Roche
IIS Portal

Requester User Guide

Requester Guide

Roche IIS Portal

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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)

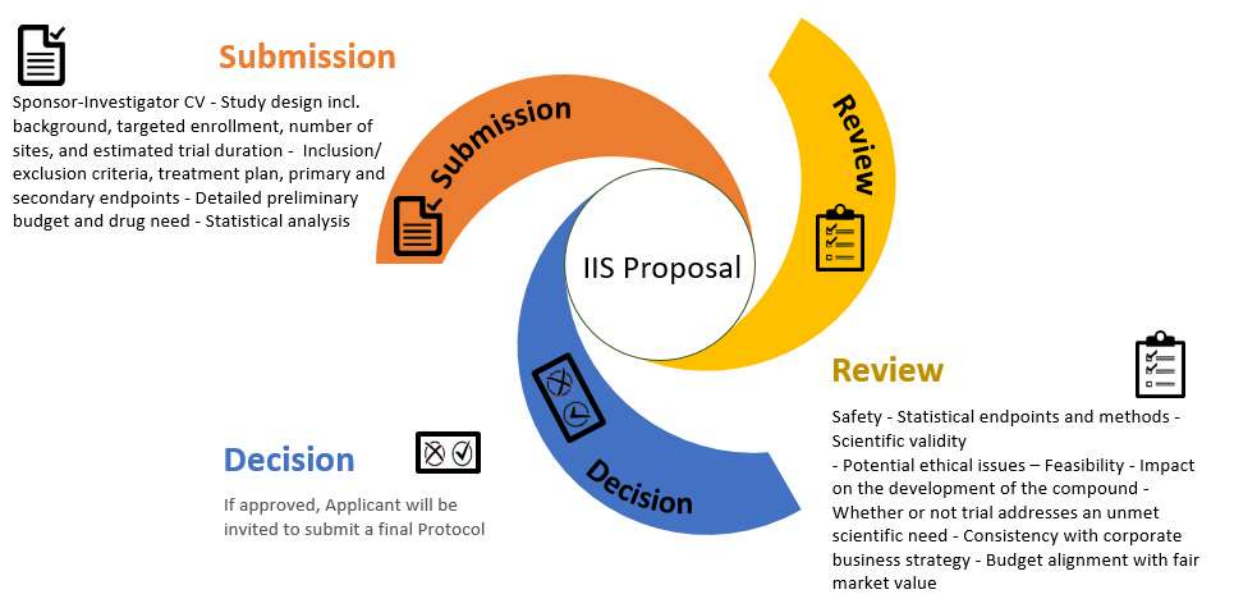
The following types of IIS requests are **out of scope**:

- 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.

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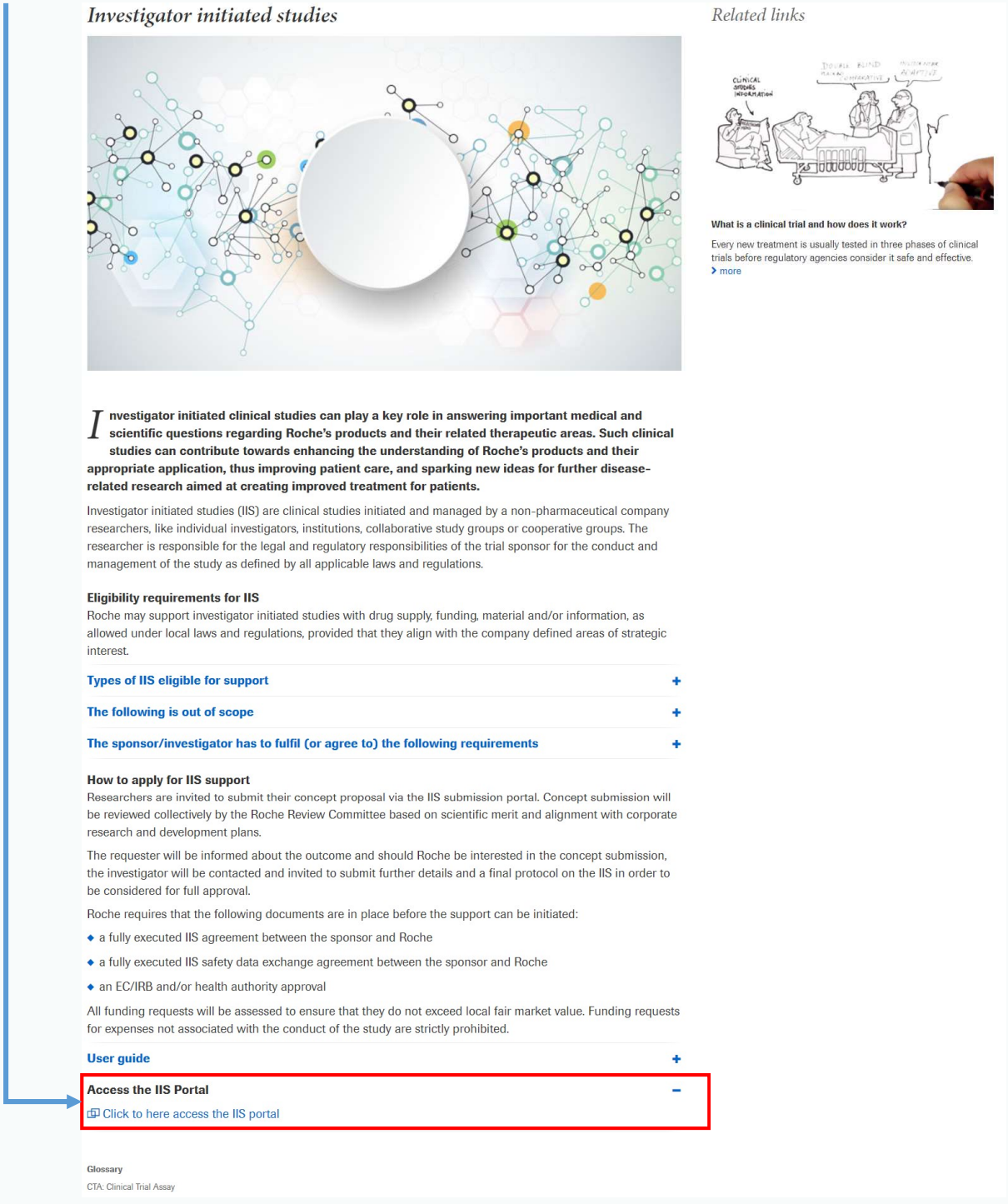
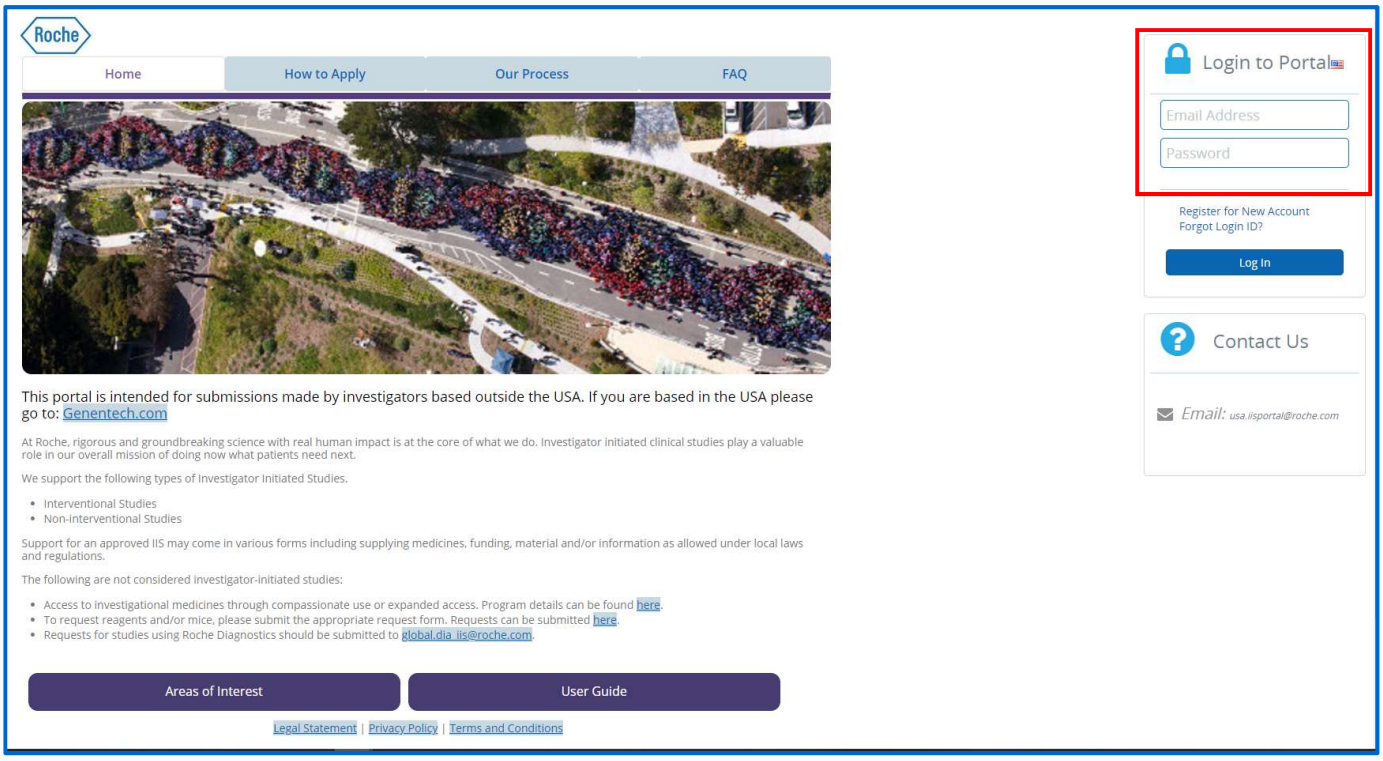
Accessing the IIS Portal

