Takeda Support | Research

Investigator Quick Reference Guide

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

| March 2022

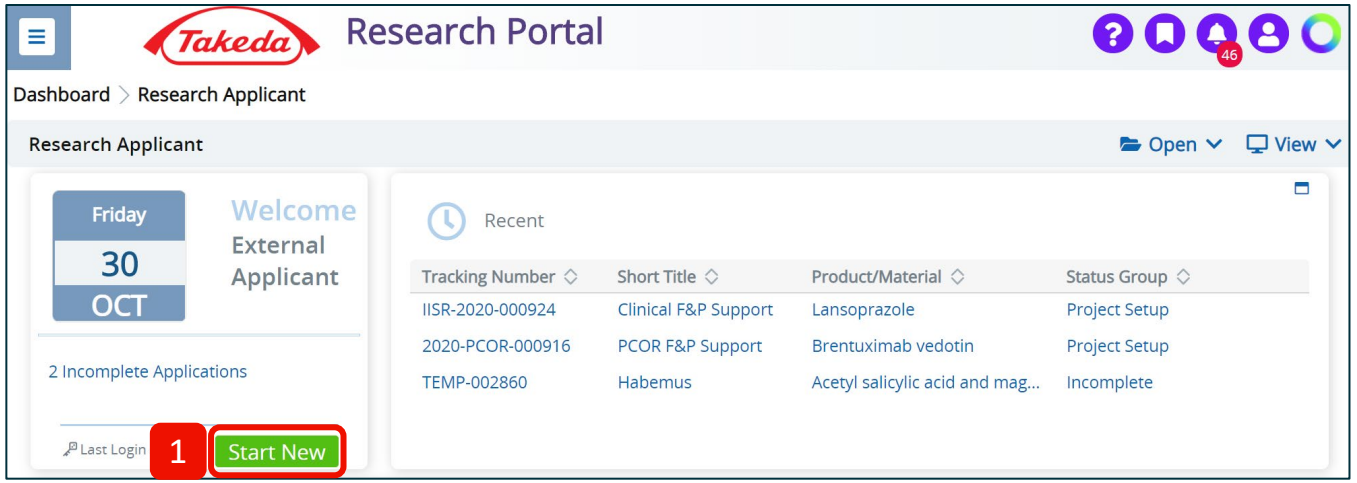
Starting a New Application

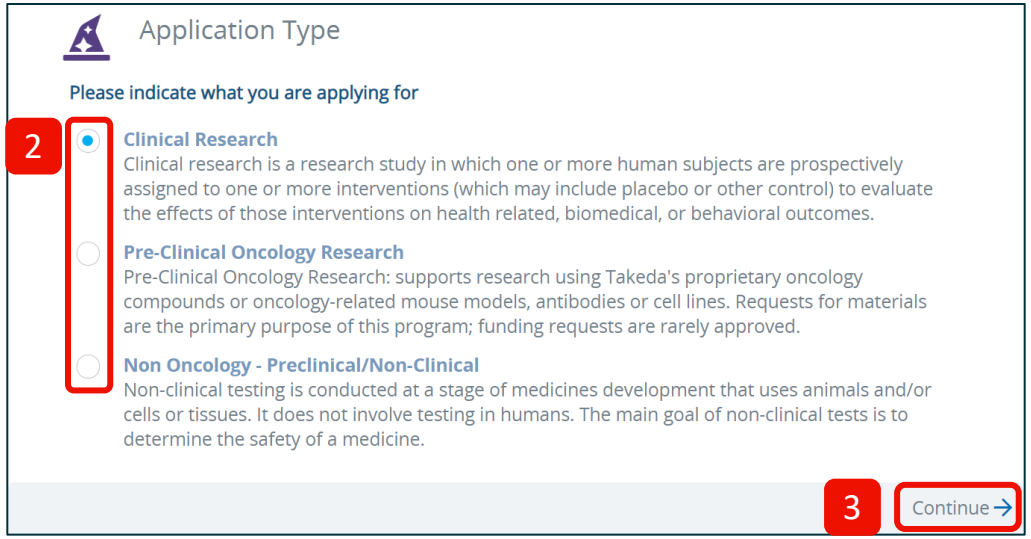
Access the Takeda Support Research system via the following link and log in using your email address as your Login ID

