Guidance to Sponsors Requesting Investigational Medicinal Product for ViiV Healthcare (VH) Supported Studies

This document has been created to guide you (as the Sponsor) when submitting a new study proposal or an update to an active study or proposal, to ViiV Healthcare (VH) where the Sponsor is requesting Investigational Medicinal Product (IMP) supply support. Details to consider as part of the submission are discussed below (not an exhaustive list) along with screenshots of what can be expected to complete when submitting your proposal.

If there are any questions related to this document or if further information is required, please reach out to your VH contact.

IMP provision is restricted to interventional studies only and the following information should be taken into consideration when submitting a proposal via VH's ISR Portal.

Study design	Include details on the type of study (ie. Randomisation arms), visit schedule, sample size. Provide sufficient detail about the study design to allow VH to complete their assessment on the study requirements and fully understand the proposal. Include details on the expected recruitment period rate, and treatment duration (per IMP).
Countries	Which countries will participate on the study? Consider whether the IMP being requested is approved/available in those countries.
Proposed study timelines	ie. First subject first visit, last subject last visit. Study start date should be aligned to the planned protocol & clinical trial application approval timelines.
Clinical Trial Application	It is the Sponsor's responsibility to create and submit the study clinical trial application in each participating country.
Regulatory and Ethics Approval	Where a CRO is used, the Sponsor must provide confirmation that the CRO will not ship out IMP until such time as the necessary local ethics approvals are in place. (Note: VH will also be unable to ship product to a CRO or site until at least one regulatory approval has been obtained for the study (ie FDA approval).

Order & Shipping Requirements	It is the Sponsor (delegate) responsibility to ensure any and all requirements are in place to support importation of IMP to the shipping address prior to placing the first order with ViiV; 1. Execution of Sponsor and delegate Legal Agreement, including the inclusion of requirements of this Appendix 2. Provision of local Customs Broker and Importer of Record (IoR), if required, including and not limited to the tax and duties custom requirements 3. Confirmation of country Regulatory/MoH for the Clinical Trial 4. Ethics approval if VH is shipping IMP directly to a site.

	5. Execution of the QP to QP Agreement between GSK and Sponsor/delegate, if applicable.
IMP Quantities Requested	1. VH and Sponsor to negotiate the drug quantities required for the study. These quantities must reflect the number of patients and the IMP supply strategy. 2. VH will apply a discretional percentage of overage based on the complexity of the study. 3. Provide details of assumptions applied, (e.g. changes in weight/growth rate for paediatric subjects, dose adjustments for tolerability or IMP interaction).
Forecasting IMP	The timelines for providing a forecast and a confirmed order will be discussed and agreed during the contracting phase, if the proposal is approved by VH.
Re-Order IMP Activities	Any stock out resulting from insufficient time provided for resupplies or lack of IMP at the trial site or CRO is the Sponsor's responsibility.
Labelling/Release/Distribution	Sponsor is accountable for clinical labelling, release and distribution, per ICH and local regulations (eg EU Directive and QP release) and/or use of Contract Research Organisation (CRO) to support these IMP activities. VH do not recommend IMP labelling CRO's. However, VH are able to support CRO queries where required and reviewed on a case-bycase basis.

Storage Facilities, Capacity and Forward Distribution	Sponsor is required to follow their own SOP & GMP/GCP process for storage, handling & distribution. 1. The receiving site or designated CRO is required to have the necessary infrastructure and GMP licenses for all packaging, labelling and release activities. 2. It is the responsibility of the Sponsor to manage shelf-life monitoring and ensure the expiry date of the IMP is calculated using the local regulatory registered shelf-life. 3. Any further processing activities such as packaging, labelling, approval and subsequent release, distribution and use of IMP, are the responsibility of the Sponsor and shall be performed at authorised facilities in accordance with GMP and any Applicable Laws and regulations. 4. Site distribution plans (NB: VH ship to 1 point of delivery location for the study). 5. Cross-border movement of IMP: custom clearance & associated paperwork is the sponsors responsibility to complete. VH will not act as the importer of record for cross border shipments. Either the Sponsor or their delegated third party may take this responsibility.
Plans for optimal background therapy (OBT) and/or standard of care (SoC)	Clarify in the submission where products for OBT &/or SoC will be sourced from, if applicable to the study.
Post medication study plan	Sponsor is accountable for arranging post study medication and the plan must be detailed in the submission.
Other Considerations	1. VH do not support comparator products (e.g, products from other pharmaceutical companies) and VH do not compensate for comparator products. 2. GSK may support drug provision on behalf of VH with the following product certifications; CoA, CoC 3. If VH recommends local commercial/marketed packs to be supplied, the study will not be able to start until VH have pricing & reimbursement and product is available in the country. 4. VH does not permit the Sponsor manufacturing a matching placebo to a commercial VH MAA product. 5. Unused IMP due to expiration dating or at the end of the trial should be destroyed per local regulations and is the Sponsor's responsibility to arrange this destruction (or via their delegated CRO). 6. VH do not share product related Intellectual Property (IP) with sponsors – e.g. VH cannot provide details of analytical methods, formulation details, manufacturing processes etc. 7. Transfer of product accountability to Sponsor will take place upon drug receipt.

