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.

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1. **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. Investigators are also encouraged to discuss their idea with a Lundbeck Medical Science Liaison (MSL), local Medical Director or other appropriate Lundbeck personnel before submitting. Investigators who do not know who their local Lundbeck contact is should email: US-IIT@lundbeck.com. Following OIG guidelines, sales representatives and marketing contacts will not be a channel for information.

2. **How can I submit my research proposal? How do I register?**

   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.

3. **When should I submit my proposal?**

   Lundbeck accepts and reviews research proposals on a monthly basis.

4. **Can you provide me with some guidance on how I should format my proposal, and what information you consider important to include?**

   The contribution portal contains a series of check/drop boxes and open-text fields to guide investigators during the process of submitting their proposal.

   In addition, 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.

5. **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.

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

   Yes. Lundbeck cannot provide after-the-fact support for research that has already been conducted. The Lundbeck IIT office also cannot provide funding for general education and training activities, fellowships or personnel costs expressed as a percent of full-time employment, capital expenses, or travel expenses for study personnel. For ME grants information, please visit the Medical Educational Grants page.

7. **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 Medical Grants Review Committee (MGRC) will review all proposals that have been submitted and issue an initial decision within 2 months, if not sooner. The investigator will receive a system generated e-mail.

8. **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.

9. **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 contact the IIT Lundbeck Team at US-IIT@Lundbeck.com

10. **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

11. What if I do not receive e-mail notifications?

Check SPAM and/or Junk e-mail folders.

12. What is the sponsor-investigator responsible for?

The sponsor-investigator 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.

13. 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.

14. What documentation is required for an IIT to be reviewed?

Investigators are encouraged to visit the Submission Guidelines page for clarification on what information should be included when writing the study background and rationale.

15. If my investigator initiated research grant application is accepted, how long does it take to receive funding?

Disbursement of funds for approved IIT grant applications vary based on the finalization of the agreement between Lundbeck and the institution with which the investigator is affiliated. Following approval, Lundbeck's legal department will prepare an initial draft agreement. In general, the agreement sets forth the obligations of the investigator/institution and Lundbeck in relation to the study. Once Lundbeck's legal department has prepared a draft of the agreement, it is forwarded to the investigator/institution for review. When a fully-executed agreement is received by Lundbeck, the IIT coordinator will commence execution of payment and/or product shipment deliverables.

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?

Lundbeck encourages publication of study results regardless of study outcomes. A copy of any abstract, presentation, or manuscript must be submitted to Lundbeck for courtesy review according to the terms outlined in the agreement.

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?

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 e-mail 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 90 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. 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. Unfortunately, I have not found the answer to my particular question on this website. Who can I contact?

The Lundbeck IIT Team may assist you with your request. 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.