https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=ISR

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**





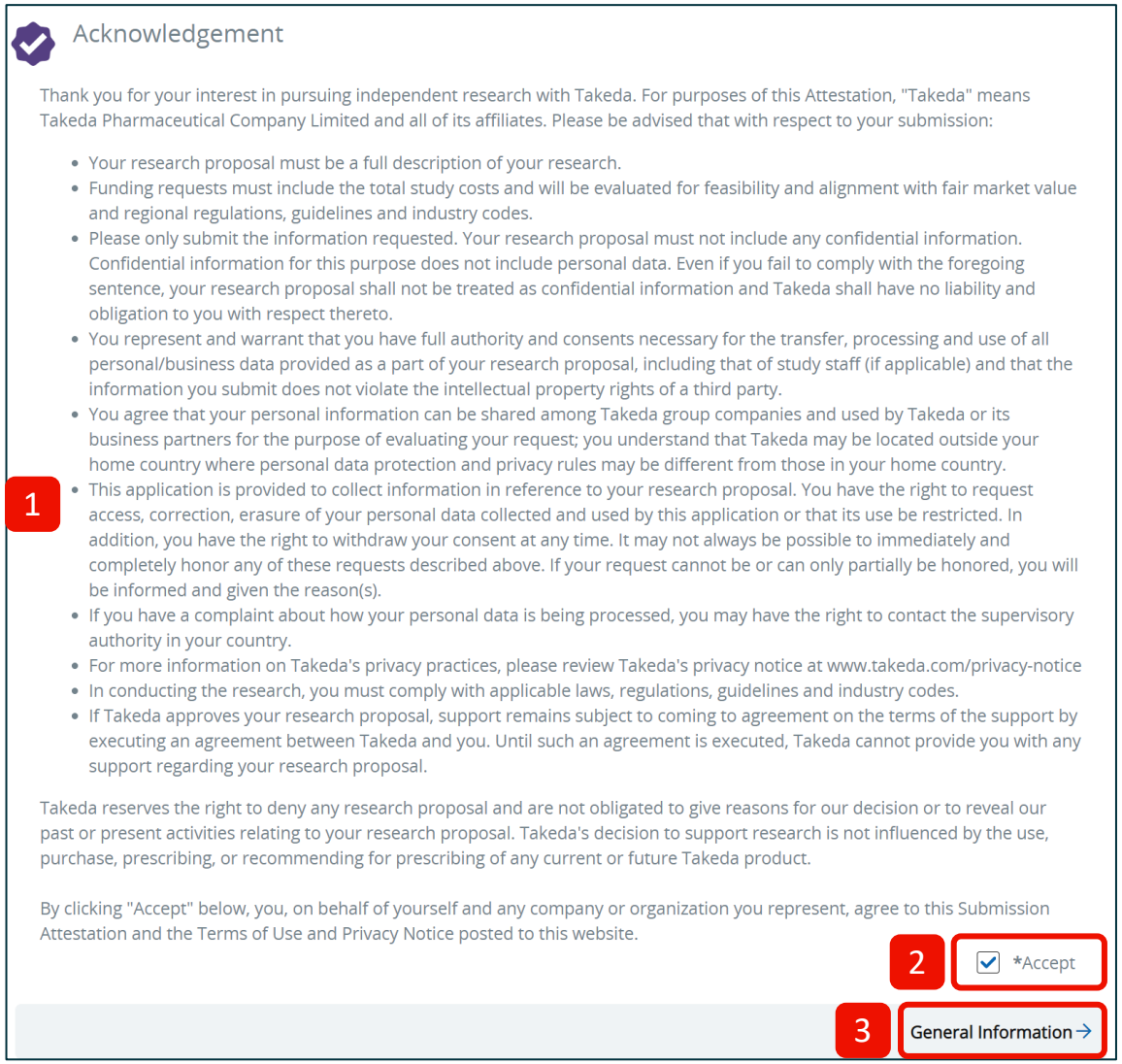
Note: A link to Takeda's Areas of Interest (AOI) document is available in the icon in Global Tools

New Application

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



Navigating the Application Screen

The application screen is setup as follows:

A. Use the **Navigation** menu to navigate across the platform

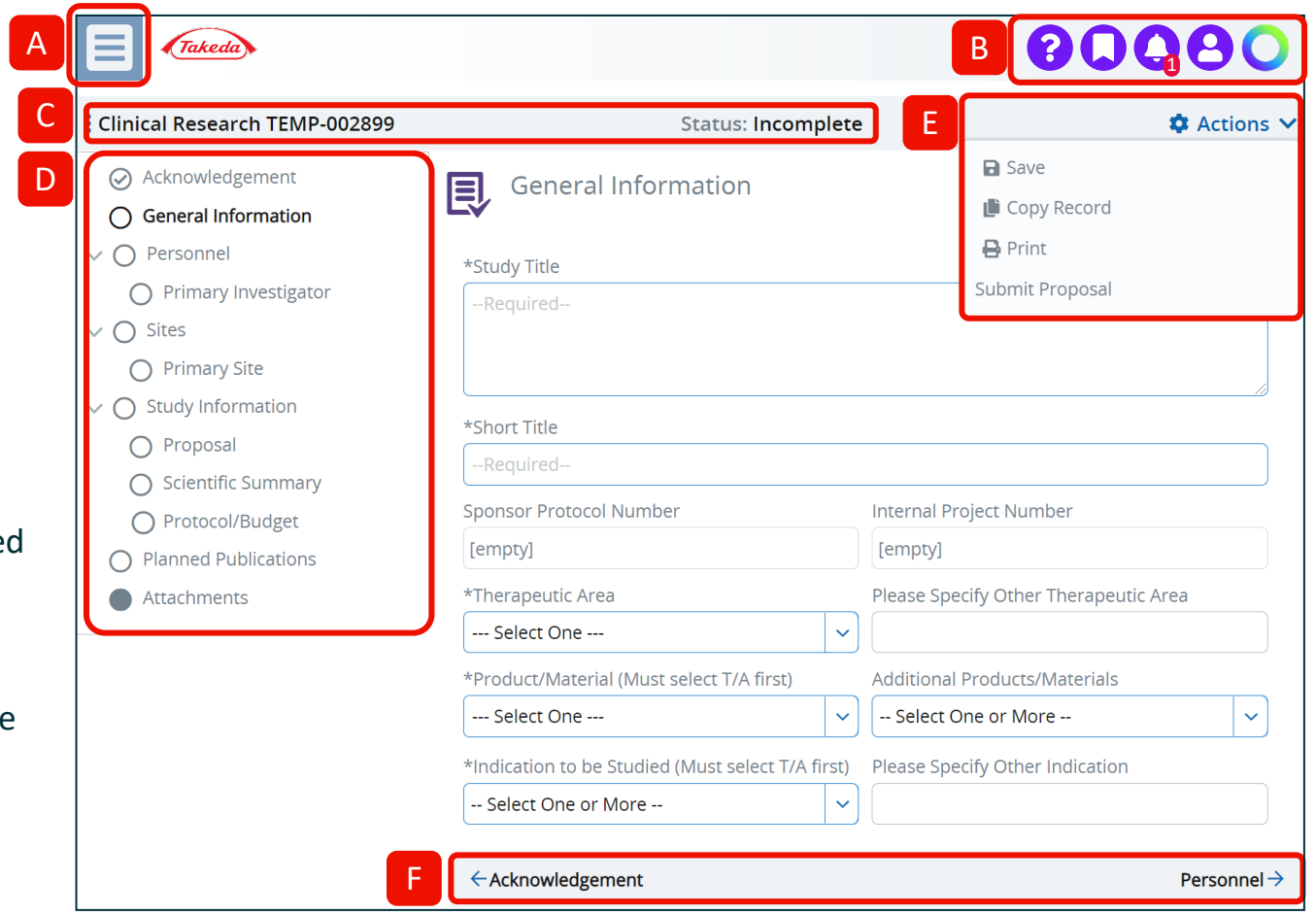
B. The **Global Tools** provide access to system support, bookmarks, notifications, and profile management

