GSK Supported Studies Programme

User Guidance – Submitting a Proposal

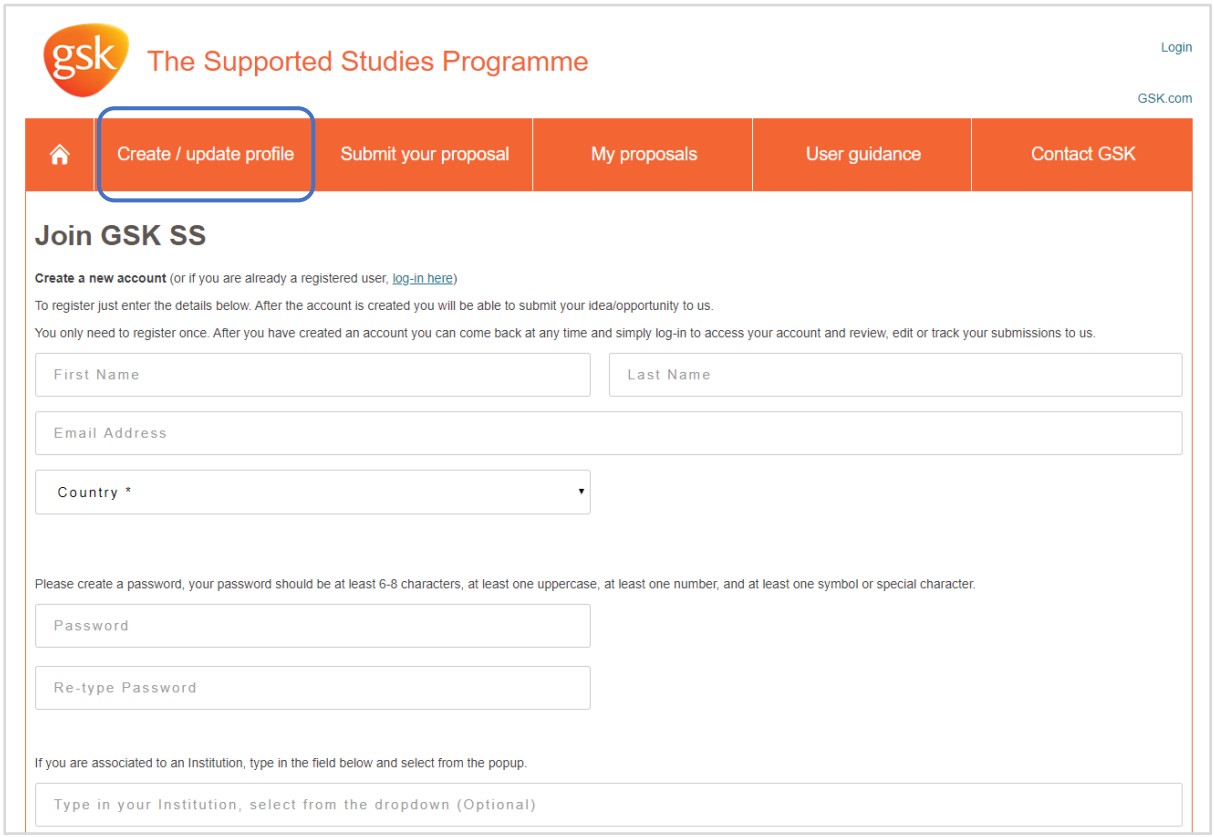
Dear Sponsor-Investigator,

Thank you for your interest in the GSK Supported Studies Programme. This document acts as a quick reference guide to support you to submit a Proposal for consideration by GSK. For information on the programme itself, and the dates of review, please visit the portal https://iss.gsk.com/

Creating a Profile- This is the first step before submitting your proposal.

