



# Takeda Support | Research

## Investigator Quick Reference Guide

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This user guide is intended for Investigator Initiated Research (IIR) Investigators and provides step-by-step instructions for submission through closure of IIR projects within the Takeda Support Research system

# Starting a New Application



Access the Takeda Support Research system via the following link and log in using your email address as your Login ID

[https://takeda.envisionpharma.com/ienv\\_takeda/visiontracker/portal/login.xhtml?pgm=ISR](https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=ISR)

After logging in, you will arrive on your **Dashboard** where you can start a new application:

1. Click the **Start New** button within the **Welcome** widget
2. Select the **Application Type**, using the provided definitions
3. Click **Continue**

**Note:** A link to Takeda's Areas of Interest (AOI) document is available in the icon in Global Tools

Tracking Number	Short Title	Product/Material	Status Group
IISR-2020-000924	Clinical F&P Support	Lansoprazole	Project Setup
2020-PCOR-000916	PCOR F&P Support	Brentuximab vedotin	Project Setup
TEMP-002860	Habemus	Acetyl salicylic acid and mag...	Incomplete

**Application Type**

Please indicate what you are applying for

- Clinical Research**  
Clinical research is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health related, biomedical, or behavioral outcomes.
- Pre-Clinical Oncology Research**  
Pre-Clinical Oncology Research: supports research using Takeda's proprietary oncology compounds or oncology-related mouse models, antibodies or cell lines. Requests for materials are the primary purpose of this program; funding requests are rarely approved.
- Non Oncology - Preclinical/Non-Clinical**  
Non-clinical testing is conducted at a stage of medicines development that uses animals and/or cells or tissues. It does not involve testing in humans. The main goal of non-clinical tests is to determine the safety of a medicine.

**Continue** →

# Acknowledgment



Once the **Application Type** has been selected, you will be prompted to read and accept Takeda's acknowledgement statement

1. Please carefully read the terms and conditions
2. Check the **Accept** box at the bottom of the screen to acknowledge your acceptance
3. Click **General Information** to continue to the application



## Acknowledgement

Thank you for your interest in pursuing independent research with Takeda. For purposes of this Attestation, "Takeda" means Takeda Pharmaceutical Company Limited and all of its affiliates. Please be advised that with respect to your submission:

- Your research proposal must be a full description of your research.
- Funding requests must include the total study costs and will be evaluated for feasibility and alignment with fair market value and regional regulations, guidelines and industry codes.
- Please only submit the information requested. Your research proposal must not include any confidential information. Confidential information for this purpose does not include personal data. Even if you fail to comply with the foregoing sentence, your research proposal shall not be treated as confidential information and Takeda shall have no liability and obligation to you with respect thereto.
- You represent and warrant that you have full authority and consents necessary for the transfer, processing and use of all personal/business data provided as a part of your research proposal, including that of study staff (if applicable) and that the information you submit does not violate the intellectual property rights of a third party.
- You agree that your personal information can be shared among Takeda group companies and used by Takeda or its business partners for the purpose of evaluating your request; you understand that Takeda may be located outside your home country where personal data protection and privacy rules may be different from those in your home country.
- 1 • This application is provided to collect information in reference to your research proposal. You have the right to request access, correction, erasure of your personal data collected and used by this application or that its use be restricted. In addition, you have the right to withdraw your consent at any time. It may not always be possible to immediately and completely honor any of these requests described above. If your request cannot be or can only partially be honored, you will be informed and given the reason(s).
- If you have a complaint about how your personal data is being processed, you may have the right to contact the supervisory authority in your country.
- For more information on Takeda's privacy practices, please review Takeda's privacy notice at [www.takeda.com/privacy-notice](http://www.takeda.com/privacy-notice)
- In conducting the research, you must comply with applicable laws, regulations, guidelines and industry codes.
- If Takeda approves your research proposal, support remains subject to coming to agreement on the terms of the support by executing an agreement between Takeda and you. Until such an agreement is executed, Takeda cannot provide you with any support regarding your research proposal.