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



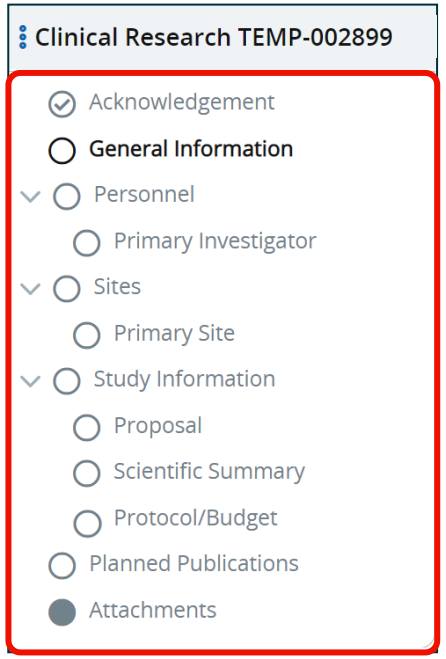
F. Move to the previous or next node using the navigation buttons at the bottom of the screen; as you move from node to node, the system will automatically save your work

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**:
    - 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
    - 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

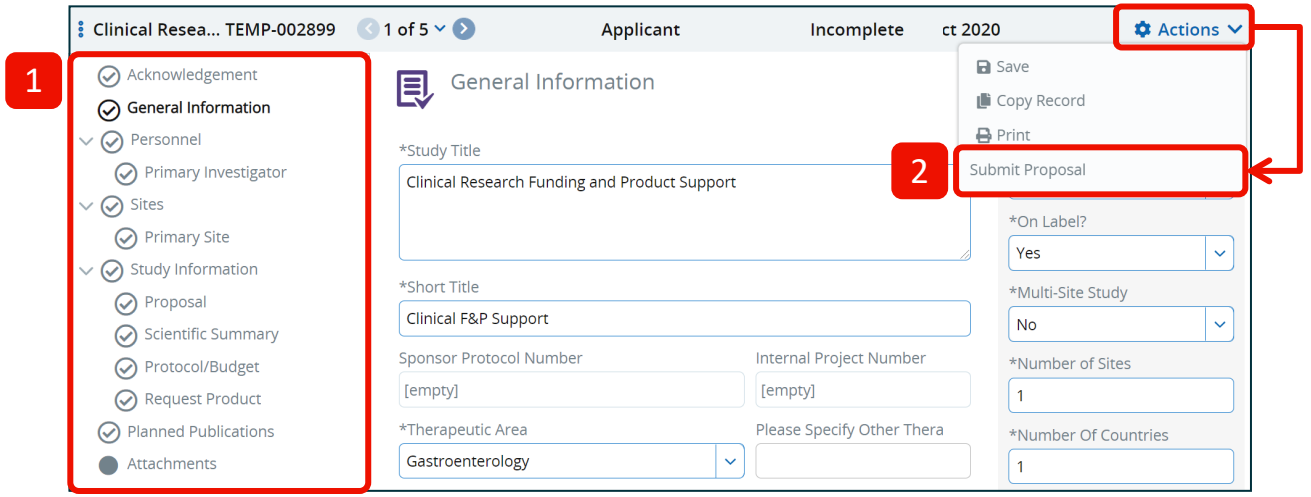
Submitting the Proposal

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

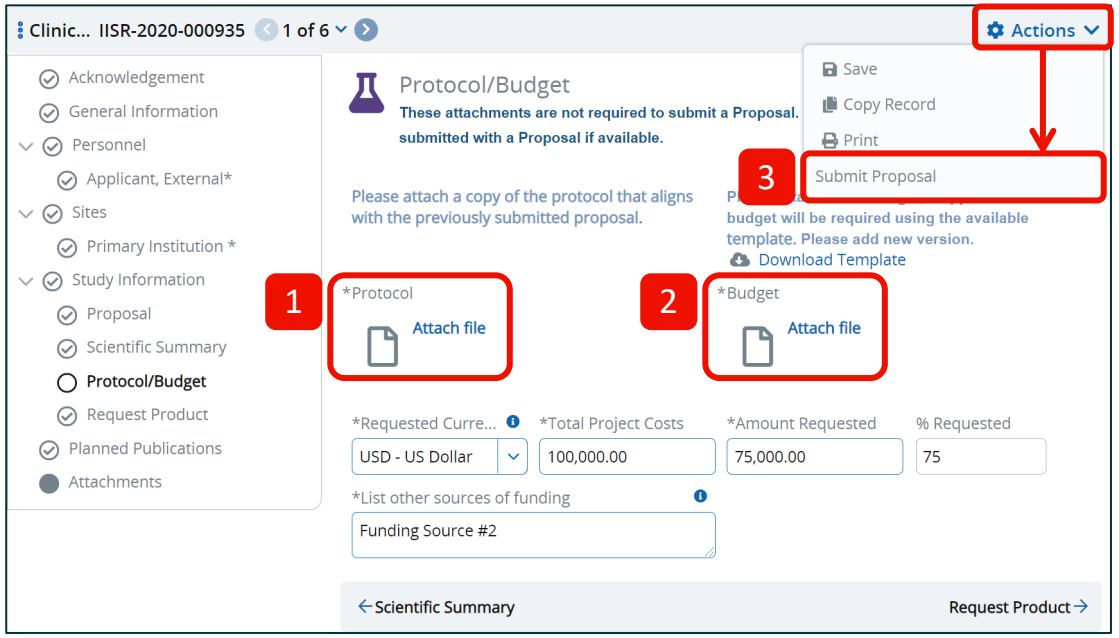
- When the proposal has been approved

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



