Takeda Support | Research

Frequently Asked Questions for External Investigators

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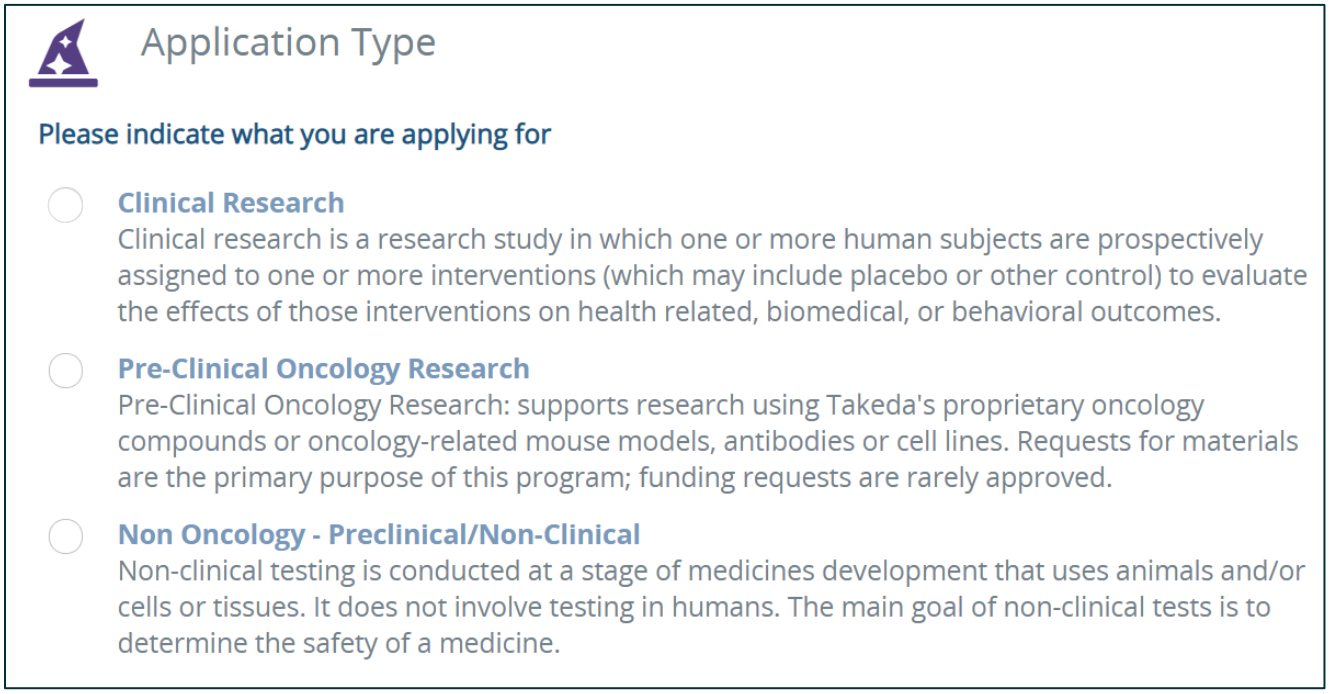
1. ABOUT TAKEDA SUPPORT | RESEARCH

1.1 Who may apply for Research support?

Takeda Support is intended for the submission of product and/or funding support for Research studies aligned with Takeda's therapeutic areas of focus.



1.2 What type of information is needed for submission?

Information about the type of study, requested support, and the related research details; this includes completing the required fields, marked with an asterisk, on the following nodes:

- **General Information**: The study title/short title, therapeutic area, product/material, indications, type of support, site information.
- **Personnel** – **Primary Investigator**: Primary Investigator contact and institution information, medical licenses, and their CV. Additional personnel can be added on this node, as needed.
- **Sites** – **Primary Site**: Primary site background and contact information. This should be a site that will serve as a regulatory study sponsor. For multicenter studies additional sites can be added on this node, as needed.
- **Proposal**: Enter the proposed study information including: timing, number and rate of subjects/samples, overview/hypothesis, and background/rationale.
- **Scientific Summary**: Enter the target population, objectives, endpoints, inclusion criteria, exclusion criteria, sample size/statistical power, treatment plan, references, and past history and experience.

- **Protocol/Budget**:
  - When submitting the proposal:
    - You must enter the requested currency, total project costs, and the requested amount of support from Takeda (if applicable).
    - You will have the option to attach the full protocol and budget at this time, if available, or prior to study activation.
    - Upload your budget or use the budget template available within the *Protocol/Budget* node
  - Prior to study activation, a full protocol and budget must be provided and approved
- **Requested Product**: If product support is requested, you will need to enter the formulation, dosage, unit of measure, and quantity of product requested.
- **Planned Publications**: Enter all planned publications by journal/congress, publication type and anticipated date.

