***Reference Name:**

Enter a name for your research proposal. This will be used to identify your research proposal on this site.

Please add a Reference Name before saving this proposal Save

Required fields are marked with an *

*Do you understand that access to data will only be provided in the secure data access system. SAS and "R" statistical software are provided and there are controls to prevent the original study datasets from being downloaded.

○ Yes ○ No

*Have you previously submitted or plan to submit an enquiry to add studies to this research proposal?

○ Yes ○ No

*Is this research proposal a re-submission of a previous research proposal that has been reviewed by the Independent Review Panel?

○ Yes ○ No

*Does your proposed research require Ethics Committee or Institutional Review Board (IRB) approval? (If No, please provide further details below).

○ Yes ○ No

Where required, Bayer require this approval before research proposals are sent to the Independent Review Panel. If your research proposal includes Bayer studies, you will be contacted and asked to provide a copy of the approval.

Following approval, access is provided after the relevant study sponsor or sponsors receive a signed Data Sharing Agreement. This agreement includes requirements for the research team to:

a. Only use the data for the agreed research purpose and not download or transfer the data for future use.
b. Protect the privacy and confidentiality of research participants; the researchers must not attempt to establish the individual identities of research participants.
c. Obtain any regulatory or ethics approvals necessary to conduct the analysis.
d. Inform the relevant sponsor(s) and regulatory authorities of any safety concerns as soon as they are identified.
e. Post a summary of the analysis plan prior to conducting the Analysis. Post summary results on a public register or website within one (1) year of completing the analysis and seek publication of the research in a peer reviewed journal.
f. Include in the publication a description of the strengths and weaknesses of the analysis and a citation or a register identification number to the original studies.
g. Provide the relevant sponsor(s) with a copy of any public disclosure of the results, including a copy of the manuscript. (Some sponsors include a provision for prior review of the manuscript and other sponsors require the manuscript after submission; refer to the terms specified in your actual Data Sharing Agreement.) Also provide the relevant sponsor(s) with the citation after publication.
h. Provide other researchers with additional details of the analysis on request.
i. Allow the relevant sponsor(s) to use any invention coming out of the research that impacts the ability of the sponsor to develop or commercialise their products. Such use will be free of charge and throughout the world. If the sponsor requests additional rights, you agree to negotiate in good faith with the sponsor.
j. Confirm that you do not have, and do not plan to have, any other agreements which would prevent you from complying with "i" above.

k. Meet any additional requirements identified by the Independent Review Panel.

Note this is a legal document and so may require legal review within your organisation prior to your signing.

The Data Sharing Agreement template is provided here. Your actual Data Sharing Agreement may have minor modifications. **Please note that the sponsors do not anticipate negotiation on the provisions in this template.**

☐ *I have read and understood these requirements. Where relevant I have provided the Data Sharing Agreement template to relevant legal staff at my institution.

☐ *I have read and accept the terms of the Privacy Website Statement. I also understand that if I, or any member of my research team, fail to comply with the terms of the Data Sharing Agreement, information related to this matter may be shared among study sponsors.

☐ *By completing a submission, you accept that the name and affiliation of the lead researcher, the title of the proposed research, the statistical analysis plan, the requested studies, lay summary, funding source and any potential conflicts of interest that are provided may be published on this site. For approved requests, the statistical analysis plan for the proposed research will be posted on this site after the research is published. Where the request is turned down the complete research proposal will be posted on this site.

Research Proposal Format

Please complete this form in English.

SECTION A : Research Plan
SECTION B : Information about the Research Team
SECTION C : Funding of the Proposed Research
SECTION D : Potential Conflicts of Interest
SECTION E : Other Information

If you already have a protocol or analysis plan for the research, please "cut" and "paste" information from that document to complete this form.

SECTION A: RESEARCH PLAN

***A.1 Title of the Proposed Research**

Limited to 200 characters.

Please provide the title for the research. This should be no more than 200 characters and reflect the aim of the proposed research. This field is required.

***A.2 Lay Summary**

Please provide a plain English summary of the proposed research suitable for a general or lay audience, explaining:

- The background to the research
  - Why does this research need to be done now?
  - How many patients / members of the public are affected?
- How the research will add to medical science or improve patient care
- The aims and objectives of the research
- How the research will be conducted
  - What design and methods have you chosen and why? (in brief)
- How the findings will be interpreted and communicated to patients and/or the public

Click this link for guidance on plain English summaries.

Limited to 3,000 characters.

***A.3 Study Design**

Limited to 2,500 characters.

Please provide a brief description of the study design. For example: case-control, cohort, cross-sectional, case-crossover, historical controlled, or hybrid designs, meta-analysis, pooled analysis. This field is required.

***A.4 Studies Selected and Study Populations**

Limited to 2,500 characters.