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

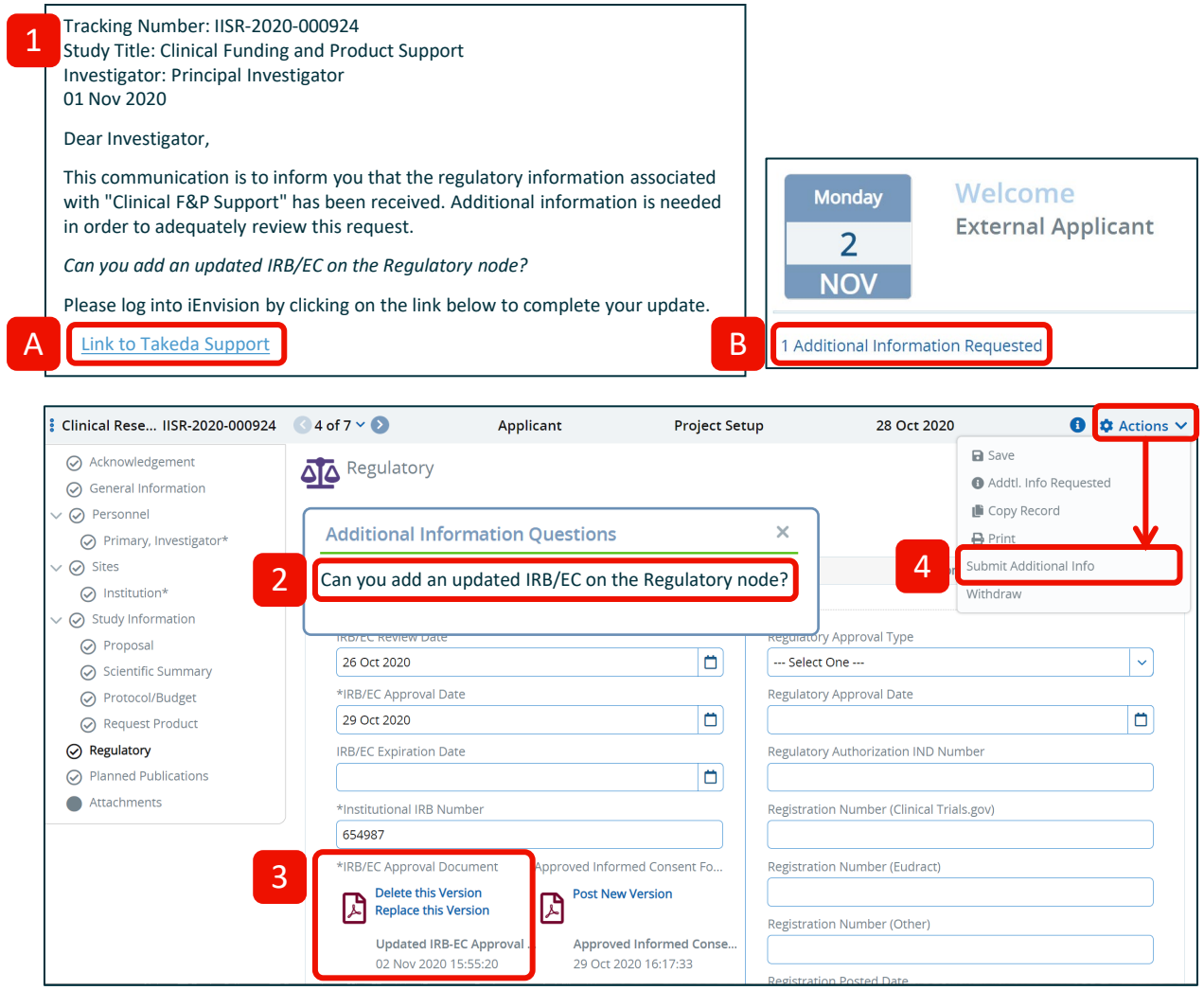
Operational Lead Feedback

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



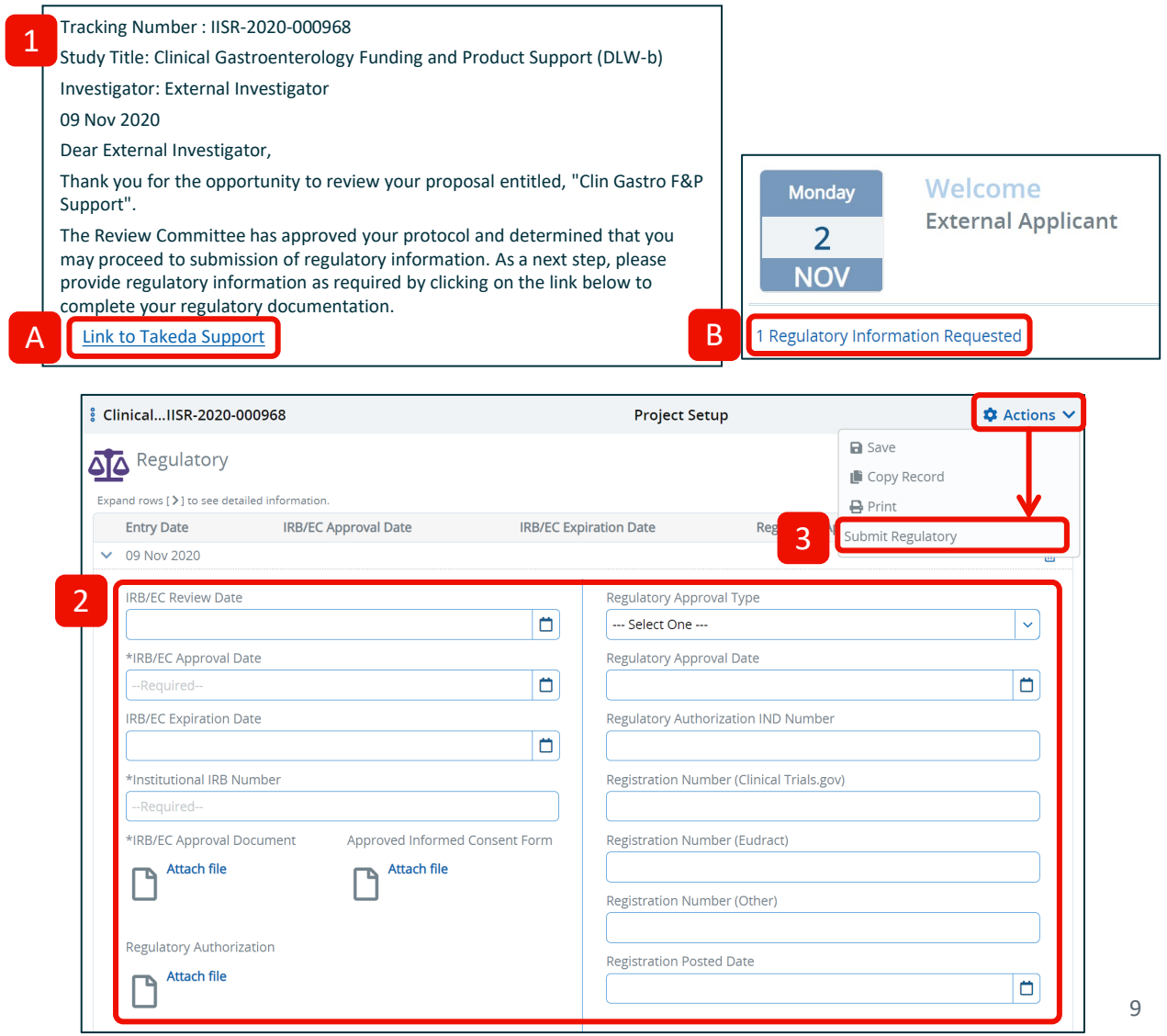
Submitting Regulatory and Contracting Information

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. Clinking 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