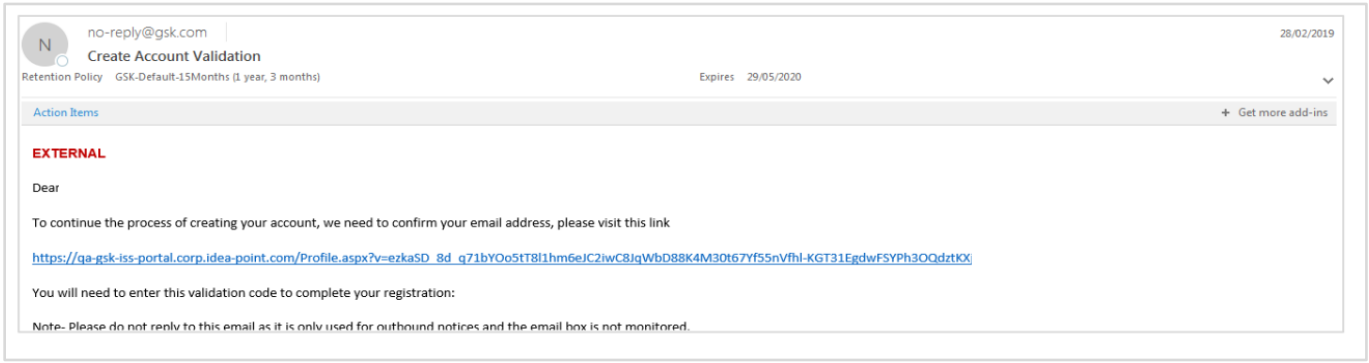
Step 1 : Click on the "Create / Update Profile" banner on the portal. You will be asked to complete some basic details and set up a login.

Step 2 : Create a password - your password should be between 6-8 characters which must include at least, one uppercase, one number, and one symbol or special character.



Step 3 : Validate your email address - Once the profile has been created, you will receive an email to validate your email address. Follow the link and enter your validation code to complete registration (check your junk or spam in case email is not received).

Once your email address is validated, you will now be able to submit your proposal. Below is the sample of a validation email.



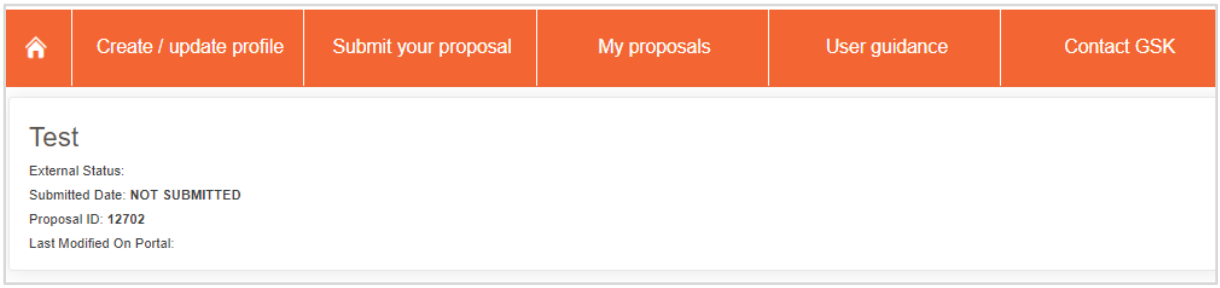
Submitting a proposal

GSK has set up a web form with guidance so that proposal submission process is as easy as possible. This has a series of mandatory and optional fields based on the nature of your study. The proposal form can be saved and revisited at any time. Once the proposal is submitted, it cannot be changed.

Step 1 : Click on the **'Submit your proposal'** button on the Supported Studies portal page to go to the Proposal Web form.

Step 2 : Enter the Title of your study and agree to the attestation statement

Following the attestation statement, the proposal form will appear with the fields to complete with definitions and guidance.



Important: In order for GSK to complete the timely and accurate review of your proposal, you need to provide the following minimum information on your proposal, either by fill in this template or by providing any other available proposal document or protocol. Please complete the information as it applies to your proposal. Use "Not Applicable" where the requested information does not apply to your proposal.

Please note you can save your proposal at any time.

