Investigators wishing to submit an IIS research synopsis will be verbally offered the option to have a CDA in place before submitting their idea. In the event of Investigator interest in a product where limited publicly available data exist (e.g., prior to first market authorization), a CDA will be initiated at the time BI expresses interest in the synopsis. Should an Investigator request BIPI confidential information (written or verbal) at any time during the IIS synopsis, proposal or protocol development steps, a CDA must be executed. BIPI will not accept paper submissions. All submissions and responses to inquiries from BIPI must be communicated directly through the internet-based tool. BIPI is continually reevaluating scientific interests for IIS. The most current information can be found on the BIPI website.
Obligations

Investigators must agree to the regulatory requirements of Sponsor-Investigator and all other FDA regulations regarding clinical research as applicable. For advice, please see the FDA requirements for Investigational New Drug Applications: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm.

All IIS Investigators must register their IIS study information on ClinicalTrials.gov. All IIS Investigators proposing research involving BIPI drugs must be willing to adhere to BIPI’s pharmacovigilance requirements.

Investigators must possess or be able to secure the needed resources to safely and efficiently conduct the study in accordance with Good Clinical Practice and all applicable US regulations. A BIPI Medical Science Liaison (MSL) will conduct a brief feasibility visit with all Investigators who submit an IIS for consideration.

Submission Requirements

The elements of the submission are outlined at: bipisupport.envisionpharma.com/vt_bi_iis.

Brief synopsis requirements include:
- Proposed title of the study
- Name & contact information of the Principal Investigator and Institution
- Brief scientific background & study rationale
- Study objectives
- Study design
- Curriculum vitae

Online support is available to add clarity to each required area. Investigators may consult their BIPI MSL for additional information regarding the level of detail required for each section.

BIPI personnel are not permitted to enter information on behalf of the Investigator or specifically guide/influence the content of the Investigator’s submission.

Should BIPI express interest in the synopsis, the following will be required for the full proposal:
- Study procedures and timelines
- Study flowchart
- Statistical methods
- Data management plan
- Drug supply request
- Preliminary budget*
- Associated/relevant and supportive literature citations
- Publication plan

* BIPI does not pay principal/sponsor-Investigator salaries. IS grants are typically less than $1.0 million US. BIPI limits allowable Institutional Overhead (F&A).

If BIPI endorses a full proposal, a complete protocol, inclusive of BIPI’s required drug safety monitoring and reporting requirements, must be submitted.

BIPI does not have specific requirements for protocol or case report form formats.

Submission Status

The status of your submission may be obtained in a number of ways:
- Accessing your submission history on BIPI’s Internet-based tool
- Contacting your BIPI MSL
- Contacting BIPI Medical Education and Research Grants

Overview of Process

BIPI is committed to the careful review of every IIS request for support that is received. As an organization with global interests, all submissions undergo an extensive evaluation process and compete with proposals at an international level. Investigators will be asked to submit their request for support in the following stages:

1. Brief Synopsis
   - Synopsis is submitted by Investigator
   - BIPI Synopsis Review Team (SRT) reviews
   - Decision is communicated

2. Full Proposal
   - Proposal & submission are requested by BIPI
   - US Clinical Development Medical Affairs (CDMA) IIS Review Committee reviews
   - Global CDMA IIS Review Committee reviews

3. Complete Protocol
   - Following each submission, Investigators will be notified of BIPI’s continued interest, need for additional information and possible endorsement of the IIS. Submission of a synopsis/proposal does not imply or guarantee endorsement. All proposals will be reviewed based on scientific merit and available funding. Full endorsement will be received only after receipt and evaluation of a complete protocol.
   - BIPI reviews proceed to provide steady insight into the endorsement of each proposal. Specific timing varies and is dependent on numerous factors, including the nature of the research being proposed.
   - BIPI employees cannot commit to IIS support.

Access to Helpful Resources

The BIPI USA Web Site
us.boehringer-ingelheim.com/our_responsibility/grants_and_funding.html

FDA Website
www.fda.gov

Guidance for Industry Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects

ICH Website
ich.org

Clinical Trials Website
clinicaltrials.gov

BIPI Medical Education and Research Grants, IIS Office—Technical Assistance in Submissions
To contact please send an email to medris.rdg@boehringer-ingelheim.com.