



Requester User Guide

Table of Contents

Page #	Section
3	Welcome
4	IIS Review Process
5	Accessing the IIS Portal
6	IIS Portal Landing Page
7	Create User Account
8	User Dashboard description
9	Navigation within a submission
10	New Submission
11	Overview of submission fields
12	General Info
13	Personnel
14	Proposal
15	Scientific Summary
16	Oncology Analysis
17	Requested Products
18	Publications
19	Attachments
20	Acknowledgement
21	Error Messages

Welcome to the Roche Investigator Initiated Studies (IIS) Portal Requester Guide

This Requester User Guide will provide you with a step by step overview of the submission and approval process when you apply for support from Roche for investigator initiated studies.

The following types of IIS requests are **eligible** for support:

- Clinical studies of approved and investigational uses, involving marketed Roche drugs or those still in development (interventional studies phase I to IV)
- Clinical observational studies, real world evidence (non-interventional studies)

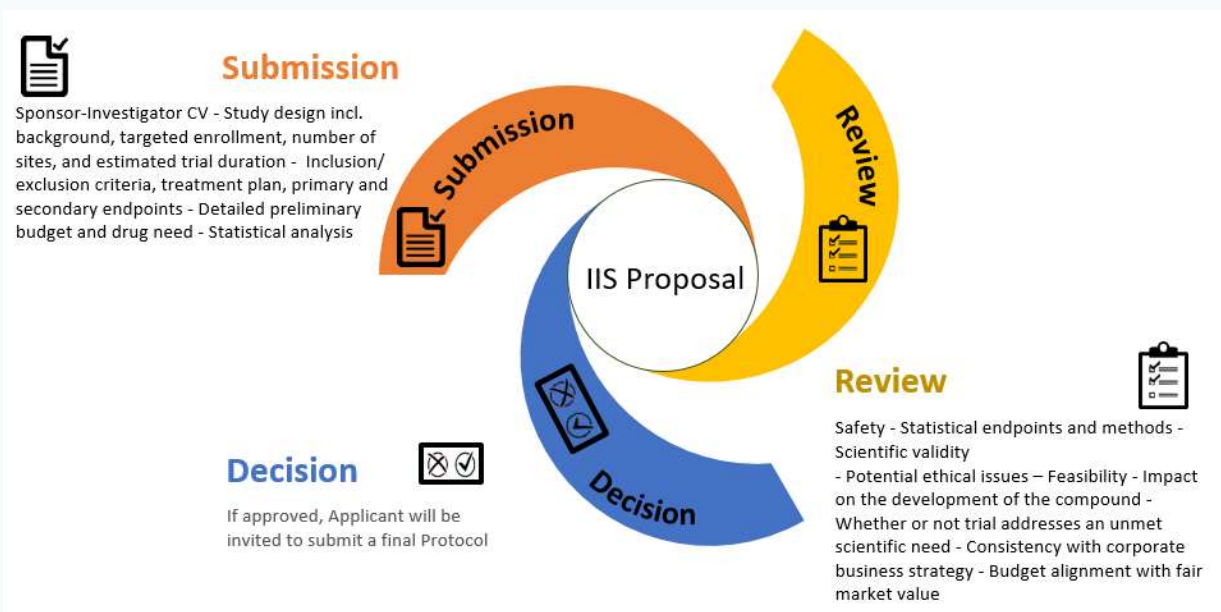
The following types of IIS requests are **out of scope**:

- Requests for Non-clinical studies (with mice or mice feed) can be submitted [here](#)
- Requests for compassionate use should be submitted to the [Roche affiliate in your country](#)
- Request for studies using Roche Diagnostics should be submitted to: global.dia_iis@roche.com

IIS Review Process

The IIS Review Process begins with the submission of the Proposal in the IIS Portal. Applicants are welcome to discuss the Proposal with Roche. You can access your submission at any time, however, once submitted, you cannot make any changes. If you want to make changes, please contact your Roche representative or our support line: support@iisportal@roche.com

Submissions are screened for completion and are then sent to the Roche Review Committee for review. You will be notified by your Roche representative (e.g. your MSL) if your request is approved or not. You will also be notified of the outcome by a system generated e-mail.



If you have an idea for a study, you are welcome, but it's not a requirement, to engage you Roche representative (e.g. Medical Science Liaison, Medical Manager etc). He or she will gladly discuss your idea with you and provide support. The submission into the IIS Portal can then either be managed by yourself or your Roche representative can perform the submission on your behalf with your authorization. The steps on the next pages describe the submission process by the Requester (you) themselves.

The submission into the IIS portal should be a robust proposal and will include the following elements:

- Sponsor-Investigator CV
- Study design incl. background
- targeted enrollment, number of sites, and estimated trial duration
- Inclusion/ exclusion criteria, treatment plan, primary and secondary endpoints
- Detailed preliminary budget and drug need
- Statistical analysis

Once you have submitted the proposal, Roche will then proceed with a cross-functional review which includes members from Medical, Biostatistics, Safety Science, Drug Supply and Regulatory functions. Should your study proposal also include elements of Foundation Medicine, members of Foundation Medicine may be part of the review. Please note, approval of a proposal does not imply or guarantee approval of a protocol.

Requester Guide

Accessing the IIS Portal

1. Go to <https://go.roche.com/IIS>
2. Choose **Click to here access the IIS portal**

Investigator initiated studies



Investigator initiated clinical studies can play a key role in answering important medical and scientific questions regarding Roche's products and their related therapeutic areas. Such clinical studies can contribute towards enhancing the understanding of Roche's products and their appropriate application, thus improving patient care, and sparking new ideas for further disease-related research aimed at creating improved treatment for patients.

Investigator initiated studies (IIS) are clinical studies initiated and managed by a non-pharmaceutical company researchers, like individual investigators, institutions, collaborative study groups or cooperative groups. The researcher is responsible for the legal and regulatory responsibilities of the trial sponsor for the conduct and management of the study as defined by all applicable laws and regulations.

Eligibility requirements for IIS

Roche may support investigator initiated studies with drug supply, funding, material and/or information, as allowed under local laws and regulations, provided that they align with the company defined areas of strategic interest.

Types of IIS eligible for support



The following is out of scope



The sponsor/investigator has to fulfil (or agree to) the following requirements



How to apply for IIS support

Researchers are invited to submit their concept proposal via the IIS submission portal. Concept submission will be reviewed collectively by the Roche Review Committee based on scientific merit and alignment with corporate research and development plans.

The requester will be informed about the outcome and should Roche be interested in the concept submission, the investigator will be contacted and invited to submit further details and a final protocol on the IIS in order to be considered for full approval.

Roche requires that the following documents are in place before the support can be initiated:

- ◆ a fully executed IIS agreement between the sponsor and Roche
- ◆ a fully executed IIS safety data exchange agreement between the sponsor and Roche
- ◆ an EC/IRB and/or health authority approval


All funding requests will be assessed to ensure that they do not exceed local fair market value. Funding requests for expenses not associated with the conduct of the study are strictly prohibited.