Takeda reserves the right to deny any research proposal and are not obligated to give reasons for our decision or to reveal our past or present activities relating to your research proposal. Takeda's decision to support research is not influenced by the use, purchase, prescribing, or recommending for prescribing of any current or future Takeda product.

By clicking "Accept" below, you, on behalf of yourself and any company or organization you represent, agree to this Submission Attestation and the Terms of Use and Privacy Notice posted to this website.

2  \*Accept

3 [General Information →](#)

# Navigating the Application Screen



The application screen is setup as follows:

- A. Use the  **Navigation** menu to navigate across the platform
- B. The **Global Tools** provide access to system support, bookmarks, notifications, and profile management
- C. The **Context Bar** contains the application number, the name of the Investigator and the application status
- D. The **Table of Contents** lists sections (called nodes) that make up an application. The node you are on appears in bold font
  - Checkmark indicates all required fields **have** been completed
  - An empty circle indicates fields **have not** been completed
  - Node has no required fields
  -  A warning symbol appears if a user attempts to progress the workflow and required fields **have not** been completed; the **Actions** menu also list errors
- E. The  **Actions** menu is used to complete actions, such as submitting your application
- F. Move to the previous or next node using the navigation buttons at the bottom of the screen; as you move from node to node, the system will automatically save your work

The screenshot shows the application interface for 'Clinical Research TEMP-002899' with a status of 'Incomplete'. The interface includes a navigation menu (A) on the left, a global tools bar (B) at the top right, a context bar (C) at the top, a table of contents (D) on the left, an actions menu (E) on the right, and navigation buttons (F) at the bottom.

**Table of Contents (D):**

- Acknowledgement
- General Information**
- Personnel
- Primary Investigator
- Sites
- Primary Site
- Study Information
- Proposal
- Scientific Summary
- Protocol/Budget
- Planned Publications
- Attachments

**Form Fields:**

- \*Study Title: --Required--
- \*Short Title: --Required--
- Sponsor Protocol Number: [empty]
- Internal Project Number: [empty]
- \*Therapeutic Area: --- Select One ---
- Please Specify Other Therapeutic Area: [empty]
- \*Product/Material (Must select T/A first): --- Select One ---
- Additional Products/Materials: -- Select One or More --
- \*Indication to be Studied (Must select T/A first): -- Select One or More --
- Please Specify Other Indication: [empty]

**Actions Menu (E):**

- Save
- Copy Record
- Print
- Submit Proposal

**Navigation (F):** < Acknowledgement Personnel >

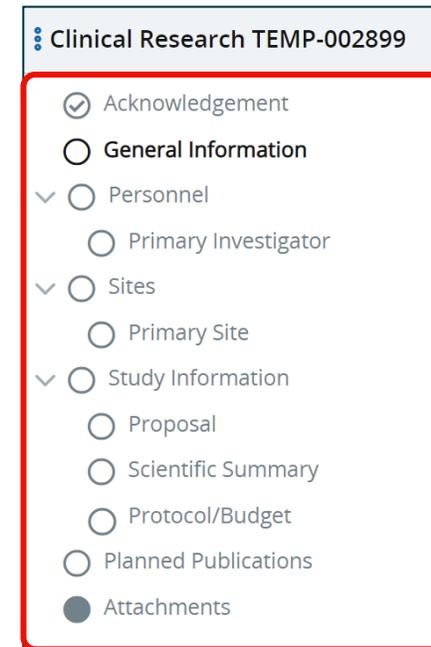
# Setting Up Your New Application



Set up and complete your application by completing each node in the table of contents

Complete the following nodes where required fields are marked with an asterisk (\*):

- **General Information:** Add the general project and support information
- **Personnel – Primary Investigator:** Provide contact and institution information on the primary investigator; add any additional personnel, as needed
- **Sites – Primary Site:** Provide site and contact information on the primary site that acts as the Study Sponsor and will be Takeda's contracting entity. Add additional sites, as needed
- **Study Information**
  - **Proposal:** Enter the proposed study timeline information, as well as the study overview and background
  - **Scientific Summary:** Enter the scientific summary information for your study
  - **Protocol/Budget:**
    - o At submission, high-level information such as research plan (objective, endpoints, etc.) and total project costs are required
      - If available, you can submit a full protocol and detailed budget at the time of proposal submission
    - o Prior to study activation, a full protocol and budget must be provided and approved
  - **Planned Publications:** Enter all planned publications