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



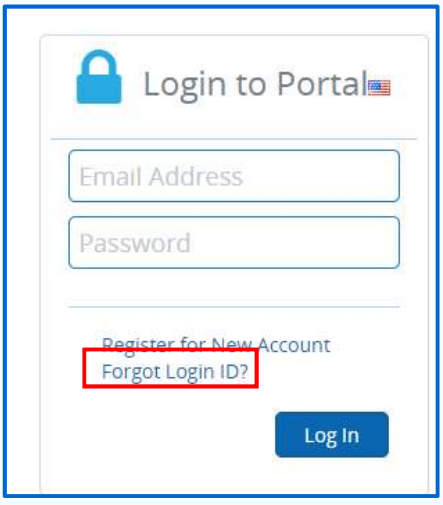
IIS Portal Landing Page

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



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

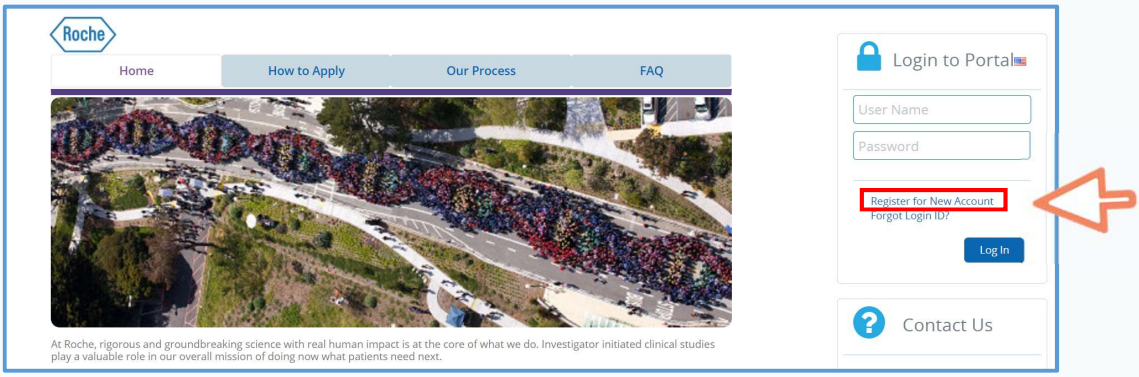
Roche will then re-set your password and send you a temporary password that you can change at the next login.