Sponsor Information *Sponsor: This is the external entity (e.g., external investigator, healthcare institution, medical network, academic research organisation) who is accountable for all aspects of the study, including compliance with all applicable ethical codes, laws and regulations that governs the research to be conducted, regardless of whether GSK is fully or partially funding the study.*

* **Is the sponsor an individual or an institution?**
○ Individual ○ Institution

* **Name of the Sponsor:**

* **Sponsor Address:**

* **Country:**

* **Sponsor email address:**

* **Sponsor phone number:**

* **Is the main study contact different from the Sponsor?**
○ Yes ○ No

Do you have other key personnel participating in the study?
○ Yes ○ No

Have you been in contact with any GSK employees with regards to this submission?
○ Yes ○ No

How did you hear about the GSK Supported Studies Program?
○ Congress ○ Website
○ GSK Medical Contact ○ Other
○ Medical Journal

Support Requested

GSK does not provide support for sponsor pay, incentive to join the study

* **In which countries will the study research take place?**

☐ Please check if multiple

Is monetary support requested?

If monetary support is requested, please ensure you have attached your completed funding request. If helpful, a budget template is provided on the external portal here: **Budget Template**

◯ Yes ◯ No

* **Supported Study type:**

Select one...

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

Public Disclosure Plan

* **Is your proposal classified as Human Subject Research?**

Human Subject Research applies to research that uses human individual data or human biological materials to evaluate use of a product or a technology in, or by, humans, or to answer a human health-related scientific question

◯ Yes ◯ No

* **Is your Human Subject Research a proposal that evaluates a product?**

This is for all products (not only GSK product)

◯ Yes ◯ No

What is the name of the public register you intend to disclose your summary protocol and summary result?

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.

Is a GSK product(s)/material(s) being requested as part of this proposal?

◯ Yes ◯ No

Any other type of support requested?

◯ Yes ◯ No

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

◯ Yes ◯ No

Publication

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

☐ Abstract
☐ Manuscript
☐ Poster
☐ Slides
☐ Study report
☐ Other

Please specify your publication plans for the proposed research, including, but not limited to: type of publication, journal, congress, and timeline:

Scientific Context

The required fields below outlining the scientific context of your proposal is required for GSK to make an assessment of your proposal, guidance on GSK requirements for these sections can be found in the User Guidance of the Submission Portal.
You can also submit your Scientific context as an attachment in the Files tabs on top of this page, please do however indicate N/A in the question boxes below.

*** Scientific Rationale**

Provide a brief summary of the overall purpose and rationale for this proposed study and/or summary of any relevant background information.

*** Hypothesis**

Provide a description of the research question(s) or hypothesis (if applicable) that you will be answering or testing in this study

*** Objectives (or Research Questions)**

Provide a description of the key Study Objective(s)

Does your proposal involve Children in Care?

○ Yes ○ No

Children in Care (CiC) are children who have been placed under that control or protection of an agency, organisation, institution or entity by the courts, the government or a government body, acting in accordance with powers conferred on them by law or regulation. The definition of CiC can include children cared for by foster parents or living in a care home or institution, provided that the arrangement falls within the definition above. The definition of CiC does not include a child who is adopted or has appointed legal guardian.