1.3 Why does Takeda request so much information during submission?

Takeda assesses several factors during the initial review in order to make an informed decision. These factors include: request type, alignment to Takeda`s research areas of interest, sponsor/site capabilities, budget availability, and risks, etc.

2. NEW USER REGISTRATION

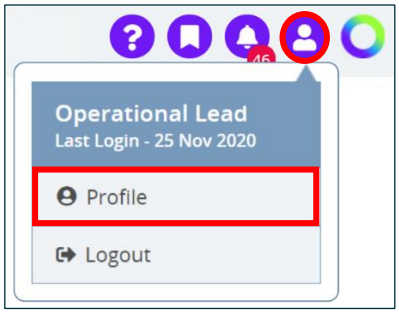
2.1 How do I register for a new account?

To register, open this link:
https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=ISR

- Then select the *Register for New Account* link
- Enter the required contact information and click *Register*
- You will receive an email to activate your account
- To login, enter your email address and password entered during the registration

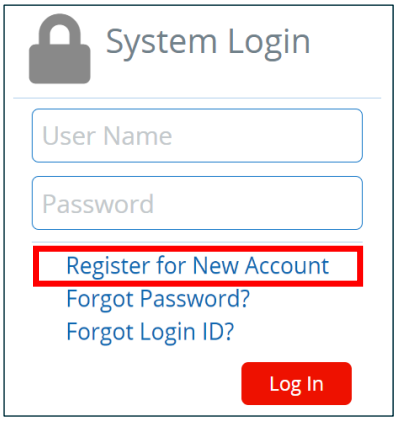
2.2 How do I update my profile?

To update your profile, click the *Profile Global Tool* icon and then select *Profile*.



2.3 What do I do if I have forgotten my password?

Click the *Forgot Password?* link on the login page.



2.4 Who do I contact for additional support?

For Pre-Clinical Oncology Research support, contact: preclinicaloncology@takeda.com

For Clinical Oncology support, contact: gmao.evidence.generation@takeda.com

For Non-Oncology support, contact: gma.research@takeda.com

3. MY STUDIES

3.1 Can I use any internet browser to use Takeda Support?

Takeda Support is a web-based system that can be used on any browser. For optimal performance, we recommend using Google Chrome.

3.2 Does the Takeda Support system time-out?

The system will log you out after 60 minutes if there has been no activity. The system will automatically save when you move between screens/nodes. It is good practice to save often.

3.3 How do I save my study record?

Select *Save* from the *Actions menu*. You can save the progress of your study record, allowing you to return later to complete it.

3.4 How can I view or open a saved study?

You can view and open saved studies from your *Dashboard* or *Workbench*.

3.5 How do I print my study details?

You can print your study de by using the gear icon on your *Workbench* or by selecting print from the *Actions menu*.

3.6 What type of attachments are required during the study life cycle?

Required documents vary based on the request/study type and may include:

- Budget, using the Takeda-provided budget template (specific to Oncology or non-Oncology)
- Drug Destruction Certificate, as applicable
- Final Study Report and/or any Interim reports, as applicable
- FMV Analysis, as applicable
- IRB/EC Approval Letter and other relevant regulatory approvals, as applicable
- Personnel (Primary Investigator) CV
- Protocol
- Draft publications, as applicable
- Amendment attachments, as applicable

4. POST SUBMISSION

4.1 How will I know if my submitted proposal and/or protocol are approved?

Once approved, you will be notified via email and in-system notification. The email will include instructions regarding the next steps in the process.

4.2 What happens if there is more information that has been requested by Takeda throughout the workflow?

You will be notified that there has been a request for additional information via email and a system notification. The *Additional Information Questions* will be listed within the study record. Once the additional information has been added to the study record, click *Submit Additional Information* from the *Actions menu*.

4.3 What is expected of me after my study has been completed?

You will be expected to provide the *Final Study Report* and a *Drug Destruction Certificate* for any unused product/material (as applicable) on the *Project Closure node* of the project. Click *Submit Project Closure* from the *Actions menu* to complete your project closure tasks.

If your study involved funding request, you may be asked to provide a financial reconciliation.

4.4 How do I access and track the status of my submissions?

You can view the status of all your studies at any time on the *My Projects* widget on your *Dashboard*.