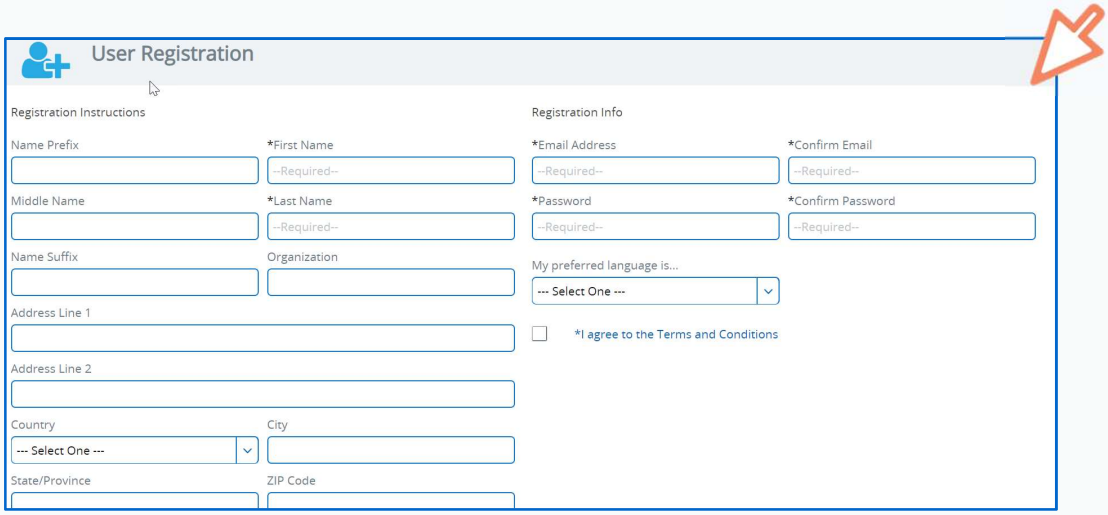


Create User Account

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

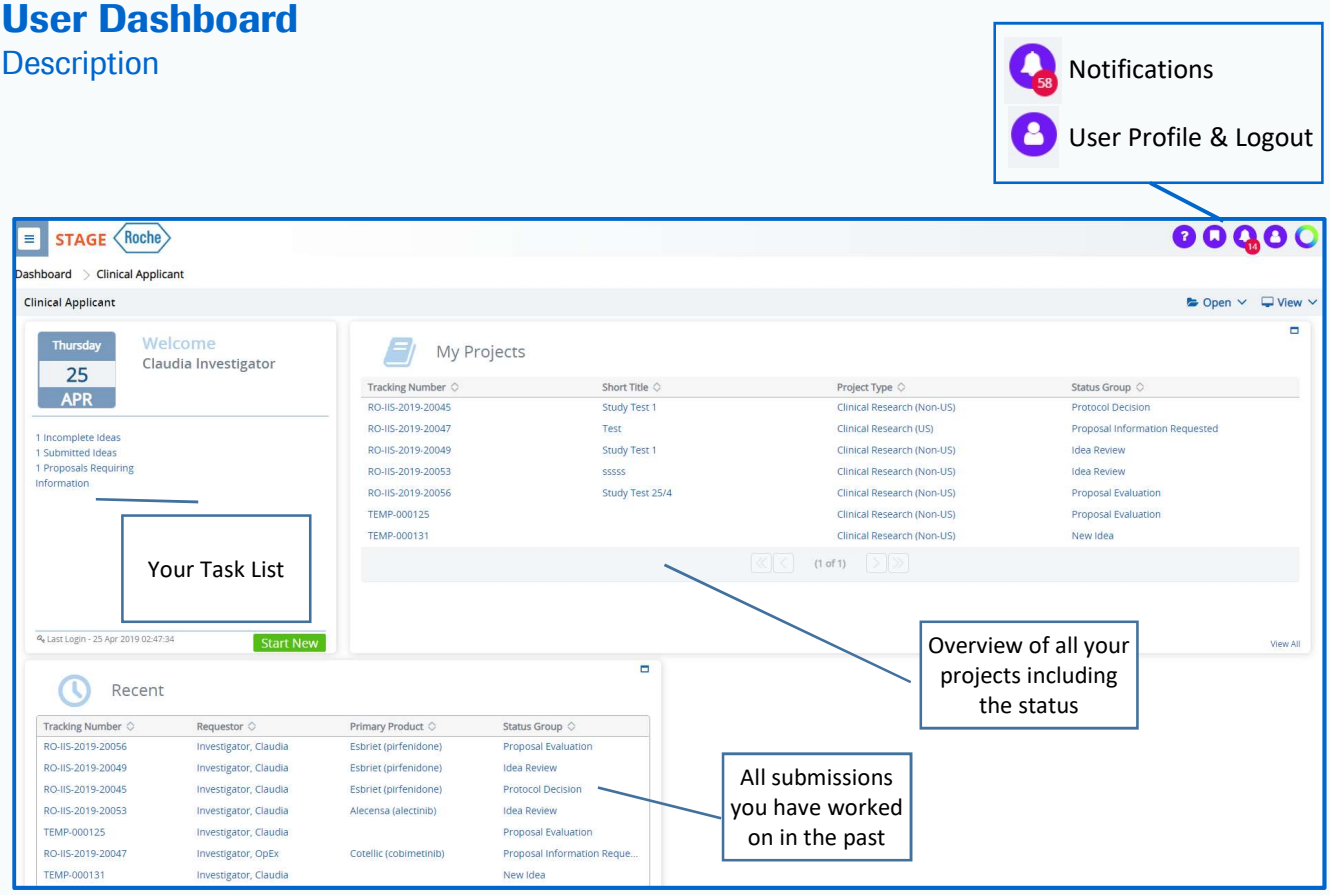




Recommendation: also complete the non-mandatory fields such as: address, country, city and zip code. This will then allow you to "copy your profile" when you complete the submission