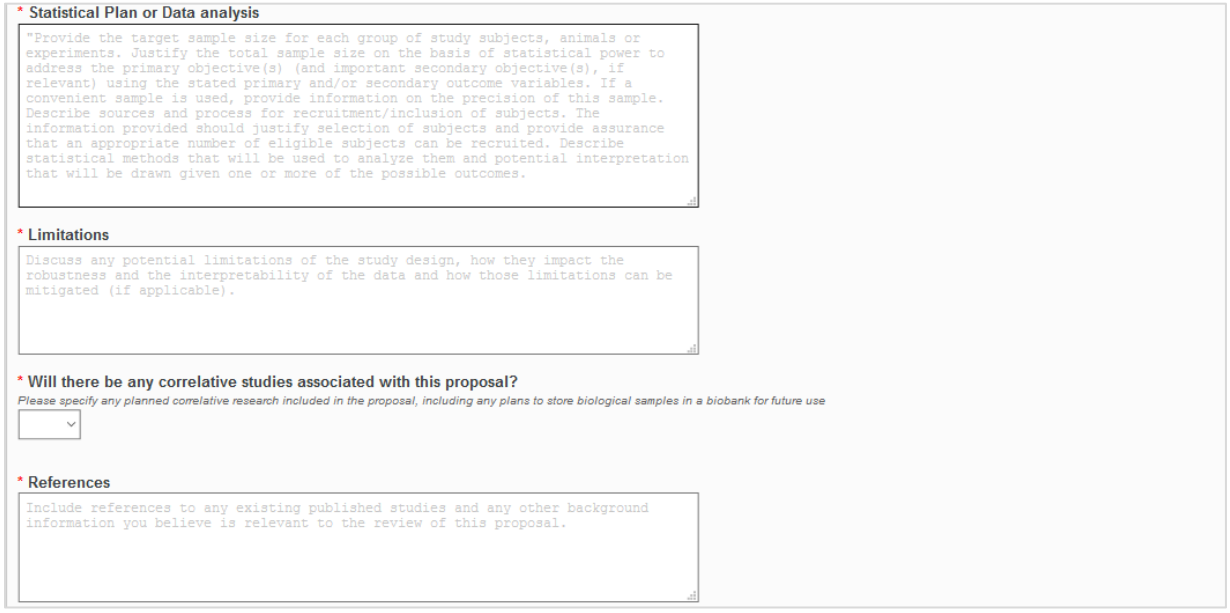
*** Inclusion Criteria**

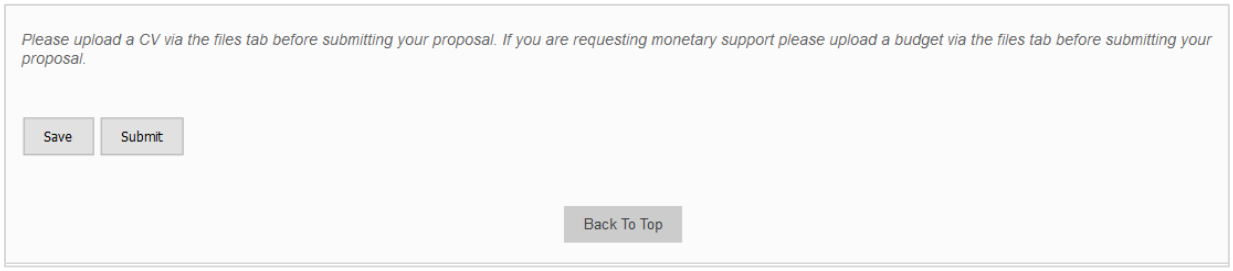
*** Exclusion Criteria**

*** Study Population**

Provide a general description of the study population (e.g. number of subjects, subject demographics such as age, sex, and other key characteristics) and specify whether the study is expecting to include Children in Care* If the proposed interventional study population includes Children in Care*, provide a justification for the enrolment, including: evidence that the benefits outweigh the risks, the scientific and/or medical question is relevant to children and any reasons why excluding children from the study is unethical.


* Number of Sites
* Target enrolment/sample size: (Required for clinical studies)
e.g., 100
* Anticipated rate of enrolment: (Required for clinical studies)
e.g., 10
patients per month
* Estimated study start date: (FSFV/Study Start/Analysis Start)
Planned Study Start Date must be a minimum of 6 months after submission close date
* Estimated study completion date: (LSLV/Study End/Analysis Complete)
* Study Design and Methods
Describe the general study design, study groups/arms, main tests or procedures. For preclinical studies include a description of the experimental model(s) and supporting rationale for their use
* Study Endpoints
Describe the primary and important secondary outcome variables that will be used in the primary analysis and any important secondary analyses


* Statistical Plan or Data analysis
"Provide the target sample size for each group of study subjects, animals or experiments. Justify the total sample size on the basis of statistical power to address the primary objective(s) (and important secondary objective(s), if relevant) using the stated primary and/or secondary outcome variables. If a convenient sample is used, provide information on the precision of this sample. Describe sources and process for recruitment/inclusion of subjects. The information provided should justify selection of subjects and provide assurance that an appropriate number of eligible subjects can be recruited. Describe statistical methods that will be used to analyze them and potential interpretation that will be drawn given one or more of the possible outcomes.
* Limitations
Discuss any potential limitations of the study design, how they impact the robustness and the interpretability of the data and how those limitations can be mitigated (if applicable).
* Will there be any correlative studies associated with this proposal?
Please specify any planned correlative research included in the proposal, including any plans to store biological samples in a biobank for future use
* References
Include references to any existing published studies and any other background information you believe is relevant to the review of this proposal.