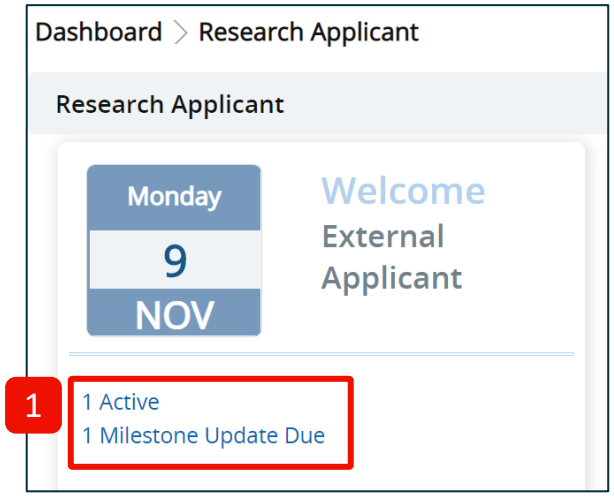
Active Project

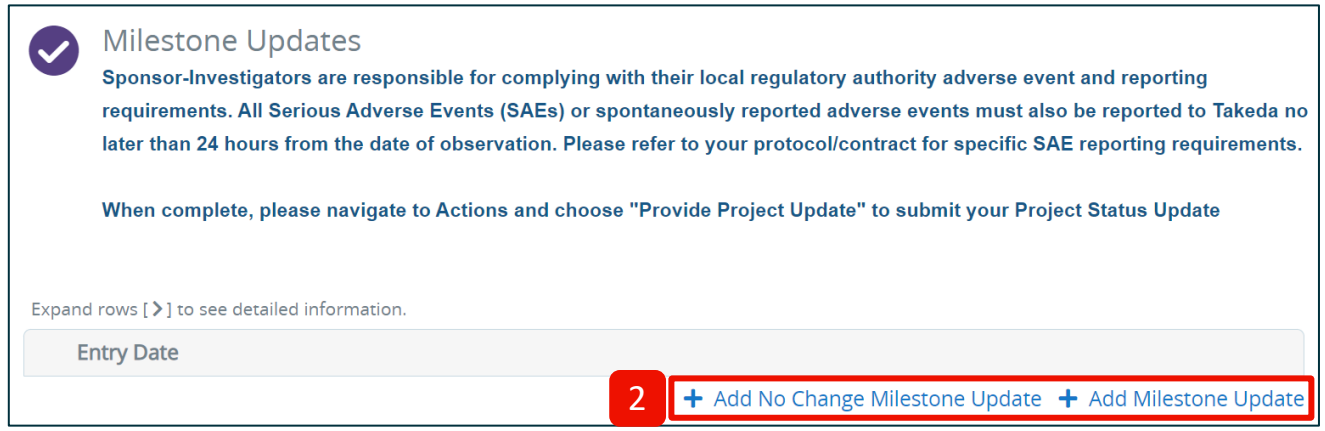
Submitting a Milestone Update (1 of 2)

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

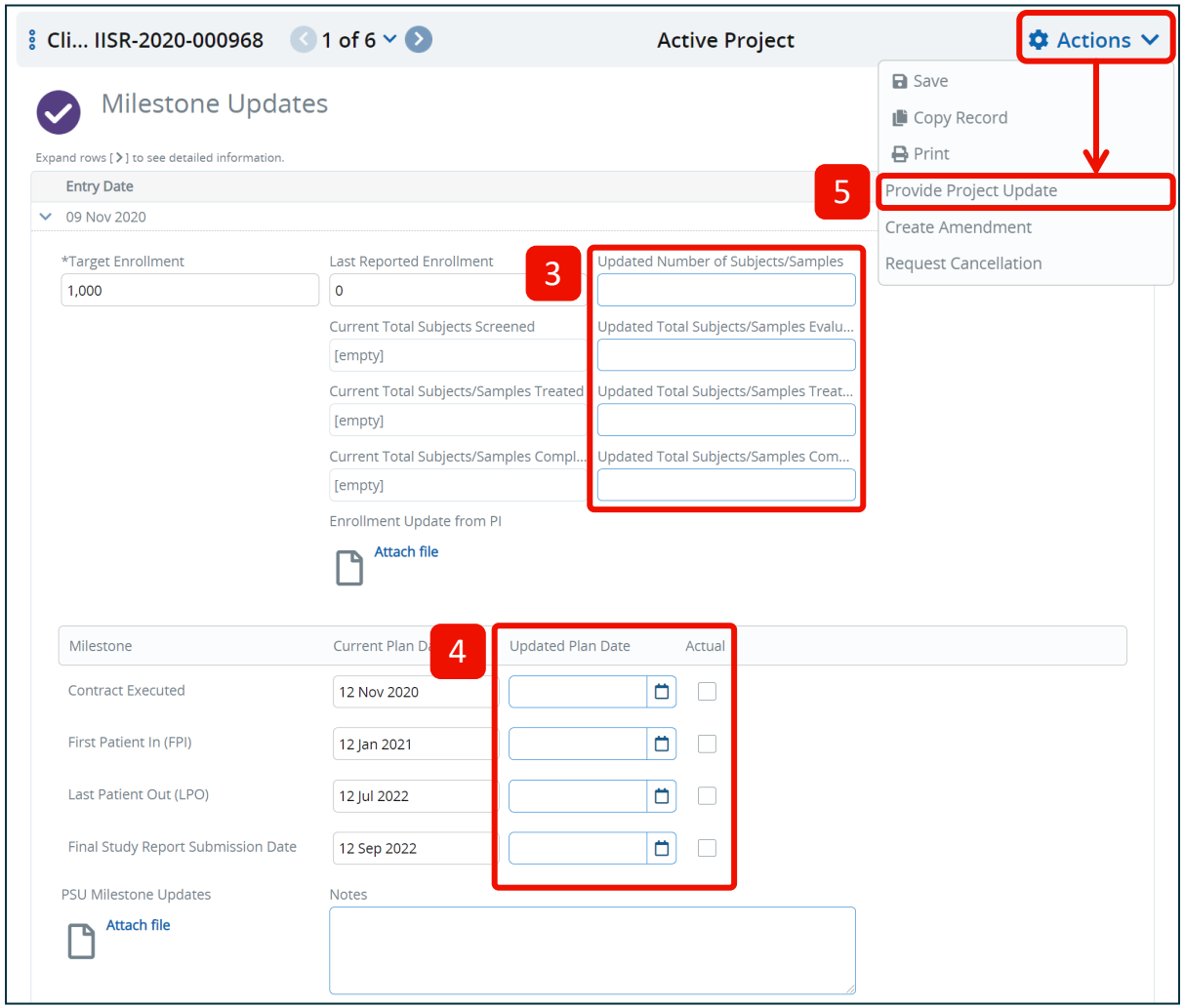




Active Project

Submitting a Milestone Update (2 of 2)