User Dashboard

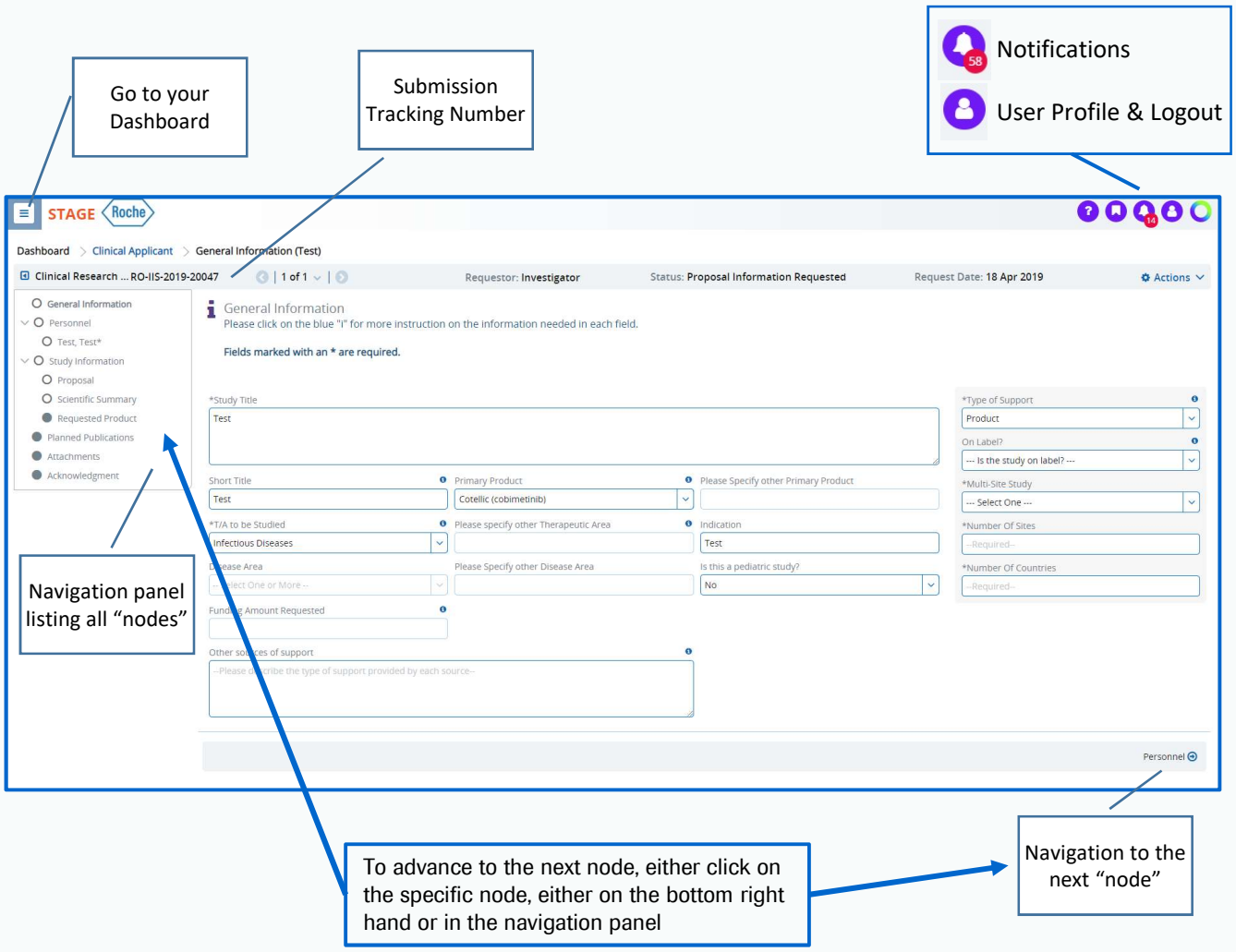
Description



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

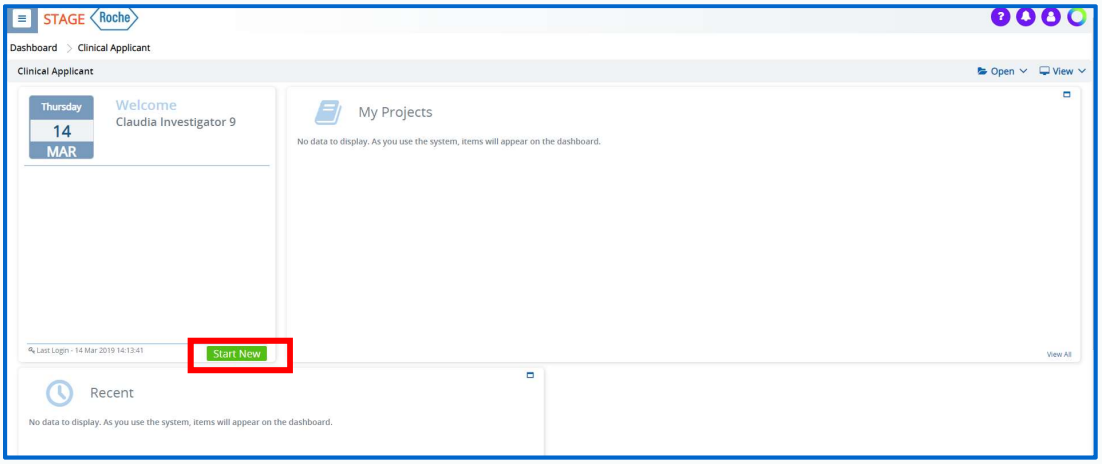
Navigation within a submission

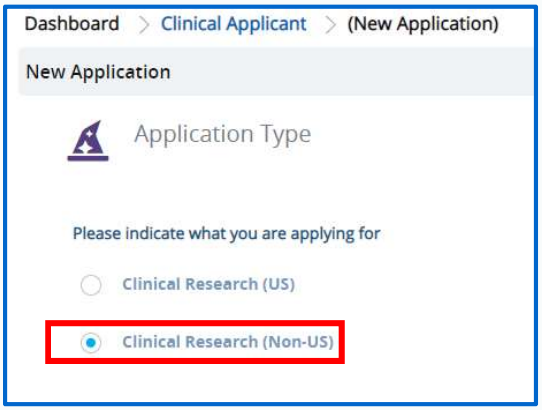
Description



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**

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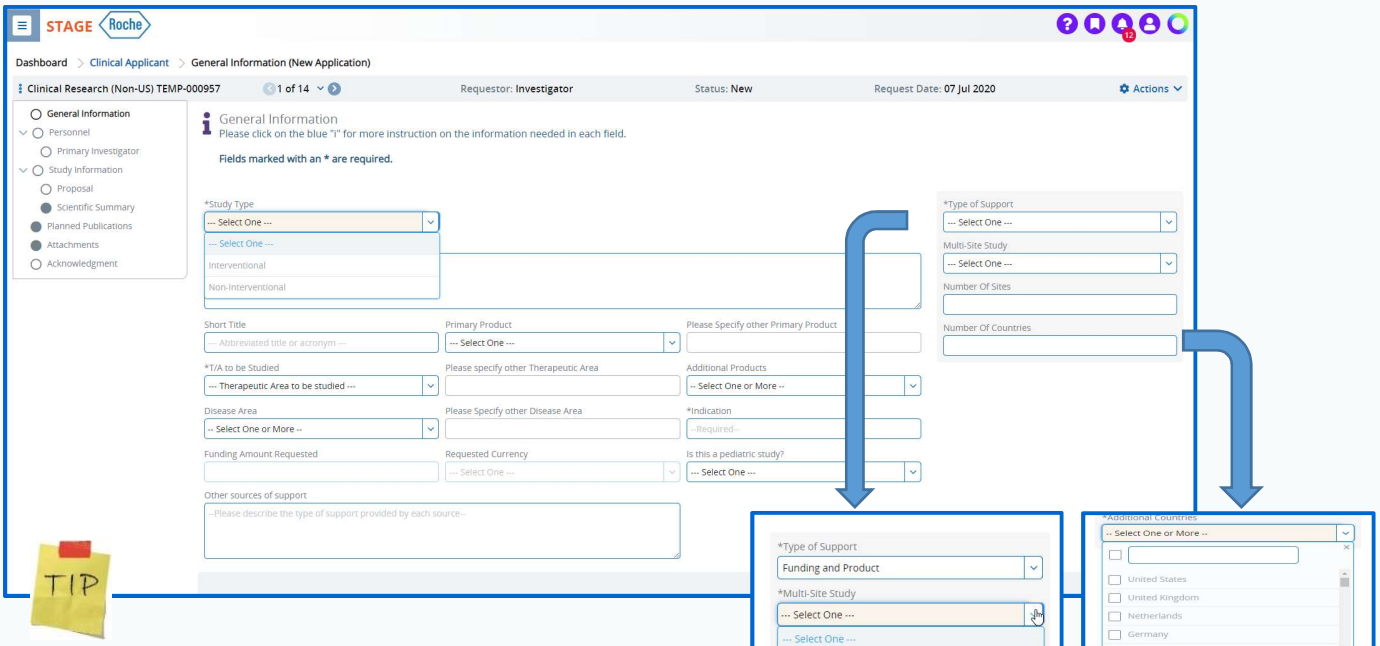
General Information Node

