ViiV Supported Collaborative Study (SCS) Proposal Template

|  |
| --- |
| * This template should be submitted as a component of a ViiV SCS Proposal application, via the [ViiV Investigator Sponsored Research (ISR) portal](https://iss.viivhealthcare.com). As you complete this template, please ensure that you take into consideration the guidance provided in each section, to facilitate the timely review of the study proposal. *As an alternative to using this proposal template, there is an option to submit a protocol along with a completed Supplementary Information Form to meet the ViiV SCS Proposal requirements*. * All proposals submitted to ViiV Healthcare are reviewed by a review committee comprising scientific and clinical experts, including statisticians, physician scientists, safety scientists, virologists, clinical pharmacologists, translational medicine scientists and others. * Please note that ViiV’s support of a study proposal is to address data gaps and therefore, it is the expectation that all studies will need to generate conference abstracts and at least one manuscript that includes the primary study outcomes for journal publication. If your study involves a ViiV medicine, then ViiV will be required by law to include such publications in periodic reports to the FDA, EMA and other regulatory authorities. ViiV is committed to fulfilling these regulatory reporting requirements in a timely manner consistent with the efficient and timely conduct and performance of a study. * ViiV, as development product owner and/or Marketing Authorisation Holder, has a responsibility to collect and analyse safety information on its Medicinal Products. This is so that the company can fully understand the risk-benefit profiles for its products and can provide accurate safety information to: study Investigators and participants; ethics committees; regulatory authorities; and prescribing physicians and their patients. As such, if your study involves a ViiV medicine, ViiV may provide requirements for safety reporting that will need to be included in the protocol as well as legal agreements, as outlined in the [linked document](https://viiv-portal.idea-point.com/Documents/ViiV%20ISR%20Safety%20Requirements.pdf). * When a proposal is approved, ViiV will require a draft protocol (and informed consent form for Interventional studies) for review prior to submission to ethics or institutional review board. For all studies, final study approval is subject to successful execution of a legal agreement between ViiV and the Sponsor. With the exception of non-clinical studies involving pure drug substance, please ensure that you and your contracts office review the general terms and conditions in the [linked document](https://viiv-portal.idea-point.com/Documents/ViiV%20ISR%20Term%20Sheet.pdf) BEFORE you submit this proposal. Failure to review and understand the requirements will result in unnecessary delays to starting research in a timely manner and may jeopardize the viability of the research project. |

TITLE of RESEARCH PROJECT

Provide a descriptive title for the topic your study addresses. Note: This title should align with the title entered on the ISR portal.

|  |
| --- |
| Add text |

STUDY BACKGROUND AND RATIONALE

Explain the significance of the proposed study. The rationale should also include relevant background information to support the proposed study (e.g., explain the setting and/or population of the proposed study and the importance of research within this setting and/or population).

|  |
| --- |
| Add text |

# RESEARCH QUESTION/INNOVATION

What is the critical research question that will be addressed by the proposed research? Explain what is innovative about your proposed approach for the current research proposal. You may include a brief review of any other studies completed (e.g., the strengths and limitations of the existing research). Please state the impact of your study if the results generated are as planned.

|  |
| --- |
| Add text |

FEASIBILITY

Describe the actions taken to ensure the feasibility of the current research proposal. Describe any preliminary data that demonstrates the feasibility and ability of successfully conducting the proposed research. Include any foreseen challenges and strategies to overcome these. Please describe what efforts will be made to facilitate the enrolment of representative participants into the study.

|  |
| --- |
| Add text |

STUDY DESIGN AND METHODS

Study Design (select more than one category if hybrid study – mark selections with an X)

|  |  |  |
| --- | --- | --- |
|  | Clinical Trial | |
|  | Pharmacology study (PK and/or PD) | |
|  | Implementation Science Study | |
|  | Health Outcomes | | |
|  | Clinical outcomes assessment/patient reported outcomes | | |
|  | Healthcare resource use/economic evaluation | | |
|  | Prospective Observational Study | |
|  | Retrospective Observational Study | |
|  | Methodology study | |
|  | Laboratory test/Technology development | |
|  | Translational Medicine study | |
|  | Meta-Analysis | |
|  | Other (specify below) | |

Describe and justify the type of study you are proposing. State whether the design is case-control, cohort, systematic review, meta-analysis, etc. and whether the participants are followed retrospectively or prospectively. Ensure any matching/control group is described in sufficient detail. Any comparison groups should also be described. This section must describe how the critical research question(s) posed will be answered. A schematic diagram of the study design may be added to improve clarity and understanding. Expand spacing as needed to ensure completeness of details.

|  |
| --- |
| Add text here |

Study Design Considerations:

1.Randomized Control Trials (RCTs): individual randomized trials, cluster randomized trials, stepped-wedged design, effectiveness-implementation hybrid design

2.Intervention optimization: multiphase optimization strategy (MOST), sequential multiple assignment randomized trial (SMART)

3.Quasi-experimental designs: interrupted time series, regression discontinuities, regression point displacement

4.Observational designs: cohort study, cross sectional, case-control

5.Systems science approaches: system dynamics, network analysis, agent-based modelling

