**The MLD initiative**

**Standard operating procedure**

**Data Request**

**APPENDIX A**

|  |  |
| --- | --- |
| Version | 1.0 |
| Status | Approved |
| Date | 02-03-2022 |
| Purpose of this document | Part of Data Request SOP v1, can be used by requester to request data. |

**Version control**

|  |  |  |
| --- | --- | --- |
| **Version number** | **Revision date** | **Summary of major changes** |
|  |  |  |
|  |  |  |

## Appendix A – Data request form

This form is published on [www.MLDinitiative.com](http://www.MLDinitiative.com) on : 15-12-2022

By submitting this request form, you agree to the conditions of the Data Access Policy. An incomplete application form will not be processed.

**Applicant (e.g. researcher)**

Name applicant Click or tap here to enter name.

Email address applicant Click or tap here to enter email address.

(use your institutional email address)

Phone number applicant Click or tap here to enter Phone number.

Affiliation applicant Click or tap here to enter Affiliation.

**Main applicant (e.g. PI)**

Name main applicant Click or tap here to enter name main applicant.

Email address main applicant Click or tap here to enter email address.

(use your institutional email address)

Affiliation main applicant Click or tap here to enter Affiliation.

**General information**

Project title Click or tap here to enter Project title.

Acronym Click or tap here to enter Acronym.

Date request (dd-mm-yyyy) Click or tap to enter a date.

Desired deadline for data delivery (dd-mm-yyyy) Click or tap to enter a date.

**Funder**

Please list all funders and collaborators of the research project/data request.

Have agreements been made with the funder with regard to data sharing, e.g. making data available for further research? If so, please explain.

**Research project**

For what type of research do you request data? Choose which item(s) apply.

Natural history study

Genotype-phenotype correlations

Biomarker discovery or validation

Effectiveness of a therapy

Compare therapies

Health technology assessment

Post-marketing authorization

Post-launch evidence generation

Other….

Please describe:

**Background of the research project (max. 150 words)**

Provide a short description of the rationale of the research and the motivation for the request.

**Research question(s)**

Provide the research question(s).

**Hypothesis (max. 150 words)**

Provide a short description of your hypothesis.

**Methodology (max. 350 words)**

Describe the methods that will be used, including the following aspects (if applicable)

* Study design:
* Study population:
* Comparator/controls:
* Size of study population:
* Intervention:
* Outcomes:
* Date/time span:
* Statistical methods that will probably be used (briefly):
  + Provide results of power analysis (if applicable):
* Other aspects:

**Impact (max. 100 words)**

How does this research contribute to the mission of the MLD initiative “To improve disease management of metachromatic leukodystrophy through an international disease registry and multi-stakeholder collaboration”?

**Requested dataset**

Below the variables are presented per component. The variables are described in the data dictionary. Select which variables are requested in the first column. If necessary, a more specific selection can be indicated in the column ‘selection criteria’, e.g. ‘only late infantile patients.’

Please note that for privacy reasons, only the minimum data necessary to properly answer the research question can be requested.

**Selection Criteria**

* Center
  + All centers
  + Specify centers:
* Follow-up period
  + No restrictions
  + Only baseline
* Survival status
  + No restrictions
  + Only alive
  + Only deceased
* Consent
  + No restrictions
  + Only patients who gave permission to be contacted for research purposes
* Other, please specify

**Level of aggregation**

Individual patient level

Group level, based on a patient/disease characteristic

Specify characteristic on which the groups are based:

Center level