

BENEFIT-RISK ASSESSMENT PLAN/REPORT

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A. INTRODUCTION Full title of the trial Enter the full title of the trial Protocol code If applicable, enter the protocol code (A unique identifier assigned by the sponsor for the trial protocol.) Phase If the trial is an investigation of a medicinal product for human use, please specify its phase/type – Phase I – Phase II – Phase III – Adaptive design-Phase I/II – Adaptive design-Phase II/III – Adaptive design-Phase I/III – Low-risk scientific study – Bioavailability/Bioequivalence study Volunteer group Describe the volunteer group planned to be included in the trial; Specify the applicable types listed below, or a group other than these – Healthy volunteers – Patients – Male – Female – Adults – Children – Vulnerable populations (explain) – Individuals unable to give consent personally (explain) Medical condition or disease under investigation Enter the name of the disease or medical condition that is the focus of the clinical trial. Scientifically recognized disease classifications (such as SNOMED, ICD and MeSH) are used and no abbreviations are made In trials conducted in healthy volunteers, the intended indication for the product under development should be specified Investigational product / method Please specify the name or code of the investigational product/method Specify the manufacturing site and facility information of the investigational product

Competent Authority: International Council for Harmonisation (ICH) founding member (US Food and Drug Administration (US FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA)) or standing member authorities (Swiss National Medicines Authority (Swissmedic) and Canadian National Medicines Authority (Health Canada)), Australian National Medicines Authority (TGA) or the UK National Medicines Authority (MHRA) B. INVESTIGATIONAL PRODUCT General information on the investigational product Active substance name: Excipients: Route of administration: Pharmaceutical form: Risk classification of the investigational product: Important risks should be provided. Identified risks should be provided. Potential risks should be provided. Assessment of clinical trial data conducted with the investigational product The effects of the limitations in the safety database (e.g., related to the size of the study population and the inclusion and exclusion criteria) on the safety profile of the investigational product should be explained, taking these limitations into account Information should be provided on the populations likely to be exposed during the intended or anticipated use of the investigational product in medical practice Risk plan; A risk plan prepared to cover all risks should be submitted Within the plan, the risks should be well defined, the adequacy of the activities related to the risks should be assessed, and the need for additional safety studies should be discussed If the investigational product is licensed in our country and/or by competent authorities Information on the authority that granted the license It should be included in the SmPC/PIL risk management plan C. TRIAL DESIGN Summary information on other clinical trials conducted with the investigational product Summary information on safety and efficacy supporting the use of data obtained from other clinical trials conducted with the investigational product in the study population should be provided.

The assessment of the relationship between the data obtained from other clinical trials conducted with the investigational product and the potential risks related to its use in the study population should be provided in this section Trial Design Risks that may arise in the trial design should be identified and measures related to the risks should be explained Where necessary, a plan should be submitted to reduce the risk of administration and dosing errors. D. VOLUNTEER The risks that may arise in the relevant volunteer group and the measures to be taken should be explained The relevant section should also include explanations regarding the long-term effects of drug treatment in the study population.