Proposal Form

In order to submit a request for access to patient-level data, please complete this form in English and do not use abbreviations. If you already have a protocol or analysis plan for the research, please "cut" and "paste" plain text from that document to complete this form.

Required fields are marked with an (*)

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

(•) Yes ( ) No

* Have you received an answer to your enquiry?

(•) Yes ( ) No

* Please provide the enquiry Reference Name and Number

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

(•) Yes ( ) No

* Please provide the research proposal Reference Name and Number

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

( ) Yes (•) No

* Please provide the reason why Ethics Committee or IRB approval is not needed. Note: The applicability of local regulations depends on the location where the research will be performed (usually the location of the lead researcher or the location of the lead researcher's institution or affiliation).

☐ *I understand that data are primarily provided in the secure data access system. SAS, "R" and Plink statistical software are provided, and there are controls to prevent the original study datasets from being downloaded.

Please refer to Access to Data for more information.

☐ *I acknowledge that I and the relevant legal staff at my institution have reviewed and understood the terms of use that apply in the Data Sharing Agreement and that access to data requires signing a Data Sharing Agreement. 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. Please refer to the Data Sharing Agreement for more information. This is a legal document and will require legal review within your organization prior to signing.

☐ *By submitting this research proposal, you accept that the name and affiliation of the lead

researcher, the title of the proposed research, the requested studies, research proposal 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.

1. RESEARCH PROPOSAL TITLE

*Please provide a full research proposal title. This should be descriptive and understandable to the general public and should reflect the aim of the proposed research.

This is a required field (500 character limit).

2. RESEARCH PROPOSAL SUMMARY IN PLAIN ENGLISH

*Please provide a brief, high-level, overview of the planned research written in Plain English language. This should be suitable for the general public and will be posted on this site after the Data Sharing Agreement has been signed.

Please provide a clear summary of the background to this research. This should include a discussion of the questions/issues or knowledge gaps and, if applicable, any unmet medical need(s) or public health issues to be addressed by this research.

Also provide succinct details of the objectives of the proposed research including any hypotheses being tested.

Click this link for guidance on Plain English Summaries.

This is a required field (4,000 character limit).

3. RESEARCH PROPOSAL PLAN

3.1 Research Background

*Please provide a summary of the research proposal background.
This section should include how this research will contribute to an unmet need or fill a gap in medical knowledge. Provide references to prior work if applicable.

This is a required field (5,000 character limit).

3.2 Objectives and Outcomes

*Please provide details of the main objectives and the outcomes being evaluated including any hypotheses being tested.
If your research proposal is not assessing specific outcomes (e.g. it is comparing data analysis methodologies) please describe the aims of your research.

This is a required field (5,000 character limit).

3.3 Do you plan to include non-CSDR data (i.e., data not listed on the ClinicalStudyDataRequest.com website in this research proposal)?

(•) Yes ( ) No

3.3a List of non-CSDR study data and sources

*Please provide a list of any external study data (i.e., any data that you have acquired from non-CSDR sources) that you wish to include in this research proposal. Also provide the source of these data, the associated sample sizes, and the interventions of interest that were studied.
Please include as much detail as possible to identify the non-CSDR study data including sponsors, titles, trial identification numbers, and other study identifiers (such as NCT numbers for each study and/or if needed PubMed IDs/references).

This is a required field (5,000 character limit).

3.3b Data Management Plan for combining non-CSDR data with CSDR data

*Please provide a plan for how you intend to combine or otherwise compare these external study data with the study data provided via this site.

(Click here to access the terms of use for the secure data access system and Click here for details about Access to Data).

This is a required field (2,500 character limit).

3.4 Rationale for Study Selection and Selection of Populations/Participants

*Please provide your rationale for choosing each study (CSDR and non-CSDR if applicable).
This section should include the criteria for considering studies and specific populations for inclusion/exclusion in the proposal and may also include the following.

- Types of studies included in your analysis (phase, interventional vs non-interventional, controls etc).
- The patient characteristics for each study.
- The interventions and comparisons of interest and the associated outcomes for each study.
- The study/population sizes for each study and any impact that may have on your analysis.
- Whether you intend to focus on intent-to-treat or per-protocol populations.
- Any relevant studies that were excluded and why.

