result in</p> <ul style="list-style-type: none"> a) increased overall PrEP uptake, adherence and/or persistence. b) a neutral or positive impact on tolerability (incl. metabolic, bone + renal markers) compared to oral PrEP options.
2	<p><u>Strategies to improve awareness of PrEP and identification of barriers and facilitators related to CAB LA for PrEP uptake:</u></p> <p>Example research questions, but not limited to:</p> <ul style="list-style-type: none"> a) How can awareness be increased in people who have never used PrEP and how can they be connected to PrEP services? b) What specific tools or settings promote identification of PWBP and/or facilitate the conversation around HIV PrEP options? c) What are the key drivers or barriers related to uptake of CAB LA for PrEP? And what strategies can be employed to address barriers?
3	<p><u>Optimise implementation and/or scale up of CAB LA for PrEP:</u></p> <p>Example research questions, but not limited to:</p> <ul style="list-style-type: none"> a) [US only] Understanding how same day/rapid start of CAB LA for PrEP can be facilitated including HIV testing approach and how it enables uptake. b) [Brazil, Canada, France, Italy, Spain, UK only] Which specific health-delivery sites outside of clinical centers demonstrate optimized implementation of CAB LA for PrEP? <p><i>Possible examples of health delivery settings could include pharmacies, mobile health clinics, family planning centers, University clinics, mobile health clinics, home/district nurses, telehealth services, campus health clinics</i></p>

Applicants

Applicants must be affiliated with a clinical or academic institution and are strongly encouraged to partner with a researcher(s) with clinical experience in the field of HIV and a proven track record of conducting ISS. We encourage researchers developing and establishing themselves (sometimes referred to as 'young investigators') to apply. The study setting(s) can include a variety of health care and academic institutions, including but not limited to, hospitals, clinics, health centres, correctional facilities, drop-in centres, integrated health systems and academic centres.

Applicants are asked to submit an initial research concept aligned with the INNOVATE 2 RFP [research priority areas](#) ('Areas of Interest') that will be reviewed and either accepted or rejected for progression to

the next stage, where a detailed proposal will be required. The application process is further outlined below.

Applicants must provide their CV or biosketch, stating relevant experience which will be uploaded as part of the application process.

Countries eligible to participate.

For Investigator sponsored studies (ISS), the product is required to be registered and available in the country to be able to support a study (i.e., reimbursement in place).

If the drug is being used as part of the study, ViiV Healthcare will not supply the drug. It must be available in participating countries at study start.

Note: Due to the real-world nature of the priority areas included in this RFP, drug supply requests are not included in this RFP

- **North America:** US, Canada
- **Europe:** Spain, Italy, France, United Kingdom
- **International Region:** Brazil

Application submission, review, and notification process

Application steps

1. The first step will be the submission of a brief concept that provides a high-level view of the proposed research to be conducted. The concept must fit with at least one of the INNOVATE 2 RFP [research priority areas](#) ('Areas of Interest'). If the concept includes more than one priority area, the investigator should choose the most relevant area during the application submission process and link the concept to that research priority area. Concepts must be submitted by the deadline provided below to be considered. *For further information, see section below on [Concept submission](#).*
2. Concepts will be reviewed to ensure alignment with research priority areas and scored based on the quality of the research idea. Investigators will be notified of the concept review outcome.
3. Investigators whose concepts are selected to progress will be invited to submit a full proposal. This will need to be submitted by the deadline provided below to be considered. *For further information, see section below on [Proposal submission](#).*
4. Full proposals will be reviewed by an internal ViiV Healthcare scientific panel against predefined criteria and will be evaluated against equivalent proposals through a competitive assessment process.