Supply Types:

See below examples of images showing the differences between unlabelled bottles and local commercial bottles (both classed as IMP). The pack type appropriate for the study will be determined by VH based on the information submitted in your proposal.

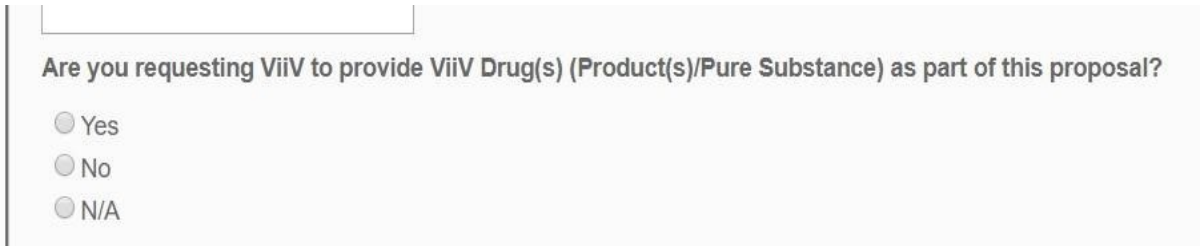
Unlabelled bottles (with DoM and batch number), with a commercial tablet image aligned to local MAA or a clinical tablet image (for a non-registered product)

Local commercial bottles

Guidance for completion of the proposal form

The first question you will see is shown in the screenshot below:

Are you requesting ViiV to provide ViiV Drug(s) (Product(s)/Pure Substance) as part of this proposal?

