**Research grant call 2023**

**Appendix – Clinical Research**

Title of the document in pdf format:   
2023FRE\_Research\_Last name\_Project acronym\_Appendix

1. Stakeholders (sponsor(s), statistics, experts…):

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1. Scope(s) of the study:

Efficacy

Safety

Acceptability

Quality of life

Health economics

Other, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_

1. Study design and methodological plan:

Observational

Please specify:

Cross-sectional

Case-control

Prospective

Interventional

Please specify:

Open or non-comparative

Comparative vs. untreated

Comparative vs. placebo

Comparative vs. reference

Randomized

Parallel group(s)

Cross-over

Multicentre

1. If the study is a trial, is it already registered?

Yes, please provide CTN number: \_\_\_\_\_\_\_\_\_\_\_

No

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1. RIPH category (1, 2 or 3):
2. Primary objective:

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1. Secondary objectives:

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1. Intervention(s) (drug / medicinal product, medical device, surgery, other …):
   1. Assessed investigational intervention and dosing schedule if drug:

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* 1. If comparative study, control intervention(s) and dosing schedule if drug(s):

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* 1. Concomitant therapy (if any):

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1. Duration of intervention(s):

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1. Target population (healthy volunteers, patients, pathology…):

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1. Patient selection:
   1. Inclusion criteria:

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* 1. Non-inclusion criteria:

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1. Assessed parameter(s) or surrogate(s) (clinical, biological, other…):

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1. Primary endpoint:

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1. Clinical and statistical hypothesis on primary endpoint (in case of comparative study: superiority, non-inferiority, equivalence, and alpha risk, beta risk or power analysis…):

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1. Sample size calculation:

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1. Secondary endpoint(s):

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1. Study schedule:

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| --- | --- |
|  | Expected date: |
| Protocol submissions to ethical committee and health authorities |  |
| First patient included |  |
| Last patient included |  |
| Last patient follow-up |  |
| Database lock and statistical analysis |  |
| Statistical and clinical reports |  |

1. Clinical research organizations (regulatory, statistics, monitoring …):

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