TIP

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

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

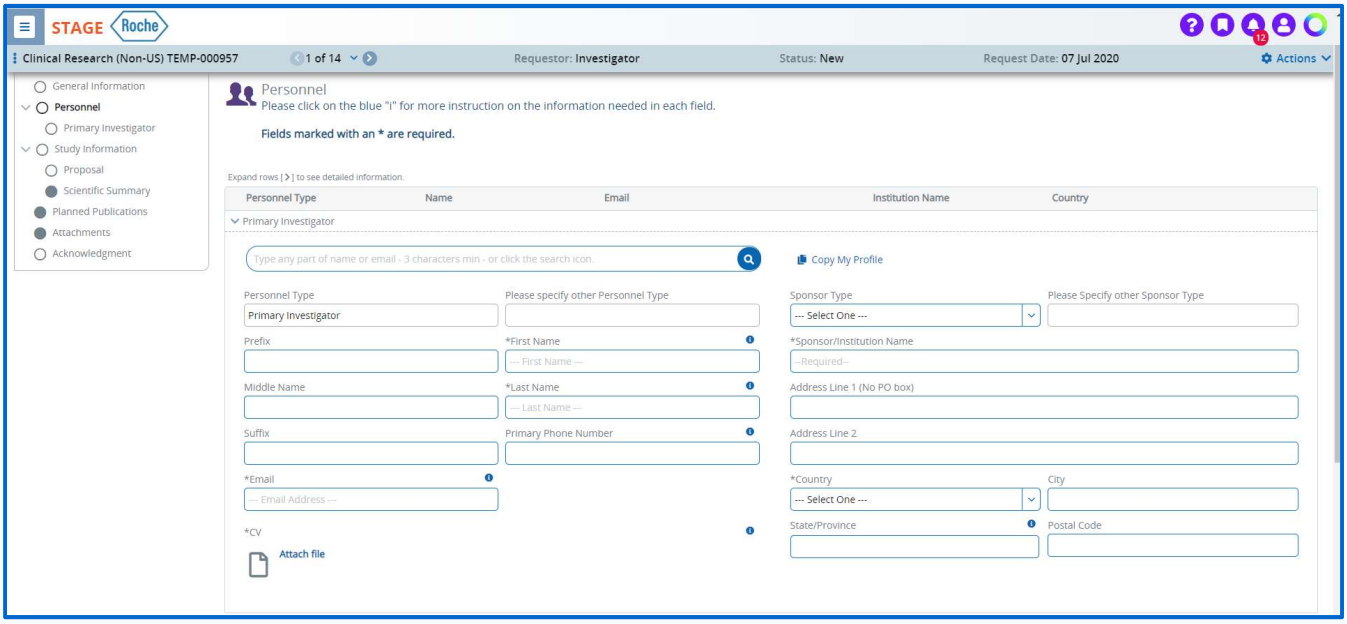


TIP

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

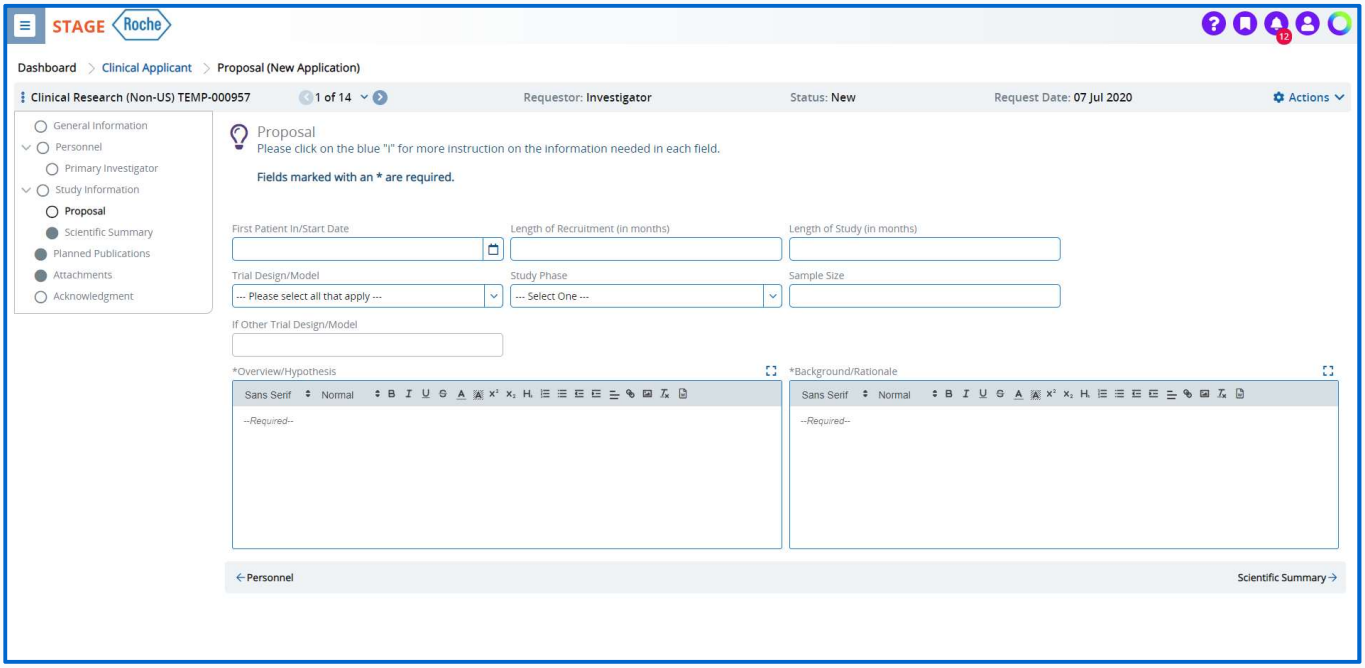
Personnel Node

