## INVESTIGATOR INITIATED STUDIES

## CONCEPT PROPOSAL

1. GENERAL INFORMATION

|  |  |
| --- | --- |
| **Date:** |  |
| **Study type and overall scientific purpose of the study** | |
| *Please provide a brief description of the type of study (e.g. aerosol chemistry, in vitro, in vivo, clinical study) you are submitted and state the purpose of the study*  *Please refer to PMI IIS guidelines to select the study type of interest* | |
| **Investigator details:** | |
| *Please fill in the contact information below, and provide a copy of the CV*  Full name:  Email: | |
| **Study facility** | |
| *Please fill in the following information about the facility where the study is intended to be conducted.*  Name:  Address:  Website: | |
| **Study start and completion date (target)** | *Start date -*  *Completion date -* |
| **Total fund requested (if applicable)** | |
| *Please indicate an estimate of the total fund requested in USD* | |

1. SCIENTIFIC INFORMATION

|  |  |
| --- | --- |
| **Study title** | *Please indicate here the title of the study:* |
| **Study Type** | *Please indicate here the type of the study:* |
| **Product to be assessed** | *Please indicate here the product to be assessed in the study:* |
| **Background & Rationale** | |
| *Please provide background on unanswered questions that the study is attempting to answer. What are the scientific questions? A brief justification of the study design and main objectives and endpoints should be provided. Please make sure to justify how the endpoints you have selected behave in the context of smoking cessation and, therefore justify why it is important to assess the main endpoints under SFP use versus cigarette smoking.* | |
| **Scientific aim(s), main objectives and endpoints** | |
| *Please describe the scientific aim of the study and list main objectives and related endpoints* | |
| **Study Design** | |
| *Please provide a concise overview of the study design and procedures to be conducted* | |
| **Regulatory standards, ethical principles and local laws intended to be followed** | |
| *Please describe here any regulatory requirements and submissions to be considered and/or any specific regulatory approvals to be obtained in order to conduct the proposed study in the country of interest (for example, Good Clinical Practices /Good Laboratory Practices, good epidemiological practices, Organization for Economic Co-operation and Development, ISO 17025, other (please specify)) as well as intended ethical submission such as Ethics Committee Approval, veterinary committee approval etc.).* | |
| **Study duration, sample size and brief description of group comparators and statistical methods to be used** | |

*Please indicate the main phases of the study and their estimated duration.*

*Please provide an estimate of the sample size, comparison between groups to be done and statistical method to be used.*

1. REFERENCES

*Please use this section to include any bibliographic references included in the concept*