Investigator Sponsored Research: External Guidance & Expectations

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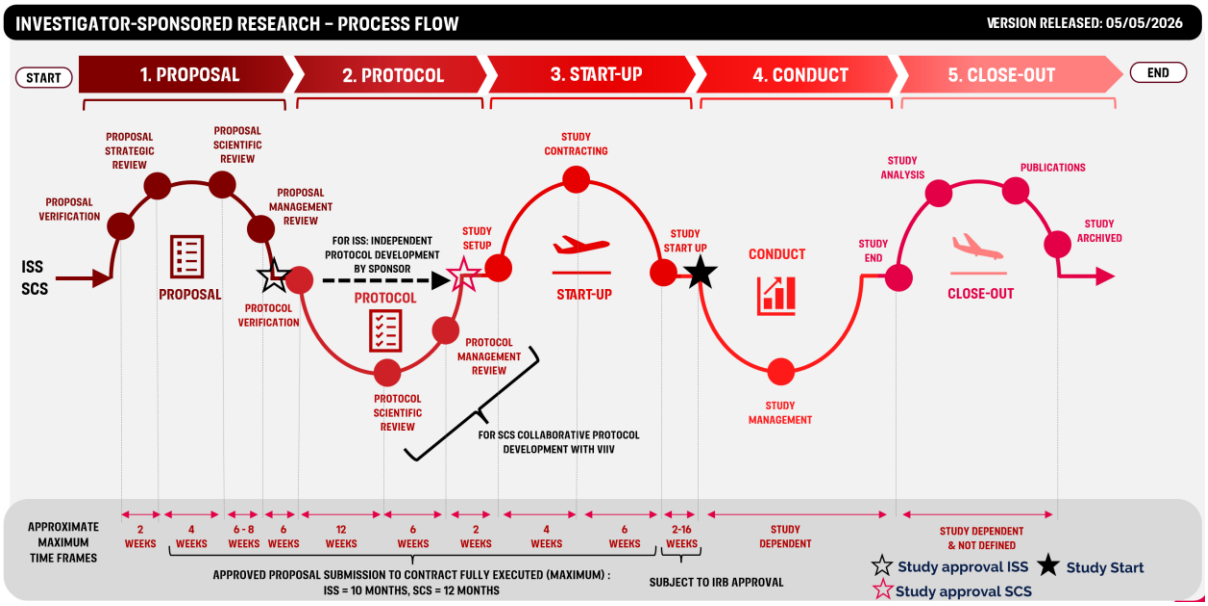
Introduction & Purpose

This guidance document provides external researchers and Sponsors with a clear overview of the purpose, expectations, and processes associated with submitting and conducting Investigator Sponsored Research (ISR) with ViiV Healthcare (VH). It outlines the types of support ViiV may offer, explains how proposals are evaluated for strategic interest and scientific merit, and details key submission requirements, review timelines, and responsibilities of both Sponsors and ViiV. The aim is to help Sponsors navigate the end-to-end ISR process efficiently, ensure compliance with ethical and regulatory standards, and support the timely development and execution of high-quality studies.

Sponsors are requested to read this guidance carefully and ensure they fully understand and comply with all requirements outlined herein. By doing so, Sponsors help facilitate efficient review, timely study start-up, and ongoing compliance with the ethical, regulatory, and contractual expectations associated with Investigator Sponsored Research.

Program Guidance

Process Visual



Important note: Our Key Performance indicators as indicated by "approximate maximum time frames" are ViiV's internal ISR targets for ensuring timely study progression. Should the study not meet these targets due to internal or external factors, your ViiV contact will discuss the delays with you.

Areas of Interest for ViiV Healthcare

Investigator Sponsored Research is research conducted by an external Sponsor with VH's support.

- VH accepts proposals aligned with VH's strategic and scientific priorities as indicated by specific **Areas of Interest (AOI).** Proposals are reviewed as they are received, working to the expected review timelines.
    - The exception is for Request For Proposals (RFPs), which are released/reviewed at set points as identified by the RFP.
    - Occasionally a proposal may be accepted for review that is not specifically linked to an AOI. It is best to discuss this with a ViiV contact prior to submission.

What types of support can be provided by ViiV?

- ViiV's support of approved proposals can be in the form of funding and/or study materials (such as ViiV products)
- In exceptional circumstances where the study requires a specialized capability to perform a specific activity (e.g. biomarker research) that the sponsor does not have and cannot feasibly retain an appropriate vendor to provide, ViiV may perform the specific activity as part of ViiV's support. Any ViiV funding for the study will reflect the fact that ViiV is providing this specialized support.

Additionally, as described below, depending on the type of study (Investigator Sponsored Study vs Supported Collaborative Study), ViiV may contribute to the study protocol/design, publications and other study materials.

There are three different ways VH can provide ISR support:

- **Investigator Sponsored Studies (ISS)** are entirely designed and managed by an external Sponsor. VH can support in the form of funding and/or VH product. Specialized Capability support may be provided in exceptional circumstances, if capability is available at VH.

- **Supported Collaborative Studies (SCS)** are conducted by an external Sponsor, with VH contributing to study design and deliverables in addition to the provision of funds and /or VH product. The level of collaboration from VH will vary from study to study and will be discussed through the proposal review process.

- **Pure Substance Requests (PSR)** are entirely designed and managed by an external Sponsor. VH can support in the form of supplying active pharmaceutical ingredient (API)/pure substance of VH product for HIV research purposes.

Please note: This guidance document does not cover submission of proposals for Pure substance requests. Contact ViiV for further details regarding this kind of proposal.

In all circumstances the Sponsor of the research is accountable for all aspects of the study as well as for complying with all applicable ethical, regulatory, and legal requirements.

