

## Ferring Investigator-Initiated Trials (IIT) Submission Guidelines

### WHAT WE SUPPORT

The mission and purpose of the Ferring Investigator-Initiated Trial Program is to provide support for investigator-initiated research that advances medical and scientific knowledge about Ferring Pharmaceutical Inc.'s products and generates promising medical therapeutics.

The following are Ferring's areas of interest for our Investigator Initiated Studies Program:

IITs studying areas that will provide patient benefit:

- Urology: GnRH antagonist use where hormonal therapy can be considered
- Orthopedics: Hyaluronic acid use in osteoarthritis where viscosupplementation can be considered
- Reproductive Health: Gonadotropin [follicle stimulating hormone (FSH), luteinizing hormone (LH), human chorionic gonadotropin (hCG) and human menopausal gonadotropin (hMG)] and progesterone use in the treatment of infertility
- Gastroenterology: Sodium picosulfate, magnesium oxide and citric acid in combination for bowel cleansing preparations
- Women's Health: Dinoprostone (PGE2) use in labor inductions

### WHO IS ELIGIBLE

The program is open to all researchers who are interested in conducting their own research.

Types of Research Eligible for Support:

- Clinical studies of approved and unapproved uses, involving approved Ferring drugs
- Observational studies, such as epidemiology studies and certain outcomes research studies where the primary focus is the scientific understanding of disease
- Other types of independent research on disease states, including diagnostic screening tools and surveys where Ferring has no direct commercial interest

### HOW TO PARTICIPATE

Investigators interested in Ferring's IIT program must submit an online application outlining their preliminary concept, protocol and detailed line-item study budget. Assessment of each IIT request will be conducted in four tiers.

- First tier assessment performed by the applicable local TA MSL or respective MA Therapeutic Head, shall focus on the preliminary concept review of general alignment with the documented strategies and Therapeutic focus.
- The second tier assessment will be performed by the Local IIT responsible and applicable local TA MSL, evaluating the completeness of the request including availability of budget and qualifications and suitability of proposed site.
- Third tier assessment, conducted by the MA Therapeutic Head, includes a full protocol review, assessment of Investigator qualifications and capabilities to conduct the suggested study.
- The fourth tier assessment conducted by the IIT RC includes a cross-functional evaluation of the request for support for medical, scientific, safety, regulatory, legal and compliance aspects.

The following minimum information is required for first tier assessment:

- IIT Preliminary Concept (protocol outline or protocol summary)
- Curriculum Vitae for Principal Investigator

The following minimum information is required for second, third and four tiers assessment:

- Detailed Protocol (complete description of the proposed research proposal, including research objectives, methods, procedures, costs and timelines)
- Detailed line-item study budget
- Documentation of Institutional Overhead, if itemized in budget

All completed submissions that meet the application criteria will be considered and evaluated on individual merit in accordance with established guidelines and policies.

The applicant will be updated on the status of the proposal throughout the review process.

Upon review and approval of the full protocol and study budget by the Review Committee, Ferring will send the researcher a Research Agreement containing terms and conditions of support to be approved by the researcher and the researcher's institution, including institutional review board or ethics committee approval of the protocol.

## RESEARCHER RESPONSIBILITIES AND REQUIREMENTS

The Investigator is the sole sponsor of the research and assumes full responsibility for the scientific and technical conduct of the Investigator Initiated Trial (IIT). The Investigator shall ensure that they have the expertise, staff and resources necessary to conduct the IIT. Investigators who seeking support from Ferring, are obligated under the Research Agreement (RA) to conduct the IIT in compliance with all applicable Federal, State and local laws and regulations, statutory requirements for safeguarding patients during clinical trials and FDA guidelines, including but not limited to:

- Good Clinical Practices
- The Federal Food Drug and Cosmetic Act
- Relevant provisions of Title 21 of the Code of Federal Regulations and Standards for Individually Identifiable Health Information.
- HIPAA Privacy Regulations
- Report Adverse Events to Regulatory Authorities and to Ferring within 24 hours of first knowledge.
- Obtaining all necessary regulatory approvals required for performance of the IIT including IRB approval and IND/IDE when mandated.
- Registering the IIT with **WWW.CLINICALTRIALS.GOV** prior to enrolling any subjects and complying with requirements associated with registered on the site.

