Research Grants: IIS/CRS FAQs

PROCESS RELATED:

Q. How does the Zogenix IIS Review committee evaluate proposals?

A. The following aspects of a study concept or full study protocol are assessed by the multidisciplinary committee:

1. *How the study aligns with the company's currently defined areas of interest.*
2. *How well the study answers a specific question/hypothesis with a protocol design that will allow the question/hypothesis to be answered. (i.e. are the right endpoints being assessed, does the study have sufficient sample size).*
3. *The rationale or justification for the proposed sample size .*
4. *The statistical analysis plan (i.e. how will the data be assessed to answer the study question/hypothesis).*
5. *That the investigator intends to publish/disclose the findings of the study.*

Q. What is the difference between a study concept and a full study protocol?

A. Initial submission of a study concept using the form provided on our website is encouraged. This document provides sufficient information for the Zogenix IIS review committee to evaluate the proposal for fit within our current areas of interest. Therefore, if the concept is rejected, you will not have spent a significant amount of time developing a full study protocol. A full study protocol is a detailed document that describes the study objectives, hypotheses, methodology, endpoints/assessments, statistical analysis, and is submitted along with a detailed and itemized budget.

Q. Are Investigator Initiated & Collaborative Research Studies only available to investigators/sites that have done research with Zogenix in the past?

A. No., Any Health Care Professional (HCP) may submit an IIS-CRS proposal. However, one of the elements that is considered in reviewing proposals is previous amount of research experience by the investigator.

Q. What does Zogenix expect from investigators submitting proposals?

A. We fund proposals that can be conducted professionally and within agreed upon timelines. We expect: (1) to receive a proposal that is well-thought-out and designed to answer the specific question being asked in the study objectives/hypothesis, (2) the investigator is willing to commit to conducting the study within timelines and provide quarterly updates on progress, and (3) the investigator will disseminate the results of the study (which at a minimum includes posting the findings on clinicaltrials.gov).

Q. Do I need to submit a proposal if all I am requesting is study drug?

A. Yes, Zogenix reviews proposals following the same standards whether the proposal involves a request for drug only, funding only, or both.

ZOGENIX

Q. How often does the Zogenix IIS Review committee meet?

A. The committee meets on a monthly basis

Q. Who is responsible for monitoring the study?

A. The site is responsible for ensuring that its data is clean and accurate. Zogenix is not responsible for monitoring the site(s) in an Investigator Initiated Study.

Q. What is expected of me once the study is completed?

A. Zogenix expects to have a manuscript quality final report regardless of the study results AND that the data are posted on clinicaltrials.gov. Generally, the timeframe for obtaining the manuscript quality final report is within 6 months of study completion and to post results on clinicaltrials.gov is within 12 months of study "completion date". "Completion date" is defined in the law as ***"the date that the final subject was examined or received an intervention for the purposes of final collection of data for the *primary outcome*, whether the clinical trial was concluded according to the pre-specified protocol or was terminated (emphasis added)".***

PROPOSAL RELATED:

Q. Who is responsible for preparing the Protocol and Informed Consent Forms (ICF)?

A. The investigator/site is responsible for preparing its own ICF. For marketed product, Zogenix will provide a copy of the FDA approved package insert which contains the necessary information on the safety and tolerability to be included in the ICF. For non-marketed or preapproved product, Zogenix will provide suggested standard safety language that details the risks associated with the use of our products.

Q. Can I propose a study and conduct the study at several sites?

A. On rare occasions a study may be allowed to be conducted at multiple sites only if adequate need can be justified. You, as the sponsor, would be responsible for monitoring the other sites and distributing study drug to them. You would also need to provide a Monitoring Plan to ensure Good Clinical Practices are being followed.

Q. I don't have a statistician; can I use one from the company?

A. No, we cannot provide statistical support for an IIS-CRS. You can budget for this and contract with a vendor for stats support.

Q. Do I have to make up case report forms (CRF) to conduct the study?

A. No, however a separate CRF that collects the specific study information that can be included in the patient's medical record is highly recommended. Sites can determine how they want to collect and organize their data for analysis. The site must ensure that the data collected/used is verifiable within the patients' source documentation, such as the medical records.

Q. Can I use a central IRB?

A. Yes

BUDGET/CONTRACT RELATED:

Q. What items do I need in the budget?

A. If submitting a study concept initially, we request a high level, rough estimate of the cost of the study; realizing that this may change depending on the final study design. When submitting a full study protocol, the detailed budget should include the costs associated with each study procedure per patient.

Q. Can I include the cost of personnel in the budget?

A. The costs of staff (study coordinator, data manager, etc.) can be included in the initial budget. If so, the costs should be accounted for on a per patient basis, similar to the costs for study procedures. The Sponsor Investigator's costs should be accounted for in the cost of each procedure being performed.

Q. Can I include the cost of equipment in the budget?

A. No. The costs of purchasing equipment for the study cannot be included in the budget.

Q. How will I be reimbursed?

A. After the full study protocol and budget has been submitted and approved, an IIS-CRS Agreement contract will be generated and payments will occur according to the agreed upon milestone payment schedule in the Agreement.

Q. Do you have a financial cap on IIS studies?

A. The budget for the study must be within fair market value and the committee will evaluate the budget relative to the study methodology being proposed. Investigators practicing within an Academic and/or Institutional setting where overhead is charged should note that Zogenix corporate policy allows for a maximum 25% overhead for investigator initiated trials.