- **Attachments:** Attach any additional documentation to the project
- Node status – see previous slide for details on node status indicators
- Use the following icons within the system to:
  - Edit a field
  - Confirm edits
  - Delete edits
  - Delete a confirmed edit

# Submitting the Proposal



When all [required proposal information](#) is entered the proposal should be submitted for review and approval

To submit your project proposal:

1. Check that all required information has been completed
2. Click **Submit Proposal** in the **Actions** menu

The project will be assigned a **Tracking Number** and the **Status** will be updated to **Proposal Evaluation**

You will be notified if the Operational Lead has [requested additional information](#) and/or when a review decision has been made

- **APPROVED:** The **Status** will be updated to **Protocol Evaluation** and you should [upload and submit the Protocol and Budget](#)
- **NOT APPROVED:** The **Status** will be updated to **Proposal Declined** and the project will close

# Submitting the Protocol



Upload and submit the **Protocol** and **Budget** to the project:

- When creating your new application
- or
- When the proposal has been approved
- or
- Prior to activation

To upload and submit the **Protocol** and **Budget** on the **Protocol/Budget** node:

1. Attach the **Protocol**
2. Attach the **Budget**; all budget requests must be submitted using the Takeda-provided budget template specific to Oncology or non-Oncology
3. Click **Submit Protocol** in the **Actions** menu

Clinic... IISR-2020-000935 1 of 6

**Protocol/Budget**  
These attachments are not required to submit a Proposal. submitted with a Proposal if available.

Please attach a copy of the protocol that aligns with the previously submitted proposal.

**1** \*Protocol Attach file

**2** \*Budget Attach file

**3** Submit Proposal

\*Requested Currency: USD - US Dollar  
\*Total Project Costs: 100,000.00  
\*Amount Requested: 75,000.00  
% Requested: 75

\*List other sources of funding  
Funding Source #2

← Scientific Summary Request Product →

You will be notified if the Operational Lead has requested additional information and when a review decision has been made

- **APPROVED:** The **Status** will be updated to **Project Setup** and you should [submit regulatory and contracting information](#)
- **NOT APPROVED:** The **Status** will be updated to **Protocol Declined** and the project will close

# Providing Additional Information



A Operational Lead can request that you provide additional information any time after the application has been submitted

To provide additional information:

1. You will receive a request for additional information via email and a system notification; access the project by either:
  - A. Clicking the link within the notification
  - B. Clicking the **Additional Information Requested** link on your **Dashboard**
2. View the **Additional Information Questions** window; you can open the window if it is closed by clicking the **i** icon in the [context bar](#)
3. Provide the requested additional information
4. Click **Submit Additional Information** in the **Actions** menu

1 Tracking Number: IISR-2020-000924  
Study Title: Clinical Funding and Product Support  
Investigator: Principal Investigator  
01 Nov 2020

Dear Investigator,

This communication is to inform you that the regulatory information associated with "Clinical F&P Support" has been received. Additional information is needed in order to adequately review this request.

*Can you add an updated IRB/EC on the Regulatory node?*

Please log into iEnvision by clicking on the link below to complete your update.

A [Link to Takeda Support](#)

B 1 Additional Information Requested

Monday  
2  
NOV

Welcome  
External Applicant

Clinical Rese... IISR-2020-000924 4 of 7 Applicant Project Setup 28 Oct 2020

Regulatory

Additional Information Questions

2 Can you add an updated IRB/EC on the Regulatory node?

4 Submit Additional Info

3 \*IRB/EC Approval Document

Delete this Version  
Replace this Version

Post New Version

Updated IRB-EC Approval...  
02 Nov 2020 15:55:20

Approved Informed Conse...  
29 Oct 2020 16:17:33

IRB/EC Review Date: 26 Oct 2020  
\*IRB/EC Approval Date: 29 Oct 2020  
IRB/EC Expiration Date:  
\*Institutional IRB Number: 654987