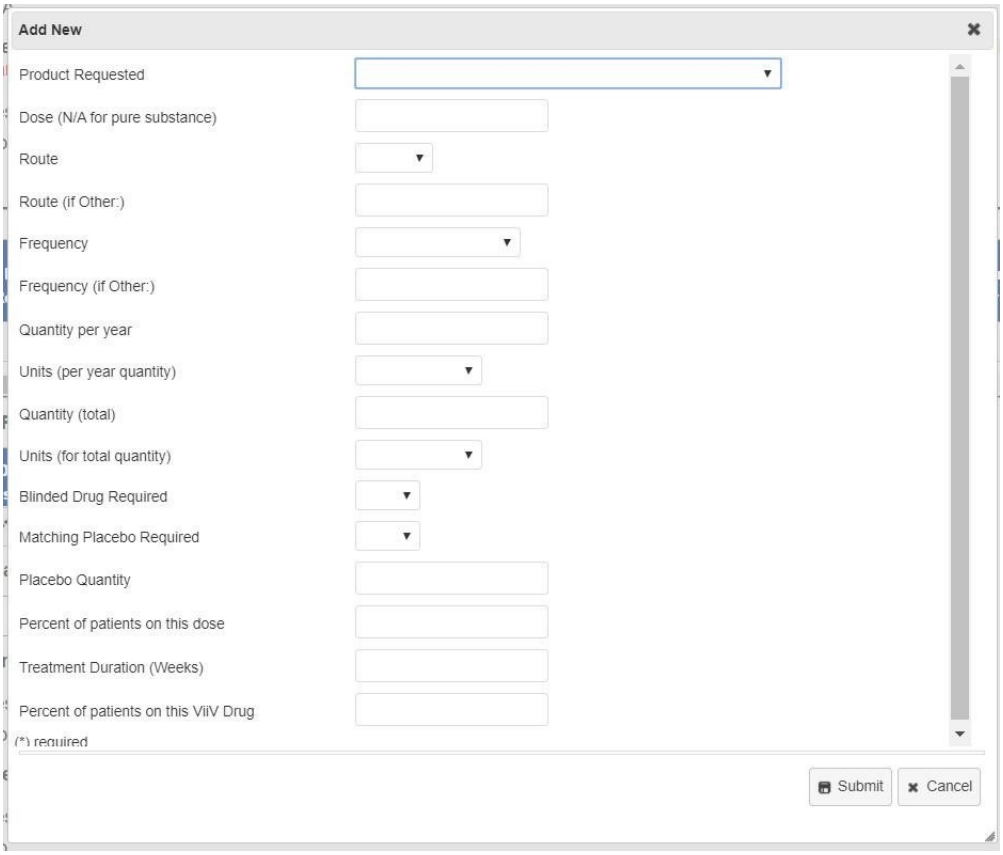


If you answer "Yes" you will be guided through additional screens where you will be able to request VH IMP products. The following screen will appear (where you will be asked to confirm that you have read this guidance document fully before proceeding):

Drug Section:

The icons in each box allow you to add a new line (one line per product is required), edit a line or remove a line should you make an error. You may add as many lines as you need. Again, do not leave any empty fields. The drop downs in each field should help you to select the exact product required.

When a line is added i.e. clicking on the "+" icon, a pop-up table will appear, and this is where you will be required to have a significant amount of detail to hand. See screenshot below:



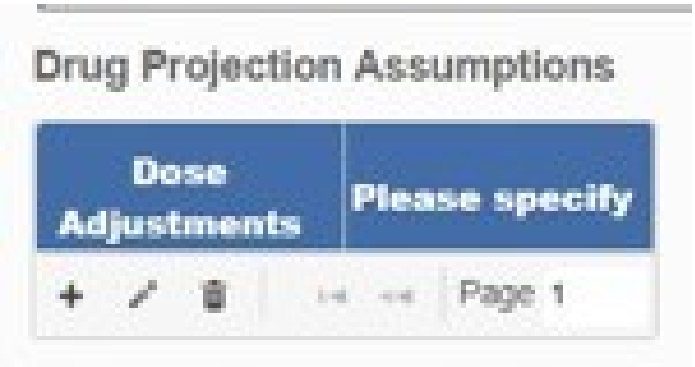
When you have completed a line for each product required, you can proceed to the next screenshot.

Note: Quantities and assumptions used to calculate drug quantity requested via the proposal submission are reviewed and assessed by VH. Final quantity will be negotiated between both parties and will be agreed up-front with the Sponsor with appropriate overages applied. Standard overages applied by VH:

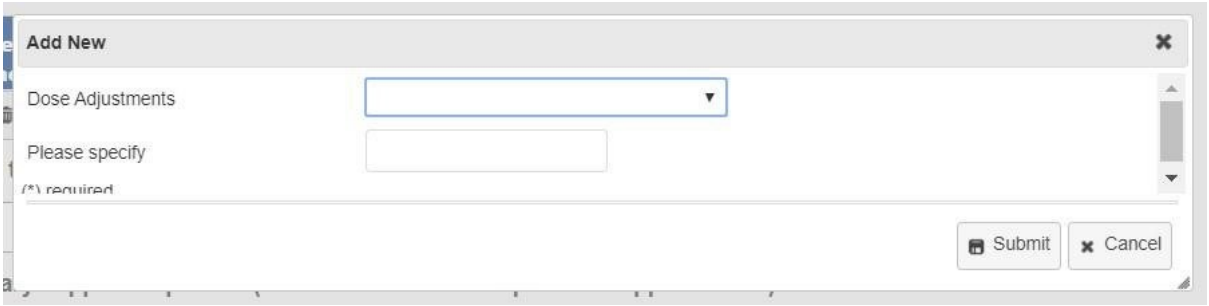
- Average overage is between 5 to 10%:
- Large / Complex study blinded studies with multiple countries and depots: up to 40%

Drug Projection Assumptions:

In the following screen, you will be asked for information about any dose adjustments that you intend to make in the study i.e. titrations or weight category adjustments etc:



You will be asked to create a line for each drug projection assumption that you would like VH to take into consideration. As you add each line a pop-up will allow you to enter the details:



Sponsor's Drug Labelling Capabilities:

Once the drug specific pages are completed, you will be asked for confirmation, as Sponsor, that the necessary drug labelling and release capabilities have been considered as per Sponsor responsibilities. See below:

There are a number of options in the drop-down list, but if your specific situation is not included, you may select "Other" and a free text box will allow you to provide further details.

Provided that all fields are completed throughout the drug request screens, this will allow VH to assess the request and determine the appropriate supply strategy for the study.