This is a required field (10,000 character limit).

3.5 Statistical Analysis Plan

*Please provide a detailed description of the statistical methods that will be used.

This methodology description should not be limited to a list of tests. It should be a discussion of such items as:

- Effect measure of interest (e.g. for inferential studies: odds ratio, risk or rate ratio, risk or rate difference, absolute difference)
- Statistical analysis methods (e.g. logistic regression, Kaplan-Meier curves, log-rank test, multiplicity adjustments)
- Planned adjustment for covariates
- Meta-analysis methods, if applicable (e.g. random effects meta-analysis, stratified meta-analysis, meta-regression)
- Power to detect a clinically important effect, or the precision of the effect estimate given the sample size available
- Planned sensitivity analyses, if relevant
- Planned subgroup analyses [e.g. by age, disease status, ethnicity, socio-economic status, presence or absence of co-morbidities, different types of intervention (e.g. drug dose)]
- Handling of missing data

This is a required field (15,000 character limit).

3.6 Publication Plan

*All research proposals must have a publication plan for the communication of the results, regardless of the findings. This requirement is part of the Data Sharing Agreement which is signed before data access is provided.

Please provide your plans for publishing and/or describe whether and how the outcome of your research will be communicated to the public.

This is a required field (2,500 character limit).

4. RESEARCH TEAM DETAILS

Please note that a suitably qualified researcher with expertise in the statistical analyses being proposed must be a member of the research team. In some cases, this may be the lead researcher while in others a designated member of the team will be the appropriately qualified researcher. The qualified researcher usually has a degree in statistics or a related discipline (e.g., mathematics, health economics or epidemiology) but other qualifications or experiences may be considered relevant by the Independent Review Panel.

For this section, please include all researchers on your team. You must notify us when there is a change in membership of the research team's lead researcher or qualified researcher after your proposal is submitted or approved.

Fees and licenses for research team members to access data in the secure data access system and use of the statistical software are paid by the CSDR Sponsors. The number of licenses for each research proposal is generally limited to five researchers per project. If more research team members are required, please consult with the Sponsors.

4.1 Lead Researcher *This is a required field.

* Name:

* Post or Position:

* Employer, Company, Research Institution or Affiliation:

* Education, Professional Qualifications and Memberships that are relevant to the proposed research:

* Potential Conflict of Interest: **?**

Please provide information on financial relationships that could be perceived to influence the planning, conduct or interpretation-bias of the proposed research. It should include a description of any of the following: Board memberships, Consultancies, Employments (e.g., pharmaceutical, biotech or similar companies), Grants/grants pending, Patents (planned, pending or

* Management of Conflict of Interest: **?**

Please summarize how real or potential conflicts of interest or biases (related to the funding of the proposed research, other financial relationships, or other real or potential conflicts of interest) will be managed. If there are no potential conflicts of interest, enter 'None'.

4.2 Statistician or Qualified Researcher

☐ 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:

* Potential Conflict of Interest: ?

Please provide information on financial relationships that could be perceived to influence the planning, conduct or interpretation-bias of the proposed research. It should include a description of any of the following: Board memberships, Consultancies, Employments (e.g., pharmaceutical, biotech or similar companies), Grants/grants pending, Patents (planned, pending or

* Management of Conflict of Interest: ?

Please summarize how real or potential conflicts of interest or biases (related to the funding of the proposed research, other financial relationships, or other real or potential conflicts of interest) will be managed. If there are no potential conflicts of interest, enter 'None'.

Additional Researchers

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

4.3 Source(s) of Funding for the proposed research:

*Please provide the funding source(s) that is being used or is planned to be used solely or in part for the proposed research.
Please record all funding sources if there are more than one.
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) organizations.
If there is no funding required for the research, enter "None".

This is a required field (5,000 character limit).

5. Other Relevant Information

Please provide any additional information that should be considered when reviewing this proposal (5,000 character limit).

Click 'Save' to save your progress and come back later, or click "Submit' if your research proposal is complete (you will not be able to edit it further).