**PROTOCOL BASIC CONTENT (v1.0 11.03.2024)**

1. **General information :**

* Title
* Roles and responsibilities of institutions and persons involved
* Study field
* Type of study (Interventional /observational study)
* Research question
* Added value of the study
* Expected study duration (start and end dates)

1. **Study design :**

* Dimension of the study (monocentric, multicentric, national, multinational)
* Randomization?
* Blind / double blind study?
* Control group? If yes, will a placebo be used in the study?
* Primary endpoints and the secondary endpoints, if any, to be measured during the trial

1. **Participant selection and benefits and risks for participants**

* Description of the population to be studied
* Description of recruitment modalities
* Inclusion and exclusion criteria
* Description of the information and informed consent obtention process
* Potential benefits for participants
* Potential risks for participants

1. **Scientific methodology**

* Parameters to be studied
* Sample/data collection procedures
* Sample size: numbers of enrolled subjects projected (and in each arm, if applicable). Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification
* Description of the statistical methods to be employed, including timing of any planned interim analysis(ses)

1. **Insurance**

* Statement regarding insurance coverage of participants, research staff and sponsor if applicable

1. **Privacy/Data protection**

* Statement of compliance with GDPR
* Sample / data storage modalities and duration
* Sample/data access modalities