6.Qualitative designs: longitudinal qualitative inquiry, in-depth interviews, focus-group discussions, observations

7.Mixed-method designs: use of both qualitative and quantitative methods and be used to inform measurement considerations and analysis rather than be proposed as a larger study design

8.Translational Medicine: laboratory assessments, statistical comparisons

Study Population

Inclusion/Exclusion Criteria: Please describe inclusion and exclusion criteria for applicable participants (e.g. patients, staff, clinics, or other unit of analysis). Describe any plans for enrolment of special patient populations in the study (e.g., women of childbearing potential, pediatric participants, or participants with renal or hepatic impairment). If using human biological samples, please provide details in the next section. Expand spacing as needed to ensure completeness of details.

|  |
| --- |
| Add text |

**Human Biological Samples (if applicable)**

If this research proposal involves the use of human biological samples, please describe in detail the types of samples that will be evaluated and how samples were collected (e.g. if they came from a clinical study). Explain the process for obtaining informed consent for use of the samples for this research, and the measures that will be taken to protect confidentiality and privacy of participants.

|  |
| --- |
| Add text |

Objectives and Endpoints

Please specify key objectives and corresponding endpoints. Include how each endpoint will be measured and at what timepoint(s) (e.g., for a health outcomes objective as indicated above, specify the patient reported outcome instrument or bespoke questions that will be used to measure the endpoint). Please delineate clinical versus implementation objectives/endpoints, as appropriate. If you consider that a co-primary endpoint is essential to your research, then please provide justification for this.

Primary

|  |  |
| --- | --- |
| Primary Objective 1 | Endpoint 1 |
| Add text | Add text |
| Primary Objective 2 (if essential) | Endpoint 2 |
| Add text | Add text |

Justification for co-primary objectives

|  |
| --- |
| Add text here |

Secondary

|  |  |
| --- | --- |
| Secondary Objective 1 | Endpoint 1 |
| Add text | Add text |
| Secondary Objective 2 | Endpoint 2 |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |
| Additional Objective | Additional Endpoint |
| Add text | Add text |

Exploratory, if applicable

|  |  |
| --- | --- |
| Exploratory Objective 1 | Endpoint 1 |
| Add text | Add text |
| Exploratory Objective 2 | Endpoint 2 |
| Add text | Add text |

Additional Details on Study Endpoints

Based on the listed endpoints in the above section, please provide further details as shown below:

| **Endpoints** | **Measurement Methods** | **Data Sources** | **Measurement Times** |
| --- | --- | --- | --- |
| **Clinical Outcomes** | |  | |
| *e.g. HIV-1 RNA* | *Real-time VL test* | *Clinic data* | *Baseline, Week 24, Week 48* |
| *e.g. Reason for drug discontinuation* | *Patient survey* | *EMR data* | *Time of drug discontinuation* |
|  |  |  |  |
|  |  |  |  |
| **Health Outcomes** | |  | |
| *e.g. Treatment satisfaction* | *HIV TSQ* | *Clinic data* | *Week 48* |
|  |  |  |  |
|  |  |  |  |
| **Implementation Outcomes** | |  | |
| *e.g. Acceptability* | *Acceptability Survey* | *Staff interview* | *Month 0, 6, 12* |
| **Laboratory Assessments** | |  | |
| *e.g. Serology* | *Antigen Elisa* | *Laboratory data* | *Day 0,7, etc* |
|  |  |  |  |
|  |  |  |  |

Additional Details on Interventions

Please provide further details on the following in your study design. Interviews, questionnaires, surveys, blood/urine samples and participant follow-up can be considered normal clinical practice, so long as the application of these is not conducted in a way that differs significantly from standard-of-care. Invasive procedures such as collecting biopsies or cerebral spinal fluid, or performing scans, x-rays or barium meals would have to be conducted as standard-of-care to be considered normal clinical practice.

|  |
| --- |
| **ViiV Healthcare (VH) Medication(s)**  *Specify the regimens, including drugs and doses (broken down by arms, if applicable), and specify the duration of treatment. Specify if VH medication(s) will be assigned to study participants per protocol, or if the decision to treat with VH medication(s) will be independent of study participation and in accordance with both standard of care and local prescribing information? OR if only generic versions of VH medication(s) will be used* |
| Add text |
| **Patient reported outcome measures.**  *Please specify if instruments planned for use are validated or not, if licenses are required, and if they are considered normal clinical practice for the study participants (see note at the top of this section)*. |
| Add text |
| **Other surveys or questionnaires** *List any other tools that will be used that are not considered normal clinical practice for the study participants (see note at the top of this section).* |
| Add text |
| **Exposure to ionising radiation**  *Will the proposed study involve ionising radiation exposure (e.g. X-rays, positron emission tomography [PET], dual-energy X-ray absorptiometry [DEXA], or computed tomography [CT] scans)? Please specify if these are considered normal clinical practice for the study participants (these would have to be conducted as standard-of-care to be considered normal clinical practice).* |
| Add text |
| **Biological tests and/or diagnostic procedures**  *List clinical & biomarker measures and/or diagnostic procedures that are not considered normal clinical practice for the study participants (see note at the top of this section).* |
| Add text |

|  |
| --- |
| **Detailed Implementation Science Strategies and Frameworks**  *Please refer to the linked* [*Implementation Science guidance*](https://viiv-portal.idea-point.com/Documents/Implementation%20Science%20Proposal%20Guidance.pdf) *document for more details to describe the implementation strategies, the frameworks, and research methods planned.* |
| Add text |