User guide



Access the IIS Portal



 [Click to here access the IIS portal](#)

Related links



What is a clinical trial and how does it work?

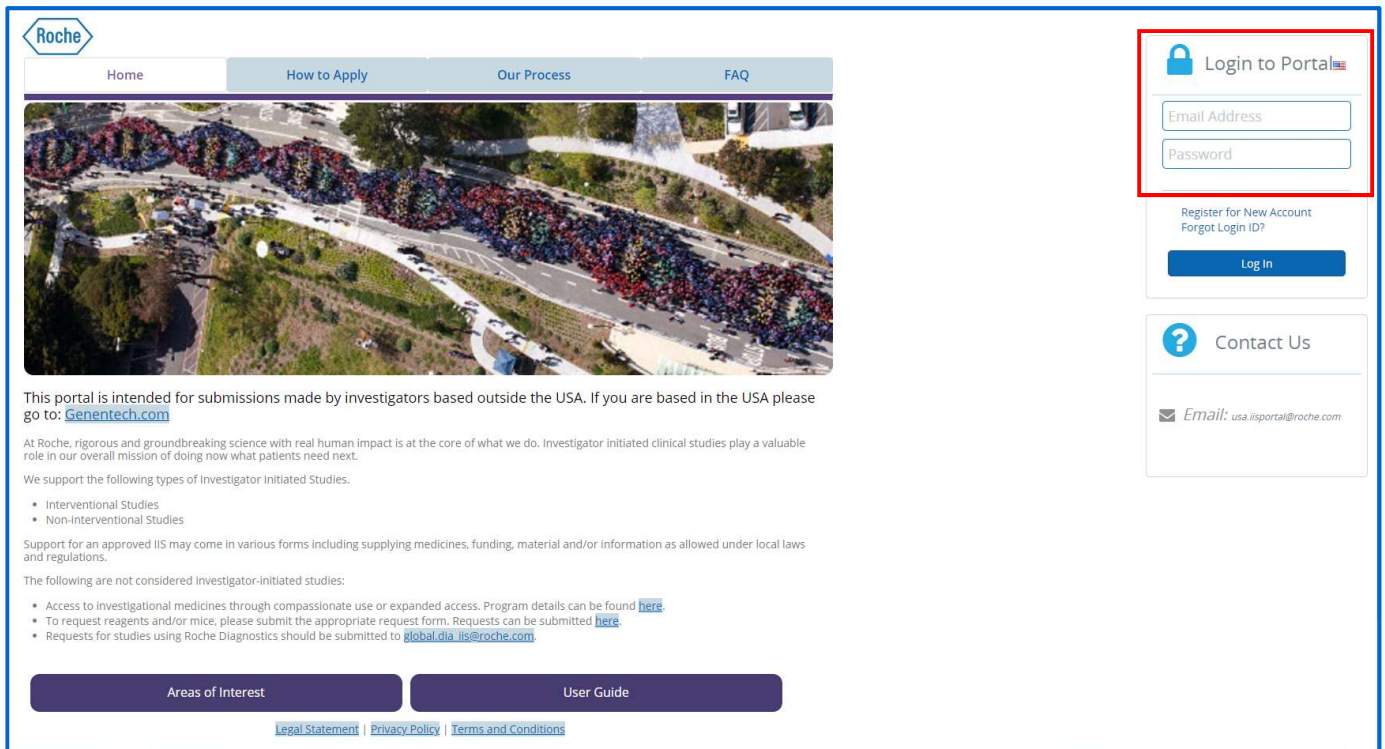
Every new treatment is usually tested in three phases of clinical trials before regulatory agencies consider it safe and effective.

[➤ more](#)

Requester Guide

IIS Portal Landing Page

Enter your **User Name** (your e-mail address) and **Password**



The screenshot shows the Roche IIS Portal landing page. At the top, there is a navigation bar with links: Home, How to Apply, Our Process, and FAQ. Below the navigation bar is a large image of a crowd of people. To the right of the image is a login section with a red box around the 'Login to Portal' link and the email/password input fields. Below the login section is a 'Contact Us' section with a question mark icon and an email address: usa.iisportal@roche.com. At the bottom of the page, there are two buttons: 'Areas of Interest' and 'User Guide'. Below these buttons are links for 'Legal Statement', 'Privacy Policy', and 'Terms and Conditions'.

Roche

Home How to Apply Our Process FAQ

This portal is intended for submissions made by investigators based outside the USA. If you are based in the USA please go to: Genentech.com

At Roche, rigorous and groundbreaking science with real human impact is at the core of what we do. Investigator initiated clinical studies play a valuable role in our overall mission of doing now what patients need next.

We support the following types of Investigator Initiated Studies.

- Interventional Studies
- Non-interventional Studies

Support for an approved IIS may come in various forms including supplying medicines, funding, material and/or information as allowed under local laws and regulations.

The following are not considered investigator-initiated studies:

- Access to investigational medicines through compassionate use or expanded access. Program details can be found [here](#).
- To request reagents and/or mice, please submit the appropriate request form. Requests can be submitted [here](#).
- Requests for studies using Roche Diagnostics should be submitted to global.dia.iis@roche.com.

Areas of Interest User Guide

[Legal Statement](#) | [Privacy Policy](#) | [Terms and Conditions](#)

Login to Portal

Email Address

Password

Register for New Account
Forgot Login ID?

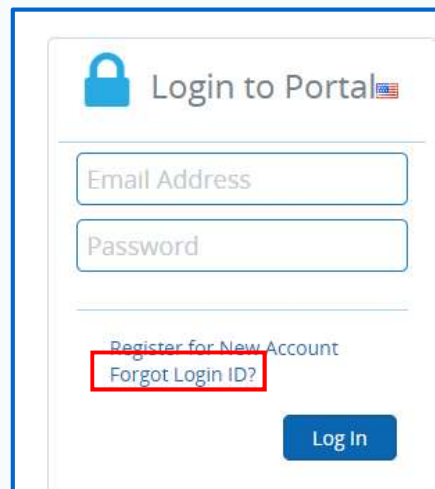
Log In

Contact Us

Email: usa.iisportal@roche.com

Should you have forgotten your user Id or password, then click **Forgot Login ID?**

Roche will then re-set your password and send you a temporary password that you can change at the next login.



This is a close-up of the login section of the Roche IIS Portal. It shows the 'Login to Portal' link with a padlock icon. Below it are two input fields for 'Email Address' and 'Password'. At the bottom of the login section, there are two links: 'Register for New Account' and 'Forgot Login ID?'. The 'Forgot Login ID?' link is highlighted with a red box. A 'Log In' button is located at the bottom right of the login section.

Login to Portal

Email Address

Password

Register for New Account
Forgot Login ID?