Regulatory Approval Type: --- Select One ---  
Regulatory Approval Date:  
Regulatory Authorization IND Number:  
Registration Number (Clinical Trials.gov):  
Registration Number (Eudract):  
Registration Number (Other):  
Registration Posted Date:

Save  
Addtl. Info Requested  
Copy Record  
Print  
Submit Additional Info  
Withdraw

# Submitting Regulatory and Contracting Information



After the **Protocol** and **Budget** have been approved you will need to provide regulatory and study activation information, as applicable:

- Ethics Approval and Ethics Approved Protocol
- Regulatory Approval
- Public Registration
- Medical Licensure
- Confirmation of drug supply contact and shipping information, if applicable

To provide additional information:

1. You will receive a request for additional information via email and a system notification; access the project by either:
  - A. Clicking the link within the notification
  - B. Clicking the **Regulatory Information Requested** link on your **Dashboard**
2. Provide the regulatory information on the **Regulatory** node; required fields are marked with an asterisk (\*)
3. Click **Submit Regulatory** in the **Actions** menu

The image shows two notification screenshots. The top one is an email notification with the following text:
   
Tracking Number : IISR-2020-000968
   
Study Title: Clinical Gastroenterology Funding and Product Support (DLW-b)
   
Investigator: External Investigator
   
09 Nov 2020
   
Dear External Investigator,
   
Thank you for the opportunity to review your proposal entitled, "Clin Gastro F&P Support".
   
The Review Committee has approved your protocol and determined that you may proceed to submission of regulatory information. As a next step, please provide regulatory information as required by clicking on the link below to complete your regulatory documentation.
   
A red box labeled '1' highlights the tracking number. A red box labeled 'A' highlights a link that says "Link to Takeda Support". A red box labeled 'B' highlights a notification that says "1 Regulatory Information Requested".
   
The bottom screenshot is a dashboard notification showing a calendar for Monday, 2 NOV, with the text "Welcome External Applicant". A red box labeled 'B' highlights the "1 Regulatory Information Requested" notification.

The image shows a screenshot of the "Regulatory" form in a system. The form has a table with columns: Entry Date, IRB/EC Approval Date, IRB/EC Expiration Date, and Reg. The first row shows "09 Nov 2020". A red box labeled '3' highlights the "Submit Regulatory" button in the "Actions" menu. A red box labeled '2' highlights the main form area with the following fields:
   
IRB/EC Review Date (text input)
   
\*IRB/EC Approval Date (text input, marked with an asterisk)
   
IRB/EC Expiration Date (text input)
   
\*Institutional IRB Number (text input, marked with an asterisk)
   
\*IRB/EC Approval Document (Attach file button, marked with an asterisk)
   
Approved Informed Consent Form (Attach file button)
   
Regulatory Authorization (Attach file button)
   
Regulatory Approval Type (dropdown menu)
   
Regulatory Approval Date (text input)
   
Regulatory Authorization IND Number (text input)
   
Registration Number (Clinical Trials.gov) (text input)
   
Registration Number (Eudract) (text input)
   
Registration Number (Other) (text input)
   
Registration Posted Date (text input)

## Submitting a Milestone Update (1 of 2)



Your active projects will be listed on your **Workbench Welcome** widget under **Active**. If you are required to submit a **Milestone Update** a notification will appear here

To submit a **Milestone Update**:

1. Click **Milestone Update Due**
2. On the **Milestones** node, click **Add No Change Milestone Update** if there are no changes or **Add Milestone Update** provide an update on one of the scheduled milestone
  - Please refer to your executed contract for required frequency of enrollment milestone updates

Dashboard > Research Applicant

Research Applicant

Monday  
9  
NOV

Welcome  
External  
Applicant

1  
1 Active  
1 Milestone Update Due

✓ Milestone Updates

Sponsor-Investigators are responsible for complying with their local regulatory authority adverse event and reporting requirements. All Serious Adverse Events (SAEs) or spontaneously reported adverse events must also be reported to Takeda no later than 24 hours from the date of observation. Please refer to your protocol/contract for specific SAE reporting requirements.

