RESEARCH PROPOSAL - REQUEST FOR CLINICAL DATA SHARING

Please complete all fields. In addition, supplementary or supportive information may be provided as attachments. If information is found in attachments, please indicate where that information can be found (e.g., see Section 3.8 of [document name]).

Text in curly brackets, i.e., {}, should be adjusted to meet the proposal requirements.

Text in blue italics is guidance text and should be deleted before document submission.

| **Research title:** | {Insert title, max. 600 characters including spaces} |
| --- | --- |
| **Requestor Name:** | {Insert the name and private address including country, and full contact details.}  The requestor is the person responsible for the conduct of the research. Full contact details, i.e., telephone (cell phone and land line), e-mail address, and fax. |
| **Requestor qualifications & experience:** | {Summarize the requestor qualifications & experience.}  Attached curriculum vitae and/or other relevant documents confirming the requestor qualifications & experience. This documentation should include any previous training in the principles of GCP, relevant ICH guidance, and relevant experience, e.g., with work with clinical trials, and/or with the planned type of research. |
| **Requestor Affiliation:** | {If the requestor is acting as an employee of an institution (e.g., academic institution), insert the requestor role at the institution, the institution name and address including country.} |
| **Research background:** | {Insert a detailed description of the background to the planned research.} |
| **Research rationale, including any hypotheses to be tested:** | {Insert}  The importance of the research question should be clarified and the need for the research in context of available evidence be demonstrated. |
| **Research objectives:** | {Insert} |
| **Primary Endpoint:** | {Insert a detailed description (including justifications) the chosen endpoint, if not appropriate for the planned research, delete this section.} |
| **Secondary Endpoints:** | {Insert a detailed description (including justifications) the chosen endpoints, if not appropriate for the planned research, delete this section.} |
| **Clinical data requested:** | {List specific trials and data / information being requested. Indicate why you have chosen this trial/these trials for your analysis.}  Only the clinical data requested will be provided. |
| **Planned statistical analyses:** | {Insert a detailed description (including justifications) of the planned statistical analyses. Alternatively, attach a suitable statistical analysis plan.}  The description should include:   * an exact description of all planned methods to handle data (including pooling of data), of all comparisons, analyses, test procedures for all parameters for all time points. * procedures planned for missing/unused values and spurious data. * possible reasons for exclusion of subjects from the analyses. * a description of the selection of subjects to be included in the analyses (e.g., all subjects allocated to treatment, all dosed subjects, all eligible subjects, evaluable subjects). * which analysis set is relevant for the different analyses. |
| **Estimated timelines for the research:** | {Insert estimated timelines for completion of the planned analyses.} |
| **Publication and posting plan:** | {Insert a description of the planned publication and posting plan. For example, indicate whether the analysis results will be published as an abstract, a manuscript, a poster, other. If possible, when and where the results will be submitted for publication.} |
| **Data protection:** | {Insert a description of the measures planned to protect patient privacy and shared data.} |
| **Source(s) of any research funding:** | {Insert a description of the source(s) of any funding for the planned research.} |
| **Named researchers:**  (Note: A qualified biostatistician with experience working for clinical trials and with knowledge of ICH guidelines must approve the statistical plan for the analyses and the corresponding report.) | {If parties other than the requestor will have access to the shared data, they will be named researchers. Insert the names of all planned named researchers together with their address including country, and full contact details.}  Full contact details, i.e., telephone (cell phone and land line), e-mail address, and fax. Prior to the planned data sharing, curriculum vitae and/or other relevant documents confirming qualifications & experience will be requested by Grünenthal. |