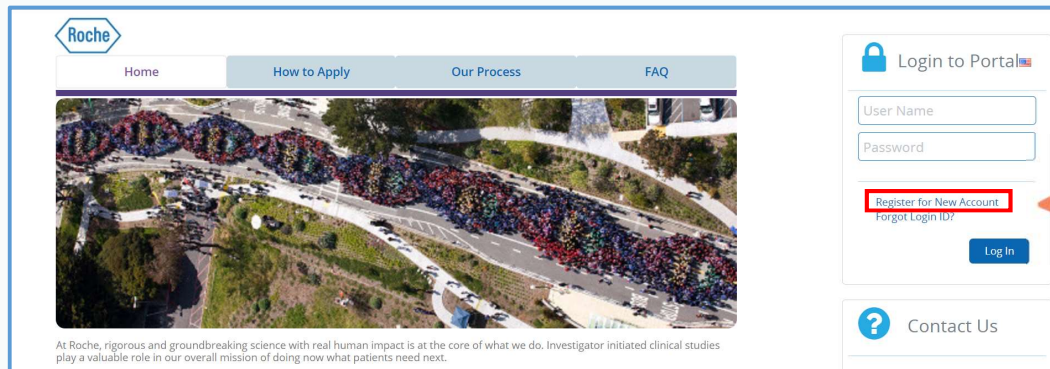
Log In

Requester Guide

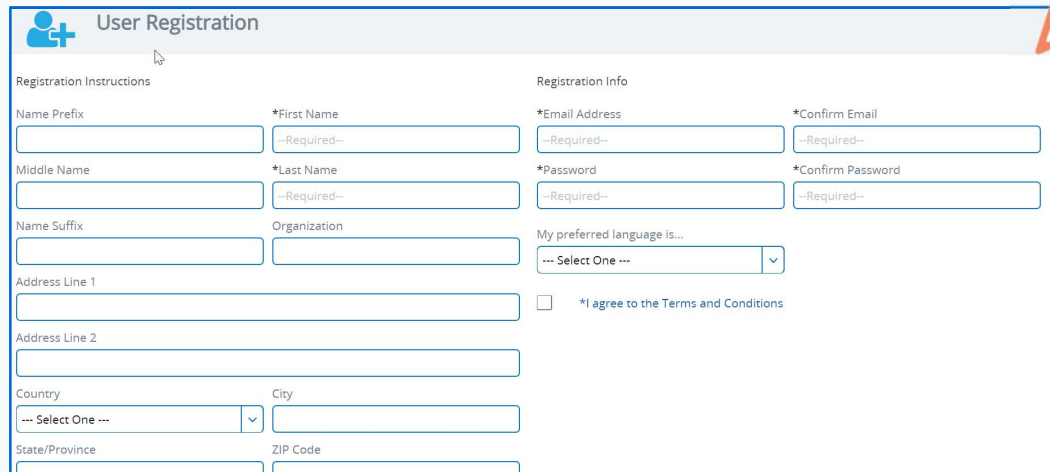
Create User Account

Do you not have a User Account? Then you need to follow the steps below to create a new account:

1. Go to <https://go.roche.com/IIS>
2. Choose **Click to here access the IIS portal**
3. Click **Register for New Account**
4. Complete all mandatory fields that are marked with an * including your own password
5. You will receive an e-mail confirming the account creation



The screenshot shows the Roche IIS Portal homepage. The navigation bar includes links for Home, How to Apply, Our Process, and FAQ. A large image of a DNA helix is displayed. On the right side, there is a 'Login to Portal' section with fields for User Name and Password, a 'Log In' button, and a link to 'Register for New Account' which is highlighted with a red box and an orange arrow. Below the login section is a 'Contact Us' link.



The screenshot shows the 'User Registration' form. The form is titled 'User Registration' and contains various fields for personal and organizational information. The fields are organized into two main sections: 'Registration Instructions' and 'Registration Info'. The 'Registration Instructions' section includes fields for Name Prefix, Middle Name, Name Suffix, Address Line 1, Address Line 2, Country, State/Province, City, and ZIP Code. The 'Registration Info' section includes fields for *First Name, *Last Name, *Email Address, *Confirm Email, *Password, *Confirm Password, and Organization. There is also a dropdown menu for 'My preferred language is...' and a checkbox for '*I agree to the Terms and Conditions'. An orange arrow points to the top right corner of the form.





Recommendation: also complete the non-mandatory fields such as: address, country, city and zip code. This will then allow you to “copy your profile” when you complete the submission

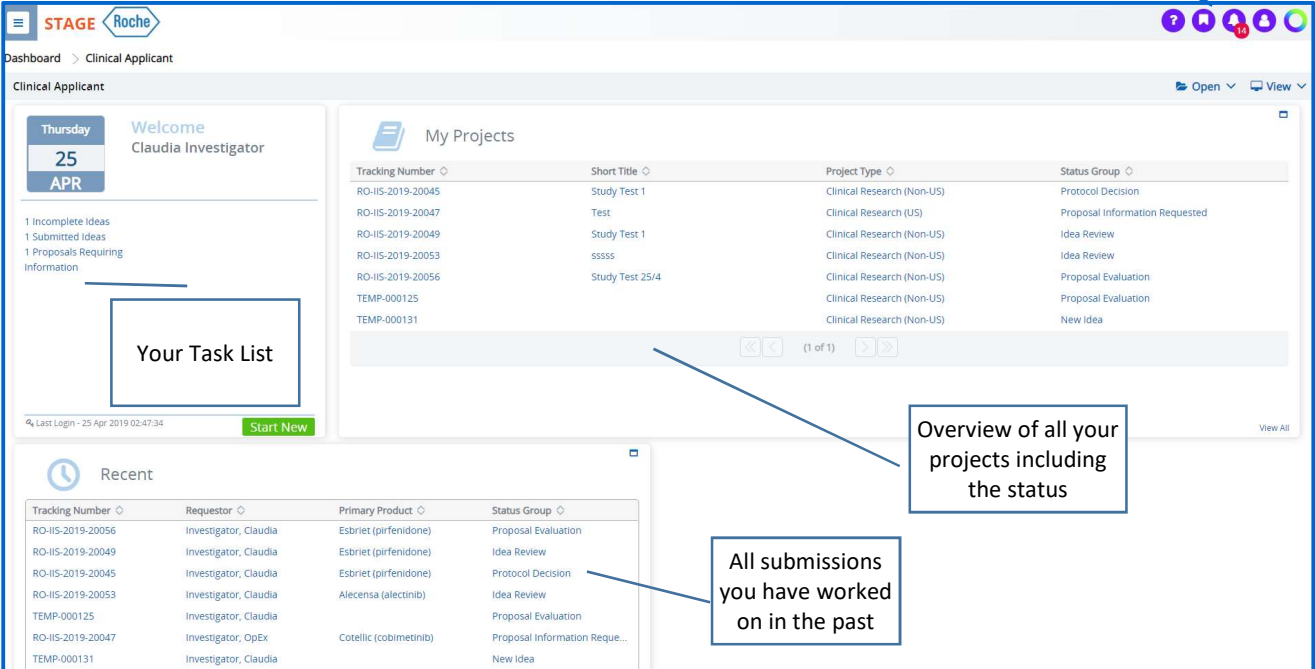
Requester Guide

User Dashboard

Description

**Notifications**

**User Profile & Logout**



Dashboard > Clinical Applicant

Clinical Applicant

Thursday
25
APR

Welcome
Claudia Investigator

1 Incomplete Ideas
1 Submitted Ideas
1 Proposals Requiring Information

Your Task List

Last Login - 25 Apr 2019 02:47:34 **Start New**

My Projects

Tracking Number	Short Title	Project Type	Status Group
RO-IIS-2019-20045	Study Test 1	Clinical Research (Non-US)	Protocol Decision
RO-IIS-2019-20047	Test	Clinical Research (US)	Proposal Information Requested
RO-IIS-2019-20049	Study Test 1	Clinical Research (Non-US)	Idea Review
RO-IIS-2019-20053	sssss	Clinical Research (Non-US)	Idea Review
RO-IIS-2019-20056	Study Test 25/4	Clinical Research (Non-US)	Proposal Evaluation
TEMP-000125		Clinical Research (Non-US)	Proposal Evaluation
TEMP-000131		Clinical Research (Non-US)	New Idea