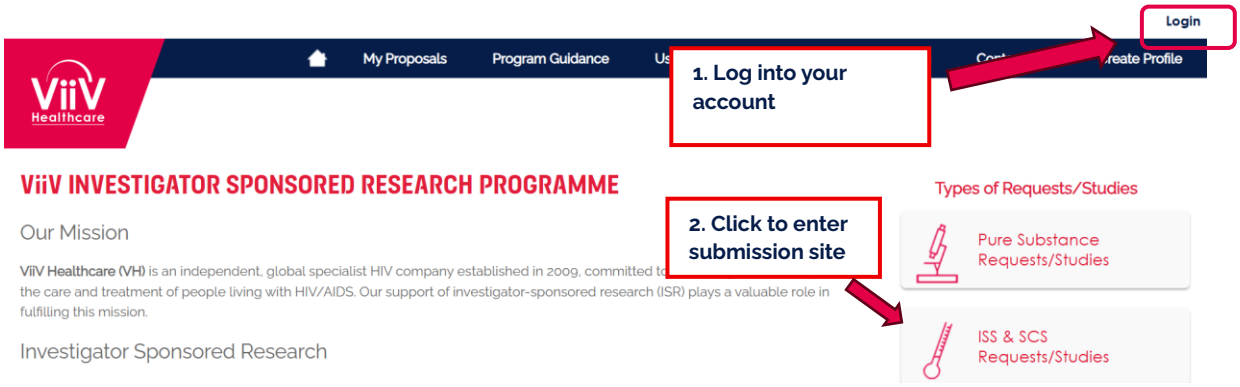
If you are interested in collaborating, please include any additional support/capability required as part of your submission.

Submission Instructions

How to apply for ISS/SCS support and what information is required as part of the submission

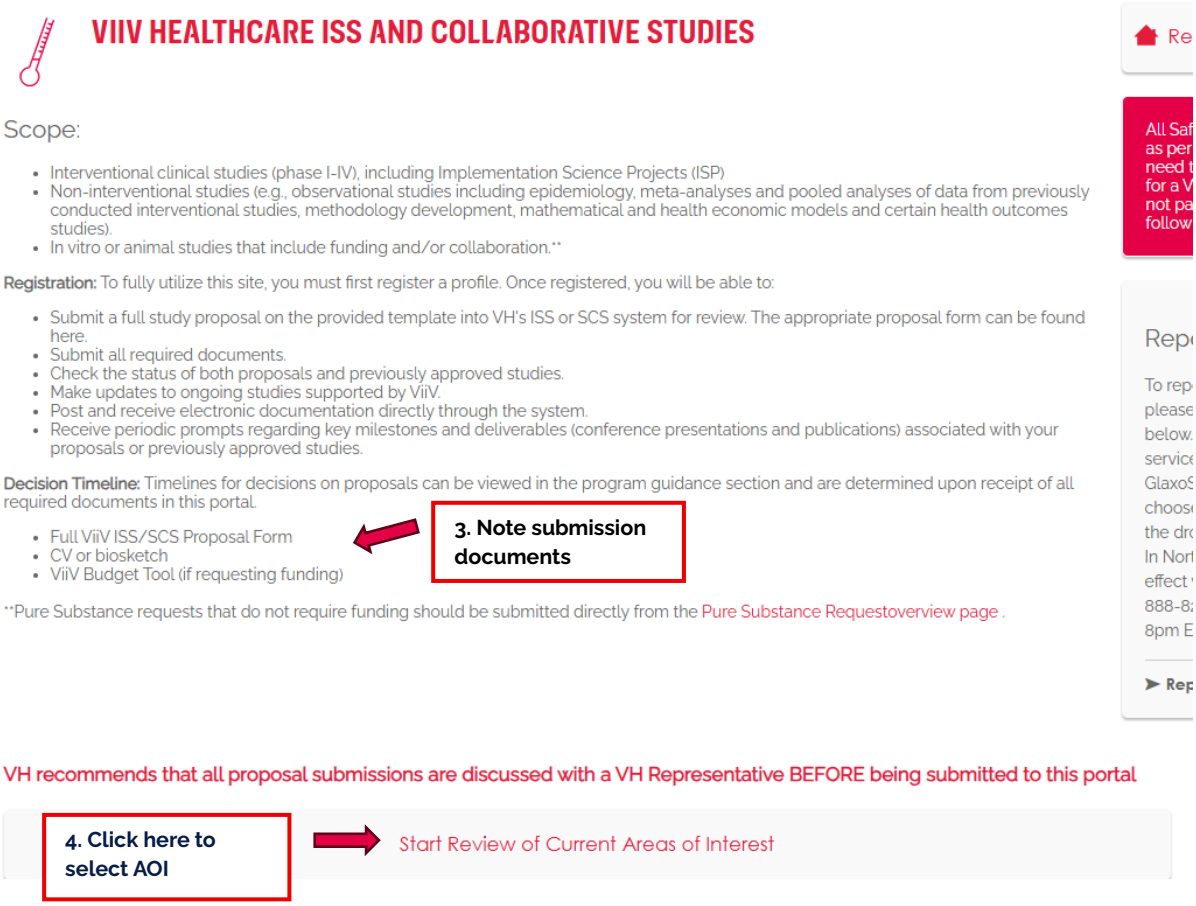
- Through the ViiV ISR Web portal, create a user profile (to complete your registration, validation of your email address will be required). See below for further details.
- Submit your study proposal by completing the online submission webform. This will require completion of the VH ISS or SCS proposal template (or provision of a protocol plus the Proposal Supplementary Information Form).
    - If you are requesting drug you will need to provide the details including dosing and estimated amounts. You will need to provide contact details for the study's pharmacist or sponsor logistics coordinator to be contacted by the ViiV Clinical Supply Team in the event your proposal advances to full review.
    - If you are requesting funding support, a detailed budget on the ViiV Budget Template will be required as part of the submission. You may opt to provide an estimate of the study budget on initial submission, however a detailed budget will be required if your proposal advances to full review. Please note, budgets that exceed the original estimate by more than 10% may result in a proposal being rejected.
- You can access your submission at any time, however, once submitted, you cannot make any changes in the system unless re-opened by ViiV.
- You will be required to provide your CV.