Please provide the reasons why you have selected these studies for your proposed research. Please also provide a description of the study population or populations for the proposed research. For example: the study arms from the requested clinical studies; intent-to-treat or per-protocol populations; the inclusion and exclusion criteria for any cohort or subgroup analysis. This

***A.5 Primary and Secondary Endpoints for the Study**

Limited to 2,500 characters.

Please describe the endpoints that will be analysed. For example, change in depression score from baseline to the last available follow-up, measured using the Beck Depression Inventory. Please note that to ensure the use of the data aligns with the informed consent provided by clinical study participants, research proposals must relate to the medicine or disease that was the subject of the original clinical studies. This field is required.

***A.6 Statistical Analysis Plan**

Please provide the statistical analysis plan for the proposed research.

The following is provided as guidance for items to include in the statistical analysis plan:

- Effect measure of interest (e.g. for inferential studies: risk or rate ratio, risk or rate difference, absolute difference; for descriptive studies: rate with confidence intervals)
- Methods to control for bias (e.g. restriction, matching, stratification, covariate adjustment)
- Assumptions and any planned adjustments for covariates or meta-regression or modelling of covariates
- The statistical approach (e.g. Bayesian or frequentist (classical), fixed or random effects)
- Meta-analysis approach where applicable (e.g. random effects meta-analysis, stratified meta-analysis)
- Statistical tests and methods (e.g. Fisher's exact test, Kaplan-Meier curves, log-rank test to compare groups, multiplicity adjustments)
- Power to detect an effect, or the precision of the effect estimate given the sample size available
- Statistical power calculations and levels of significance
- Model fit tests, sensitivity or heterogeneity analyses (e.g. Chi-Squared Test, I squared statistic)
- Analysis of subgroups (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of intervention (e.g. drug dose)
- Handling of missing data

Limited to 25,000 characters.

***A.7 Publication Plan**

Limited to 2,500 characters.

Please include a description of when and where a summary of the proposed research plan and the results will be posted (e.g. on clinicaltrials.gov); and a description of when and where a manuscript will be submitted for publication. This field is required.

SECTION B: INFORMATION ABOUT THE RESEARCH TEAM

Please note that a statistician with a degree in statistics or a related discipline should be part of the research team.

Fees, including licenses, are paid by the study sponsors for research team members to access data on the website and use the statistical software. The number of licenses for each research proposal may be limited to a maximum of five.

For this section, please include all researchers on your team. We should be notified where there is a change in membership of the research team.

Up to 20 researchers can be entered.

Lead Researcher

*Name:	
*Post or Position:	
*Employer, Company, Research Institution or Affiliation:	
*Education, Professional Qualifications and Memberships that are Relevant to the Proposed Research:	

☐ Add Researcher (Unchecking this box will delete all research team members below)

Statistician

☐ Same as Lead Researcher

*Name:

*Post or Position:

*Employer, Company, Research Institution or Affiliation:

*Education, Professional Qualifications and Memberships that are Relevant to the Proposed Research:

SECTION C: FUNDING OF THE PROPOSED RESEARCH

***Source of Funding for the Proposed Research.**

Please provide the name (e.g. NIH, MRC) of the funding source(s) that is being used or is planned to be used solely or in part for the proposed research.

Please include research grants from governments or government agencies, other grants or donations, funding from employers through employment contracts, other contracts, consultancies, honoraria and other payments that will be used for the research.

Please including any funding from commercial (e.g. for profit) organisations.

If there is no funding for the research, enter "None".

Limited to 2,500 characters.

SECTION D: POTENTIAL CONFLICTS OF INTEREST

***D.1 Potential Conflicts of Interest Outside the Funding of the Proposed Research**

For each member of the research team, please provide information on financial relationships that could be perceived to influence the planning, conduct or interpretation of the proposed research. This should include but not be limited to financial relationships with the study sponsors involved in this initiative and other pharmaceutical or biotechnology companies within the last three years. It should include:

- Board memberships
- Consultancies
- Employments
- Grants/grants pending
- Patents (planned, pending or issued)

- Royalties
- Stocks or shares (including options)

Please also include any other (e.g. non-financial) real or potential conflicts of interest that could be perceived to influence the planning, conduct or interpretation of the proposed research. For example potential biases based on pre-existing personal views, academic or commercial competition, personal relationships or institutional affiliations.

If none, please enter "None".

***Lead Researcher**

***Statistician**

***D.2 Management of Real or Potential Conflicts of Interest**

Please summarise how real or potential conflicts of interest related to the funding of the proposed research, other financial relationships, or other real or potential conflicts of interest will be managed. For example through disclosure of interests when the research is presented and published.

If none, please enter "None".

SECTION E: OTHER INFORMATION

Please provide any additional information that should be considered when reviewing this proposal

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