(1 of 1)

Recent

Tracking Number	Requestor	Primary Product	Status Group
RO-IIS-2019-20056	Investigator, Claudia	Esbriet (pirfenidone)	Proposal Evaluation
RO-IIS-2019-20049	Investigator, Claudia	Esbriet (pirfenidone)	Idea Review
RO-IIS-2019-20045	Investigator, Claudia	Esbriet (pirfenidone)	Protocol Decision
RO-IIS-2019-20053	Investigator, Claudia	Alecensa (alecetinib)	Idea Review
TEMP-000125	Investigator, Claudia		Proposal Evaluation
RO-IIS-2019-20047	Investigator, OpEx	Cotellic (cobimetinib)	Proposal Information Reque...
TEMP-000131	Investigator, Claudia		New Idea

Overview of all your projects including the status

All submissions you have worked on in the past

Note: If you are new to the IIS Portal, then this dashboard will be empty and will gradually fill as you use it

Requester Guide

Navigation within a submission

Description

Go to your Dashboard

Submission Tracking Number

Notifications

User Profile & Logout

Navigation panel listing all "nodes"

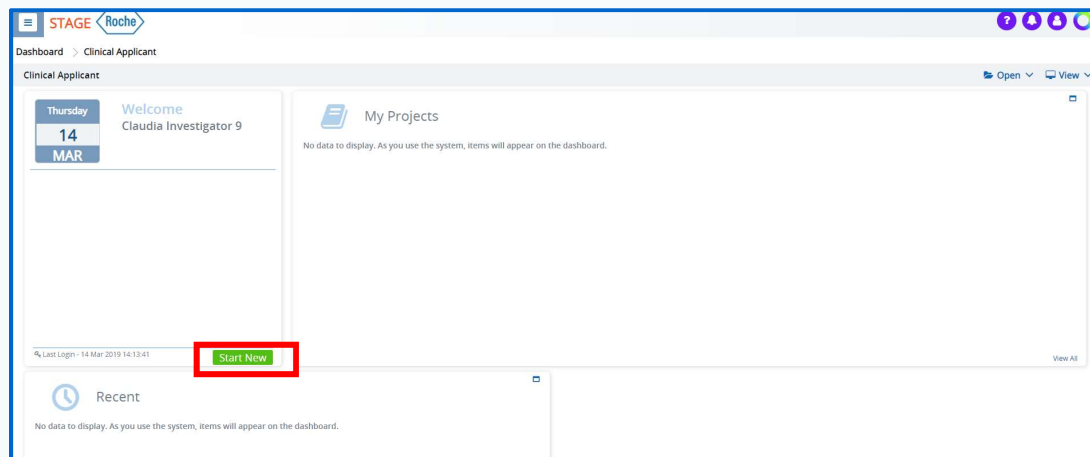
To advance to the next node, either click on the specific node, either on the bottom right hand or in the navigation panel

Navigation to the next "node"

The screenshot displays the Roche IIS Portal submission interface. At the top, a navigation bar includes a menu icon, the 'STAGE Roche' logo, and user icons for help, notifications (58), and user profile/logout (14). Below this, a breadcrumb trail shows 'Dashboard > Clinical Applicant > General Information (Test)'. The main header area contains the submission ID 'Clinical Research ... RO-IIS-2019-20047', page indicator '1 of 1', and status details: 'Requestor: Investigator', 'Status: Proposal Information Requested', and 'Request Date: 18 Apr 2019'. A left-hand navigation panel lists nodes: General Information, Personnel, Test, Test*, Study Information, Proposal, Scientific Summary, Requested Product, Planned Publications, Attachments, and Acknowledgment. The 'General Information' node is selected. The main form area contains various input fields for study details, including 'Study Title' (Test), 'Short Title' (Test), 'Primary Product' (Cotellic (cobimetinib)), 'Indication' (Test), and 'Disease Area' (Infectious Diseases). A bottom right section shows 'Personnel' information. Annotations with arrows point to the 'Go to your Dashboard' link, the 'Submission Tracking Number', the top right user icons, the left navigation panel, and the bottom right 'Personnel' section.

New Submission

1. Click **Start New**
2. Choose **Clinical Research (Non-US)** if this option is available and then click **continue**



The application automatically assigns a temporary tracking number. ...TEMP-000331

Overview of required fields

3. Please complete the following mandatory fields marked with an * (see next pages for screen shots):

- **General Information node:**

- Interventional or Non-interventional Study > *different additional fields may be applicable* depending on the study type chosen
- Study Title
- Primary Product & Additional Products, if applicable
- Therapeutic Area
- Indication to be Studied
- Type of Support Requested
 - Funding Amount & Currency (if funding is requested)
- Multi-Site Study (Yes/No)
- Number of Sites
- Number of Countries > if more than 2 countries, tick the countries that are foreseen in the study (this can be changed at a later stage and is not binding)
- Pediatric Study

- **Personnel node:**

- Primary Investigator First & Last Name
- Primary Investigator Email
- Sponsor/Institution Name
- Country

- **Proposal node:**

- Dates for: First Patient In/Start Date; Length of Recruitment; Length of Study; Trial Design; Study Phase; Sample Size (*Note: not all fields are required for non-interventional studies*)
- Details Study Budget (if funding is requested)
- Overview/Hypothesis
- Background/Rationale

- **Scientific Summary node** (*only for interventional studies*)

- Primary & Secondary Objectives
- Primary & Secondary Endpoints
- Inclusion & Exclusion Criteria
- Population
- Sample Size
- Treatment Plan

- **Oncology Analysis**

- Malignancy Type
- Correlative Study (Yes/No)

- **Acknowledgement node**

Requester Guide



Please click the blue **i** for more instruction on the information needed in each field

General Information Node

Choosing **Interventional** or **Non-interventional** study type will show or remove certain fields

General Information
Please click on the blue "i" for more instruction on the information needed in each field.

Fields marked with an * are required.