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



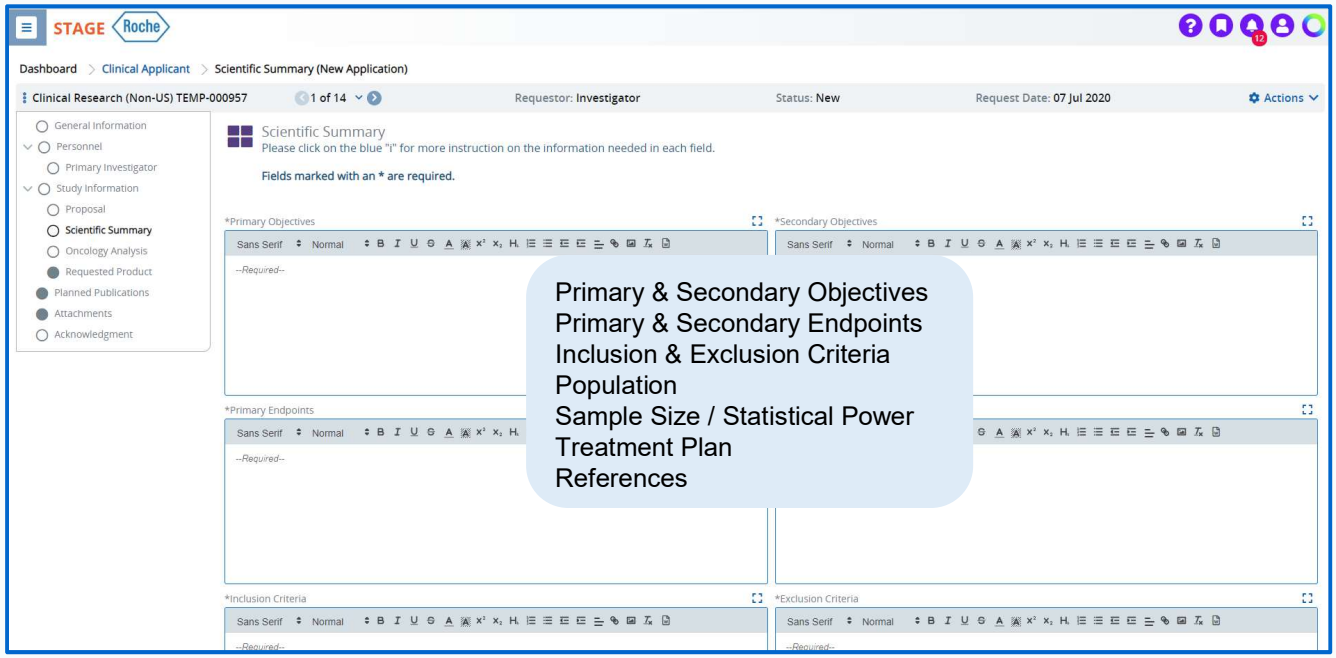
Proposal Node

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



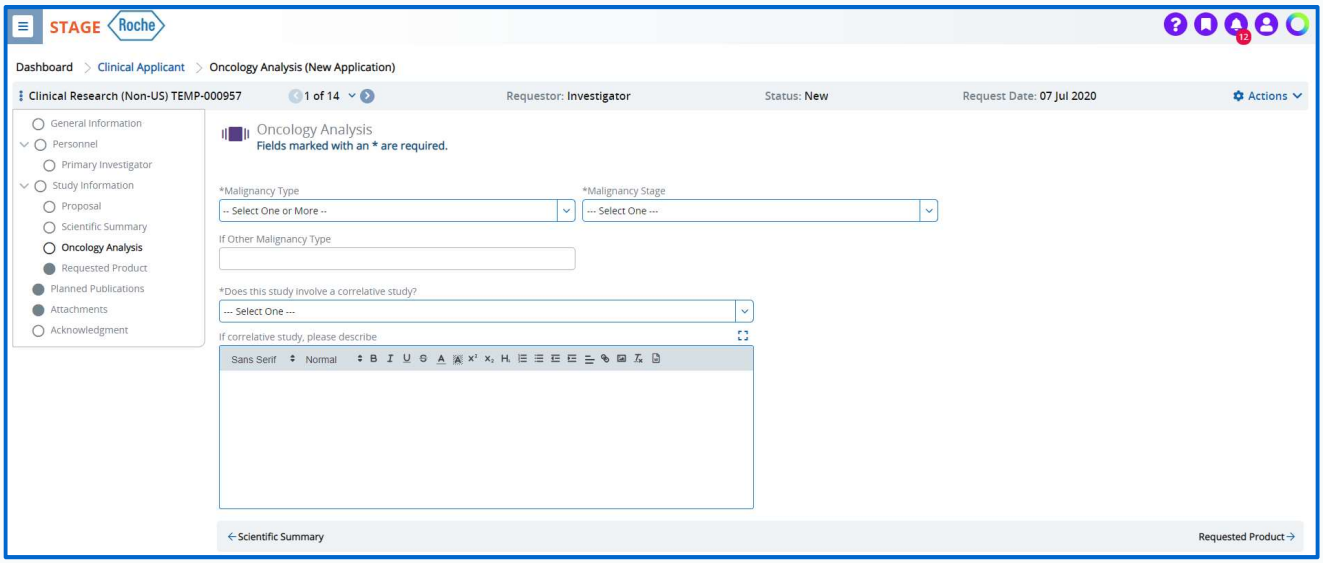
Scientific Summary Node

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.



