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| **Interlaken Leadership Awards**  **Protocol Template** | |
| **Requirements for Submitting a Full Proposal** | |
| **Section #1 - Protocol Identification** | |
| **Study Title:** | *The title of the protocol should include study design, indication and, where applicable, dosage, dosage form, and comparative agent(s).* |
| **Request Date:** |  |
| **Institution Name** |  |
| **Investigator Contact Information:**   * Full address * Phone No. * Fax No. * e-mail address |  |

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| **Section #2- Core Protocol** | |
| **2.1 Objectives & Hypotheses** | 2.1 List the objectives.  *The objectives must clearly define and specifically state what the study is intended to accomplish*.  2.1.1 List the primary hypotheses.  *The primary hypotheses should correspond directly with the primary objectives of the study listed above.* |
| **2.2 Background & Rationale, Significance of Selected Topic & Preliminary Data** | *A presentation should be made of the reasons for conducting the clinical study based on current knowledge of the product and /or disease state so that the study is presented in the proper perspective. Include the rationale for conducting the study and selecting the dose(s). Selected literature references critical to the study design, dosage selection, or rationale for the study should be cited, as appropriate.* |
| **2.3 Study Design** | *This section is an overview of the study design stating the type of experimental design (observational or interventional; randomized, crossover, etc.); whether the study is controlled (treatments other than the test product and/or placebo); whether the study is open or blinded/masked (single blind or double blind); and the number of study centers (single or multicenter). The total number of patients (or animals) included in the study and how they will be assigned to treatment groups must be indicated. When appropriate, state if the patients (or animals) will be stratified. The procedures must be clear and concise. A description of the specific patient (or animal) population to be studied should be stated. Both inclusion and exclusion criteria should be listed.* |
| **2.4 Study Flowchart** | *A study flow chart is highly recommended. It should display all clinical and laboratory measurements and the time periods (e.g., hours, days, weeks) at which data are to be collected.* |
| **2.5 Study Procedures** | *This section is a detailed explanation of the experimental design. The use of subheadings, lists, tables, or outlines are recommended. Describe the initial screening period(s), baseline period(s), treatments to be compared, study configuration (parallel, crossover, etc.), duration of the treatment period(s), control group(s), follow-up procedures, and length of time specified for washout intervals and safety follow-up.* |
| **2.6 Study Duration** | *Estimate the length of time (e.g., number of days, weeks, months) required to recruit patients and complete the study.* |
| **2.7 Statistical Analysis and Sample Size Justification** | *State who will be responsible for analyzing the study data (Investigator, contract CRO, etc.). When appropriate state how the blind will be maintained during the study, as appropriate, and when the data will be unblinded.*  Variables/Time Points of Interest  *All variables (primary and secondary) that are listed in the study hypotheses, and the time points at which they will be analyzed, need to be described in detail.*  Statistical Methods  *All planned primary analyses and key secondary analyses should be discussed in this section. If other secondary and tertiary analyses are planned, then a statement should be included in this section as to what these analyses are.*  *Describe in detail the statistical methods that will be used for the primary hypotheses or estimation. State the statistical tests which will be used (e.g., ANOVA, Kaplan-Meier) along with other important considerations (e.g., factors in ANOVA, pre-specification of covariates, strata for Mantel-Haenszel, use of historical controls).*  Multiplicity  *If appropriate, describe the multiplicity approach to support the statistical conclusions of the trial.*  Power/Sample Size:  *For the primary endpoint of the study, a power statement needs to be included to show the detectable difference relative to the primary hypothesis.* |
| **2.8 Specific Drug Supply Requirements** | *The following should be indicated in the study protocol or provided by the investigator:*  *A description of the total drug supply required.*  *A description of how the study drug is to be administered.*  *A description as to how the clinical supplies are to be packaged and labeled.*  *If placebo is used (CLS Behring will not supply placebo)*  *A description of the placebo used*  *A description how blinding is ensured*  *If a specific placebo is produced for the trial: Description of facilities responsible for placebo production,*  *The investigator will be responsible for the destruction of the supplies at the study center pursuant to the ICH/GCP Guidelines, local regulations and the investigator’s institutional policies. Clinical supplies must be received by a designated person at the study site, handled and stored safely and properly, and kept in a secured location to which only the investigator and designated assistants have access. Clinical supplies are dispensed in accordance with the protocol. The investigator is responsible for keeping accurate records of the clinical supplies, the amount dispensed to and returned by the patients, and the disposition at the end of the study.* |
| **2.9 Adverse Experience Reporting** | *The study protocol must specify how adverse events are to be captured and recorded.* |
| **2.10 Itemized Study Budget** | *An itemized budget detailing the costs associated with the study should be provided with the final protocol.* |
| **2.11 References** | *All literature references cited in the protocol should be listed accordingly in the reference section.* |
| **2.12 Publication Plan** | *The following should be considered for the publication plan:*   * *What are your publication plans? How many manuscripts do you anticipate?* * *Include projected target date for manuscript submission and name of the journal* * *Do you anticipate abstracts? How many?* * *What scientific meetings would you consider presenting the study results?* |
| **2.13 Curriculum Vitae** | *The investigator should provide a curriculum vitae in English.* |