Frequently Asked Questions

This document provides FAQs for investigators interested in registering or who have registered on the Lundbeck Contribution Portal for support of an Investigator Initiated Trial (IIT). We highly recommend that investigators review the information in its entirety before creating a login/registration and/or submitting a proposal.

1. **What is an investigator-initiated trial?**
   Investigator Initiated trials are clinical trials initiated, developed, designed and managed by a qualified sponsor who assumes responsibility for conduct and management of the trial.

2. **What types of support can be provided?**
   Support of approved proposals can be in the form of funding and/or study materials (including products, placebo, or other medicinal products necessary for the research)

3. **What is the role of the investigator-sponsor?**

   - Design the protocol
   - Develop and maintain the case report forms
   - Initiate and monitor the study
   - Understand and comply with any and all pertinent laws, regulations, and guidelines
   - Understand and comply with any and all requirements of institution(s) with which they are associated or in which research will occur
   - Report safety data to regulatory authorities and the IRB/IEC

   The investigator-sponsor for an IIT is responsible for all facets of the trial, including concept and protocol development, budget development, ethics and review board submissions, and trial management.

4. **What is Lundbeck's role?**
   Lundbeck will provide support as outlined in the legal agreement in a timely manner.

   Lundbeck will provide any scientific/medical feedback to the investigator-sponsor at any time regarding the proposal, the protocol, or any aspect of study conduct where we have a concern about the scientific integrity of the study or the patient well being

5. **Can Lundbeck help develop a protocol, statistical analysis plan, etc.?**
   No. As part of the legal requirements, investigator-sponsored trails must be unsolicited. Lundbeck can post generalized areas of interest but cannot participate in study concept generation or protocol development.

6. **I have an idea for a study I'd like to conduct. How do I know whether it's something Lundbeck might be interested in supporting?**
   Potential investigators are encouraged to review Lundbeck's IIT areas of interest; however, please note that submission in these areas of interest does not guarantee support. Lundbeck will review and consider all relevant research proposals but is not obligated to provide support for any research proposals received. Lundbeck will only undertake IITs with third-party sponsors/investigators that are able to demonstrate clear evidence of high ethical and scientific standards as it relates to clinical research in human subjects as stipulated by the International Conference of Harmonization (ICH) Efficacy Guidelines E6 - GCP. Investigators undertaking non-clinical studies using animal subjects will have to provide equivalent evidence of ethical standards and/or Good Laboratory Practices (GLP).

7. **How can I submit my research proposal? How do I register?**
   Investigators are encouraged to discuss their idea with a Lundbeck Medical Science Liaison (MSL) before submitting. Investigators who do not know who their local Lundbeck contact is should email: US-IIT@lundbeck.com.

   Proposals can be submitted through the Lundbeck Contribution Portal, which is Lundbeck's online submission portal.
   - Click on the Register button and complete the required information. The contribution portal contains a series of check/drop boxes and open-text fields to guide investigators during the process of submitting their proposal.
   - You will receive an e-mail acknowledgement from Lundbeck within 24 hours confirming the new account.
   - Throughout this step and all phases of the process, the IIT portal sends auto notifiers as the proposal advances through the review.

   Following OIG guidelines, sales representatives and marketing contacts will not be a channel for information.

8. **When should I submit my proposal?**
   Lundbeck accepts and reviews research proposals on a monthly basis.

9. **Can you provide guidance on how the proposal should be formatted, and what information is important to include?**
   Investigators are encouraged to visit the Submission Guidelines page for clarification on what information should be included when writing the study background and rationale, describing the study objectives and endpoints, inclusion and exclusion criteria, methodology, sample size calculations and statistical analysis, etc.

10. **What items should I include in my study budget?**
    A detailed line-item budget should be provided which outlines in good faith reasonable and necessary anticipated costs.

Before submitting your budget, please ensure that all study-related expenses have been appropriately itemized and are included and are commensurate with fair market value.

Suggested items to consider in calculating the budget:
Direct Study costs (including overhead costs) such as:

- Subject related costs
- Study related personnel costs
- Diagnostic fees and services
- Data management expenses

Indirect Study costs (not including overhead costs) such as:

- Publication costs (e.g., preparation of manuscript, etc.)
- IRB review fees
- Equipment/supply expenses
- Animal-related costs *(if appropriate)*

11. Are there any expenses I should not include in my budget?

Lundbeck will not compensate for the following:

- After the fact support for research that has already been conducted
- General education and training activities
- Support for ongoing clinical programs that are part of an organization's routine operations
- Purchase of capital equipment unrelated to the study or that would generate revenue
- Construction funds to build new facilities
- Hiring of staff that are not dedicated to the study

12. Once I submit a research proposal to Lundbeck, how long will I have to wait to be notified of a decision?

On a monthly basis, the Lundbeck IIT Committee) will review all proposals that have been submitted and issue an initial decision within 2 months. The investigator will receive a system generated e-mail.

