

Research Proposal for Access to Data

Submission Date

(DD-MM-YYYY)

Title of the proposed research (reference name as used on the "Data Feasibility Form")
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Following approval, access is provided after LEO Pharma has received a signed Data Sharing Agreement. By completing a submission, you accept that after LEO Pharma receives a signed Data Sharing Agreement, LEO Pharma may publish the name and affiliation of the lead researcher, the title of the proposed research, the requested studies, lay summary, funding source and any potential conflicts of interest that are provided.

I have read and understood the above

The research is not to be undertaken for commercial purposes

I have read and understood the above

Research Proposal (Please complete in English) A maximum of 5000 words

1. Research Plan

1.1 Lay Summary

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

- Background
- Aims and objectives
- How the research will provide relevant information for patients
- How the research will advance the scientific understanding of and ability to treat dermatological and other diseases
- How the research will be conducted
- How the findings will be interpreted and communicated

1.2 Proposal Summary

Please provide a summary of the research proposal, with a maximum of 800 words.

1.3 Study Design

Please provide a brief description of the design of the study (e.g. meta-analysis, historical control, etc.)

1.4 Studies Selected and Study Populations

Please describe:

- The reason(s) for selecting the studies requested
- The treatment arms
- The study population(s) (e.g. full analysis set (intent-to-treat), per-protocol) to be used
- Criteria for any cohort or subgroup

1.5 Primary, Secondary and Other Endpoints for the Study

Please describe the endpoints that will be analysed and for which time-points (e.g. change in score from baseline to the last available follow-up), clearly identifying which are primary and secondary endpoints.

1.6 Statistical Analysis Plan

Please describe the planned statistical analysis. The following list gives an indication of the points to be considered/included:

- Statistical methodology (e.g. summary statistics, models, hypothesis testing, significance level, estimation, confidence intervals, adjustment for covariates, investigation of interactions, adjustment for multiplicity, meta-analysis (if applicable)) including assumptions
- Handling of missing data and methods to control for bias
- Model checking, sensitivity analyses
- Analysis of subgroups (described in Section 1.4)
- Discussion of the power to detect an effect or precision of the estimate given the sample size available (particularly with respect to the primary end-point).

1.7 Publication Plan

Findings will be presented at a scientific meeting (if applicable).
A manuscript will be submitted for publication.

2. Research Team

2.1 Lead Researcher

Attach a professional CV.

Name:

Address:

Telephone:

E-mail:

2.2 Other Names of the Research Team

Please note that a statistician with a degree in statistics or a related discipline should be part of the research team. For this section, please include all researchers on your team. LEO Pharma should be notified where there is a change in membership of the research team. Attach a professional CV for each member.

Name 1:

Name 2:

Name 3:

Name 4:

Name 5:

Name 6:

Name 7:

Name 8:

Name 9:

Name 10:

3. Funding of the Proposed Research

3.1 Source of Funding for the Proposed Research

Please provide information on funding source(s) that will 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 include any funding from commercial (e.g. for profit) organisations.

4. Potential Conflicts of Interest

4.1 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 LEO Pharma 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 research. For example potential biases based on pre-existing personal views, academic or commercial competition, personal relationships, political or religious beliefs and institutional affiliations. If none, please enter "None".

Lead Researcher:

Member 1:

Member 2:

Member 3:

Member 4:

Member 5:

Member 6:

Member 7:

Member 8:

Member 9:

Member 10:

5. Other Studies

5.1 List of Other Studies

If you plan to merge data from more than one study, please list below the studies sponsored by other organisations than LEO Pharma. The studies can be given by clinicaltrials.gov identifier or EudraCT number.

Study 1:

Study 2:

Study 3:

Study 4:

