

# EXPAND

## EXPANDING REAL WORLD EXPERIENCE WITH DOVATO

### DOVATO (DTG/3TC) REQUEST FOR RESEARCH PROPOSALS

#### 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 EXPAND DTG/3TC 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 in the system
- / 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

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: [dolutegravir.rfp@viivhealthcare.com](mailto:dolutegravir.rfp@viivhealthcare.com)

## Purpose

ViiV Healthcare is announcing the EXPAND Programme to support research efforts of the HIV and medical communities to help optimise treatment goals and support healthy living for People Living with HIV (PLHIV).

DTG/3TC (dolutegravir/lamivudine) is a complete regimen recommended by international guidelines for treatment of HIV-1. This is your opportunity to apply for an Investigator Sponsored Study (ISS) research award to help address scientific and knowledge gaps with the two-drug regimen DTG/3TC.

## Objective

We are seeking proposals for clinical research studies within specific areas of interest for DTG/3TC – *See section below on [Research priority areas](#).*

Successful proposals will be awarded grants to undertake independent research through our ISS programme.

## Research priority areas

The EXPAND RFP has three research priority areas ('Areas of Interest') for scientific data on DTG/3TC.

### 1. DTG/3TC impact on patient experience and overall health-related quality of life

- / What is the impact of DTG/3TC on overall health and wellbeing, as determined by patient reported outcomes and/or patient experience?
- / What are the drivers for DTG/3TC decision/choice among PLHIV and physicians?

### 2. Real-world experience with DTG/3TC highlighting the barrier to resistance versus BIC/FTC/TAF (bictegravir/emtricitabine/tenofovir alafenamide)

- / What is the effectiveness and barrier to resistance of DTG/3TC versus BIC/FTC/TAF in populations with conventionally more difficult to treat HIV, including:
  - / Individuals at risk of non-adherence?
  - / PLHIV with high VL (viral load) and/or low CD4 (cluster of differentiation 4)?

### 3. Use of Implementation and/or dissemination research to support identification of PLHIV who would benefit from DTG/3TC

- / How can clinical support tool(s) or mechanism(s) be integrated into routine care to help identify PLHIV most suitable for DTG/3TC?
- / How can dissemination research help identify strategies to communicate patient experience and preferences around two-drug regimens effectively?

## 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 EXPAND 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 ISS approved under the EXPAND RFP programme, DTG/3TC must be registered and locally available in the country where the study is to be conducted.

### List of countries eligible to participate

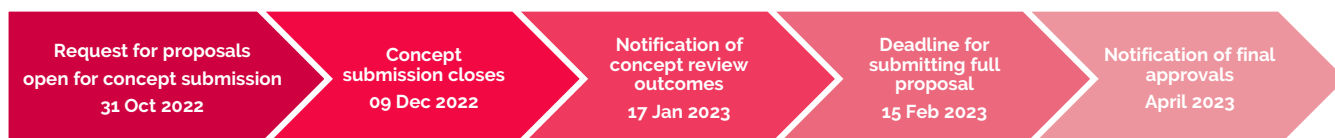
Argentina	Colombia	Hungary	New Zealand	Slovenia
Australia	Croatia	Ireland	Norway	South Korea
Austria	Czech Republic	Israel	Oman	Spain
Bahrain	Denmark	Italy	Poland	Sweden
Belgium	Estonia	Japan	Portugal	Switzerland
Brazil	Finland	Latvia	Qatar	Taiwan
Bulgaria	France	Lithuania	Romania	United Arab Emirates
Canada	Germany	Malta	Saudi Arabia	United Kingdom
Chile	Greece	Mexico	Singapore	United States of America
China	Hong-Kong	Netherland	Slovakia	Uruguay

# 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 EXPAND 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	31 Oct 2022, 00:01hrs GMT
Deadline for concept submission	09 Dec 2022, 10:00pm GMT/5:00 pm EST
Notification of concept review outcomes	17 Jan 2023
Deadline for submitting final proposals	15 Feb 2023
Internal review and final selections	16 Feb 2023 to 31 Mar 2023
Notification of proposal approvals	April 2023