When complete, please navigate to Actions and choose "Provide Project Update" to submit your Project Status Update

Expand rows [ > ] to see detailed information.

Entry Date
<b>2</b> + Add No Change Milestone Update + Add Milestone Update

# Submitting a Milestone Update (2 of 2)



- 3. Enter any **Subject/Sample** updates, as applicable
- 4. Reforecast **Updated Plan Date** items, as needed
- 5. Click **Provide Project Update** in the **Actions** menu to submit your updates

The screenshot shows the 'Milestone Updates' page for project 'Cli... IISR-2020-000968'. The page is titled 'Active Project' and has an 'Actions' menu in the top right corner. The 'Actions' menu is open, showing options: Save, Copy Record, Print, Provide Project Update, Create Amendment, and Request Cancellation. The 'Provide Project Update' option is highlighted with a red box and a red arrow pointing to it, labeled with the number 5. Below the 'Actions' menu, there is a section for 'Entry Date' with a dropdown set to '09 Nov 2020'. Below this, there are several input fields for enrollment and subject data. A red box labeled 3 highlights the 'Updated Number of Subjects/Samples' field. Below that, there is a table for 'Milestone' updates. A red box labeled 4 highlights the 'Updated Plan Date' column in this table. At the bottom, there is a 'PSU Milestone Updates' section with an 'Attach file' button and a 'Notes' text area.

Milestone	Current Plan Date	Updated Plan Date	Actual
Contract Executed	12 Nov 2020	<input type="text"/>	<input type="checkbox"/>
First Patient In (FPI)	12 Jan 2021	<input type="text"/>	<input type="checkbox"/>
Last Patient Out (LPO)	12 Jul 2022	<input type="text"/>	<input type="checkbox"/>
Final Study Report Submission Date	12 Sep 2022	<input type="text"/>	<input type="checkbox"/>

# Submitting an Amendment



To submit an amendment (e.g. additional funding request, administrative change, etc.) on an active project:

1. Click **Create Amendment** in the **Actions** menu
2. Add the **Amendment** information and any attachments
3. Click **Submit Amendment** to submit your amendment for review

The screenshot shows two screenshots of the Takeda system interface. The top screenshot is the 'Proposal' page for project 'Clini... IISR-2020-000968'. It features a 'Proposal' header and several input fields: '\*Contract Execution to FPI (in mo...)' with value '2', '\*Length of Study (in months)' with value '18', and '\*Study End to FSR (in months)' with value '2'. Below these are 'CRO Name' (empty), '\*Study Type' (Observational), and '\*Study Phase' (Phase I/II). A red box labeled '1' highlights the 'Actions' menu in the top right, which is open to show options like 'Save', 'Copy Record', 'Print', 'Provide Project Update', 'Create Amendment', and 'Request Cancellation'. A red arrow points from the 'Actions' menu to the 'Create Amendment' option.

The bottom screenshot is the 'Amendments' page for the same project, dated '09 Nov 2020'. It shows a table with one amendment entry: '#1 - 09 Nov 2020' with status 'New'. A red box labeled '2' highlights the form fields for creating an amendment: '\*Description of change' (with a placeholder '--Required--'), '\*Reason' (with a dropdown menu), 'Additional Amount Requested', 'IRB/EC Approval Date', '\*Status' (with a dropdown menu), 'Decision Date', and 'Additional Amount Approved'. A red box labeled '3' highlights the 'Actions' menu in the top right, which is open to show options like 'Save', 'Copy Record', 'Print', 'Provide Project Update', 'Submit Amendment', 'Cancel Amendment', and 'Request Cancellation'. A red arrow points from the 'Actions' menu to the 'Submit Amendment' option.

