Research proposal form

**Submission procedure**

After approval by *Scientific Review Board* and receipt of a signed *Data Sharing Agreement*, ALK will grant access to the data.

The *Data Sharing Agreement* includes requirements for the applicant to:

a. Only use the data for the agreed research purpose and not to download or transfer the data for any other use.

b. Protect the privacy and confidentiality of research participants. The applicant 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 ALK of any safety concerns, as soon as they are identified.

e. Seek publication of the research in an article or abstract/poster without disclosing company confidential information or individual patient data.

f. Provide ALK with a copy of any public disclosure of the results, including a copy of the manuscript prior to the submission to a peer-reviewed journal. Also provide ALK with the citation after publication.

g. Allow ALK to use any invention originating from the research, free of charge and throughout the world. Sign a legally binding agreement affirming that the analyses conducted will not now or at any point in the future be used by the applicant for commercial purposes.

h. Confirm that the applicant does not have, and does not plan to have, any other agreements that would prevent the applicant from complying with the terms of the *Data Sharing Agreement,* including section g. above.

i. Meet any additional requirements identified by ALK.

j. Complete the research project in the period of time decided upon mutually after access.

k. Not share in any way or format data accessed with anyone outside the research team identified in the proposal.

**Form instructions**

Provide comprehensive details for each field. Proposals in an alternate format may be provided as an attachment. If information is provided in an alternate format, state where the information can be found in the attachment(s). Required fields are marked with an \*.

Note: Research proposals will not be reviewed until all required information is supplied.

**Application for data access**

**1. Primary Researcher information\***

The Researcher's curriculum vitae (CV) must be submitted along with this application.

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Institution |  |
| Street |  |
| City, postal/zip code |  |
| Country |  |
| Phone |  |
| e-mail |  |

**2. Research title\***

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**3. Research background/rationale\***

Include a description of how such research is intending to advance medical knowledge.

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**4. Provide relevant literature references for this application\***

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**5. Research objective(s)\***

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| --- | --- |
| Primary objective |  |
| Secondary objective |  |

**6. Research hypothesis\***

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**7. Description of data or information requested\***

List specific studies, data and time points being requested.

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**8. Research/Study design\***

Check all that apply

|  |  |
| --- | --- |
| □ | Systematic review |
| □ | Case-controlled |
| □ | Cohort |
| □ | Cross-sectional |
| □ | Historical controlled |
| □ | Meta-analysis with studies: |
| □ | Pooled analysis with studies: |
| □ | Other: |

**9. Studies and study populations requested for research\***

Provide the reason(s) why you have selected these studies for your proposed research.

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| --- | --- |
| Study number or title: | Population for proposed research (e.g., intent-to-treat, per protocol population, inclusion and exclusion criteria for any cohort or subgroup analysis): |
|  |  |

Add rows as applicable.

**10. Primary & secondary endpoints to be analysed\***

|  |  |
| --- | --- |
| Primary endpoints |  |
| Secondary endpoints |  |

**11. Statistical Analysis Plan (SAP)\***

Please provide a summary of the SAP, including a summary of the primary and secondary endpoints, population to be analysed and key statistical tests.

Please submit a detailed SAP with this application.

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**12. Statistician information\***

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

The statistician's CV must be submitted along with this proposal.

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| --- | --- |
| Name |  |
| Title |  |
| Institution |  |

**13. Publication plan\***

Provide where the research results will be submitted for publication.

|  |  |  |  |
| --- | --- | --- | --- |
| Documentation type | | Submit to | Estimated submission date (Mmm/yyyy) |
| □ | Abstract |  |  |
| □ | Manuscript |  |  |
| □ | Poster |  |  |
| □ | Other |  |  |

**14. Research funding sources\***

Provide the name (e.g. NIH) of the funding source(s) that is being used or is planned to be used solely or in part for the proposed research. 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. Include any funding from commercial (e.g., for profit) organisations.

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Add rows as applicable

**15. Research team members\***

Provide the names of the research team members (other than the primary researcher and statistician) who will have access to the data, as applicable. If none, enter “None”.

|  |  |  |
| --- | --- | --- |
| Title: | Name: | Institution: |
|  |  |  |

Add rows as applicable

**16. Additional/Other information**

Describe any aspects of the research proposal that have not already been provided that would be relevant to and should be considered when reviewing this proposal.

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**17. Potential conflicts of interest outside the funding of the proposed research\***

The primary researcher should complete the section. When the application has been granted, statements will be required from the other research team members; they will be required to provide information on financial relationships that could be perceived to influence the planning, conduct or interpretation of the proposed research. This will include but not be limited to financial relationships with ALK and other pharmaceutical or biotechnology companies within the last 3 years. Check all that apply.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes | □ | No | □ | I currently work for a pharmaceutical company, or have done so in the last 3 years. |
| Yes | □ | No | □ | I work for a contract research and development company, or have done so in the last 3 years. |
| Yes | □ | No | □ | I provide expert advice (consulting) to a pharmaceutical company, or have done so in the last 3 years. |
| Yes | □ | No | □ | I participate in a strategic advisory role on an Advisory Board/Steering Committee that drives the strategic direction of a pharmaceutical company, or have done so in the last 3 years. |
| Yes | □ | No | □ | I receive an honorarium from a pharmaceutical company. |
| Yes | □ | No | □ | I hold a patent (planned, pending, or issued) relating to a pharmaceutical product. |
| Yes | □ | No | □ | I earn royalties related to a pharmaceutical product. |
| Yes | □ | No | □ | I am a principal investigator, or have been in the last 3 years. |
| Yes | □ | No | □ | I am an investigator, or have been in the last 3 years. |
| Yes | □ | No | □ | My organisation currently receives funding/a grant, or has funding/a grant pending, from a pharmaceutical company. |
| Yes | □ | No | □ | Someone in my household (spouse/partner, minor children) works for a pharmaceutical company. |
| Yes | □ | No | □ | I own shares (including options) in a pharmaceutical company. |
| Yes | □ | No | □ | Someone in my household (spouse/partner, minor children) owns shares in a pharmaceutical company. |
| Yes | □ | No | □ | I am involved in a law suit related to the pharma industry as an expert witness. |

Additional information on any checked item(s) that could be considered a potential conflict of interest:

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**18. Management of real or potential conflicts of interest\***

Summarize 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, enter “None”.

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The following attachments must be provided with the proposal:

* Primary Researcher's CV (item 1)
* Statistical Analysis Plan (SAP) (item 11)
* Statistician's CV (item 12)