

Information for Investigators



Venus' Investigator Initiated Studies Hub



VENUS MEDICINE RESEARCH CENTRE

(2019)

Venus Medicine Research Centre (VMRC) is devoted to exploring medical and scientific knowledge related to its products, disease conditions of interest and medical practice through the provision of Investigator Initiated Studies (IIS).

Investigator Initiated Studies (IIS) grants are provided to assist qualified investigators in conducting research they alone have conceived and designed and will execute, analyze and report.

VMRC may provide IIS grants in the form of funding and/or material support (including drug products) in response to unsolicited requests from external investigators wishing to conduct an independent scientific investigation.

IIS designs supported by an IIS grant may include but are not limited to:

- Epidemiological studies,
- Preclinical (*in vitro* or *in vivo* animal) studies or
- Clinical investigations

### **Encouraging Scientific Evidences through Investigator-Initiated Research**

The research from investigator-initiated studies may expand our understanding of our products and their potential applications. Further, it may improve patient care and ignite new ideas for further disease-related research.

The VMRC IIS Program provides an opportunity to academic and community-based physicians and researchers worldwide interested in conducting their own research to apply for research support.

### **How to apply**

If you're an investigator, you can initiate the application process by submitting a brief summary of the proposed research to VMRC through our IIS Portal. IIS applications are accepted on a rolling submission basis.

For update on VIISH portal, please show your Expression of Interest (EOI) on [www.viish.vmrcindia.com](http://www.viish.vmrcindia.com) .

### **After you apply**

Following the review of the initial submission, you may be asked to submit a full protocol and final study budget for further evaluation. We hold protocol review meetings bi-monthly. Submission of a proposal does not imply or guarantee approval. The committee evaluates proposals according to their scientific merit, alignment with our areas of research interest and available funding. Financial and/or product support is contingent upon full execution of the research agreement by both parties.

### **Therapeutic Areas of Interest**

To learn more about our priority products and therapeutic areas for IIS grant 2019, Click on link [www.viish.vmrcindia.com](http://www.viish.vmrcindia.com) .

### **Program Guidelines**

- Investigator Initiated studies support is only provided to independent investigator or academic sponsor associated with institutions/ organizations.
- IIS grant requestors and their institutions/ organizations, must be in good standing with VMRC as it pertains to any current contractual obligations (*e.g.*, ongoing IIS) and in compliance with all applicable laws and regulations.
- VMRC reviews all IIS requests for scientific soundness, safety, legal, and ethical considerations. IIS requests are also reviewed according to local applicable laws and regulations.
- VMRC does not fund any portion of a study that may have taken place prior to a fully executed agreement.
- VVMRC does not provide operational support (*e.g.*, authorship of a protocol, statistical analysis, study report, publication, site monitoring) for an IITs. Operational support for IIS research is the responsibility of the sponsor-investigator.
- A written agreement between the requesting organization/Institution and VMRC must be fully executed before payment or materials are provided as part of an IIS grant.

VMRC is not the sponsor of an IIS. The investigator and institution/organization assume all legal and regulatory responsibilities as a sponsor-investigator.

The sponsor/investigator has to fulfil (or agree to) the following requirements:

- have the scientific, technical and operational capabilities to conduct a study as a sponsor including adequately trained staff to execute a study (GCP, GMP, etc.)
- have expert statistical support
- submit a scientifically well designed and well-written study proposal
- deliver to agreed timelines
- be able to fulfill all regulatory requirements (including submitting a NDA/IND/CTA, writing of final study report and manuscripts etc.)
- deliver a written report of the final study results to VMRC
- publish the study in a scientific journal
- agree to safety reporting to health authorities and to VMRC
- agree to provide study updates to VMRC

### **VMRC IIS Life Cycle:**

Researchers are invited to submit their concept proposal via the VMRC IIS portal(VIISH). Concept submission will be reviewed collectively by the VRL Review Committee based on scientific merit and alignment with corporate research and development plans.

1 . **PREPARE:** Prior to making a submission please review the program guidelines, area of interest, review cycle time line and FAQ related to IITs program.

2. **REGISTER/LOG-IN:** Register with VMRC IIS Portal (VIISH) as a first time user,or login with your previously established credentials.

3. **APPLY** : Once registered, you will be asked to select your proposal request type(brief or full), complete fields in the system and upload request documents.
4. **REVIEW** : VMRC will review your request for completeness,alignment with our research priorities and overall feasibility and scientific merits.
5. **DECISION NOTIFICATION** : VMRC will notify you via email as to whether we require more information, your proposal is declined or approved.
6. **CONTRACT** : If approved,VMRC will request appropriate regulatory and ethics approval verifications from you and develop an IIS agreement(Contract) with you and your institution.
7. **INITIATE** : Once a agreement is finalized and any required ethics and regulatory approvals in place, VRL will provide drug product and agreed upon funding is appropriate milestones so you may initiate your study.
8. **MONITORING** : During the course of your study VMRC will request periodic updates be submitted to monitor your progress against he agreed upon milestones(e.g. enrollment rates).
9. **CLOSE** : Once your study has concluded you will provide a final report and/or manuscript to VMRC as evidence



For questions around the submission process and technical support, please contact:

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[iissupport@vmrcindia.com](mailto:iissupport@vmrcindia.com)

[www.viish.vmrcindia.com](http://www.viish.vmrcindia.com)