Timeline



Key dates

Concept submission opens	15 th February 2024
Deadline for concept submission	10 th April 2024, 10:00pm BST/5:00 pm EDT
Notification of concept review outcomes	13 th May 2024
Deadline for submitting final proposals	26 th June 2024 10:00pm BST/5:00 pm EDT
Internal review and final selections	1 st – 30 th July 2024
Notification of proposal approvals	September 2024

Creating an applicant profile

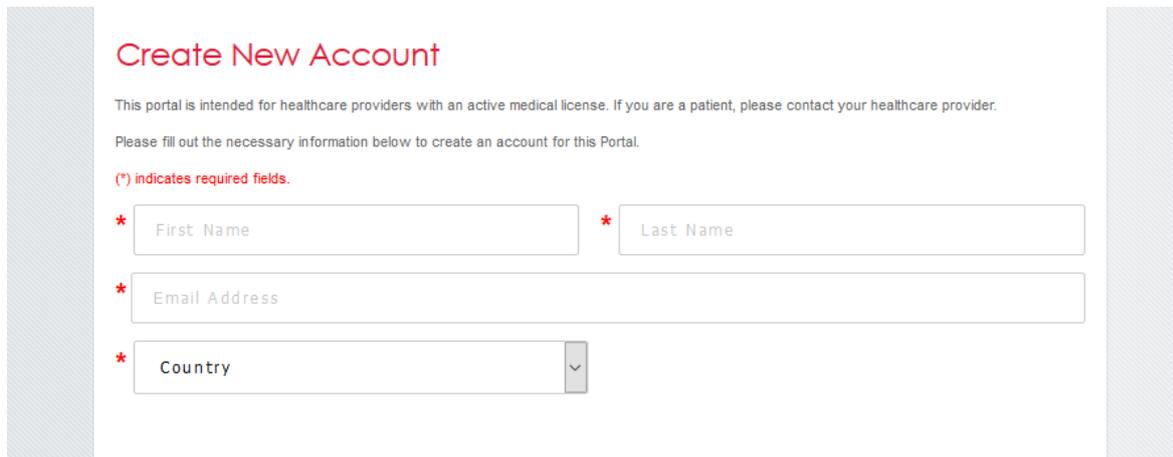
For researchers that have not previously created an account on the ViiV ISR Portal, the steps in this section should be followed to create your account **before** attempting to start the concept submission process.

For researchers that already have an account in the ViiV ISR Portal, this step is NOT required, and the existing account should be used.

Note: When on the ViiV ISR Portal, if the user has not logged in and attempts to start submission of a concept, the system will prompt them for account information and the user can either log in to their existing account or create an account.

Step 1: Visit: ISS.viivhealthcare.com

Step 2: Select the "Create Profile" menu option



Create New Account

This portal is intended for healthcare providers with an active medical license. If you are a patient, please contact your healthcare provider.

Please fill out the necessary information below to create an account for this Portal.

(*) indicates required fields.

* First Name * Last Name

* Email Address

* Country

Step 3: Complete the requested information and click "I AGREE"

1. Details (Investigator/Institution)
2. Medical/Healthcare Professional Certification Information
3. Conflict of Interest Check

Step 4: Follow the steps to validate your account and set your password

Concept submission instructions

From the ISS.ViiVHealthcare.com page, before selecting to respond to an RFP, the investigator should be logged in or they will be prompted to enter new account information. When the process to respond is initiated, investigators will be prompted to confirm/update the existing profile information. Please confirm that the current information is correct, update the date verified and then select the "Update Profile" button at the bottom.

From the ISS.ViiVHealthcare.com page select ISS Requests/studies button and then select the appropriate RFP topic from the list to submit your request. You can optionally click on this [link](#) to go directly to the page with INNOVATE 2 RFP research priority areas ('Areas of Interest') listed.

Please ensure that you do **NOT** select "Start "Open" ISS Concept Approval". This will not associate your concept submission with the INNOVATE 2 RFP research priority areas and your concept will **NOT** be accepted as part of the INNOVATE 2 RFP. Please ensure you select the most relevant one of the three INNOVATE 2 RFP research priority area ('Areas of Interest') for your concept, listed in red text as below.