13. On what basis does the Lundbeck Grant Review Committee make its decision?

- Welfare of research study subjects
- Scientific merit of the research
- Overall soundness of study design
- Adherence to Good Clinical Practice
- Alignment with our objectives
- Principal and sub-investigators experience in conducting research
- Compliance with company policy and requirements

14. Does previous support of my research by Lundbeck guarantee future support?

No, each request submitted to Lundbeck will be evaluated based on its individual merit, as well as the amount of overall funding still available in a particular calendar year. Please do not consider any request approved until you receive written confirmation from Lundbeck and all necessary parties have signed the applicable written agreement.

15. **If my investigator-initiated research grant application is accepted, how long does it take to receive funding?**
    Following the initiation of a study, funding will be released as key milestones are achieved, in accordance with the payment schedule noted in the IIT Agreement.

16. **What types of deliverables are required during and following completion of the study?**
    The amount and frequency of deliverables vary by study and are set forth in the agreement milestones. Common milestones are study update reports or achieved enrollment.

17. **Is a publication required for my study?**
    As part of Lundbeck's commitment to publishing research, Investigators are encouraged to publish the study results whether favorable or not to Lundbeck or its' products. As the Investigator, the content of any publication is your responsibility, and Lundbeck will not be involved in authorship selection or writing and should not be included as a co-author of IIT publications.

    Lundbeck maintains the right to review each publication and/or presentation (including, but not limited to, full manuscripts, abstracts, poster presentations and oral presentations) of results of the research prior to its submission to anyone not affiliated with Lundbeck or the principal investigator. You should submit any publications to Lundbeck for review at least 15–30 days prior to submission, depending on the publication type.

    The principal investigator will comply with recognized ethical standards concerning publications, authorship and disclosure of funding, including without limitation the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, **www.icmje.org**, established by the International Committee of Medical Journal Editors.

18. **How do I check the status of my grant request or payment?**
    You may check the status of your grant request by logging on to the Lundbeck Contribution Portal.

19. **How are study protocol changes handled?**
    Lundbeck requires disclosure of any protocol changes made since the commencement of the research.

    Study protocol changes must be submitted when there is a significant change in the design and/or implementation of the study when compared to the original submission. Requests for a protocol change will be considered on a case-by-case basis, but approval is not guaranteed.

Please log on to the Lundbeck Contribution Portal with the following information:

- Anticipated changes to the study design, if applicable
- Anticipated changes to the study implementation, if applicable
- Anticipated changes to the personnel involved with the study, if applicable

If it is determined that Lundbeck no longer wishes to support the study based on the changes, Lundbeck may cancel the request post-funding.

20. **What does "Clarifications Needed" mean and how much time do I have to respond?**
    A request for additional information is made when more information is needed to consider the request. This request will be sent by e-mail to the email address provided by the requestor during the registration process. Please review the e-mail carefully and submit the additional information through the Lundbeck Contribution Portal.

    If Lundbeck has not received the necessary information within 30 calendar days of the request for additional information, the original request will be closed.

21. **What is the Study Update Report?**
    The study update report is used to provide information to Lundbeck on the progress of the study. In accordance with the research agreement, a study update report must be submitted on a regular basis throughout the duration of the study. Study updates must be submitted online through the Lundbeck Contribution Portal.

22. **What is the Final Study Report?**
    The final study report is a detailed summary of study results. The principal investigator (ie, sponsor-investigator) is required to provide Lundbeck with a written, manuscript quality report of the final study results. Upon study closure, the investigator is required to provide a detailed budget reconciliation demonstrating that IIT funds and/or product were used solely to conduct the study, all safety reporting obligations were met, and unused study drugs/product were destroyed or returned in accordance with the organization's policies.

    Lundbeck requires that a final study report be submitted before the final milestone payment may be released. The final study report must be submitted online through the Lundbeck Contribution Portal.

23. **Why doesn't my password work?**
    If you have tried several times and are still unable to login, you may reset your password by clicking the "Forgot Password" link. If you are still unable to access the system, please email SteepRock at Lundbeck@SteeprockInc.com

24. **May I complete part of the online application and come back to it later?**
    Yes. If you are unable to complete your online application in one session, you may save it and come back to it later by clicking "Save & Continue Later" at the bottom of the page. At

any time before the submission, you will have the opportunity to come back and make changes to the application.

25. **How will I know if my proposal was received?**
    E-mail notifications will be sent to the registered user account throughout the process to acknowledge registration and receipt of proposal, to convey the review committee's decision and to request periodic study updates for previously approved studies. Once proposals are submitted, you may also log onto the Lundbeck Contribution Portal to check for status updates

26. **What if I do not receive e-mail notifications?**
    Please check SPAM and/or Junk e-mail folders.

27. **Unfortunately, I have not found the answer to my particular question on this website. Who can I contact?**
    Please email US-IIT@Lundbeck.com for assistance. Investigators are also encouraged to contact their local Lundbeck Medical Science Liaison (MSL), local Medical Director, or other appropriate Lundbeck personnel.

    Those who do not know who their local Lundbeck contact is should please email: US-IIT@Lundbeck.com.

    Following OIG guidelines, sales representatives and marketing contacts will not be a channel for information.

For any Investigator Initiated Trial question/s not answered by viewing this website please contact the Lundbeck IIT Team by calling (844) 634-7867 or via email at: US-IIT@Lundbeck.com. Please allow at least 2-3 business days for a response to your email inquiry.