User guidance

What is needed for submission?

1) Create profile
2) Completed online Proposal Part I forms. Please complete all sections prior to submission
3) Completed Proposal Part II (as an attachment) together with:
   a) CV (and medical license for USA only)
   b) Itemised budget template
   c) Protocol if available
   d) Drug supply required (if required) and lab request

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. The proposal being of interest is an initial response and is subject to agreement of the final protocol and contract in line with the Proposal, and GSK's requirements checks such as ABAC (Anti-Bribery and Anti-Corruption) and Fair Market Value (whether the funding request is in line with market rates)
- The status of your proposal will be available on "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, and
- the ability of the study Sponsor to deliver a high-quality ethical study
- assessment of the resource request matched against what GSK has available (supplies or funding) – this ensures we only progress to final protocol if we have the resources requested

Full approval of the support is dependent upon agreement of the protocol and a contract. Although GSK are 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 product, a medical condition or advancing a technology that supports human subject research.

What response will I receive?

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. We may get back to you in advance of this to request further information. The Proposal being of interest is subject to agreement of the final protocol and contract in line with the Proposal, and GSK's requirements checks such as ABAC (Anti-Bribery and Anti-Corruption) and Fair Market Value (whether the funding request is in line with market rates)

Is there an opportunity to collaborate on a study?

In limited circumstances we may want to collaborate scientifically with the study Sponsor. If GSK is interested in collaborating, we will contact you following submission in order to discuss this.

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

- We will ask you to produce the full protocol for review
- We will then progress to contract drafting and agreement. GSK have a template which 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 and contract is agreed
- Upon finalisation of the contract 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 contractual agreement
- Once the study is complete, the Sponsor is required to provide the final deliverables/publication as detailed in the contractual 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
- 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 not to support the current 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 support contractual 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 regulations, including data protection laws with respect to the personally identifiable information of the sponsors/investigators

Relevant form links:

- FDA Forms – For US
- US W-9 Tax form – For US
- US W-9 Tax form instructions – For US
- ENCePP Checklist - For Pharmacoepidemiology and Pharmacovigilance Study Protocols
- How to create an Account - ClinicalTrials.gov – Required for Public Disclosure. Public Disclosure plan is required for Part I form
- Create a EudraCT Number – For European Clinical Trials – GSK will ensure this is completed ahead of study start