Research Proposal Form
FOR ACCESS TO CLINICAL TRIAL DATA

A Our Commitments

Servier adheres to the **Principles for Responsible Clinical Trial Data-Sharing** laid out by the EFPIA (European Federation of Pharmaceutical Industries and Associations) and PhRMA (Pharmaceutical Research and Manufacturers of America).

This includes:

- the timely registration of clinical trial protocols,
- communication and publication of results from our clinical research programs,
- and sharing results with the patients who participate in our clinical trials.

Servier makes clinical trial data and anonymized patient data available to qualified scientific and medical researchers, in accordance with international statutory requirements regarding the disclosure of clinical studies.

B How to Access to the Clinical Trial Data

Servier supports provision of access to anonymized patient-level and study-level clinical trial data to qualified researchers engaged in rigorous, independent scientific research, under the first prior condition of a Research/Study Proposal Form, fully documented with four parts:

- **Part 1:** Research Study Proposal Plan (Topic category, Objectives and Scope of the Research…)
- **Part 2:** Research Team Description (Research place, professional qualifications…)
- **Part 3:** Load Specification Manual (Data Base, Data Management tools, Statistical Analysis Plan…)
- **Part 4:** Other information

PLEASE NOTE THAT:

The Research Proposal Form will not be reviewed until all mandatory fields are supplied.

C Data Sharing Agreement

Prior to migration of data, a Data Sharing Agreement will have to be signed with Servier, including requirements for the research team to:

- Only use the data for the agreed research purpose;
- Protect the privacy and confidentiality of clinical trial participants;
- Complete planned analysis in 12 month of access;
- Not share in any way, including for formatting, Servier data with anyone else outside of the research team identified in the proposal;
- Agree to destroy all data and supporting documentation at the end of the research project, and to provide written confirmation of destruction.

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1 Research Study Proposal Plan

1.1 Scope of the Research *(mandatory)*

1.2 Research title *(mandatory)*

1.3 Research objective(s)

Primary objective *(mandatory)*

Secondary objective *(mandatory)*

1.4 Research background/rationale *(mandatory)*

Give a description of how such research is intended to advance medical knowledge

1.5 Which clinical data are requested *(mandatory)*

Protocol number or name of the study : ……

- ☐ Protocol
- ☐ Patient level data
- ☐ Study level data
- ☐ Clinical study report (body)
- ☐ Appendice of clinical study report *(please specify which one you would like to obtain)*

2 Research Team Description

2.1 Person in charge of the Research Study Proposal *(mandatory)*

Name: …… First name: ……

Title: ……

Institution: ……

Pleased add a recent CV (mandatory)

Address: ……

City: ……

State/Province: …… Post/Zip Code: ……

Country: ……

Phone: …… Fax: ……

E-mail: ……

2.2.3 People involved in the Research Study Proposal *(mandatory)*

*(Description of the team : Physician, Statistician and other Scientists…)**

Name: …… First name: ……

Title: ……

Institution: ……

Pleased add a recent CV (mandatory)

Name: …… First name: ……

Title: ……

Institution: ……

Pleased add a recent CV (mandatory)

Name: …… First name: ……

Title: ……

Institution: ……

Pleased add a recent CV (mandatory)

Name: …… First name: ……

Title: ……

Institution: ……

Pleased add a recent CV (mandatory)

** If more than three people, please use copies of this form*

3 Load Specifications Manual

3.1 Data Base, Data management Specifications

3.1.1 Technical environment for reception of the Data

Computer - Operating System *(mandatory)*:……

Software environment *(mandatory)*: ……

Security Process *(mandatory)*: ……

3.1.2 Data Transfer Request form

Expected file format:

☐ SAS datasets SAS operating system version: ……
☐ SAS transport file
☐ XLS
☐ CSV
☐ Other: ……

Transfer mode:

☐ SharePoint name : ……
☐ FIT/TRUCK email address : ……

Expected Data Package:

☐ Raw study datasets ☐ SDTM datasets

Efficacy Data Requested

Safety Data Requested

Other

3.2 Methodological and Statistical Specifications

3.2.1 Research Study Design *(mandatory)*

3.2.2 Primary Endpoint *(mandatory)*

3.2.3 Secondary Endpoint *(mandatory)*

3.3 Statistical Analysis Plan - SAP

Preamble:

- A statistical analysis plan (SAP) describes the planned analysis for a clinical trial or more generally for any analysis of data coming from clinical trials.
- The SAP must be carefully reviewed by statistical programmers working on the project for clarity and comprehension in order to construct analysis data sets and prepare planned tables, figures and listings.
- SAP review is a challenging task that requires both statistical expertise and abstract thinking skills.
- SAP may include detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.

STUDY DESIGN *(mandatory)*
(e.g.: Case-control, cohort, cross-sectional, crossover, historical controlled, meta-analysis, pooled analysis, comparative, non-comparative…)

STUDY POPULATION AND SUBGROUPS *(mandatory)*

Provide a description of the study population or populations for the proposed research (e.g.: the study arms from the requested clinical studies, intent-to-treat or per protocol populations, the inclusion and exclusion criteria for any cohort or subgroup analysis

ANALYSIS PERIOD *(mandatory)*

Describe on which periods will be done the analysis (Baseline, treatment period, follow-up period, a focus on one period…

DETERMINATION OF SAMPLE SIZE *(mandatory)*

(Hypothesis, effect size targeted, expected, statistical test, power, alpha risk at one sided, two sided…)

STATISTICAL METHOD

Effect measure of interest *(mandatory)*

E.g. for inferential studies: risk or rate ratio, risk or rate difference, absolute difference; for descriptive studies: rate with confidence intervals

Methods to control for bias *(mandatory)*
E.g. restriction, matching, stratification, covariate adjustment

Assumptions and any planned adjustments for covariates or meta-regression or modeling of covariates *(mandatory)*

The statistical approach *(mandatory)*
e.g. Bayesian or frequentist (classical), fixed or random effects

Meta-analysis approach where applicable *(mandatory)*
E*.g. random effects meta-analysis, stratified meta-analysis*

Statistical tests and methods *(mandatory)*
E.g. Fisher's exact test, Kaplan-Meier curves, log-rank test to compare groups, multiplicity adjustments

Statistical power calculations and levels of significance *(mandatory)*

Model fit tests, sensitivity or heterogeneity analyses *(mandatory)*

E.g. Chi-Squared Test

Analysis of subgroups *(mandatory)*

E.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities - different types of intervention (e.g. drug dose)

Handling of missing data *(mandatory)*

4 Other information

4.1 Publication plan *(mandatory)*

Provide any details of publication plan scheduled after analysis of the transferred data

4.2 Research funding sources *(mandatory)*

Provide the name of the funding source(s) used or planned for the proposed research. Include any funding from commercial organizations

4.3 Other Information *(mandatory)*

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

4.4 Potential conflicts of interest outside the funding of the proposed research *(mandatory)*

Describe any potential conflict of interest such as work for a (pharmaceutical) company or an Advisory Board