*Study Type
--- Select One ---
Interventional
Non-Interventional

Short Title
--- Abbreviated title or acronym ---

Primary Product
--- Select One ---

Please Specify other Primary Product

*I/A to be Studied
--- Therapeutic Area to be studied ---

Please specify other Therapeutic Area
--- Select One or More ---

Disease Area
--- Select One or More ---

Please Specify other Disease Area

Funding Amount Requested

Requested Currency
--- Select One ---

*Indication
--- Required ---

Is this a pediatric study?
--- Select One ---

Other sources of support
--- Please describe the type of support provided by each source ---

*Type of Support
--- Select One ---
Funding and Product

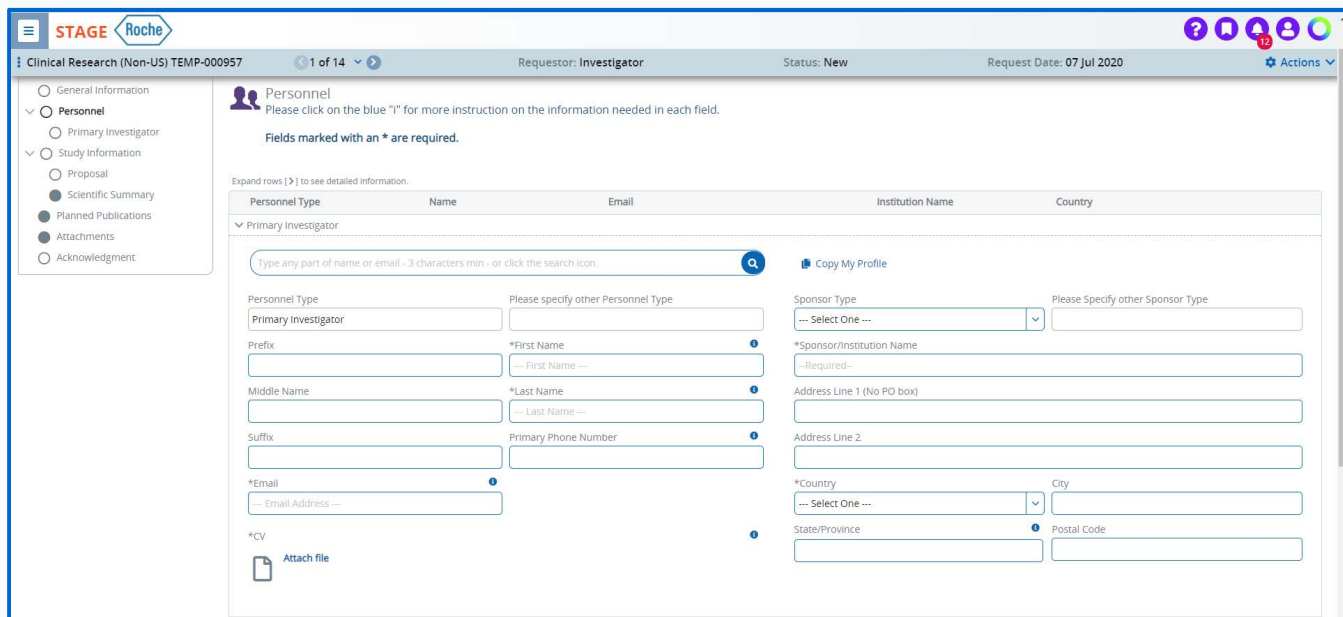
*Multi-Site Study
--- Select One ---
Yes
No
--- Required ---

*Additional Countries
--- Select One or More ---
United States
United Kingdom
Netherlands
Germany
Japan
Afghanistan

The application saves automatically when you navigate to a new page.

Personnel Node

If you have previously completed your user profile, you can copy the information by clicking **“Copy My Profile”**



STAGE Roche

Clinical Research (Non-US) TEMP-000957 1 of 14 Requestor: Investigator Status: New Request Date: 07 Jul 2020 Actions

Personnel
Please click on the blue "i" for more instruction on the information needed in each field.
Fields marked with an * are required.

Expand rows (>) to see detailed information.

Personnel Type	Name	Email	Institution Name	Country
Primary Investigator				

Type any part of name or email - 3 characters min - or click the search icon.

Copy My Profile

Personnel Type: Primary Investigator Please specify other Personnel Type:

Sponsor Type: --- Select One --- Please Specify other Sponsor Type:

Prefix: *First Name: *Sponsor/Institution Name:

Middle Name: *Last Name: Address Line 1 (No PO box):

Suffix: Primary Phone Number: Address Line 2:

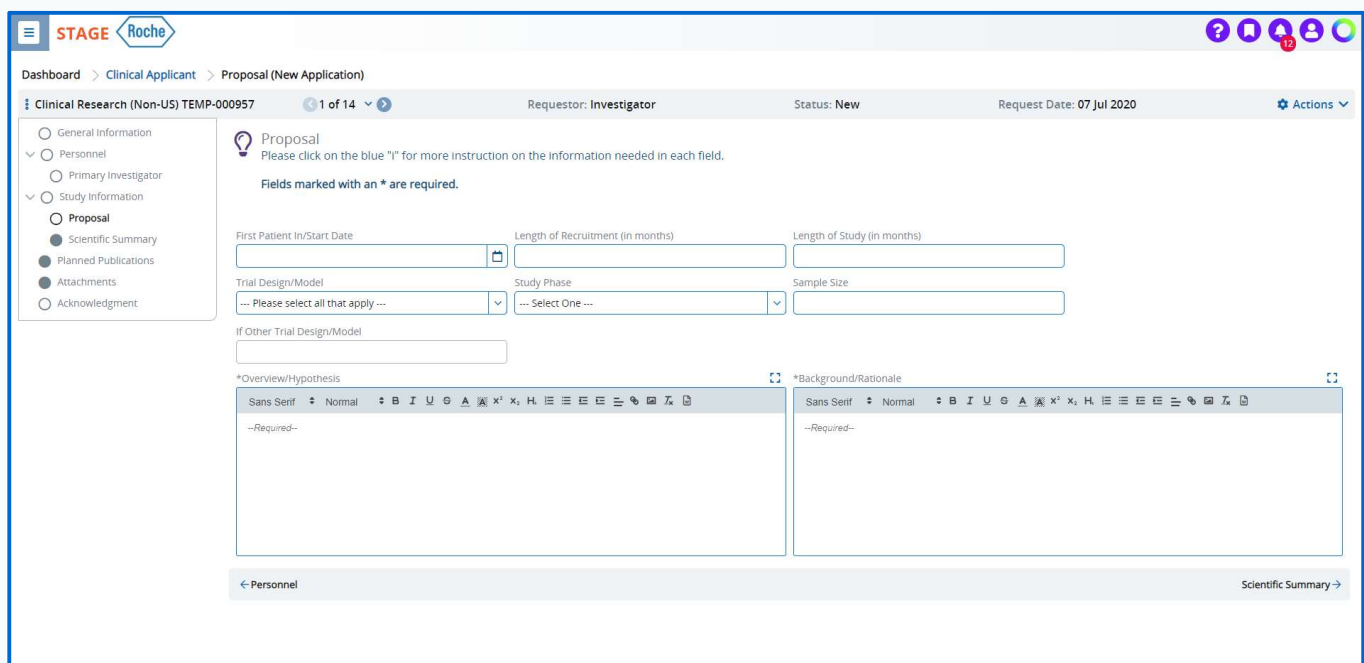
*Email: *Country: City:

*CV: State/Province: Postal Code:

Attach file

Proposal Node

Not all fields are required if the study type is Non-Interventional



The screenshot displays the 'Proposal (New Application)' form within the Roche IIS Portal. The interface includes a top navigation bar with the 'STAGE' logo and a user profile icon. Below this, a breadcrumb trail shows 'Dashboard > Clinical Applicant > Proposal (New Application)'. The main header area contains the following information: 'Clinical Research (Non-US) TEMP-000957', '1 of 14' (indicating the current step), 'Requestor: Investigator', 'Status: New', 'Request Date: 07 Jul 2020', and an 'Actions' dropdown menu.

