**Investigator Initiated Study – IIS**

**Abbreviated Study Outline (Initial Request)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Principal Investigator | |  | | | |
| Name | |  | | | |
| Institution | |  | | | |
| Address | |  | | | |
| Phone | |  | | | |
| E-mail | |  | | | |
| Years of Clinical Trial Experience | |  | | | |
| **Study Title** | |  | | | |
| 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 * confirmatory // exploratory pilot * clinical // pre-clinical * humans // animals // food animals * length of study   *other* | |  | | | |
| Planned number of study sites  * Only for multi-center studies | |  | | | |
| **Primary Objective**  Major goal of the study | |  | | | |
| **Secondary Objectives** Most important to be listed | |  | | | |
| **Evaluation Criteria**   * Primary analysis variable/endpoint * Most important secondary analysis variables/endpoints * Safety variables * Quality of life (*if applicable*) * Health economics (*if applicable*) | |  | | | |
| Study Treatment Plan  * Treatment plan and study goals * Schedule of visits displayed in a graph * Diagnostic/therapeutic/dosimetry goals for all study periods * Blinding techniques (*if applicable*) | | *Please describe the study design and display a graph including study treatment arms and visit schedule* | | | |
| **Study Population**   * Brief description of major inclusion criteria and major exclusion criteria | | **Inclusion criteria**  **Exclusion criteria** | | | |
| **Sample Size** | | Plan is to recruit up to n = x subjects  *For hypothesis generating exploratory clinical studies  the sample size calculation and justification should refer  to the primary objective/primary endpoint solely* | | | |
| **Estimated number of publications and timeline** | | *Indicate best estimate of the publications that will be generated from the data and the timeline necessary to complete the work.* | | | |
| **Safety Reporting** | | *Responsibilities of the investigator include all SUSAR/SAE reporting, drug accountability, posting and maintaining study on clinicaltrials.gov and responding promptly to requests for study updates.* | | | |
| Required Study Drug Support from Curium | | *Indicate if study drug support is being requested from Curium, and if so, indicate the quantity in this field (e.g. number of vials).* | | | |
| Estimated Total Study Budget | | *Indicate the estimated study budget. Please indicate the support being requested from Curium and the support that is the responsibility of the study site.* | | | |
| **Additional information** on the study concept to support IIS application | | *Please add additional information if applicable* | | | |
| **Compliance and Capability of Investigator to Conduct Research** | |  | | **True** | **False** |
|  | | The research study described herein was not solicited by Curium and Curium has had no influence over its proposed study design, objectives, or budget in any way. If approved, the study is not and will not be conditioned in any way on any existing or future business relationship between Curium and you or any affiliated entities on any decision you or any such affiliated entities may make in the future relating to Curium commercial products. | |  |  |
|  | | The research has clinical or scientific merit and will provide valuable scientific data and insight. | |  |  |
|  | | The study budget requested represents a fair estimate of the actual costs to conduct the study and is sufficient to achieve the objectives, methodology, and timelines.  If approved, the payments received from Curium will be used solely for the purposes described in the Study budget and do not represent an inducement to purchase any Curium commercial products. | |  |  |
|  | | You (the Investigator) in the conduct of the Study will adhere to all relevant standards including Good Clinical Practice, Good Pharmacovigilance Practice, obtaining Institutional Review Board /Ethics Committee approval, patient consent. | |  |  |
|  | | You (the Investigator) agree to use diligent efforts to seek study publication in accordance with the agreed publication plan. | |  |  |
|  | | You (the Investigator) will sign an IIS agreement prior to start of the study. | |  |  |
|  | | You (the Investigator) are qualified through education, training, and experience to properly conduct the research and have the appropriate resources in place in order to properly conduct the research with no additional assistance from Curium | |  |  |
|  | | There is no Institution patented (filed/unfiled) technology required for the study. | |  |  |
| **Condition of Submission** | | In submitting this information, you (the investigator) attest to having authorization to do so from any other originator of this information. Curium reserves the rightto refer this proposed request for IIS/IITs to a number of different persons within the company in order to evaluate each proposal.  Curium has no intention of publicizing thissubmission. Curium will exercise reasonable efforts to keeping the contents of thissubmission confidentialand you (the investigator) acknowledge and agree that Curium will not be liable for damages in the unlikely event that information in this submission is disclosed.  The rights of the originator(s) and submitter will be only those that are given under patent laws and/or written contract(s) to which the originator(s), the submitter, and Curium mutually agree. | | | |
| **Personal Data** | | With regards to personal data provided by European citizens, these will be handled in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and Council of the 27 April 2016, regarding the protection of individuals with regards to the processing of personal data, and the free movement of these data (General Data Protection Regulation) | | | |
| **Investigator Signature** |  | | **Date:** | | |

***Please enclose the following supporting documentation:***

Signed and dated Curriculum Vitae (CV) for Investigator and Sub-investigator(s) *(required)*

Letter of support from institution *(required)*

Disclosures of any sponsor or regulatory letters or actions in the past 5 years concerning any study conduct deficiencies, or unsatisfactory Investigator or study-site conduct OR confirmation that there have been no sponsor or regulatory letters or actions in the past 5 years concerning any study conduct deficiencies, or unsatisfactory Investigator or study-site conduct.  *(required)*

Copy of Study Protocol Synopsis (required) and Copy of Final Study Protocol *(if available)*

Copy of Study Project plan including expenses and funding plan *(if available)*

Copy of Ethics Committee (EC) / Institutional Review Board (IRB) approval *(if available)*

Return to [IIS@curiumpharma.com](mailto:IIS@curiumpharma.com)