Protocol Synopsis (preferably in lay language, max. two pages)

EU trial number and Full trial title

Rationale
Specify background and hypothesis of the trial

Objective
Specify the main and secondary objectives of the trial

Main trial endpoints
Describe the main trial endpoints and when they are assessed, *e.g. the main trial endpoint is the percent change in the number of events from baseline to a specified time or the total number of adverse reactions at a particular time after baseline*

Secondary trial endpoints
Describe the secondary trial endpoints, and when they are assessed *e.g. number of adverse events until 30 days post end of treatment.*

Trial design
Describe the design and the expected duration of the trial for the individual subjects, *e.g. double-blind placebo controlled clinical trial where subjects are participating for X weeks*

Trial population
Describe the trial population, indicating the main inclusion criteria including age and disease/healthy volunteer and the main exclusion criteria to protect the subject, *e.g. patients with moderate asthma 18-55 years with normal kidney and liver function and without gastrointestinal ulcer or risk factors for a cardiac arrhythmia; healthy volunteers 18-60 years not exposed to X-Ray examinations during the last 12 months*

Interventions
Describe interventions and treatment duration, also including background treatment if any, *e.g. one group receives a 10 mg tablet of product X twice daily for Z weeks while also receiving product Y as background treatment and the other group receives a placebo tablet twice daily as well as product Y*

Also describe trial-related diagnostic and monitoring procedures used

Ethical considerations relating to the clinical trial including the expected benefit to the individual subject or group of patients represented by the trial subjects as well as the nature and extent of burden and risks
A benefit-risk analysis should be done for the trial-specific treatments and interventions, clearly explaining if the trial involves an expected individual benefit (e.g. as required in emergency situations) or a group benefit. When a trial is placebo-controlled, a brief justification should be given. If a non-therapeutic trial is carried out in vulnerable groups, e.g. in minors, incapacitated persons, pregnant or breastfeeding women, their inclusion has to be justified and it should be explained why the risks and burden are considered minimal and why the trial can only be performed in this particular patient group. The trial-specific risks and burdens for subjects and caregivers (if applicable) related to diagnostic, therapeutic and monitoring procedures should be justified, e.g. the amount and number of blood samples, the number of site visits, physical examinations or other tests, as well as physical and physiological discomfort associated with trial participation.