

Investigator Sponsored Research: External Guidance & Expectations

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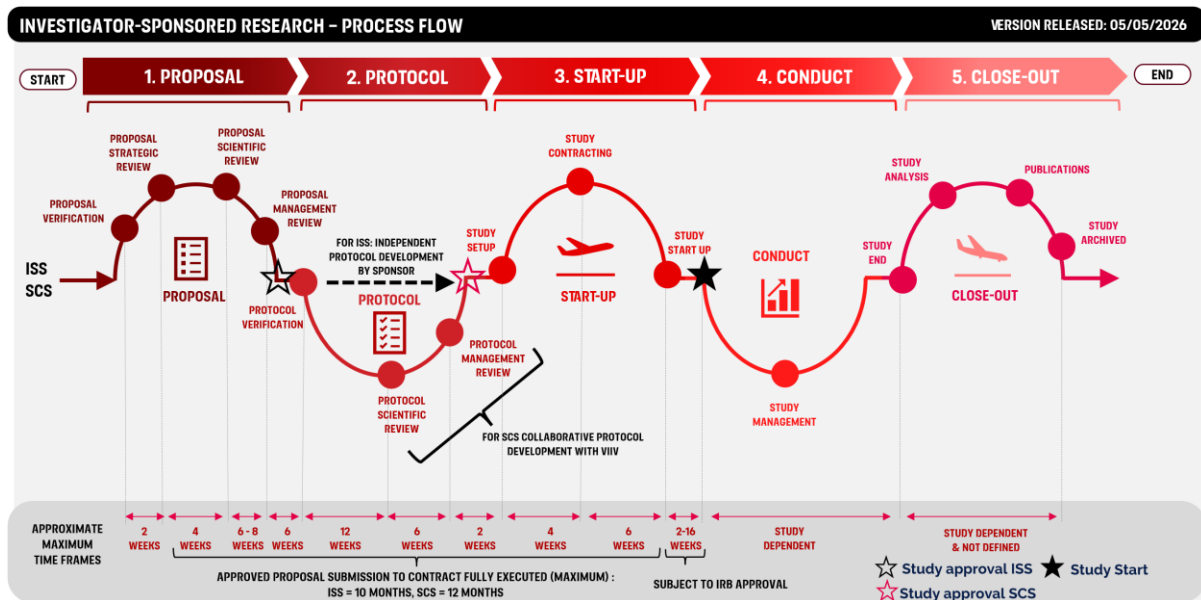
Introduction & Purpose

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](#)

1. Log into your account

2. Click to enter submission site

ViiV INVESTIGATOR SPONSORED RESEARCH PROGRAMME

Our Mission

ViiV Healthcare (VH) is an independent, global specialist HIV company established in 2009, committed to the care and treatment of people living with HIV/AIDS. Our support of investigator-sponsored research (ISR) plays a valuable role in fulfilling this mission.

Investigator Sponsored Research

Types of Requests/Studies

- Pure Substance Requests/Studies
- ISS & SCS Requests/Studies

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.

VIIIV HEALTHCARE ISS AND COLLABORATIVE STUDIES

Scope:

- Interventional clinical studies (phase I-IV), including Implementation Science Projects (ISP)
- Non-interventional studies (e.g., observational studies including epidemiology, meta-analyses and pooled analyses of data from previously conducted interventional studies, methodology development, mathematical and health economic models and certain health outcomes studies).
- In vitro or animal studies that include funding and/or collaboration."

Registration: To fully utilize this site, you must first register a profile. Once registered, you will be able to:

- Submit a full study proposal on the provided template into VH's ISS or SCS system for review. The appropriate proposal form can be found here.
- Submit all required documents.
- Check the status of both proposals and previously approved studies.
- Make updates to ongoing studies supported by ViiV.
- Post and receive electronic documentation directly through the system.
- Receive periodic prompts regarding key milestones and deliverables (conference presentations and publications) associated with your proposals or previously approved studies.

Decision Timeline: Timelines for decisions on proposals can be viewed in the program guidance section and are determined upon receipt of all required documents in this portal.

- Full ViiV ISS/SCS Proposal Form
- CV or biosketch
- ViiV Budget Tool (if requesting funding)

3. Note submission documents

"Pure Substance requests that do not require funding should be submitted directly from the [Pure Substance Request overview page](#)."

Re...

To rep please below. service GlaxoS choos the dr In Nort effect 888-8; 8pm E

► Rep

VH recommends that all proposal submissions are discussed with a VH Representative BEFORE being submitted to this portal

4. Click here to select AOI

Start Review of Current Areas of Interest

5. Click "+" aligned to the AOI your proposal is addressing

6. Select Add to a NEW list

7. Click here to progress to next

8. Choose the type of proposal to initiate (ISS or SCS)*

Search Functions
There are two ways to search on this page to narrow down the list of results:

- Use the "Search Filters" on the left side of the page.
- Use the "Search" box and enter keywords.

