How to apply for ISS/SCS support and what information is required as part of the submission?

1. GSK reviews proposals received at set points throughout the year. Check the disease area associated to your proposal for submission period as well as for GSK's Areas of Interest
2. Create a user profile (to complete your registration, a validation of your email address will be required)
3. Submit your study proposal by completing the online submission webform. You can access your submission at any time, however, once submitted, you cannot make any changes in the system.
4. You will be required to provide your CV and a detailed budget template, in case funding is requested as part of your submission.

What happens after submission?

- After submission, Sponsors receive an automatic e-mail notification from the system confirming that the proposal has been submitted successfully
- Sponsors may be contacted by a GSK representative (e.g. MSL) in case further information is required
- A GSK multidisciplinary group review all proposals and protocols submitted within each cycle
- GSK is committed to get back to all Sponsors on whether proposals are 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)
- The status of your proposal submissions can be viewed at any time be available via logging in to "My proposals"

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 (if applicable) and signature of the legal agreement

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?

GSK may get back to you before a decision is made in case GSK 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 an initial assessment and it is not a guarantee that studies will be supported. For proposals of interest, GSK progresses to the next stage of evaluation, including development of the full protocol, fair market value assessment, and finalization 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 include any additional support/capability required as part of your submission.

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 legal agreement template 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?

Supported Studies are conducted independent of GSK. 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. Responsibilities of the Sponsor include:

- Develop the study concept/ proposal
- Submit research proposal via the system, by completing all mandatory sections as per the forms on this site

- 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
- 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

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:

i. FDA Forms
ii. US W-9 tax form
iii. US W-9 Tax form instructions
iv. Federation of State Medical Boards – Medical Licensure Information
v. OIG Exclusions Database
vi. FDA Debarment list
vii. FDA Disqualified/Totally Restricted List for Clinical Investigators
viii. PHS Administrative Action Bulletin Board
ix. ENCePP Checklist For Study Protocols
x. *Curriculum Vitae* (CV) Template

Data Privacy

- Privacy

Cookie Policy

- Privacy