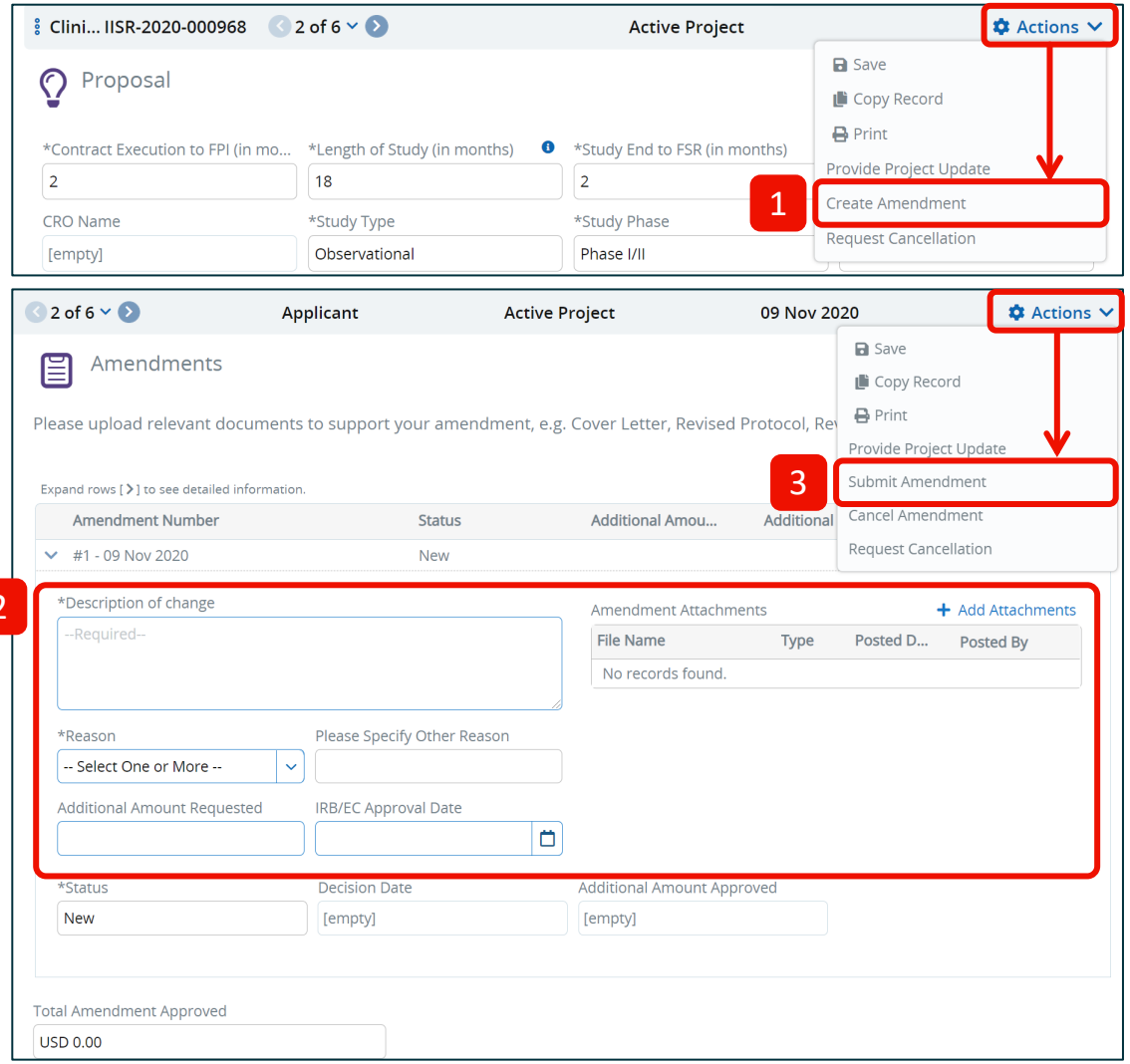
3. Enter any **Subject/Sample** updates, as applicable
4. Reforecast **Updated Plan Date** items, as needed
5. Click **Provide Project Update** in the **Actions** menu to submit your updates