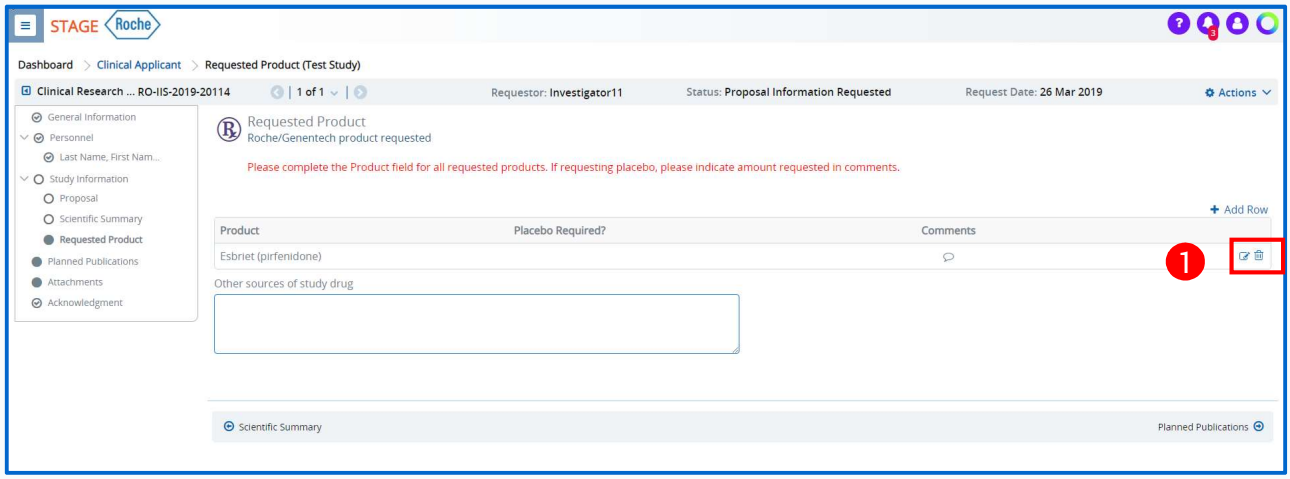
Oncology Analysis Node

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



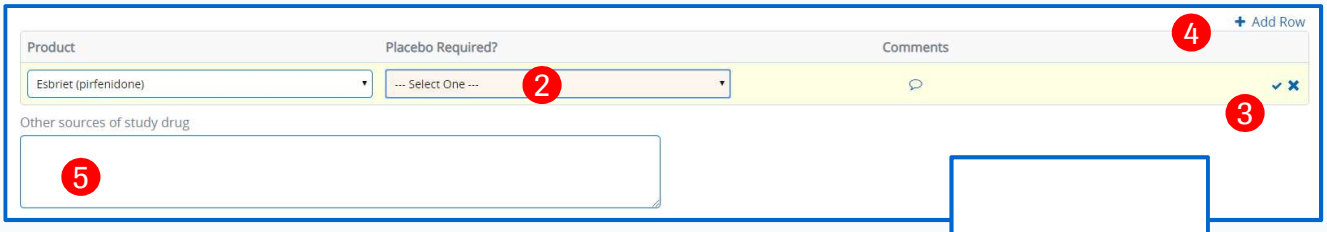
Requested Product Node

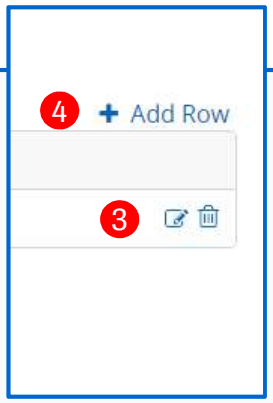
Requested Product node:
This node will only show if you have chosen **Product** or **Funding and Product** in the **General Information node**



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





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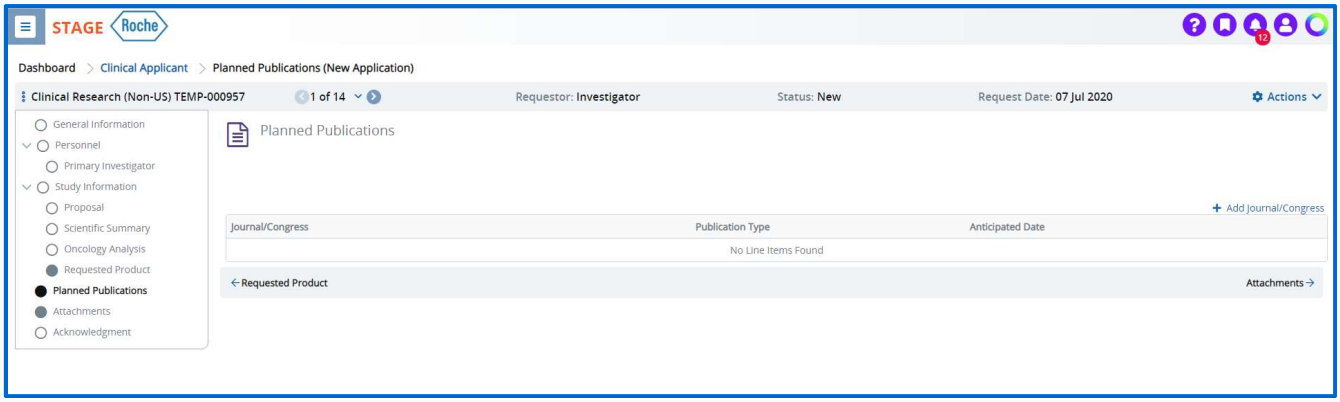
Publication Node