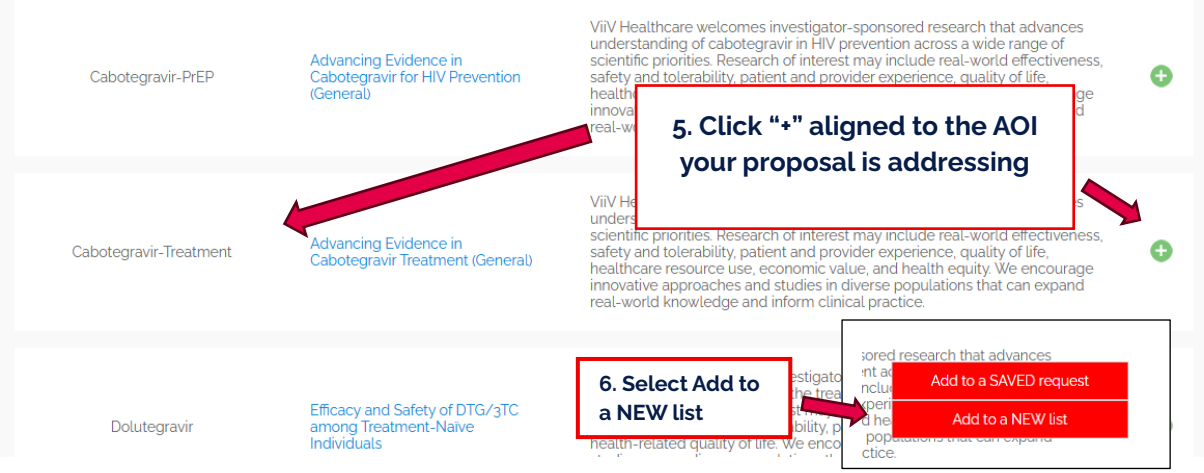
Access the ViiV Investigator Sponsored Research Programme portal: ViiV ISR Web portal

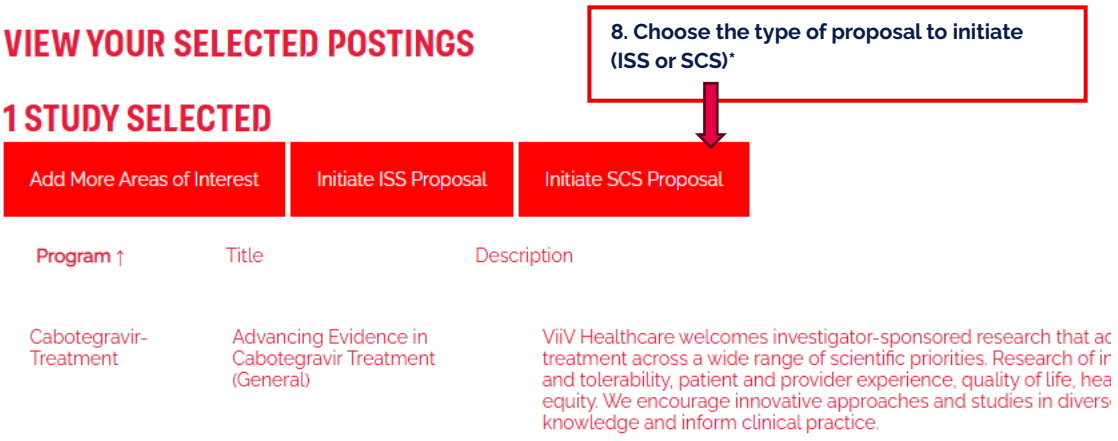


Please note: This guidance document does not cover submission of proposals for Pure substance requests. Contact ViiV for further details regarding this kind of proposal.

Take note of the documents required for submission, then progress through the "Start Review of Current Areas of Interest" tab.







please refer to prior definitions of ISS versus SCS as required on page 3 of this document.

You will then be asked to confirm your profile details are correct, including your medical licence certification, and to complete a conflict-of-interest form. Once confirmed, you will be asked to agree to an attestation statement and enter the title for your study submission. Hit the "Create New" button to progress.

- Note, if you do not agree to the Attestation statement you will not be able to progress further. Contact your ViiV contact if you have any questions or concerns at this stage.

The next section will ask you for details related to your specific study proposal and the request to ViiV.

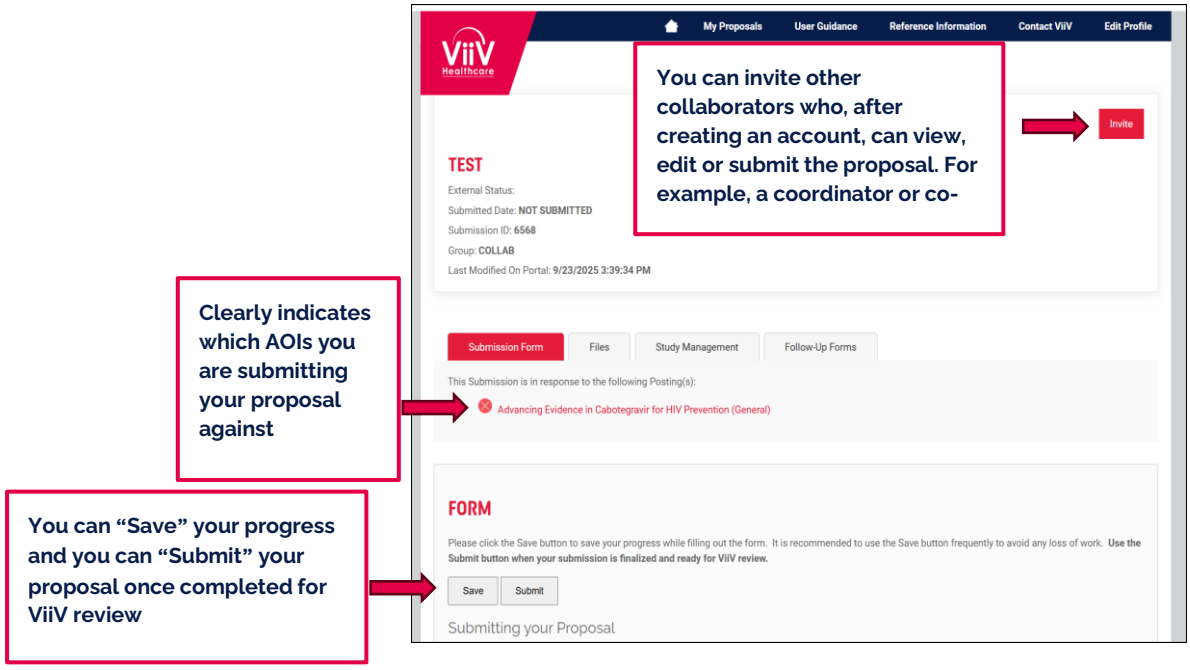
You will need to complete Part A and Part B to submit (see below for further details). You can **save** the submission and make changes later however you will need to hit **submit** to trigger the ViiV review process. Once you submit you will not be able to make changes to the initial submission information unless re-opened by ViiV.