The left sidebar contains a list of navigation options: 'General Information', 'Personnel', 'Primary Investigator', 'Study Information', 'Proposal' (selected), 'Scientific Summary', 'Planned Publications', 'Attachments', and 'Acknowledgment'.

The main content area is titled 'Proposal' and includes a lightbulb icon and the instruction: 'Please click on the blue "i" for more instruction on the information needed in each field.' Below this, a note states: 'Fields marked with an * are required.'

The form fields are organized as follows:

- First Patient In/Start Date:** A text input field with a calendar icon.
- Length of Recruitment (in months):** A text input field.
- Length of Study (in months):** A text input field.
- Trial Design/Model:** A dropdown menu with the option '--- Please select all that apply ---'.
- Study Phase:** A dropdown menu with the option '--- Select One ---'.
- Sample Size:** A text input field.
- If Other Trial Design/Model:** A text input field.

At the bottom of the form, there are two large text areas for rich text editing:

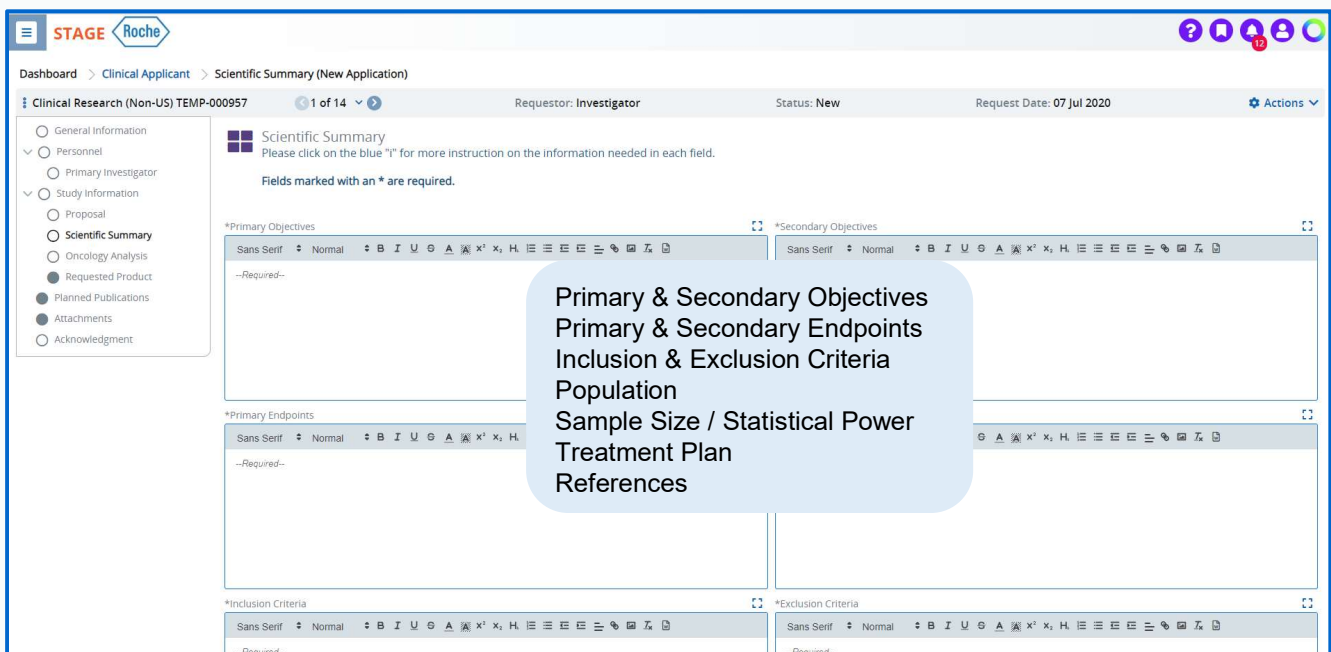
- *Overview/Hypothesis:** A text area with a 'Sans Serif' font and 'Normal' style. It contains the placeholder text '--Required--'.
- *Background/Rationale:** A text area with a 'Sans Serif' font and 'Normal' style. It contains the placeholder text '--Required--'.

At the bottom of the form, there are two navigation buttons: '← Personnel' and 'Scientific Summary →'.

Scientific Summary Node

Only applicable if study type = Interventional

All fields must be completed. In case all this information is already available in another document, for example a synopsis, then you have to possibility to attach the synopsis in the **Attachment node** and just write “see synopsis attached” into each mandatory field. You also have to possibility to attach screen shots or photos or even insert a word document.



Dashboard > Clinical Applicant > Scientific Summary (New Application)

Clinical Research (Non-US) TEMP-000957 1 of 14 Requestor: Investigator Status: New Request Date: 07 Jul 2020 Actions

- General Information
- Personnel
- Primary Investigator
- Study Information
- Proposal
- Scientific Summary**
- Oncology Analysis
- Requested Product
- Planned Publications
- Attachments
- Acknowledgment

Scientific Summary
Please click on the blue "i" for more instruction on the information needed in each field.
Fields marked with an * are required.

