**INVESTIGATOR-INITIATED TRIAL (IIT) INFORMATION**

CGBio’s R&D activities are focused on the Key Therapeutic Areas; Orthopedic & Neuro Surgery.

CGBio offers support as funding and/or Investigational Device (ID) concerning locally commercially available CGBio products to Investigators who are interested in conducting Investigator-Initiated Trials (IITs) assuming responsibilities as the trial sponsor.

**IIT Application Evaluation Criteria**

Potential of the IIT to provide answers to the hypothesis and the objectives in the protocol.

Scientific merit and quality of the IIT (i.e. novelty and importance of the research question, quality of the research plan).

Investigator ability and resource to complete the IIT.

Patient safety adequately protected and defined in the process for serious adverse events reporting.

Alignment with the Key Therapeutic Areas as outlined in the global internet homepage of CGBio (www.cgbio.co.kr).

Budget clearly itemized and within fair market value.

**The Review Process**

The Clinical trial manager of CGBio will acknowledge receipt of the IIT via email.

The review of IITs is conducted by a CGBio IIT review committee and decisions are made based upon medical and scientific merit as well as available resources and research priorities. Notification on the status of the application will be provided by the clinical trial manager of CGBio.

**\*\*Investigator Responsibilities (list not exhaustive, see below references for full details)**

* Protocol writing.
* Agreement negotiation(s).
* Ethics Committee/Institutional Review Board and Regulatory submissions and approvals.
* Registration of the trial protocol and the results in the applicable local and/or public trial registry/clinical trials results database.
* Management of the medical device (If necessary).
* Trial conduct.
* Adherence to ICH/GCP and any locally applicable laws and regulations.
* Serious Adverse Event reporting to the applicable Regulatory Authorities, Ethics Committees and CGBio.
* Trial insurance
* Reporting of trial progress to the clinical trial manager of CGBio.
* Analysis and interpretation of trial results.
* Provision for review by CGBio (before submission) - the results summary to be published in the applicable public accessible intranet-based clinical trials database - the trial report and any journal manuscripts/ scientific congress abstracts/posters/slides.
* Further Information: Please address all questions related to your IIT application to the clinical trial manager of CGBio.

**References:**

1. International Conference on Harmonisation. Guideline for Good Clinical Practice; E6/R1. 1996
2. DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 4 APRIL 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
3. Draft guidance on ‘specific modalities’ for non-commercial clinical trials referred to in Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice.
4. Food and Drug Administration. 21 CFR 312. Investigational New Drug Application; section 312.3.
5. Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use, rev. 2. April 2006, ENTR/CT 3, European Commission.