Submission Form

For any submission, there is an expectation that the following is either pre-determined or in a solid draft state;

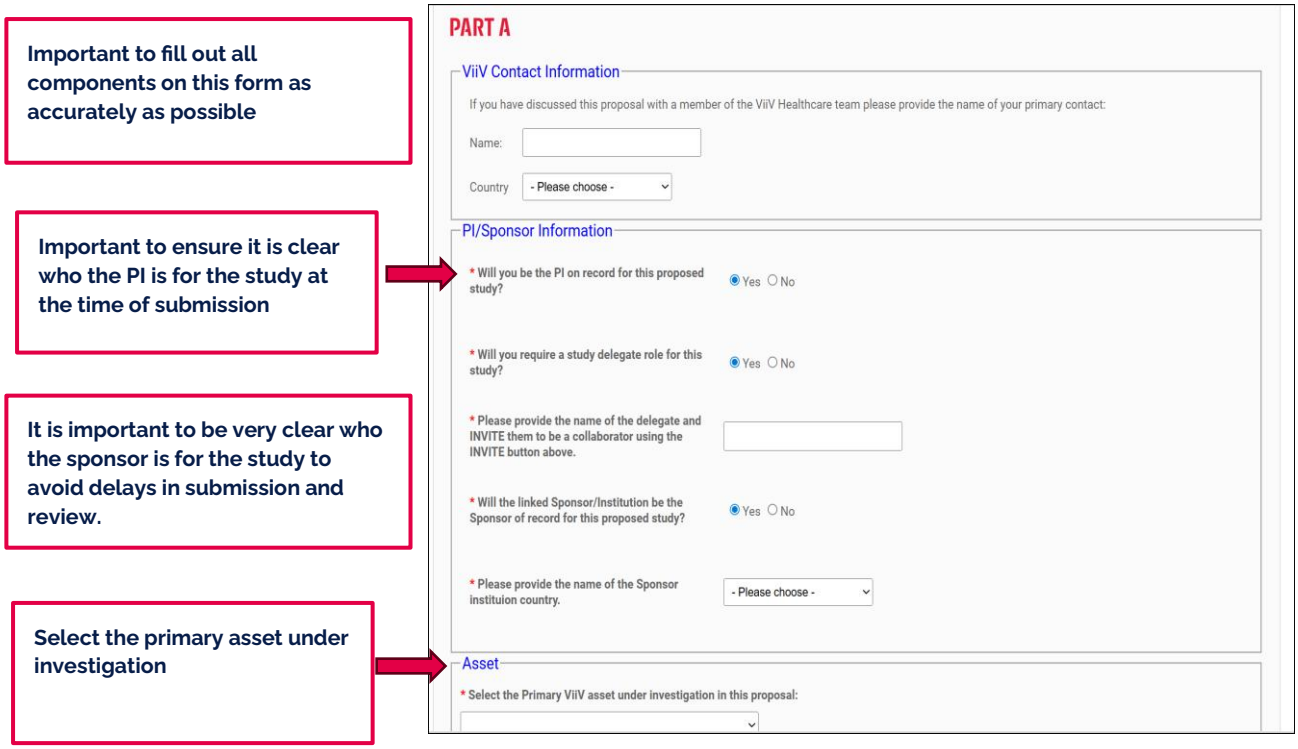
- Clearly defined sponsor (**This will not be ViiV Healthcare**)
- Assigned PI leading the study
- Study title
- Proposal or protocol
- Study type (ISS/SCS)
- Specific drug request: ViiV product, quantities & dosing details (if applicable)
- Funding estimates (if applicable)

Details of proposal and budget templates, and additional guidance can be found on page 12 of this document



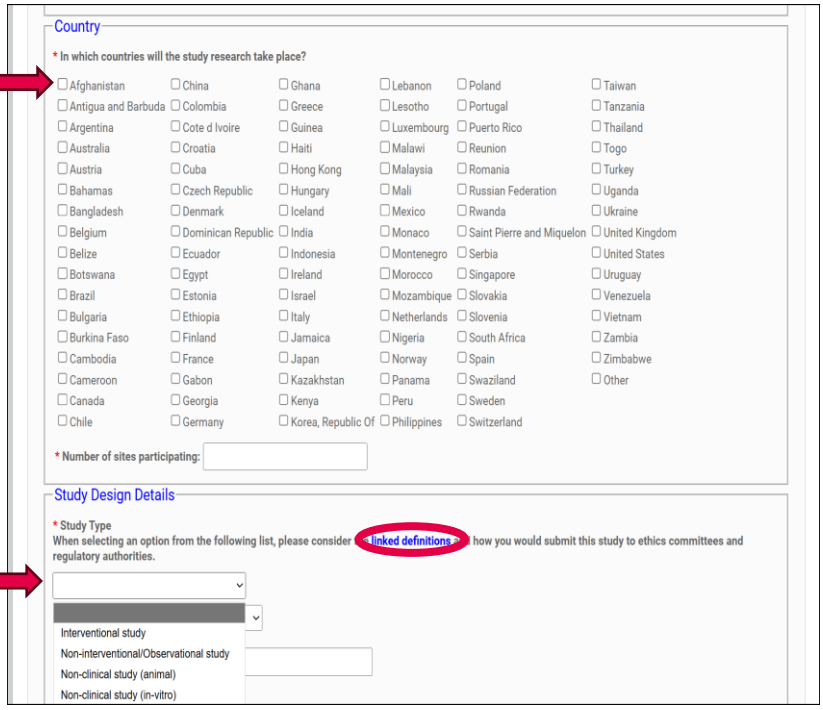
Note: this is also the page where you will be able to submit follow up and future documents relating to your study.