*Primary Objectives

*Secondary Objectives

*Primary Endpoints

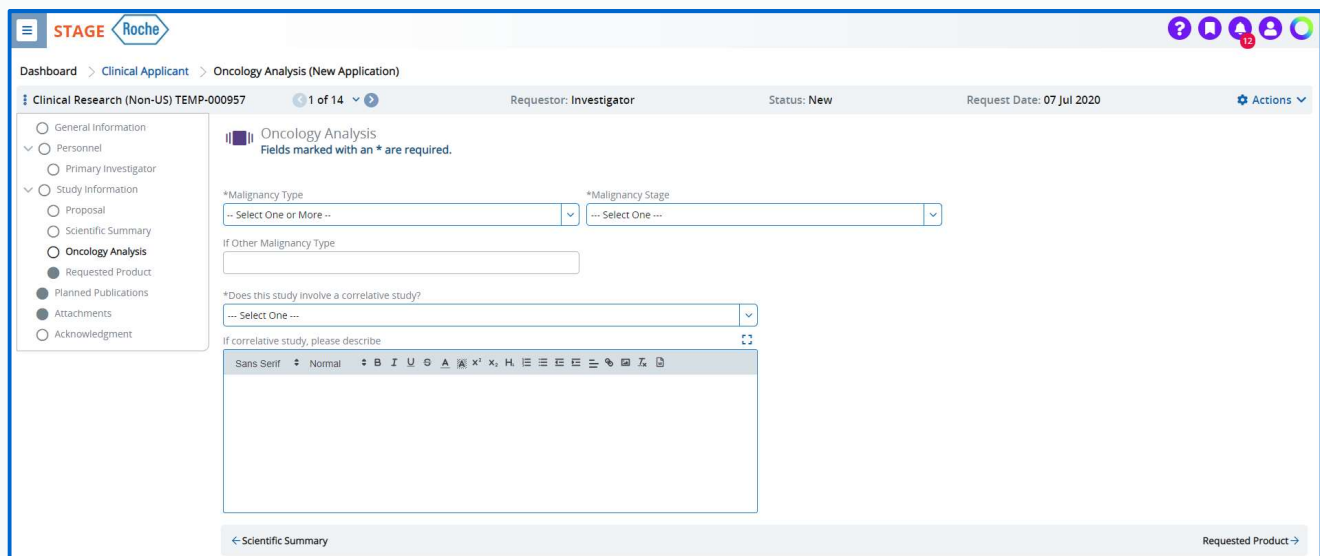
*Inclusion Criteria

*Exclusion Criteria

Primary & Secondary Objectives
Primary & Secondary Endpoints
Inclusion & Exclusion Criteria
Population
Sample Size / Statistical Power
Treatment Plan
References

Oncology Analysis Node

Only if study type = **Interventional**, and TA = **Oncology**



The screenshot shows the 'Oncology Analysis (New Application)' form in the Roche IIS Portal. The form is titled 'Clinical Research (Non-US) TEMP-000957' and is for a 'Requestor: Investigator' with a 'Status: New' and 'Request Date: 07 Jul 2020'. The form is divided into several sections: 'General Information', 'Personnel', 'Study Information', 'Oncology Analysis', 'Requested Product', 'Planned Publications', 'Attachments', and 'Acknowledgment'. The 'Oncology Analysis' section is currently active and contains the following fields:

- *Malignancy Type**: A dropdown menu with the option '-- Select One or More --'.
- *Malignancy Stage**: A dropdown menu with the option '-- Select One --'.
- If Other Malignancy Type**: A text input field.
- *Does this study involve a correlative study?**: A dropdown menu with the option '-- Select One --'.
- If correlative study, please describe**: A rich text editor with a toolbar containing options like 'Sans Serif', 'Normal', 'Bold', 'Italic', 'Underline', 'Text Color', 'Background Color', 'Link', 'Unlink', 'List', 'Indent', 'Outdent', 'Table', 'Image', 'Video', 'Audio', 'Code', and 'Source'.

At the bottom of the form, there are two buttons: '< Scientific Summary' and 'Requested Product >'.

Requested Product Node

Requested Product node:

This node will only show if you have chosen **Product** or **Funding and Product** in the **General Information node**

STAGE Roche

Dashboard > Clinical Applicant > Requested Product (Test Study)

Clinical Research ... RO-IIS-2019-20114 | 1 of 1 | Requestor: Investigator11 Status: Proposal Information Requested Request Date: 26 Mar 2019 Actions

Requested Product
Roche/Genentech product requested

Please complete the Product field for all requested products. If requesting placebo, please indicate amount requested in comments.

Product	Placebo Required?	Comments
Esbriet (pirfenidone)		

+ Add Row

Other sources of study drug

Scientific Summary Planned Publications

The Primary Product that you have chosen in the General Information node is automatically listed here. However, you will need to confirm if you are requesting this product.

1. Choose functionality to **confirm** or to **delete**
2. Select **Yes** or **No** for question **Placebo Required?**
3. **Confirm selection**
4. If you wish to **request other Roche Products**, choose **+Add Row**, choose **Product** and **repeat steps 2-3**
5. You can inform us if you are receiving study drug from other sources

Product Placebo Required? Comments

Esbriet (pirfenidone) ... Select One ...

Other sources of study drug

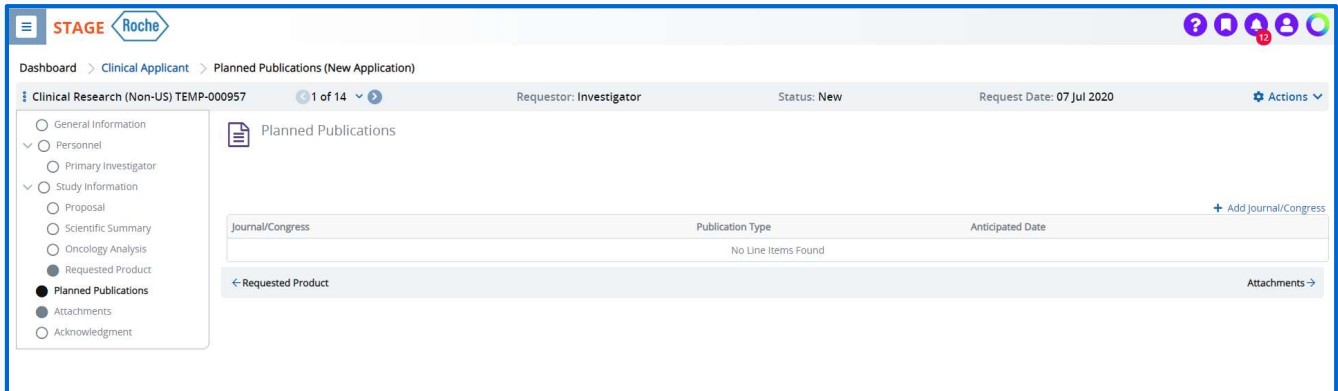
+ Add Row

Confirm selection

Requester Guide

Publication Node

Optional Information for Roche's review



STAGE Roche

Dashboard > Clinical Applicant > Planned Publications (New Application)

Clinical Research (Non-US) TEMP-000957 1 of 14 Requestor: Investigator Status: New Request Date: 07 Jul 2020 Actions

General Information
Personnel
Primary Investigator
Study Information
Proposal
Scientific Summary
Oncology Analysis
Requested Product
Planned Publications
Attachments
Acknowledgment