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



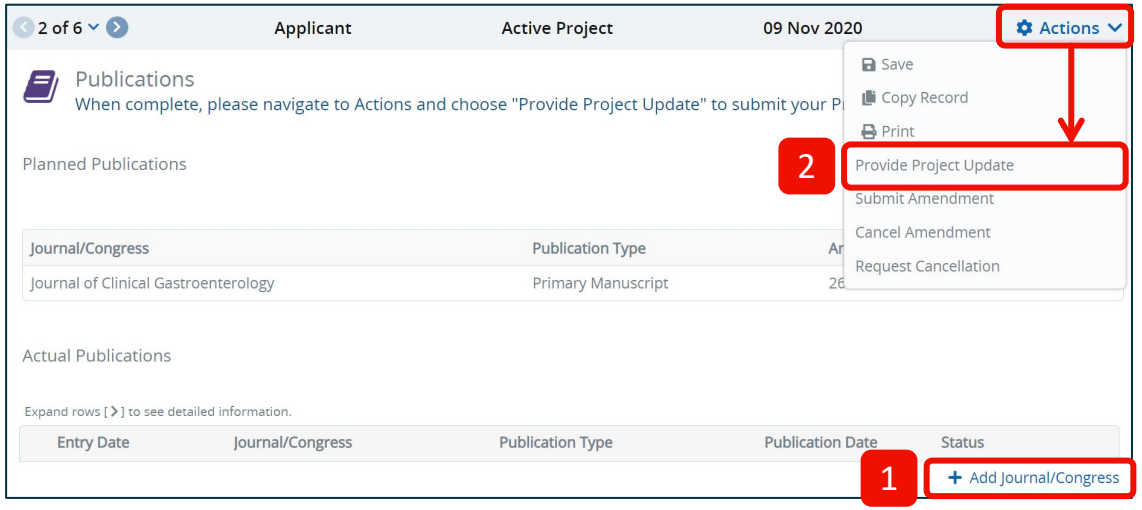
Project Setup

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

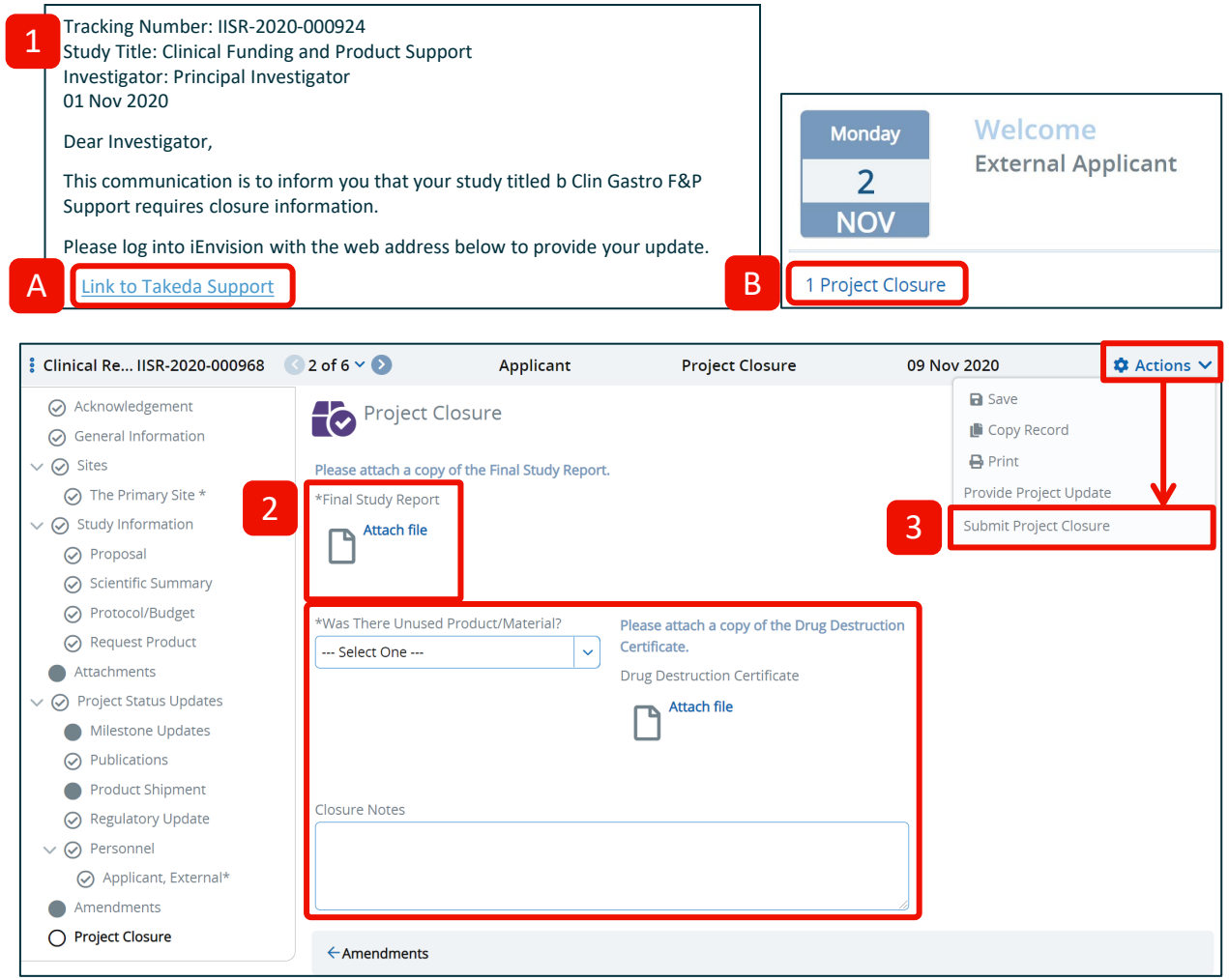


Submitting Project Closure Information

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. Clinking the **Project Closure** link on your **Dashboard**
2. Provide the **Project Closure** information
3. Click **Submit Project Closure** in the **Actions** menu



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

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

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