**Study Outline for an Investigator Initiated Study – IIS**

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| --- | --- |
| Principal Sponsor-Investigator |  |
| **Address** |  |
| **Phone/Fax** |  |
| **E-mail** |  |
| *Only for multi-center IIS*:Principal Investigator of **Collaborating Study Center No. *n*** |  |
| **Address** |  |
| **Phone/Fax** |  |
| **E-mail** |  |
| **Study Title** |  |
| **Study Short Title** |  |
| **Keywords** Up to seven study specific keywords should be listed |  |
| **Study Drug Trade Name ®** |  |
| **Study Drug INN** International Non-proprietary Name |  |
| **Comparator Drug(s) INN if applicable** International Non-proprietary Name |  |
| **Indication** |  |
| **Study Type**   * interventional study or * non-interventional |  |
| **Medical Study Rationale** Description of evidence and medical need Definition of study hypothesis |  |
| **Study Design**   * single-center // multi-center * prospective // retrospective * controlled // non-controlled * open // single-blind or double-blind * randomized // non-randomized * *n* arm parallel // *n* arm cross-over * interventional // observational * confirmatory // exploratory pilot * *other* |  |
| Treatments and Visits  * Treatment plan and therapeutic goals * Schedule of visits displayed in a graph * Dosage and dosing regimen for all study periods * Formulation and strength(s) for study products * Route of administration for study products * Blinding techniques (*if applicable*) |  |
| **Primary Objective**  Major goal of the study |  |
| **Key Secondary Objectives** Additional important aspects to be evaluated |  |
| **Evaluation Criteria**   * Primary analysis variable//endpoint * Key secondary analysis variables/endpoints * Safety variables * Quality of life variables (*if applicable*) * Health economics variables (*if applicable*) |  |
| **Study Population**  Brief description of subjects to be recruited by  addressing the major inclusion and exclusion criteria  **Background medication should be clearly defined** | **Inclusion Criteria:**  **Exclusion Criteria:** |
| Biometry  * Sample size * Number of patients per treatment arm * Sample size justification including  **alpha and power calculation** * 1-sided or 2-sided * Primary study population (FAS, PPS, other) * Interim analysis (*if applicable*) * *For multi-center IIS*: Description of competitive recruitment procedure *or*  Intended fixed distribution per study center | *For hypothesis generating exploratory clinical studies  the sample size calculation and justification in this section should refer to the primary objective/primary endpoint solely* |
| Safety Reporting Classification requested | ❑ Solicited reporting  *Safety data reporting should be performed in   accordance with BI pharmacovigilance requests*  ❑ Spontaneous stimulated reporting |
| Required Study Drug Support | Available study medicinal product originated by BI:   * Empagliflozin 10 mg in total n = x pills * Empagliflozin 10 mg Matching Placebo in total n = x pills * Empagliflozin 25 mg in total n = x pills * Empagliflozin 25 mg Matching Placebo in total n = x pills   CAVEAT - Any kind of financial support is not intention of this IIS grant program. |
| **Study Duration and Timelines** Best case scenario based on feasibility | **Recruitment pool of eligible subjects**  Number of potentially eligible patients entered  the study site within the past 3 months: n = x  Estimated number of eligible patients/1 month  who are willing to sign informed consent: n = y  Estimated number of eligible patients/1 month  randomized into the study: n = z  **Estimated duration or recruitment period:** **n months**  **Major Study Periods**  Study set up (signed IIS contract to FPI): n months  First Patient In (FPI) to Last Patient In (LPI): n months  LPI to Last Patient Out (LPO): n months  LPO to Data Base Lock (DBL): n months  DBL to First Results available: n months  DBL to final Clinical Study Report: n months  **Estimated total duration or study conduct:** **n months**  **Publication Plan – Submission Date**  Abstract: Q n/yyyy  Oral presentation: Q n/yyyy  Full paper: Q n/yyyy |
| Dedicated Ethical Review Board Name and address |  |

Signature of the principal sponsor-investigator

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[*Please insert place and date*] [*Please insert name of sponsor-investigator*]  
Principal Sponsor-Investigator

**Confirmation of GCP compliance for IIS clinical trials phase I-IV**

**Excerpt from ICH Topic E6 (R1) – Guideline for Good Clinical Practice regarding certain rights and obligations of a sponsor-investigator**

**ICH E6 - GCP Sponsor-Investigator**

* 1.54 An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

**ICH E6 - GCP Investigator Adequate Resources**

* 4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
* 4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
* 4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
* 4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

**ICH E6 - GCP Sponsor, Quality Assurance and Quality Control**

* 1.53 The sponsor takes responsibility for the initiation, management,   
  and/or financing of a clinical trial.
* 5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
* 5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.
* 5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

I, [*Please insert name and address of PI*] agree and accept to take over the responsibilities of a sponsor-investigator as set forth in ICH E6 – Guideline for Good Clinical Practice (GCP), in particular, but not limited to, the responsibilities specified in the above cited sections 1.54, 4.2-1-4.2.4, 1.53 and 5.1.1-5.1.3 ICH-E6, for the following clinical trial “[*Please insert study title*]”. I confirm to perform this clinical trial in accordance with ICH-GCP as well as all local laws, rules, regulations and codes applicable to the conduct of clinical trials phase I-IV.

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[*Please insert place and date*] [*Please insert name of sponsor-investigator*]  
Principal Sponsor-Investigator