If the concept includes more than one research priority area, the investigator should choose the most relevant area during the application submission process and link the concept to that research priority area.

VH expects that all Open Concepts are discussed with a VH Representative BEFORE being submitted to this portal

Start Open Concept Proposal
(Do not use this button for RFP concepts)

Do Not Select "Open" ISS Concept Proposal

Current Request for Proposals (RFPs) 'Areas of Interest'

CLICK on the title below to navigate to RFP information page that includes more information about the particular RFP (for example: Summary, Application Guide, Timeline) and the button to create your RFP response.

INNOVATE 2 #1 - Real-world use and impact on overall PrEP uptake and overall patient health in broad populations:
List of Countries eligible to participate: Brazil, Canada, France, Italy, Spain, United Kingdom and United States

INNOVATE 2 #2 - Strategies to improve awareness of PrEP and identification of barriers and facilitators related to CAB LA for PrEP uptake:
List of Countries eligible to participate: Brazil, Canada, France, Italy, Spain, United Kingdom and United States

INNOVATE 2 #3a - Optimise implementation and/or scale up of CAB LA for PrEP:
List of Countries eligible to participate: United States

INNOVATE 2 #3b - Optimise implementation and/or scale up of CAB LA for PrEP:
List of Countries eligible to participate: Brazil, Canada, France, Italy, Spain and United Kingdom

Select from the most relevant "Area of Interest" for the concept

After selecting the relevant INNOVATE 2 RFP research priority area ('Areas of interest') for your concept, complete the concept information details and "Save" regularly until your RFP concept template, CV and any other documentation supporting your concept are completed and uploaded to the "Files" tab. As the portal has a 'timeout' function, we advise you to "Save" your concept application regularly to avoid losing your work. Once the form has been saved, you may leave and return to the system as required. The saved concept information may be accessed from the "My Submissions" section of the site. A saved concept application will appear on the "Editable by Investigator" tab and submitted concepts will be listed on the "Submitted to ViiV" tab.

As part of the concept submission process, it is expected that you will download the RFP Concept Template from the site – this document will be available for download once you click on the relevant research priority area ('Areas of Interest'). Completing the requested information on the template will allow you to provide an overview of your proposed research in a common format for review by the internal team. Concepts submitted without the expected documents attached will not be accepted as completed submissions.

Once the concept application information has been completed and related documents uploaded to the "Files" tab (particularly the completed RFP Concept Template and investigator CV), the concept application should be **submitted**. Once submitted, the concept will be listed on the "Submitted to ViiV" tab for review. Additional files may be requested.

Concepts will be reviewed to ensure alignment with research priority areas and quality of research idea. Investigators will be notified of the outcome of their concept application by the deadline noted above.

If your concept is accepted, you will be invited to complete and submit a full proposal and an additional, specific guidance document for this activity will be provided to you at that time. However, initial points to consider regarding the full proposal submission are provided [below](#).

CV instructions

Applicants must provide their CV or biosketch stating relevant experience applicable to the execution of the proposed research study. This should be provided for all named principal or co-investigators of the study at the time of concept submissions.

A CV or biosketch must be uploaded to the "Files" tab on the [ViiV ISR external portal](#). Select your submission under the "My Submissions" option to access the "Files" tab.

Proposal submission

If your concept is accepted, you will be invited to submit a full proposal. Your application as submitted on the ViiV ISR portal will be set to editable, and you will be able to revisit the existing application to submit a full proposal. The proposal submission will include completion of an RFP Proposal Submission Template that has broader scientific questions about the proposed research study, and the full budget for the study (see below for budget instructions)

Each proposal will be reviewed by a team of reviewers and scored according to set criteria, which are included in the Proposal Submission guidance document that will be provided at a later stage, for concepts approved to progress to full proposal submission. Each proposal will be evaluated through a competitive assessment process.