Submission Part A



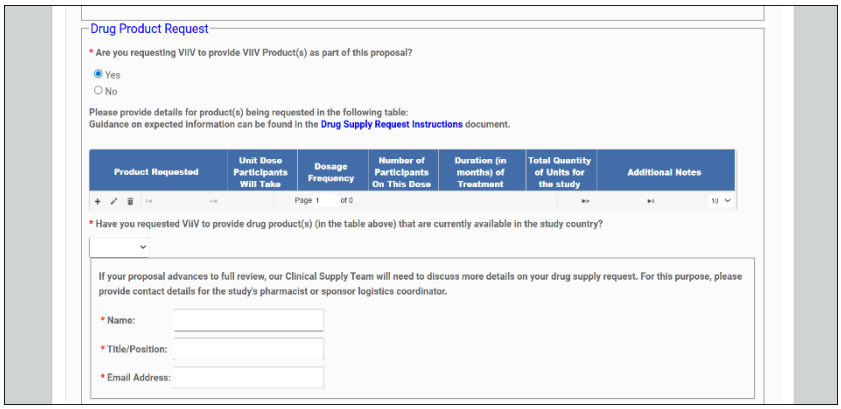
Select all countries in which research will take place

Carefully select study design with review of the linked definitions and in consultation with your VH contact as applicable



Submission form – Drug Supply

If applicable, complete drug product request information



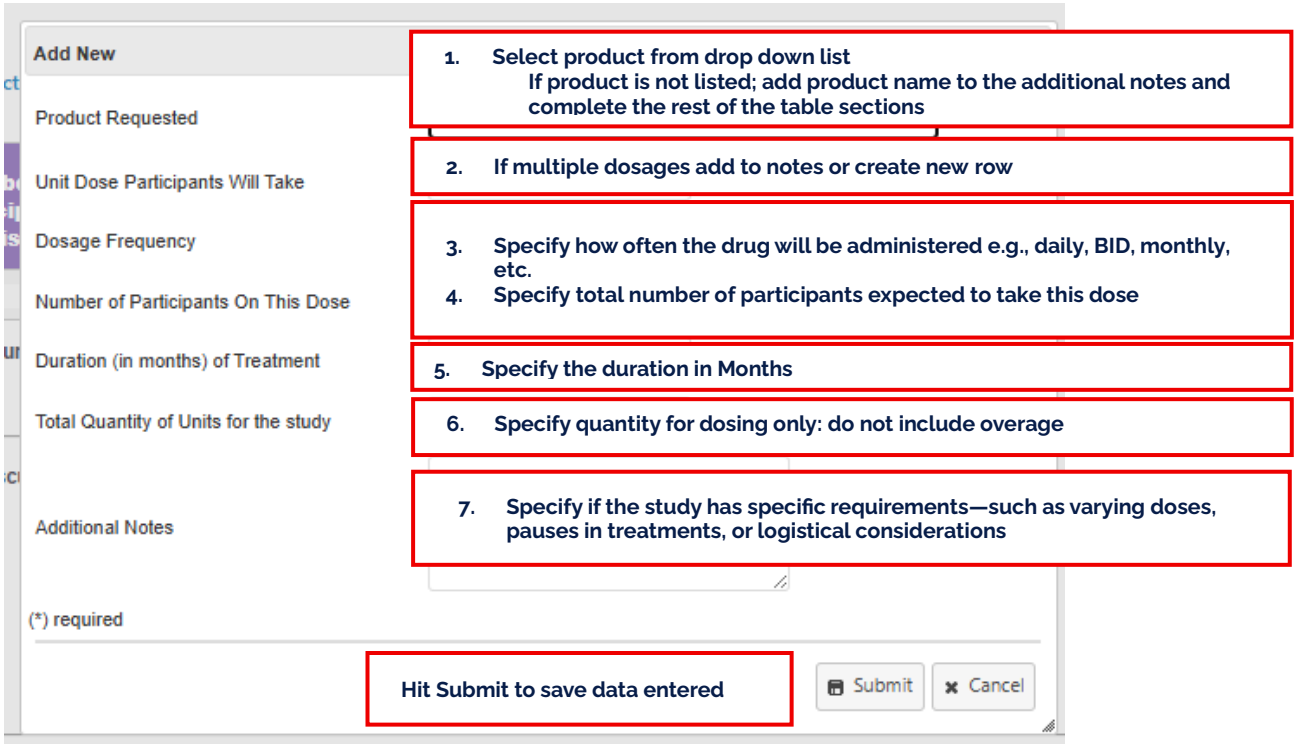
Please provide details for product(s) being requested in the following table:
Guidance on expected information can be found in the Drug Supply Request Instructions document.

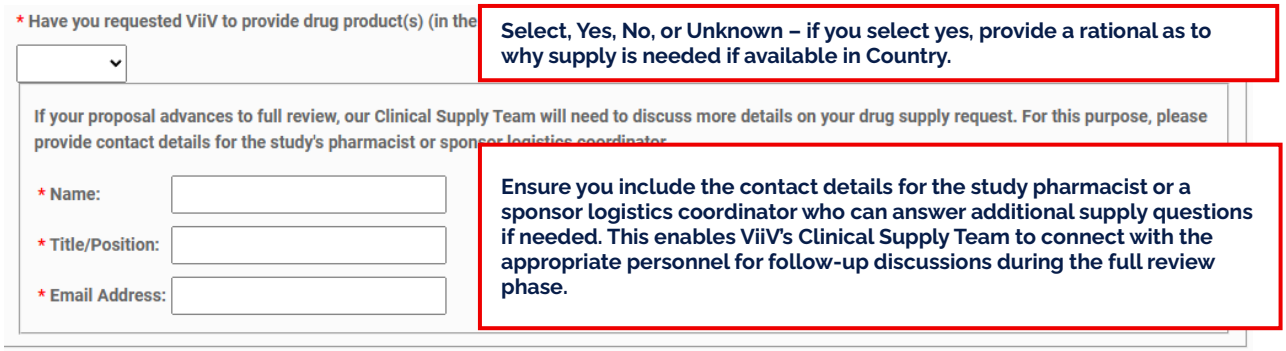
Product Requested	Unit Dose Participants Will Take	Dosage Frequency	Number of Participants On This Dose	Duration (in months) of Treatment	Total Quantity of Units for the study	Additional Notes
Cabotegravir (LA) 3mL						The 3rd does will occur at month 4 and c

View 1 - 1 of 1

Select + icon to add drug details being requested
Select + to add additional rows (*one row per Product or strength)*
Select pencil icon to edit an entry.
Select trash bin icon to delete an entry (row).