Please upload a CV via the files tab before submitting your proposal. If you are requesting monetary support please upload a budget via the files tab before submitting your proposal.
Save
Submit
Back To Top

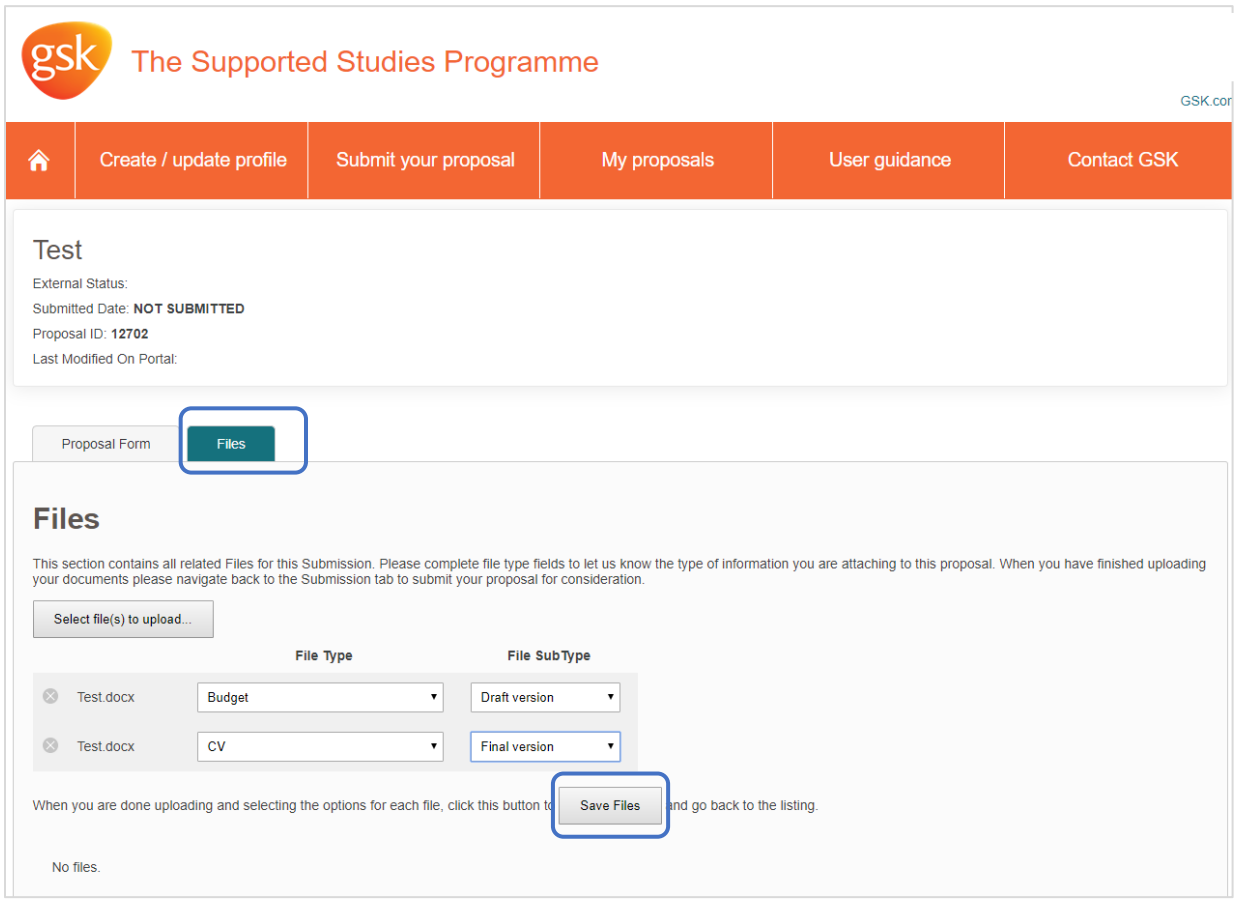
Uploading documentation as part of your submission

Please upload your CV via the “Files” tab before submitting your proposal.

