



GSK Investigator-sponsored studies programme

Submit a proposal

Notification for all users:

For HIV-specific proposals, please contact your ViiV Healthcare representative.

Thank you for your interest in the GSK investigator sponsored studies (ISS) programme. To ensure a timely review of your proposal, there are two steps that must be completed. Step one is to complete the form below. This will take you to step two which involves either submitting your own protocol file or completing the provided proposal template. At any point, if you need to leave the system before completing your submission, simply click the “Save” button on the bottom of the page. The proposal will be saved into your account and you can complete it later. Once your submission is complete, you will receive a confirmation e-mail from the system letting you know that your submission was successful.

Study title:

Are you the principal investigator of this study? <input type="text" value="▼"/>
Medical / Healthcare Professional Certification Are you registered to practice and prescribe medicines? <input type="text" value="▼"/>
Conflict of Interest check

Employment and Other interests

In order to ensure that there is no conflict of interest, please provide details of all current positions, appointments and interests:

Primary Job
title and
Employer:

Other
Appointments:

Business
interests:

Please note: If you have responded YES to any of the questions below, please provide appropriate details in the section to the right, indicating whether you are involved or an immediate family member.

Are you or an immediate family member:

A temporary or permanent government employee or official (other than acting solely in the capacity of a healthcare profession prescribing or administering medicines, conducting clinical trials or scientific research)?

A member of any advisory board to a government?

A member of a formulary committee, or responsible for purchasing decisions for Government hospitals or other state-owned bodies, or responsible for allocating or

influencing expenditures of government funds?

Responsible for performing regulatory inspections, or granting government authorisations or licenses?

Do you or an immediate family member:

Have ownership of any entity that provides services or products to GSK?

Have an ownership control interest in any healthcare entity that has business with government (excluding interests of less than 0.1% in publicly traded companies and excluding interests of less than £3,000 in value)?

Do you have other key personnel to support the study?

Please indicate which GSK business area you would like this to be directed:

Study type:

Are there any other GSK assets tied to this proposal?

Do you know the name of your local Medical contact (e.g. MSL, others)?

In which countries will the study research take place?

Please check if multiple

Is the GSK asset(s) defined above being requested as part of this proposal?

Is monetary support requested (Not to include the GSK product support above)?

Is other support requested?

Is this study funded or supported by, or under consideration for funding or support, from another agency or sponsor?

Study milestones & metrics (best estimates at this time)

Is your proposal a human research study that evaluates a product?

Registration of the protocol summary and results on a public register to meet legal requirements is mandatory. Please note that the first payment milestone and/or provision of supplies (as appropriate) and last payment milestone (as appropriate) will be linked to compliance with this public disclosure requirement.

What is the name of the public register?

The summary protocol

The results summary (this date should be within the regulatory required timeline that is no later than 12 months of primary completion or for retrospective studies within 12 months of analysis completion).

****Primary completion is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.***

Target enrollment/sample size: (required for clinical studies)

e.g., 100

Anticipated rate of enrollment: (required for clinical studies)

e.g., 10 patients per month

Estimated study start date: (FSFV)

Estimated study completion date: (LSLV/analysis complete)

What is your planned publication? (check all that apply)

- Abstract
- Manuscript
- Study report
- Other