After selecting + icon the following pop-up table will appear:





Important Next Steps:

If your proposal advances to the full review phase, a member of ViiV Healthcare's Clinical Supply Team will contact the Sponsor and the Sponsor Logistics Coordinator for further discussions. This includes reviewing additional details needed to finalize the drug supply requirements as part of ViiV Healthcare's internal governance approval and planning process.

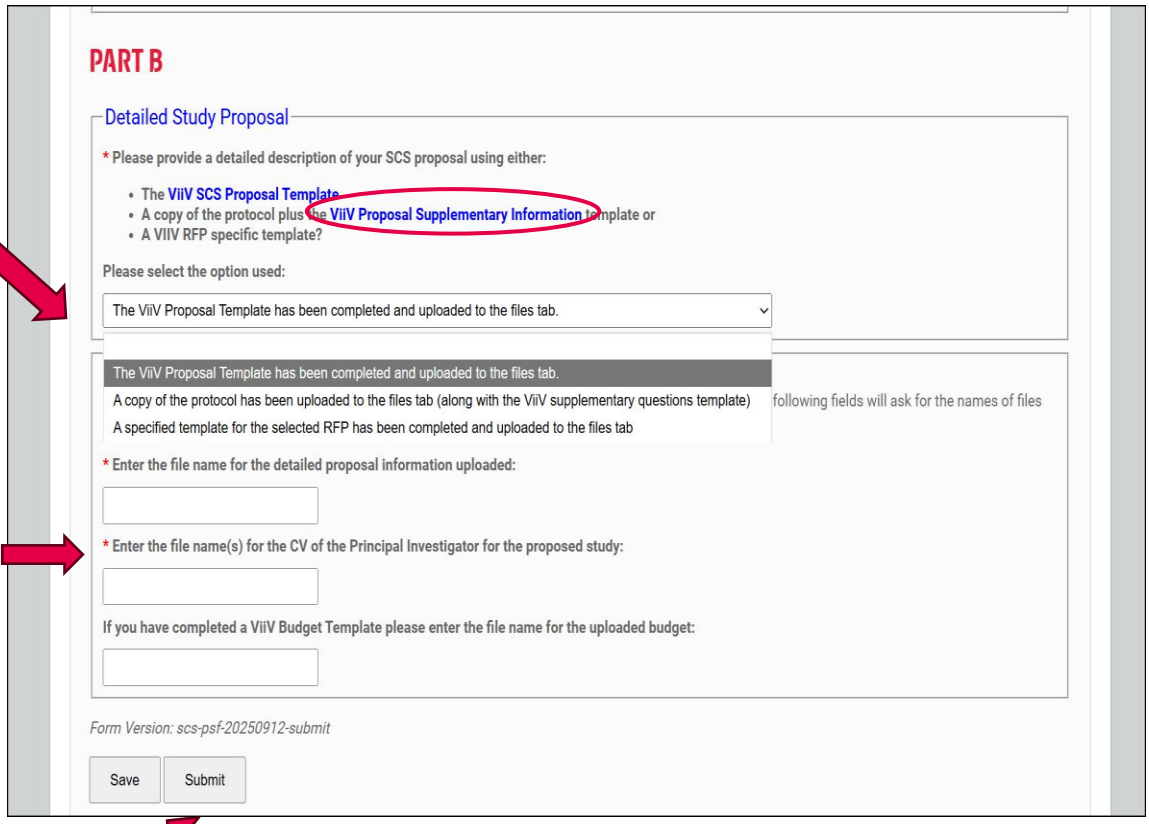
Important note: *To minimize delays, if your proposal includes a request for drug you must designate a POC (pharmacist or logistics coordinator) during the proposal stage.*

Submission Part B

If you choose to submit a protocol instead of the proposal template, you need to also complete and submit the "ViiV Proposal Supplementary Information" template to ensure key proposal details are available for VH review

You can submit a proposal via 3 options:

- **The standard proposal template**
- **A copy of the protocol**
- **The standard RFP template (when applicable)**