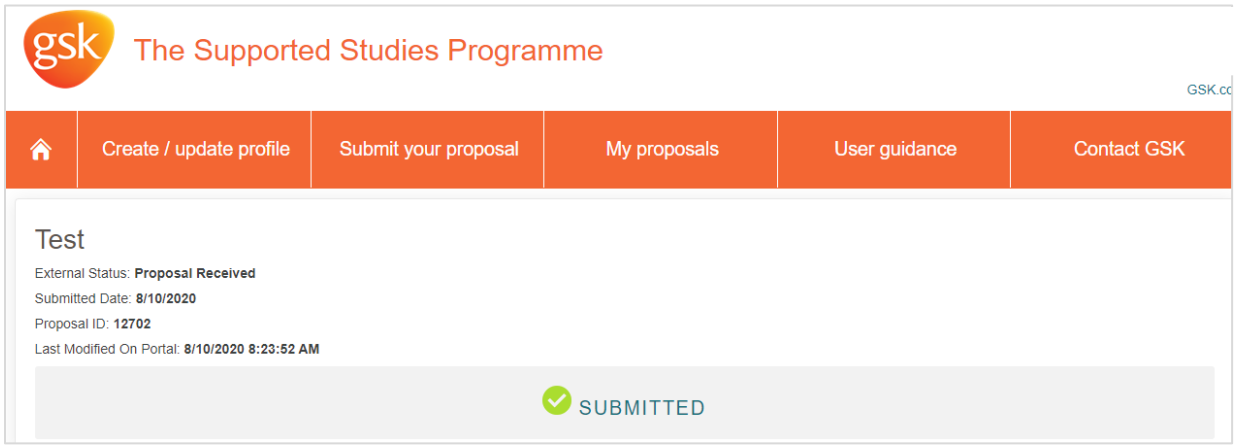
If you are requesting monetary support, please also upload a budget breakdown.

You can also attach any additional supporting documentation that you feel may be useful and relevant.

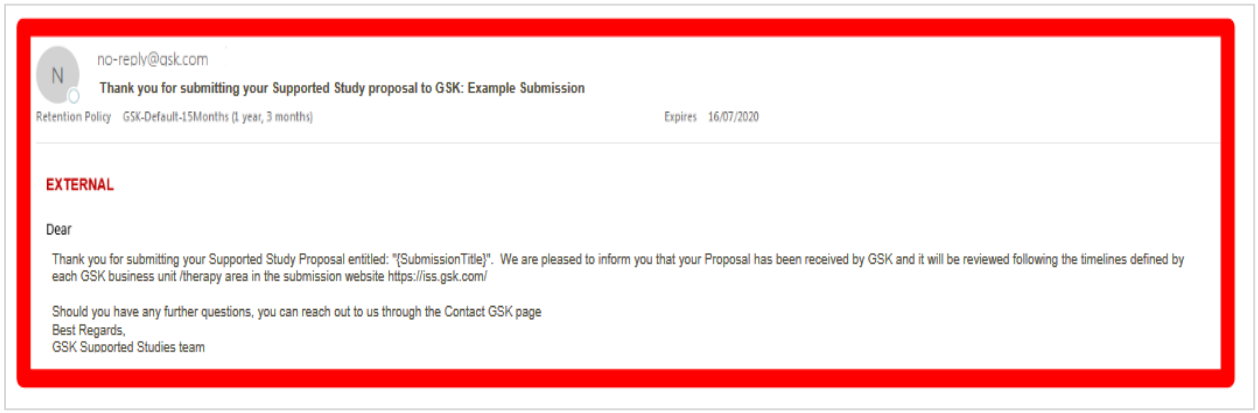
For each file, it will ask you the file type and the File SubType. Please complete all fields then hit ‘Save Files’



Once submitted, a banner will appear as below to confirm the proposal has been successfully submitted and provide you with the unique Submission ID number. The proposal as submitted will also display.



You will also receive an email from no-reply@gsk.com to confirm the proposal has been submitted successfully.



At any time, you can go to the “My Proposals” section to view your submitted proposals in the “Submitted” tab and your saved proposals in the “In Process / Editable” tab as below: