

When submitting a new study proposal to ViiV Healthcare (VH) for Investigator Sponsored Research (ISR) studies, it is important to include a study budget that is detailed to support Fair Market Value (FMV) assessment of the requested funds. This will also help ensure that all items needed for the study are properly planned and resourced.

**FMV analysis is based on appropriate local market benchmark data for the medical procedures and clinical care outlined within the study proposal. All funding support must be consistent with and not exceed FMV for work performed and/or legitimate expenses. The FMV will be established on ViiV's behalf by a third party selected by ViiV.**

*Please note that the budget submitted may not be the final budget approved for support based on FMV analyses and the VH proposal review process.*

**All funding provided will be reported as “Transfer of Value” according to local requirements.**

## BUILDING A STUDY BUDGET

Please use the [ViiV ISR Budget Tool](#) to build your budget. Instructions on how to use the budget tool are included within the Budget Tool workbook. (The ViiV ISR Budget Tool is in the [Toolbox](#) section of the ViiV ISR Portal.)

### Key Principles

- Only include costs that are attributed to the conduct of this study.
- VH will not provide funding for line items that can be used for the conduct of other studies or for general research at your site. For example, electronic Trial Master File (eTMF) system, freezers, internet service, general office equipment, buildings, vehicles, etc.
- Each budget will be reviewed by VH and the FMV assessed based on its own merit according to type of study and study design.
  - **Investigator Sponsored Studies (ISS)** –VH assumes that the site has the infrastructure and capability to complete the study as proposed. The budget should reflect cost of study procedures (listed on a Time and Events (T&E) Table of protocol), personnel costs and study related site costs that are being requested as part of this proposal.
  - **Supported Collaborative Studies (SCS)** – VH assumes that the site has the infrastructure and capability to complete the study as proposed in collaboration with VH. The budget should reflect cost of study procedures (listed on a T&E Table of protocol), personnel costs and study related site costs that are being requested as part of this proposal. VH *may* also cover costs for items that have been requested by VH and/or are required for this collaboration.
- Previous support of a budget line item does not automatically guarantee support on subsequent study proposals.
- VH does not pay for public presentations of the study data/results (e.g., travel, hotel, conference fees, etc.).
- VH will only make payments to the Sponsor and not directly to sites or third parties, unless specifically authorized in the legal agreement.

# Budget Workbook

The Budget Workbook is an Excel application that facilitates the collection of budget information in a way that will facilitate the review by VH and the FMV analysis.

## **Instruction Tab**

The instruction tab will provide high level instructions about the use of the workbook and is for reference only. No information should be entered on this worksheet.

## **Study Information Tab**

This tab provides the basic information about your proposal. Provide all the information as it is applicable to your proposal. (Note: There will be an "N/A" option available to indicate if the answer to the question is not applicable.)

## **Planned Costs Tab**

### **Currency (For FMV Analysis)**

Select one of the 5 types of currency listed on the drop down (US Dollars, British Pounds, Euros, Australian dollars and Japanese Yen), to simplify the review and FMV analysis. If your proposal is approved, your legal agreement will reflect the correct country currency.

### **Currency (For Contract Payments)**

Indicate the currency that you will need your contract payments listed in. VH will contact you during the review process if there is a potential issue with the currency type you provide for the contract. If your proposal is approved, your contract (legal agreement) will reflect the correct country currency.

### **Countries Involved in the Study**

Include all countries that will be participating in the study, including the Sponsor Country (if Sponsor Country will not have Subjects or Sites, please enter "0" in the % Subjects and # Sites). There is an "optional" site name column that can be used to designate a site within the country that may have a different overhead rate.

### **Overhead**

Your site may require overhead fees be included in support of your study. If sites within the same country have different overhead rates, use the "Site" identifier column. Overhead percentage is an indirect cost that may be charged in addition to patient-related procedures (e.g., medical procedures (e.g., x-ray), non-medical procedures (e.g., obtaining informed consent)), and personnel costs (e.g. physician time, nurse time, study coordinator time). The cost often covers indirect services such as heating, lighting, internet services, and use of general office equipment and administrative functions (these details do not need to be itemized; the overhead percentage rate is all that is needed).

**Any rate requested above 25% will require additional information.**

### **% of Subjects**

Provide the planned % of Subjects that will be enrolled in each country. This estimate will be used in the FMV analysis. Additionally, the workbook will auto calculate a balanced overhead based on planned patient distribution for procedures if no specific country is identified.

## **Number of Sites**

Provide the number of sites planned in each country. This estimate will be used in the FMV analysis.

## **Personnel Costs**

Identify the type of personnel costs requested for this proposal using the Selection list in the budget tool to pick an appropriate description.

The costs can be provided as an hourly or annual salary rate.

If you are unable to locate the appropriate staff member Description provided list, you may add your own description in the budget tool. Please provide supporting information such as title, education level/degrees and years of experience to help VH understand the staff description correctly.

**Do not** include fringe benefits costs in the hourly or salary rates. VH **will not** cover these costs.

Fringe benefits include, but are not limited to:

- Medical Insurance
- Disability Insurance
- Health Savings Accounts (HSA)
- Malpractice Insurance
- Education Tuition Assistance
- Vacation / Holiday Time
- Commuter benefits
- Any benefits provided by the employer to the employee

The country specific overhead rate will apply to each staff member line using the country overhead rate entered in the budget tool.

## **Protocol Procedure Costs**

Provide the procedures and costs requested for this proposal using the Selection list in the budget tool.

If you are unable to locate the procedure in the Description list, you will be provided a section to add your own procedure description. Please provide sufficient detail about the procedure, including name, time to complete, supplies needed and any other information that will clarify your request and support the appropriate FMV analysis.

### **Tips for completing this section:**

Only include procedures that pertain to the patient, assay, sample or chart in this section. Do not include personnel time or data entry time, this should be included on the Personnel Cost section of the budget.

Break down the procedures in as much detail as possible using the Selection list in the budget tool.

The quantity should be the number of times the procedure will be executed for the entire study. *Examples: (a) If a questionnaire will be used for all patients as part of screening and then again for all enrolled patients at the end of the study, the quantity will be the number of planned screened patients + the number of planned enrolled patients. (b) If a test will be completed at each visit then the quantity will be the number of planned enrolled patients X number of visits.*

For the Country information – If a procedure will only be used in 1 country then the overhead rate for that country will be applied to the cost. If the test is not unique to one country than the overhead will be calculated by splitting and applying the % of subjects in each country with subjects to calculate the blended overhead.

**For *Interventional studies*** it is best practice to use the T&E Table from the protocol or study plan to complete this section.

**For *non-interventional studies*** such as retrospective chart reviews it is best practice to list procedures that are completed on each chart review (for example: Informed Consent, Chart Review)

The country specific overhead rate will apply to each procedure line using the country overhead rate entered in the budget tool.

The pro-rated per patient amount will be calculated automatically for inclusion in the legal agreement.

### **Site Costs**

This category includes a list of site costs/other direct costs. Include item description from Selection List, quantity expected for each item for the entire study.

If you are unable to locate the site cost item in the Description list, you will be provided a section to add this site cost in the budget tool. Please provide the as much detail as possible about the site cost, including name, time to complete, supplies needed and any other information that will clarify your request and help support the review and FMV Analysis.

Examples of Items that are classified as site costs, may be, but are 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
- Pharmacy Fees (Set-Up Costs, storage, etc.)
- IRB / EC Costs (initial and renewals)
- Site Start-Up Costs
- Translations
- Shipping
- Archiving Fees
- Drug Management (labeling and distribution-Outsourced)
- Study Monitoring (Outsourced)

If any of the Site Costs are being outsourced to a Third Party, you must obtain and provide a copy of the detailed quote along with the budget tool.

### **Additional site cost guidance**

- If study drug labelling is required, any cost required to conduct this, whether performed by the Sponsor or a third party, should be included in the budget.
- Cost of essential study conduct-related activities (e.g., Trial Steering Committee, site monitoring, IDMC)
- Patient reimbursement for visits should be included as a "Site Cost". This cost will not have overhead rates applied.
- The cost for the following types of activities should be captured in Personnel Costs, based on the time that will be needed to conduct these activities rather than including as a Site Cost.
  - Protocol Writing
  - CRF Development
  - Data Management
  - Statistical Plan Development
  - Manuscript Writing
  - Contract Preparation and Negotiation
  - Preparation of Conference Materials
  - Study Monitoring (by Sponsor)