Enter your Search Criteria Search Clear All

7 RESULTS:

1

VIEW YOUR SELECTED POSTINGS

1 STUDY SELECTED

Add More Areas of Interest Initiate ISS Proposal Initiate SCS Proposal

Program ↑	Title	Description
Cabotegravir-Treatment	Advancing Evidence in Cabotegravir Treatment (General)	ViiV Healthcare welcomes investigator-sponsored research that advances understanding of cabotegravir in HIV prevention across a wide range of scientific priorities. Research of interest may include real-world effectiveness, safety and tolerability, patient and provider experience, quality of life, healthcare resource use, economic value, and health equity. We encourage innovative approaches and studies in diverse populations that can expand real-world knowledge and inform clinical practice.

*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

TEST

External Status:
Submitted Date: NOT SUBMITTED
Submission ID: 6568
Group: COLLAB
Last Modified On Portal: 9/23/2025 3:39:34 PM

FORM

Please click the Save button to save your progress while filling out the form. It is recommended to use the Save button frequently to avoid any loss of work. Use the Submit button when your submission is finalized and ready for ViiV review.

Submitting your Proposal

Annotations:

- You can invite other collaborators who, after creating an account, can view, edit or submit the proposal. For example, a coordinator or co-** (points to 'Invite' button)
- Clearly indicates which AOIs you are submitting your proposal against** (points to 'Advancing Evidence in Cabotegravir for HIV Prevention (General)')
- You can "Save" your progress and you can "Submit" your proposal once completed for ViiV review** (points to 'Save' and 'Submit' buttons)

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

PART A

ViiV Contact Information

If you have discussed this proposal with a member of the ViiV Healthcare team please provide the name of your primary contact:

Name:

Country:

PI/Sponsor Information

* Will you be the PI on record for this proposed study? ☒ Yes ☐ No

* Will you require a study delegate role for this study? ☒ Yes ☐ No

* Please provide the name of the delegate and INVITE them to be a collaborator using the INVITE button above.

* Will the linked Sponsor/Institution be the Sponsor of record for this proposed study? ☒ Yes ☐ No

* Please provide the name of the Sponsor institution country.

Asset

* Select the Primary ViiV asset under investigation in this proposal:

Annotations:

- Important to fill out all components on this form as accurately as possible** (points to contact information)
- Important to ensure it is clear who the PI is for the study at the time of submission** (points to PI/Sponsor information)
- It is important to be very clear who the sponsor is for the study to avoid delays in submission and review.** (points to sponsor information)
- Select the primary asset under investigation** (points to asset selection dropdown)

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

Country

* In which countries will the study research take place?

☐ Afghanistan	☐ China	☐ Ghana	☐ Lebanon	☐ Poland	☐ Taiwan
☐ Antigua and Barbuda	☐ Colombia	☐ Greece	☐ Lesotho	☐ Portugal	☐ Tanzania
☐ Argentina	☐ Cote d'Ivoire	☐ Guinea	☐ Luxembourg	☐ Puerto Rico	☐ Thailand
☐ Australia	☐ Croatia	☐ Haiti	☐ Malawi	☐ Reunion	☐ Togo
☐ Austria	☐ Cuba	☐ Hong Kong	☐ Malaysia	☐ Romania	☐ Turkey
☐ Bahamas	☐ Czech Republic	☐ Hungary	☐ Mali	☐ Russian Federation	☐ Uganda
☐ Bangladesh	☐ Denmark	☐ Iceland	☐ Mexico	☐ Rwanda	☐ Ukraine
☐ Belgium	☐ Dominican Republic	☐ India	☐ Monaco	☐ Saint Pierre and Miquelon	☐ United Kingdom
☐ Belize	☐ Ecuador	☐ Indonesia	☐ Montenegro	☐ Serbia	☐ United States
☐ Botswana	☐ Egypt	☐ Ireland	☐ Morocco	☐ Singapore	☐ Uruguay
☐ Brazil	☐ Estonia	☐ Israel	☐ Mozambique	☐ Slovakia	☐ Venezuela
☐ Bulgaria	☐ Ethiopia	☐ Italy	☐ Netherlands	☐ Slovenia	☐ Vietnam
☐ Burkina Faso	☐ Finland	☐ Jamaica	☐ Nigeria	☐ South Africa	☐ Zambia
☐ Cambodia	☐ France	☐ Japan	☐ Norway	☐ Spain	☐ Zimbabwe
☐ Cameroon	☐ Gabon	☐ Kazakhstan	☐ Panama	☐ Swaziland	
☐ Canada	☐ Georgia	☐ Kenya	☐ Peru	☐ Sweden	
☐ Chile	☐ Germany	☐ Korea, Republic Of	☐ Philippines	☐ Switzerland	

* Number of sites participating:

Study Design Details

* Study Type
When selecting an option from the following list, please consider [linked definitions](#) how you would submit this study to ethics committees and regulatory authorities.