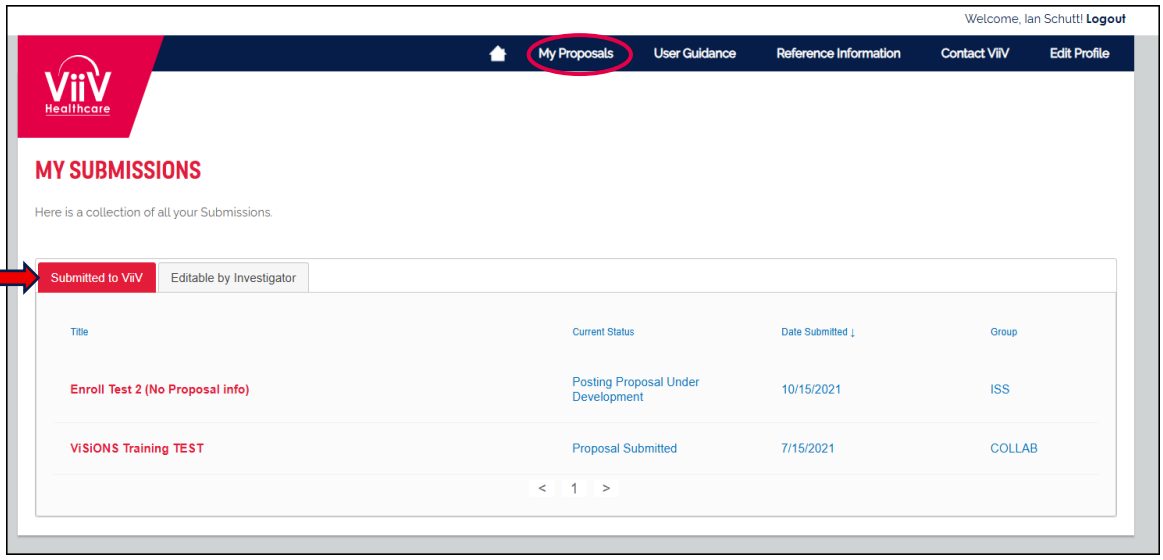


To reduce delays in the review process, you are now required to provide the file names of the documents that must accompany each submission. This step helps ensure the required documents are uploaded.

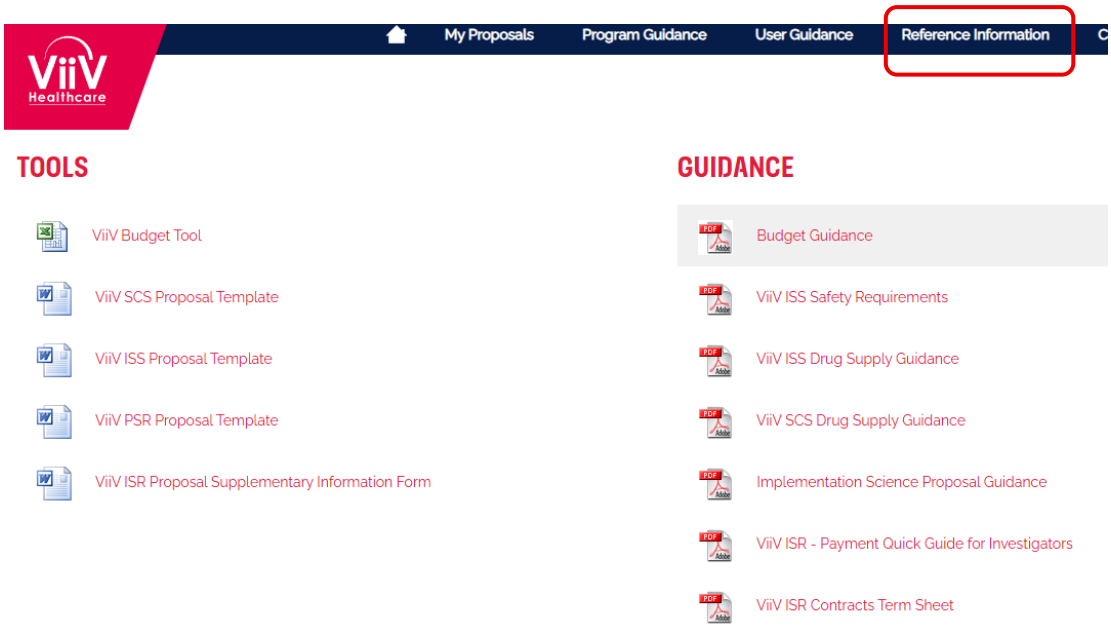
PLEASE REMEMBER TO EITHER SUBMIT OR SAVE

How to view your existing submissions

Once submitted, proposals will move from the "Editable by Investigator" tab to the "Submitted to ViiV" tab. You can access your proposals via the "My Proposals" page.



Note: study submission templates (including the budget tool) can be found under Reference Information at the top of the page



What to Expect After Submission and Throughout the ISR Lifecycle

Following submission, you can expect a structured review and study management lifecycle with defined phases, clear timelines, and formal decision points. Status updates are communicated via system notifications at key milestones, and the status of your proposal can be accessed at any time via the "My Proposals" section of the system.

Progression through each phase is dependent on submission completeness, study complexity, and timely responses to information requests.

Proposal Submission & Review Phase

(Formal entry into the ISR system and governance review)

What Happens

- You will receive an automated email confirming successful submission.
- A completeness check will be performed to ensure all required documentation has been received:
    - VH proposal template
    - Principal Investigator (PI) CV
    - VH Budget Tool (if applicable)
- VH may contact you (e.g., via an MSL) to request additional information or clarification.
- If required information is missing, your proposal will not progress until it is provided.

Timelines

- Completeness check: typically, within the first **2 weeks**
- Strategic interest decision: within **~4 weeks** of receiving all required documentation

Strategic Interest Assessment

Your proposal will be assessed based on:

- Alignment with VH AOI or Requests for Proposals
- Importance and innovation of the research objectives
- Potential contribution to scientific knowledge or patient care

This is an initial assessment only and does **not guarantee support**.

It is advised to discuss any proposal not specifically addressing a VH AOI with a VH contact prior to submission.

If of Strategic Interest

Your proposal will progress to scientific review, followed by management review;

- **Scientific Review (6–8 weeks):**
  - Scientific merit and quality
  - Feasibility of completing the study according to design and timelines
  - Sponsor capability to conduct a high-quality, ethical study
  - Drug supply feasibility (if applicable), including handling requirements
  - Fair Market Value (FMV) assessment (if funding is requested)

- **Management Review (up to 6 weeks):**
  - Senior-level review of the proposal's scientific merit and alignment with ViiV Healthcare's research priorities
  - Consideration of whether ViiV Healthcare may support the proposal, following completion of the scientific review process
  - Review of any key questions, conditions, or follow-up information needed before a final decision can be communicated
  - Final endorsement decision

You should expect to receive questions requiring clarification/ further information during this period. The timing of review will be dependent on the timeliness and completeness of your responses.