## Creating an applicant profile

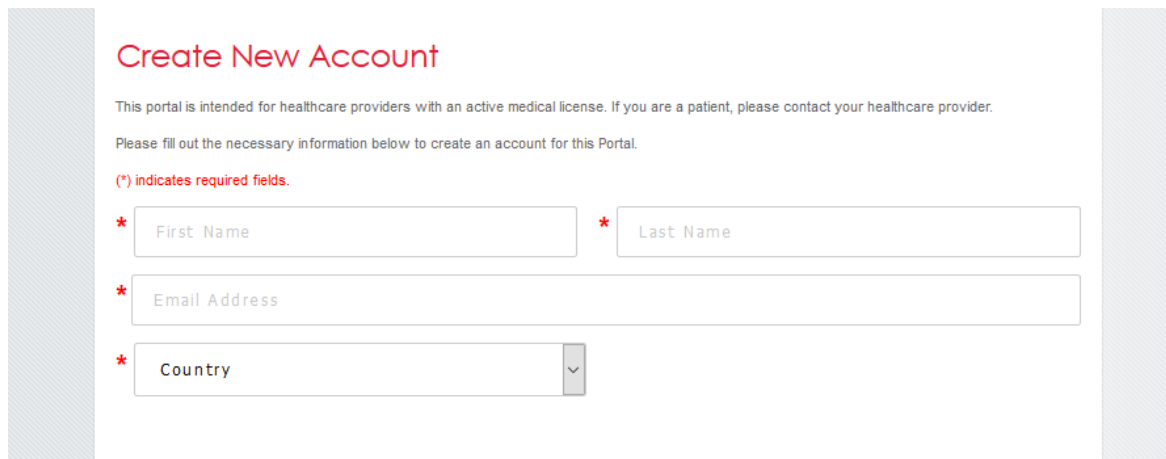
For researchers that have not previously created an account on the ViiV ISR Portal, the steps in this section should be followed to create your account **before** attempting to start the concept submission process.

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](https://iss.viivhealthcare.com)

**Step 2:** Select the "Create Profile" menu option



**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

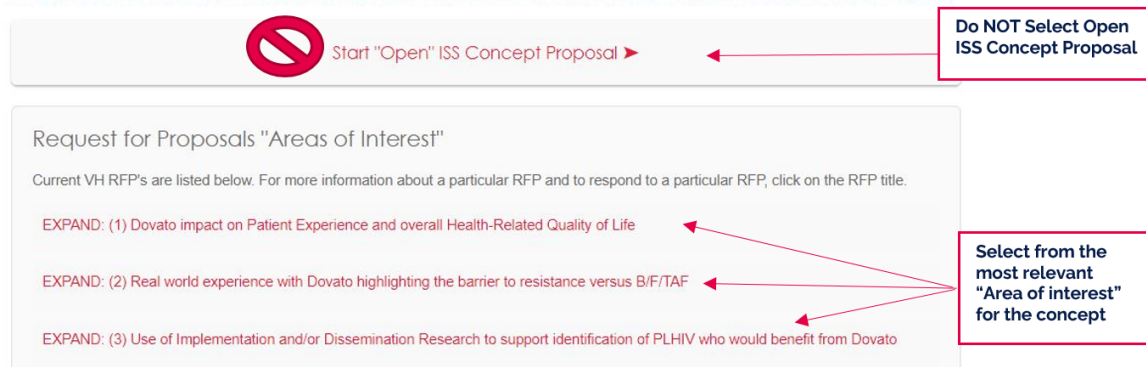
From the [ISS.ViiVHealthcare.com](https://iss.viivhealthcare.com) page, before selecting to respond to an RFP, the investigator should be logged in or they will be prompted to enter new account information. When the process to respond is initiated, investigators will be prompted to confirm/update the 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](https://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 EXPAND 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 EXPAND RFP research priority areas and your concept will **NOT** be accepted as part of the EXPAND RFP. Please ensure you select the most relevant one of the three EXPAND 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



Do NOT Select Open ISS Concept Proposal

Request for Proposals "Areas of Interest"

Current VH RFP's are listed below. For more information about a particular RFP and to respond to a particular RFP, click on the RFP title.

EXPAND: (1) Dovato impact on Patient Experience and overall Health-Related Quality of Life

EXPAND: (2) Real world experience with Dovato highlighting the barrier to resistance versus B/F/TAF

EXPAND: (3) Use of Implementation and/or Dissemination Research to support identification of PLHIV who would benefit from Dovato

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

After selecting the relevant EXPAND 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.

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 Template that has broader scientific questions about the proposed research study.

Each proposal will be reviewed by a team of reviewers and scored according to set criteria, which be 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 £300,000.

### 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 grant costs

**Grant 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 grant costs

**Grant 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 current 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.

## Abbreviations and definitions

**3TC:** lamivudine

**BIC:** bictegravir

**CD4:** cluster of differentiation 4

**DTG:** dolutegravir

**FTC:** emtricitabine

**IDMC:** independent data monitoring committee

**ISR:** injection site reaction

**ISS:** investigator-sponsored studies

**IRB/EC:** investigational review board/ethics committee

**PLHIV:** people living with HIV

**PRO:** patient reported outcome

**RFP:** request for proposals

**TAF:** tenofovir alafenamide

**VL:** viral load