# User guidance – Supported Studies Programme Information

## What is needed for submission?

1. Create a user profile
2. Completed the online webform, both the submission and the files to be attached (CV, itemised budget template if required)

For additional guidance on how to do this and screenshots, please download the guidance document named "Submitting a Proposal"

## What happens after submission?

- After submission you will receive an automatic notification from the system via e-mail confirming your proposal has been submitted successfully
- You may be contacted if GSK requires further information
- GSK will review and get back to you on whether the proposal is of interest within 8 weeks of the closure of the submission cycle. For detail on the submission and review dates, please refer to the relevant GSK disease area page
- Please note, proposal being of interest is an initial response and the final decision of GSK to provide support is subject to, among other things, agreement of the final protocol and signature of the legal agreement
- You will receive an email to confirm whether the proposal is of interest. The status of your proposal submissions can be viewed at any time be available via logging in to "My proposals"

## How does GSK assess whether a proposal is of interest?

The decision as to whether a proposal is of interest is based on:

- The importance and innovation of the research objectives to medical science or patient care
- Alignment with GSK's current areas of interest
- The ability of the study Sponsor to deliver a high-quality ethical study
- Assessment of the resource request matched against what GSK has available

Although GSK is more likely to support studies aligned to our current areas of interest for supported studies, we are interested in supporting studies that are innovative and contribute to scientific knowledge relating to a medicine, a medical condition or advancing a technology that supports human subject research. Full approval of the support is dependent

upon agreement of the protocol and signature of the legal agreement.

## What response will I receive?

We may get back to you in advance of this to request further information ahead of review. Once we have all the necessary information, we will review the proposal submissions as per the timelines detailed in the disease area pages.
GSK commits that you will receive a response within 8 weeks of submission period close date, indicating either the Proposal is of interest, or it is not at this time. Proposal of interest is initial interest subject to development of the full protocol, and signature of the legal agreement.

## Is there an opportunity to collaborate on a study?

Supported Studies are research conducted by an external Sponsor with GSK's support. There are two different ways GSK can provide support:

- **Investigator Sponsored Studies** are entirely designed and managed by an external Sponsor. GSK can support in the form of funding, product (including GSK products, adjuvant for vaccines, placebo, or other medicinal products necessary for the research) or both. These studies are also known as Investigator-Initiated Studies, Investigator-Initiated-Trials, Investigator Initiated Research or Investigator Sponsored Research.
- **Supported Collaborative Studies** are conducted by an external Sponsor, with GSK contributing to study design and deliverables, in addition to the provision of funds and /or medicines.

In both 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 submit a SCS proposal and detail the additional support/capability requested beyond ISS support.

## What happens next if I hear back that the Proposal is of interest?

- We will ask you to produce the first draft of the full protocol within 5 weeks. Depending on the complexity of the protocol and agreement with GSK this deadline can be increased
- We will then progress to drafting and finalization of the legal agreement. GSK has a template legal agreement that will be tailored with you to reflect the specific support being provided and expectations of both parties. Final approval to support a study is when the full protocol is accepted and the legal agreement is signed
- Upon finalisation of the legal agreement and GSK requirements checks the study will then start
- Throughout the life of the study, the Sponsor is required to provide study progress reports and documentation as per the legal agreement

- Once the study is complete, the Sponsor is required to provide the final deliverables/publication as detailed in the legal agreement

## What are the responsibilities of the Sponsor?

- Produce the Proposal, completing all sections as per the forms on this site
- Produce the Protocol
- Conduct high quality ethical study
- Develop and maintain the case report forms
- Initiate and monitor the study
- Understand and comply with any and all pertinent laws, regulations, and guidelines
- Understand and comply with any and all requirements of the institution(s) with which they are associated or at which research will occur
- Meet applicable deadlines and all other requirements as defined in the legal agreement
- Report safety data to regulatory authorities, the IRB/IEC (institutional review board, also known as an independent ethics committee), and GSK as defined in the legal agreement
- Provide updates on study progress to GSK as defined in the legal agreement
- Disclose any affiliation or financial conflicts of interest
- Provide a Public Disclosure Plan (PDP) as requested in the submission form including details around publications and postings to a worldwide public register for all human subject research

Any failure by the Sponsor to meet the above commitments may result in a decision by GSK to cease supporting a Proposal, and GSK would not support any subsequent proposals submitted by the Sponsor.

## What should the Sponsor expect of GSK?

- Review Proposals received and communicate within 8 weeks of the close of the submission window whether the Proposal is of interest or not at this time
- Provide a template for the legal agreement
- Provide approved support as outlined in the legal agreement in a timely manner
- Provide any scientific/medical feedback to the Sponsor at any point in time regarding the proposal, the Protocol, or any aspect of the study where GSK has a concern about the scientific integrity of the study or patient well-being
- Timely responses to any inquiries or requests coming from the Sponsor, including decisions on completed Proposals
- Compliance with all applicable laws and regulations, including data protection laws with respect to the personal information of the sponsors/investigators

Relevant form links:

Data Privacy

Cookie Policy