Interventional study

Non-interventional/Observational study

Non-clinical study (animal)

Non-clinical study (in-vitro)

Submission form – Drug Supply

If applicable, complete drug product request information

Drug Product Request

* Are you requesting ViiV to provide ViiV Product(s) as part of this proposal?

☒ Yes
☐ No

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
Page 1 of 1						

* Have you requested ViiV to provide drug product(s) (in the table above) that are currently available in the study country?

If your proposal advances to full review, our Clinical Supply Team will need to discuss more details on your drug supply request. For this purpose, please provide contact details for the study's pharmacist or sponsor logistics coordinator.

* Name:

* Title/Position:

* Email Address:

Drug Product Request

* Are you requesting ViiV to provide ViiV Product(s) as part of this proposal?

☐ Yes
☐ No

Select Yes and a product table will appear.
Complete the table as part of the proposal.

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
  						

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:

Add New	
Product Requested	1. Select product from drop down list If product is not listed; add product name to the additional notes and complete the rest of the table sections
Unit Dose Participants Will Take	2. If multiple dosages add to notes or create new row
Dosage Frequency	3. Specify how often the drug will be administered e.g., daily, BID, monthly, etc.
Number of Participants On This Dose	4. Specify total number of participants expected to take this dose
Duration (in months) of Treatment	5. Specify the duration in Months
Total Quantity of Units for the study	6. Specify quantity for dosing only: do not include overage
Additional Notes	7. Specify if the study has specific requirements—such as varying doses, pauses in treatments, or logistical considerations
(*) required	
Hit Submit to save data entered Submit Cancel	

* Have you requested ViiV to provide drug product(s) (in the

Select, Yes, No, or Unknown – if you select yes, provide a rationale as to why supply is needed if available in Country.

If your proposal advances to full review, our Clinical Supply Team will need to discuss more details on your drug supply request. For this purpose, please provide contact details for the study's pharmacist or sponsor logistics coordinator.

* Name:

* Title/Position:

* Email Address:

Ensure you include the contact details for the study pharmacist or a sponsor logistics coordinator who can answer additional supply questions if needed. This enables ViiV's Clinical Supply Team to connect with the appropriate personnel for follow-up discussions during the full review phase.

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)

PART B

Detailed Study Proposal

* Please provide a detailed description of your SCS proposal using either:

- The **ViiV SCS Proposal Template**
- A copy of the protocol plus the **ViiV Proposal Supplementary Information** template or
- A ViiV RFP specific template?

Please select the option used:

The ViiV Proposal Template has been completed and uploaded to the files tab.

The ViiV Proposal Template has been completed and uploaded to the files tab.

A copy of the protocol has been uploaded to the files tab (along with the ViiV supplementary questions template)

A specified template for the selected RFP has been completed and uploaded to the files tab

following fields will ask for the names of files

* Enter the file name for the detailed proposal information uploaded:

* Enter the file name(s) for the CV of the Principal Investigator for the proposed study:

If you have completed a ViiV Budget Template please enter the file name for the uploaded budget:

Form Version: scs-psf-20250912-submit

Save

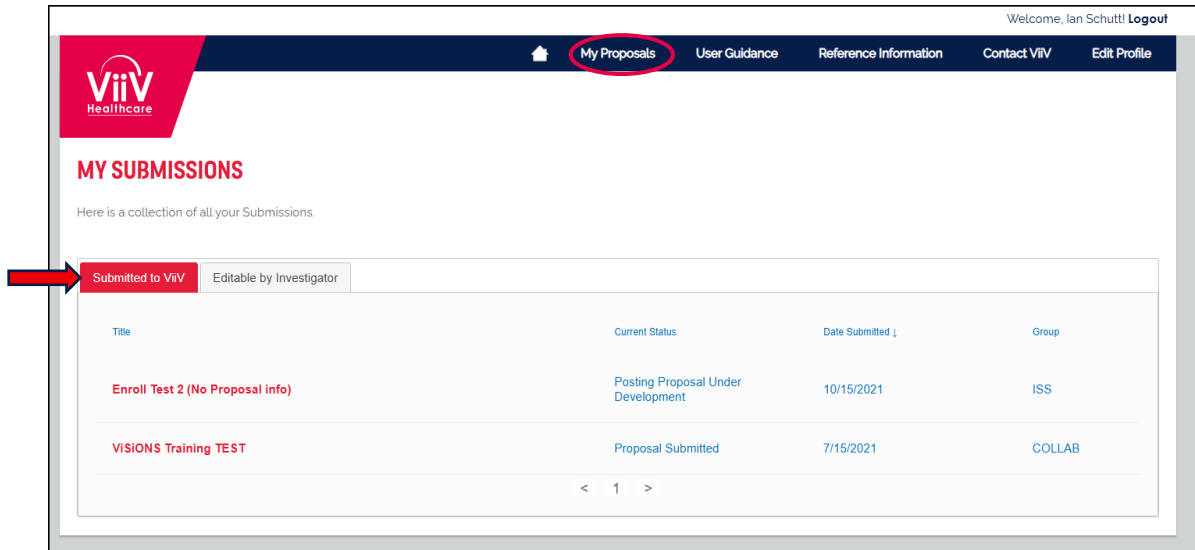
Submit

PLEASE REMEMBER TO EITHER SUBMIT OR SAVE

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.

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.



Welcome, Ian Schutt! [Logout](#)

[My Proposals](#) [User Guidance](#) [Reference Information](#) [Contact ViiV](#) [Edit Profile](#)

MY SUBMISSIONS

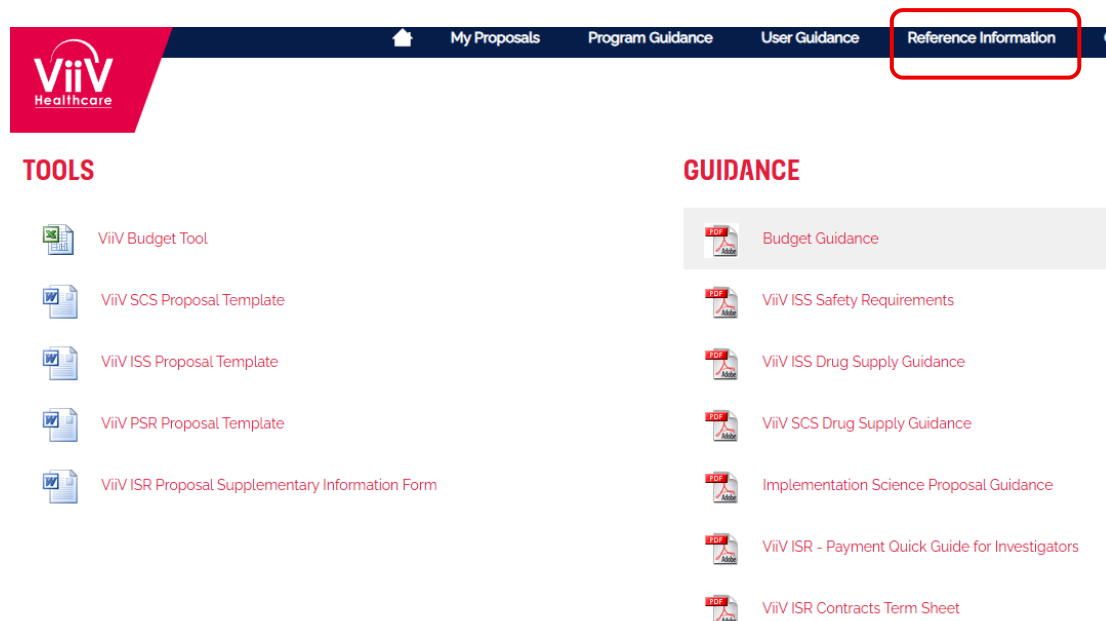
Here is a collection of all your Submissions.

Submitted to ViiV Editable by Investigator

Title	Current Status	Date Submitted ↓	Group
Enroll Test 2 (No Proposal info)	Posting Proposal Under Development	10/15/2021	ISS
VISIONS Training TEST	Proposal Submitted	7/15/2021	COLLAB

< 1 >

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



[My Proposals](#) [Program Guidance](#) [User Guidance](#) **[Reference Information](#)** [Contact ViiV](#)

TOOLS

-  [ViiV Budget Tool](#)
-  [ViiV SCS Proposal Template](#)
-  [ViiV ISS Proposal Template](#)
-  [ViiV PSR Proposal Template](#)
-  [ViiV ISR Proposal Supplementary Information Form](#)

GUIDANCE

-  [Budget Guidance](#)
-  [ViiV ISS Safety Requirements](#)
-  [ViiV ISS Drug Supply Guidance](#)
-  [ViiV SCS Drug Supply Guidance](#)
-  [Implementation Science Proposal Guidance](#)
-  [ViiV ISR - Payment Quick Guide for Investigators](#)
-  [ViiV ISR Contracts Term Sheet](#)

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

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
-

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 <u>proposal</u> 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.

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