## Submitting Publication Information



Throughout your active project, you can update the **Publication** node with any draft publication

To add an **Actual Publication**:

1. Click **Add Journal/Congress**
2. Click **Provide Project Update** in the  **Actions** menu

The screenshot displays the Takeda project management interface. At the top, there is a navigation bar with '2 of 6' on the left, 'Applicant' and 'Active Project' in the center, and '09 Nov 2020' on the right. A red box highlights the 'Actions' dropdown menu in the top right corner, which contains options: 'Save', 'Copy Record', 'Print', 'Provide Project Update', 'Submit Amendment', 'Cancel Amendment', and 'Request Cancellation'. A red arrow points from the 'Actions' menu to the 'Provide Project Update' option, which is also highlighted with a red box and a red circle containing the number '2'. Below the navigation bar, there is a 'Publications' section with a sub-header 'When complete, please navigate to Actions and choose "Provide Project Update" to submit your P'. Underneath, there is a 'Planned Publications' table with columns 'Journal/Congress', 'Publication Type', and 'Ar'. A row is visible with 'Journal of Clinical Gastroenterology' and 'Primary Manuscript'. Below this is an 'Actual Publications' section with a sub-header 'Expand rows [ > ] to see detailed information.' and a table with columns 'Entry Date', 'Journal/Congress', 'Publication Type', 'Publication Date', and 'Status'. A red box highlights the '+ Add Journal/Congress' button in the bottom right corner, with a red circle containing the number '1' next to it.

# Submitting Project Closure Information



Once all milestones are complete and the study record is ready to be closed, the Operational Lead will request the closure information be submitted

To provide closure information:

1. You will receive a request for closure information via email and a system notification; access the project by either:
  - A. Clicking the link within the notification
  - B. Clicking the **Project Closure** link on your **Dashboard**
2. Provide the **Project Closure** information
3. Click **Submit Project Closure** in the **Actions** menu

1 Tracking Number: IISR-2020-000924  
Study Title: Clinical Funding and Product Support  
Investigator: Principal Investigator  
01 Nov 2020

Dear Investigator,

This communication is to inform you that your study titled b Clin Gastro F&P Support requires closure information.

Please log into iEnvision with the web address below to provide your update.

A [Link to Takeda Support](#) B 1 Project Closure

Monday  
2  
NOV  
Welcome  
External Applicant

Clinical Re... IISR-2020-000968 2 of 6 Applicant Project Closure 09 Nov 2020 Actions

- ✓ Acknowledgement
- ✓ General Information
- ✓ Sites
  - ✓ The Primary Site \*
- ✓ Study Information
  - ✓ Proposal
  - ✓ Scientific Summary
  - ✓ Protocol/Budget
  - ✓ Request Product
  - Attachments
- ✓ Project Status Updates
  - Milestone Updates
  - ✓ Publications
  - Product Shipment
  - ✓ Regulatory Update
- ✓ Personnel
  - ✓ Applicant, External\*
  - Amendments
  - Project Closure

Project Closure

Please attach a copy of the Final Study Report.

2 \*Final Study Report  
Attach file

3 \*Was There Unused Product/Material?  
--- Select One ---  
Please attach a copy of the Drug Destruction Certificate.  
Drug Destruction Certificate  
Attach file

Closure Notes

← Amendments

Save  
Copy Record  
Print  
Provide Project Update  
Submit Project Closure

# Support Resources

To access **Takeda Support**, click the URL below or type the address into your browser:

[https://takeda.envisionpharma.com/ienv\\_takeda/visiontracker/portal/login.xhtml?pgm=ISR](https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=ISR)

For system **login support** or research **policy** questions:

- **Rare Diseases, Neuroscience, Gastroenterology, and Plasma Derived Therapies (excluding US):** [GMA.Research@takeda.com](mailto:GMA.Research@takeda.com)
- **Clinical Oncology:** [GMAO.Evidence.Generation@takeda.com](mailto:GMAO.Evidence.Generation@takeda.com)
- **Preclinical Oncology:** [PreclinicalOncology@takeda.com](mailto:PreclinicalOncology@takeda.com)
- **Vaccines:** [smb.VbuGmoOperations@takeda.com](mailto:smb.VbuGmoOperations@takeda.com)
- **US (excluding Oncology):** [US.Medical.Research@takeda.com](mailto:US.Medical.Research@takeda.com)