Final Decision Outcomes

You will receive notification of one of the following:

- Approval of the proposal (**ISS**)
- Approval to progress to protocol development (**SCS**)
- Decision not to proceed at this time

For:

- **ISS:** proposal approval follows Management Review, after which protocol receipt and contract execution are required before the study can begin
- **SCS:** proposal approval is followed by full protocol submission and subsequent review/endorsement

  Important Distinction: Protocol provision is expected for both ISS and SCS however unlike SCS where protocols undergo full review, and in some cases joint development with VH, for ISS, protocols are required to ensure alignment with proposal approved and ensure key components related to safety reporting and drug provision (where applicable) are included, prior to contracting.

Protocol Phase

(Protocol development, submission, and approval)

What Happens Following Approval

- You will be requested to submit a first draft of the full protocol, typically within **8–12 weeks** post proposal approval (dependent on complexity and prior agreement).
- VH may continue to engage with you during this phase to request clarification or provide feedback.

Expectations

- Develop a protocol aligned with the approved proposal
- Consider, and where applicable, incorporate feedback and commitments raised during review
- Respond to VH queries in a timely manner

Review Approach

- **ISS (~4 weeks*):**
    - Review focuses on:
        - Alignment with the approved proposal
        - Inclusion of appropriate safety information
        - Accuracy of product-related information (if VH drug is supplied)
        - Consideration of post-study supply where applicable

- **SCS (~8 weeks*):**
    - Protocol may be developed collaboratively with VH (if agreed). It is still the responsibility of the PI/sponsor to generate the first draft and incorporate changes as agreed with ViiV.
    - Requires formal scientific review and management endorsement prior to approval

**dependant on level of complexity*

Key Outcome

- Protocol approval is required before contracting can proceed

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Contracting & Approval Phase

(Legal agreement development and execution)

What Happens

- You will receive a **Study Approval Letter** from your ViiV contact detailing next steps.
- You will be required to complete a **Contract Start Checklist** to support contract drafting.
- VH will initiate drafting of the legal agreement using its standard template.

Sponsor Expectations

- Provide all required information to support agreement drafting
- Engage institutional legal/contracts teams early
- Review deadlines and timelines included in the contract checklist

Best Practices

- Return the Contract Start Checklist within **~2 weeks** of receipt (or notify if extension needed)
- Review the ViiV ISR Contract Terms Sheet early with your legal team
- Provide consolidated feedback to minimise multiple negotiation cycles
- For studies requesting funding:
    - Review ViiV ISR - Payment Quick Guide for Investigators and ensure readiness to receive payments

Timelines

- Contracts are expected to be finalised and executed within **6 months** of proposal approval

Key Outcome

- **Full study approval is achieved only when:**
    - The protocol is approved, and
    - The legal agreement is fully executed

Study Start-Up Phase

(Post-contract execution)

What Happens

- Once the legal agreement is executed, study start-up activities may begin.
- System notifications will confirm key milestones (e.g., contract execution).

Sponsor Expectations

- Initiate and prepare for study conduct
- Ensure readiness across sites, systems, and regulatory requirements

Study Conduct Phase

(Active study delivery)

Sponsor Responsibilities

- Conduct a high-quality, ethical study
- Operate within approved funding allocation
- Manage drug supply (where applicable), including:
    - shipment
    - storage
    - distribution and labelling requirements
- Report safety data to:
    - regulatory authorities
    - IRB/IEC
    - VH (as defined in the legal agreement)
- Provide study progress updates to VH in line with contractual requirements
- Notify VH in advance of any proposed changes to the protocol

ViiV Healthcare Commitments

Throughout the study, you can expect VH to:

- Provide scientific and medical feedback where there are concerns regarding:
    - scientific integrity
    - participant safety or wellbeing
- Respond to Sponsor inquiries and requests in a timely manner
- Ensure decisions on proposals and study matters are communicated clearly
- Maintain compliance with applicable laws and regulations, including data protection
- Conduct periodic reviews of study progress against:
    - agreed milestones
    - KPIs

Publication & Close-Out Phase

(Study outputs, transparency, and closure)

Sponsor Responsibilities

- Provide VH with all planned publications for internal review prior to:
  - congress submission
  - journal submission
- Meet timelines defined in the legal agreement for publication review
- Fulfil transparency obligations, including:
  - public registry posting (e.g., ClinicalTrials.gov), where required
- Provide evidence of drug destruction as applicable

Sponsor Responsibilities Across All Phases

For Investigator Sponsored Research, the Sponsor remains accountable for all aspects of the study, including:

- Compliance with all applicable:
  - laws and regulations
  - institutional requirements
  - ethical standards
- Disclosure of financial interests or conflicts of interest
- Development and maintenance of a publication plan
- Ensuring overall study integrity and quality

Important Note on Compliance

Failure to meet the expectations outlined above may result in:

- Discontinuation of VH support for the study
- Impact on the consideration of future proposals submitted by the Sponsor

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Summary of Key Timelines

Milestone	Typical Timing*
Proposal Submitted, ViiV proposal review begins	
ViiV Completeness check	2 weeks
ViiV Strategic interest decision	4 weeks
ViiV Scientific review	6–8 weeks
ViiV Management review	6 weeks
Proposal Approved, ViiV protocol review begins	
Sponsor Protocol draft submission	8–12 weeks
ViiV Protocol Review and Approval	ISS: 4 weeks SCS: 8 weeks
Contract execution	Within 6 months of proposal approval
Study fully approved, Sponsor proceed to Study Start	

*timing will be influenced by multiple factors including the level of complexity of the study, the responsiveness of the PI/Sponsor during the VH review process, the timeliness of protocol development and contract finalisation.

Data Privacy

GSK and ViiV Healthcare are committed to protecting personal data and respecting privacy in accordance with applicable data protection laws and regulations.

Any personal data provided by investigators or their institutions or otherwise collected in connection with investigator-sponsored research activities, will be processed securely and used only for legitimate research, regulatory, and business purposes.

Personal data will be shared only with authorised parties (such as affiliates, service providers, and regulatory authorities) where necessary and handled in line with GSK and ViiV Healthcare privacy standards. Sponsors remain responsible for determining the purposes and means of data processing (as data controller). VH (as data processor) will process personal data only as necessary to support its role and in accordance with applicable agreements.

Further information, including information on data subject rights and international data transfers, is available in the GSK Privacy Notice.

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