## REGULATORY, ETHICAL, and SAFETY RESPONSIBILITIES

Ferring is committed to supporting innovative research by providing financial and/or product support for IITs independently initiated, developed and conducted by eligible Investigators, organizations and institutions in accordance with the following guidelines:

- Office of the Inspector General of the Department of Health and Human Services (HHS-OIG) *Compliance Program Guidance for Pharmaceutical Manufacturers*
- FDA Guidance on *Industry-Supported Scientific and Educational Activities*
- American Medical Association, *Code of Medical Ethics*
- Applicable FPI guidelines related to ethical corporate conduct
- Applicable federal and state regulations, including the Anti-Kickback Statue and False Claims Act

## STATUS REPORTING

Researchers who receive support will agree to keep Ferring informed on the progress and status of their research, including (but not limited to):

- Prior to public disclosure, submission to Ferring of the description of the study that is required to be posted on a public website, e.g., [clinicaltrials.gov](http://clinicaltrials.gov).
- Any amendments to the original protocol.
- Proof of approval of the study (and any changes requested or required) by local or national regulatory authorities and ethics committees.
- Quarterly Status updates on study such as patient enrollment, randomization, estimated timelines for study completion, etc.
- Plans to publish or present interim and/or final study results by providing Ferring with any manuscript, abstract, presentation or publication arising from an IIT prior to submission to any third party other than the FDA.
- Notification of study completion.

## STUDY COMPLETION/CLOSE-OUT

Upon study completion, the investigator is required to submit a final budget reconciliation and evidence that the IIT has been completed. This evidence may be in the form of a manuscript or abstract suitable for submission to a scientific journal or meeting, or a detailed final study report. Failure to submit this information will prevent payment of any remaining milestone payments and will affect the consideration of future IIT proposals received from the Investigator.

Any financial support not use exclusively for the IIT must be returned to Ferring. Investigator shall destroy any product not used exclusively for the IIT and provide Ferring with written documentation of destruction.

## IIT PRODUCT SUPPLY PROCESS

Investigator may obtain marketed product as part of an IIT Review Committee approved request or from independent commercial source as defined within the executed research agreement. Active comparator and/or placebo cannot be provided by Ferring and must be obtained by the Investigator from an independent commercial source.

The provision of IIT Study Drug will be initiated following:

1. Approval by the IIT Review Committee
2. Execution of the Research Agreement

3. Copy of the Primary Investigator's current Medical License
4. Investigator must acknowledge receipt of product supply in order to receive subsequent supply.

All approved product for IIT use will be supplied from the distribution center directly to investigator (or Institutional designee). If the product is available, a minimum of 14 days lead time is required from receipt of the completed request and expected delivery to the Investigator. If the product is not available, Investigator (or Institutional designee) will be informed by Ferring and a minimum of 30 days lead time is required. Certain situations may require further extension of these lead times.

The Investigator is responsible for fulfilling the following product related tasks:

- Obtaining necessary regulatory and institutional approvals required to prescribe and provide product to subjects participating in the study.
- Providing appropriate shipping information (including Investigator and site contact, pharmacy or institution recipient name, address, email, fax.)
- Providing progress reports on study status on a quarterly basis, at minimum.
- Submission of requests for product at least 14 days prior to treatment.
- Appropriate handling, storage monitoring and product accountability in accordance with labeling and applicable legal requirements.
- Packaging, blinding and labeling operations in accordance with appropriate packaging and labeling regulations, if applicable.
- Releasing product to subjects after blinding and labeling.
- Reporting of Product Complaints to Ferring, within 24 hours of first knowledge to the Ferring Call Center.
- Fulfilling all regulatory requirements prior to release.
- Limiting product use and evaluation to activities directly related to the IIT protocol approved by the IIT Review Committee.
- Destruction of product not used for the approved study and completing/signing Ferring template as proof of destruction.
- Notifying Ferring if audited by FDA in regard to a Ferring product used in an Investigator Initiated Trials

## BUDGET & OVERHEAD COSTS

Before submitting your budget, please ensure that all study-related expenses have been itemized and are appropriate with fair market value. Further documentation will be required for overhead costs.

## FINANCIAL DISCLOSURE

The Centers for Medicare & Medicaid Services (CMS) has issued its final rule to implement the Federal Physician Payments Sunshine Act. The Sunshine Act requires pharmaceutical and device manufacturers to annually report certain payments or other transfers of value made to "Covered Recipients," including US-licensed physicians and teaching hospitals. The Sunshine Act promotes transparency by requiring the disclosure of financial relationships between drug manufacturers, investigators and study sites.

It requires Ferring to disclose funding provided in connection with Investigator-Initiated Trial Agreements. While Ferring's reporting will differentiate between payments made to institutions and payments made to individuals, the Sunshine Act does require Ferring to report the names of the principle investigators conducting IITs.