Planned Publications

+ Add Journal/Congress

Journal/Congress	Publication Type	Anticipated Date
No Line Items Found		

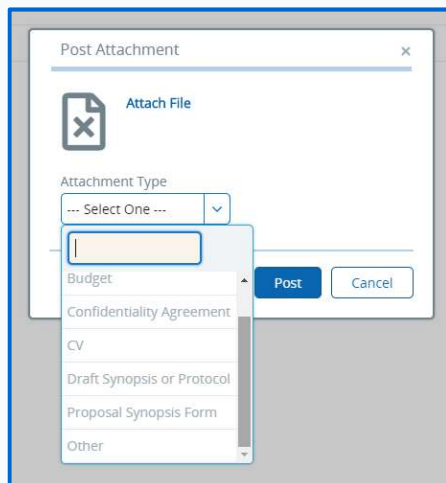
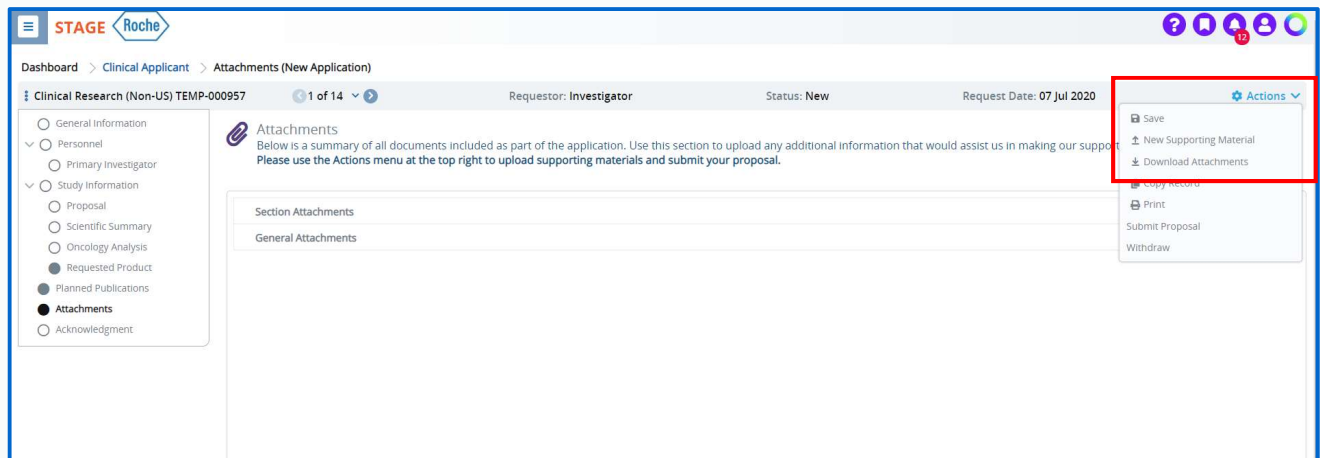
< Requested Product Attachments >

Requester Guide

Attachment Node

To upload any supporting documents, such as a synopsis, draft protocol etc. that you want to share with Roche.

1. Go to **Actions** and choose **New Supporting Material**
2. Click “Attach file” to upload the document
3. Select the attachment type from the dropdown list and post



Requester Guide

Acknowledgement Node

Acknowledgement node

Accept the disclaimer and once all fields are completed, click the **Actions** menu, select **Submit Idea**

The screenshot shows the 'Acknowledgement (New Application)' form. The sidebar on the left contains navigation links: General Information, Personnel, Primary Investigator, Study Information, Proposal, Planned Publications, Attachments, and Acknowledgment. The main content area displays a disclaimer: '*By accepting this agreement, you confirm that any information submitted will be accurate and complete. Roche/Genentech confirms that your information will be kept confidential, however, you acknowledge that any support provided by Roche/Genentech may be publicly disclosed. In addition, you acknowledge that Adverse Events cannot be submitted using this portal. If the study is sponsored by Roche/Genentech, attest that Roche/Genentech has not unduly influenced submission of this IIS concept.' Below the disclaimer is a dropdown menu labeled '- Select One -'. On the right, the 'Actions' menu is highlighted with a red box, and a red arrow points to the 'Submit Idea' option.

A unique **submission tracking number** will be issued

Log out

The screenshot shows the user profile dropdown menu. It displays the user's name 'Claudia Investigator11' and last login date '26 Mar 2019'. Below this, there are three options: Profile, English / United States, and Logout. The Logout option is highlighted with a red box.

When all mandatory fields are completed in a node, the status changes from

to ☒ Personnel ☐ Study Information ☐ Proposal

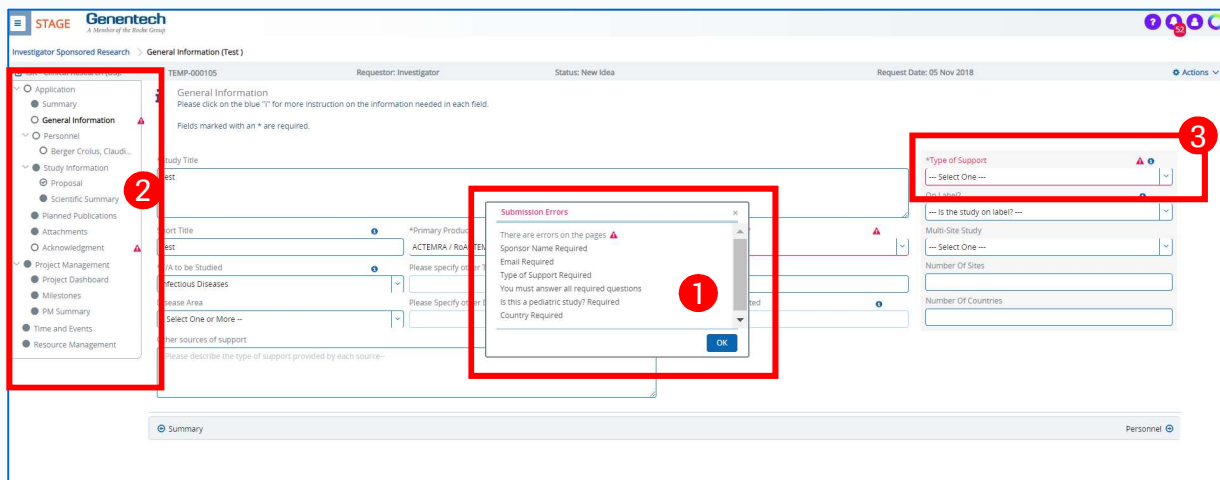
☒ Investigator, Claudia*

TIP



Error Messages

Any mandatory field that is not completed when submitting the IDEA will trigger a **Submission Errors** message 1

TIP



The screenshot shows the 'General Information (Test)' section of the STAGE Genentech Investigator Sponsored Research form. A red box labeled '2' highlights the left-hand navigation menu. A red box labeled '1' highlights a 'Submission Errors' modal dialog box in the center, which lists errors such as 'Sponsor Name Required', 'Email Required', 'Type of Support Required', 'You must answer all required questions', 'Is this a pediatric study? Required', and 'Country Required'. A red box labeled '3' highlights a dropdown menu for '*Type of Support' on the right side of the form, which is currently set to 'Select One'.

1. The **missing fields** will be listed in the **Submission Errors Message**
2. The **nodes** that have missing fields are flagged with an 
3. The **fields** with missing information are flagged with an 

Requester Guide



Version	Date Issued	Reason for Change
1.0	30 April 2019	NEW
2.0	31 July 2020	Removal of IDEA & PROTOCOL submissions via the IIS Portal Updated functionalities