Budget instructions

Budget limits

ViiV Healthcare will prioritise research projects with funding requests less than £400,000.

Budget submission

Applicants must submit a detailed budget at proposal stage, using the ViiV budget tool. Additional guidance will be provided in the Proposal Submission guidance document for concepts approved to progress to full proposal submission.

Allowable costs

Funding can be used for, but not limited to:

- / Advertising costs for recruitment purposes
- / Study related clinical insurance
- / Assay reagents and other consumables for use with site's equipment

- / Study close-out fee
- / Supplies
- / Printing fees
- / Journal fees
- / Personnel costs specific to the study
- / Pharmacy fees (set-up costs, storage etc.)
- / IRB/EC costs (initial and renewal)
- / Site start-up costs
- / Translations
- / Licence fees for clinical support tools or instruments used in the study
- / Study participant reimbursement for visits (where required)
- / Shipping fees
- / Archiving fees
- / Cost of essential study-related activities (e.g., Trial Steering Committee, site monitoring, IDMC)
- / Software that is needed and will be used ONLY for the proposed study

Non-allowable costs

Funding cannot be used for, but not limited to:

Information technology hardware, software, or services for general research use (Note: Telehealth equipment or services are considered clinical equipment, not IT).

Research team travel costs (Note: Study participant reimbursement for study visit where required may be supported)

Indirect/institutional overhead costs

ViiV Healthcare allows indirect/institutional overhead costs. The indirect cost cap is 25%. Any amount over 25% will require the applicant's institution rate documentation for justification. If the request is over 35%, the rate may not be approved. Note: Indirect costs are included in the budget maximum limit.

Frequently asked questions

1) I submitted a strong concept/proposal, why was my application not funded?

Research concepts and proposals will be reviewed by an internal ViiV Healthcare scientific panel against predefined criteria, with each proposal evaluated through a competitive assessment process. Not all proposals will be approved for funding.

2) Can one institution submit multiple applications?

Yes. However, proposals from the same institution should be substantively different. Further, investigators cannot be named as the principal investigator on more than one approved research award.

3) Will I receive the score or review comments from my application?

No, you will only receive the review outcome of your application. ViiV Healthcare will not provide the application scores or reviewer comments for applications received.

4) What is the difference between the RFP ISS vs. the open ISS process?

The RFP is a competitive process, where ViiV Healthcare requests applications on timely and important areas of interest. The open ISS is an unsolicited process, whereby applicants submit their research applications to ViiV Healthcare for consideration. A scientific panel reviews application under both processes and not all proposals are successful.

5) Can I collaborate with other institutions to submit a proposal?

Yes.

6) How can I track the progress of my proposal?

The status of your proposal is available by selecting "My Submissions" and locating your submission by its title. Additionally, the system will send status update emails when the status changes.

7) Do I need to complete the ViiV budget tool?

Applicants must submit a detailed budget at proposal stage, using the ViiV budget tool. Additional guidance will be provided in the proposal submission guidance document for concepts approved to progress to full proposal.

8) If during the internal ViiV scientific review process, the reviewers reach out to me and require some additional information and clarifications on my proposal, does this mean my proposal will be accepted if I provide these clarifications?

Proposals are reviewed carefully and sometimes it may be necessary to seek clarifications from applicants to check for understanding. The process of seeking additional information does not mean that your proposal will be accepted or that your proposal is a finalist. We strongly encourage that investigators submit clearly written, complete and robust proposals.

Appendix

Definition of terms

Implementation science research: The study of methods to promote the integration of research findings and evidence into healthcare policy and practice. It includes implementation research, dissemination research and other disciplines.

Implementation research: The study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice.

Dissemination research: The scientific study of the targeted distribution of information and intervention materials to a specific audience.

Patient Reported Outcome (PRO): A PRO is a report directly from a patient of the status of their health condition without interpretation of others. Instruments to measure PROs can be generic or disease specific.