

**Research grant call 2024**

**Appendix – Clinical Research**

Title of the document in pdf format:
2024FRE\_Research\_Last name\_Project acronym\_Appendix

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. Secondary objectives:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

* 1. Concomitant therapy (if any):

|  |
| --- |
|  |

1. Duration of intervention(s):

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. Patient selection:
	1. Inclusion criteria:

|  |
| --- |
|  |

* 1. Non-inclusion criteria:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

1. Primary endpoint:

|  |
| --- |
|  |

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…):

|  |
| --- |
|  |

1. Sample size calculation:

|  |
| --- |
|  |

1. Secondary endpoint(s):

|  |
| --- |
|  |

1. Study schedule:

|  |  |
| --- | --- |
|  | 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 …):

|  |
| --- |
|  |