Optional Information for Roche's review



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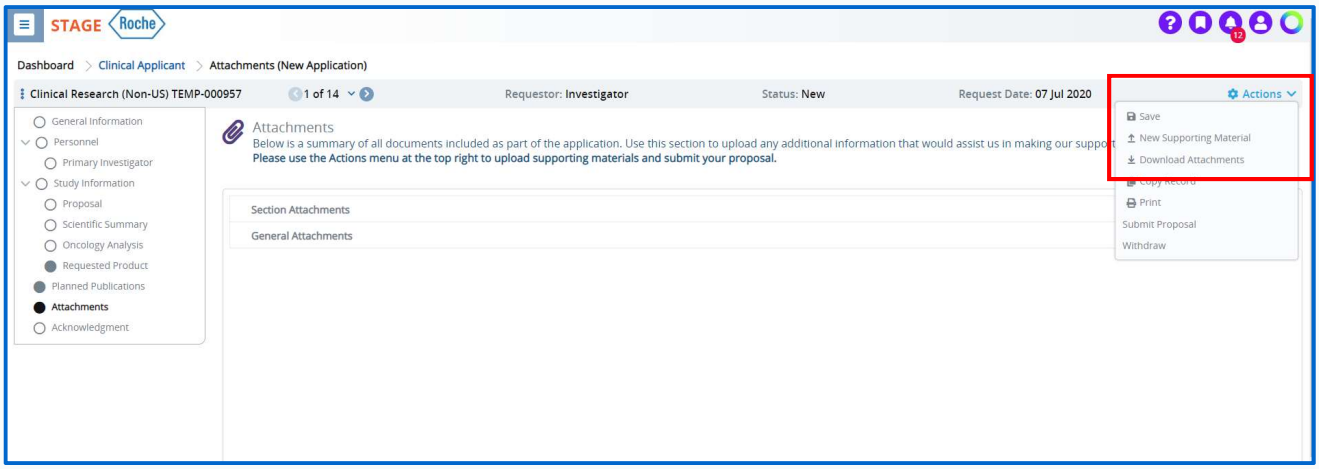
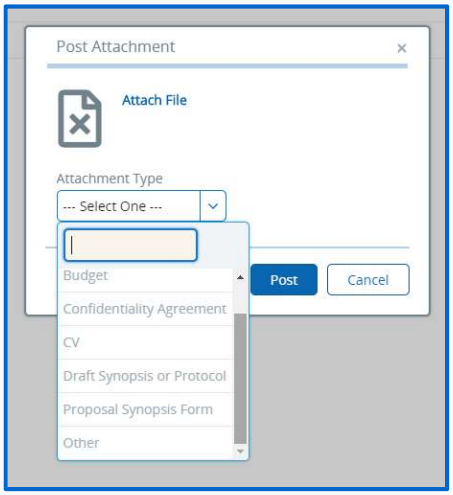
Attachment Node

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





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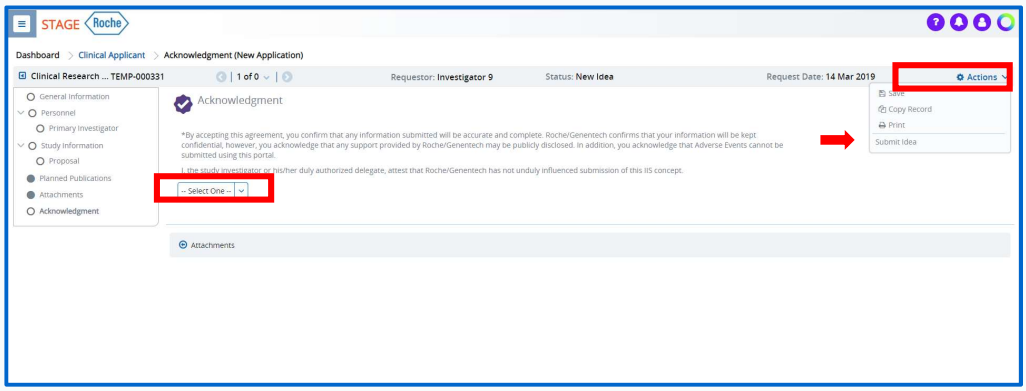
Acknowledgement Node

Acknowledgement node

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

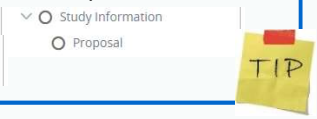


A unique **submission tracking number** will be issued

Log out

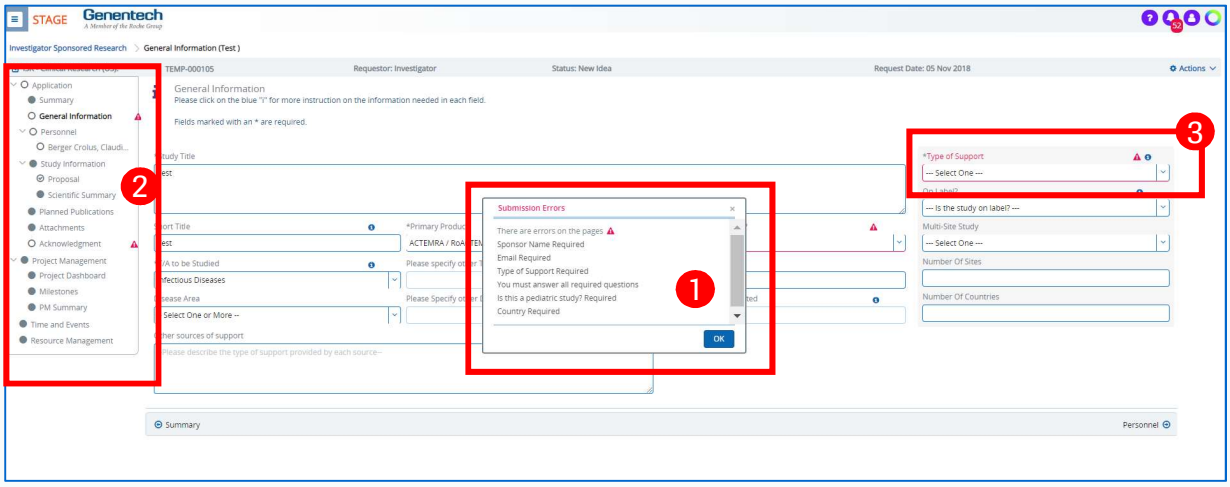
When all mandatory fields are completed in a node, the status changes from

to



Error Messages

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



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 ⚠

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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