Measures to Safeguard Study Participants

Please describe considerations for the management of participant safety in your study:

|  |
| --- |
| In terms of potential impact of the study and/or the investigational medical products on participant safety, what, if any, specific risk/toxicity monitoring and mitigation strategies would need to be incorporated into the design for the study and communicated to participants and investigators? Please list specific inclusion/exclusion criteria; monitoring strategies; toxicity management guidance; stopping/withdrawal criteria. If this is considered not applicable for this study, then please provide justification (for example, if this is considered a non-interventional/observational study; this would be aligned with treatment guidelines or prescribing information). |
| Add text |
| If women of childbearing potential become pregnant on study, will they be allowed to remain on the study medications? If this is considered not applicable for this study, then please provide justification (for example, women of childbearing potential will not be able to participate in this study). |
| Yes/No |
| If no, what recommendations will be given per protocol to prevent women of childbearing potential from becoming pregnant? For example, what contraception/birth control guidance will be given to study participants; how often will women be tested for pregnancy during the study? If this is considered not applicable for this study, then please provide justification (for example, if this is considered a retrospective non-interventional/observational study involving secondary data collection) |
| Add text |

# STATISTICAL PLAN

Hypothesis

Provide a description of the hypothesis that you will be testing in this study, if applicable.

|  |
| --- |
| Add text |

Sample Size and Statistical Power Considerations

You are encouraged to seek statistical advice, as needed, as you write this section, to help ensure the most robust proposal. Sample size justification is required. Provide the target sample size for the primary objective. Please describe each assumption made for the sample size calculation: in particular, variability estimates, and the definition of clinically relevant difference. If the sample size is not powered for the primary endpoint, you are expected to consider an estimation approach and will need to describe the anticipated precision of estimates for the confidence interval generated from the study. You may include a table indicating sample sizes or power for a range of outcomes to assess study sensitivity. Expand spacing as required to provide robust details.

|  |
| --- |
| Add text |

Description of Statistical Analyses

Describe statistical analyses planned for the primary endpoints and key secondary endpoints. Please include details of any covariates you propose to adjust for in the analysis. You are encouraged to seek statistical advice as needed as you write this section to help ensure the most robust proposal.

|  |
| --- |
| Add text |

Data Monitoring Committee

Will an Independent Data Monitoring Committee (IDMC), Data Safety Monitoring Board (DSMB), or an equivalent committee such as a Safety Monitoring Committee or Steering Committee be established for this study?

|  |
| --- |
| Add text |

Study Timelines

Please provide details of timings for achieving key milestones in study (e.g., proposed start date, enrolment duration, data collection timepoints, study end date). If your proposal is approved by ViiV, please note that a legal agreement will need to be in place before the study can begin and funding is paid to the institution. Please factor no more than 6 months to execute the study agreement in your study timelines. Please be sure to communicate to your contracts office that proposals which fails to achieve a fully executed agreement by 6 months after approval may be subject to further re-evaluation of support and may be at risk of defunding depending on strategic priorities. Below is the minimum expected planned milestones. Please add any additional milestones at your discretion.

|  |  |
| --- | --- |
| Milestone | Planned Date6 |
| EC/IRB Submission (This can be actual date if already approved) (N/A for non-clinical studies) |  |
| EC/IRB Approval1 (This can be actual date if already approved) (N/A for non-clinical studies) |  |
| Study Start Date2 |  |
| Enrolment Complete |  |
| Primary Completion3 |  |
| Study End4 |  |
| Report Complete5 |  |

1. Approval = Date of Final Protocol or Final Analysis Plan approved by 1st ethics committee (EC)/IRB or equivalent Sponsor approval committee
2. Start Date = First Participant First Screening Visit (or Data Collection Starts for studies where no participants will be recruited)
3. Primary Completion = Date on which data collection is completed for all the primary outcomes. This date may occur prior to Study End (SE) milestone or be the same date as the Study End milestone.
4. Study End = Last Participant Last Visit (or Data Collection Ends for studies where no participants will be recruited)
5. Report Complete = Date of Submission of Primary Manuscript or Study Results Summary (as defined in Contract)
6. Planned Date = Date the milestone is planned to be completed

Data Dissemination and Publication/Presentation Plan

Include an overview of the data dissemination and publication/presentation plan.

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Data/Endpoint/Interim or Final | Abstract or Manuscript | Target Conference or Journal | Estimated Submission (Quarter/Year) |
| E.g. Interim 24-week clinical & safety data  E.g. Baseline characteristics of cohort | Abstract  Manuscript | EACS 2025  AIDS Patient Care | 2Q2025  3Q2024 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

References

List no more than 10 key references relevant to your research

|  |
| --- |
| Add text here |