Research proposal 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 blue italics is guidance text and should be deleted before document submission.

Information about Orion-sponsored clinical trials can be found in the public registries.

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| **General information** |
| **Requestor Name:** | The requestor/Lead Researcher is the person responsible for the conduct of the research. Please provide full contact details, i.e., name and address including country, telephone (cell phone and land line) and e-mail address. |
| **Name of all researches involved in research project:** | *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.* |
| **Qualifications & experience:** | *Summarize the requestor qualifications & experience.**Please attached Curriculum Vitaes (CV’s) for all members of the research team.*  |
| **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.* |
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| **Research plan** |
| **Research title:** |  |
| **Research background:** | *Insert a detailed description of the background to the planned research.* |
| **Research rationale, including any hypotheses to be tested:** | The importance of the research question should be clarified and the need for the research in context of available evidence be demonstrated.  |
| **Research objectives:** |  |
| **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.* |
| **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.
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| **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.* |
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| **Data sharing details** |
| **Clinical data and/or documents requested:** | *List specific trials and data / documents being requested. Indicate why you have chosen this trial/these trials for your analysis.*Only the clinical data requested will be provided. |
| **Data protection:** | *Insert a description of the measures planned to protect patient privacy and shared data.* |
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| **Other relevant information** |
| **Conflicts of interest related to this research:** | *Provide any and all real or potentially perceived conflicts of interest related to this research (e.g. official position or share ownership in the pharmaceutical company, role as investigator in the clinical trial sponsored by pharmaceutical company)* |
| **Source(s) of any research funding:** | *Insert a description of the source(s) of any funding for the planned research.**Include details of financial interests such as funding, salary or ownership for the investigators and/or their affiliated institutions, employers or similar.* |
|  |
| **Signature & affirmation** |
| I/We confirm that the information presented within is correct and truthful. All provided data will not be used for any purpose other than what has been identified in this request, and that the requested data will not be used in pursuit of litigation or for commercial purposes. |
| **Print name:** |  |
| **Signature:** |  |
| **Date:** |  |