Requester User Guide
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## Version

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<th>Version</th>
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<tr>
<td>1.0</td>
<td>30 April 2019</td>
<td>NEW</td>
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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

The process consists of 3 steps:

IDEA
You have an Idea

You can discuss your Idea with your MSL, MM or IMD or you can immediately submit your Idea through the IIS Portal

PROPOSAL
Submit Proposal

A link inviting you to complete your Proposal in the IIS Portal will be sent if your idea is of interest

PROTOCOL
Submit Protocol

If your Proposal is approved, you will be invited to submit a full Protocol before support can be initiated

You will be notified by your Roche representative (e.g. your MSL) if the submission can proceed to the next step as well receive a notification out of the IIS Portal directly. 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.

In case of questions, please do not hesitate to contact us at: support.iisportal@roche.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 what patients need most.

We support the following types of investigator-initiated studies:

- Interventional Studies
- Non-interventional Studies

These studies 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 inquiries and/or more, please submit the appropriate request form. Requests can be submitted here.
- Requests for studies using Roche Diagnostics should be submitted to RocheDiagSupport@roche.com

Areas of Interest

User Guide

Legal Statement Terms and Conditions

Roche, Roche Diagnostics, Diagnostics Division, Roche Diagnostic Systems, Roche Diagnostics Systems, Roche Diagnostics Diagnostics Division, Roche Diagnostics Systems, and Diagnostics Division are registered trademarks of Roche Diagnostics Corporation. All other trademarks are the property of their respective owners.
User Dashboard

Description

- Notifications
- User Profile & Logout

Your Task List

Overview of all your projects including the status

All submissions you have worked on in the past
**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”
User account

Did you already have a user account in the previous Roche IIS Portal?

- **If yes**, then your account has been moved over and all you need to do is get it activated. Either use the activation e-mail that was sent to you on 30 April 2019 or contact us at support.iisportal@roche.com to get your account activated.

- **If no**, 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
1 | IDEA Submission
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 IDEA submission 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 themselves.

Once Roche has received the IDEA submission, we will be evaluating the IDEA and will do our best to provide you with our feedback – IDEA interest or not – within 2-3 weeks. Please note that some IDEAs need further information from you or a decision may need to be postpone. In any case, Roche will keep you informed.
1. **IDEA Submission by Requester**

   **Log in**

1. Login into iEnvision: [https://go.roche.com/IIS](https://go.roche.com/IIS)
2. Choose **Click to here access the IIS portal**
3. Enter your **User ID and Password**
4. Click **Start New, New IIS Request** to create a new submission

The application automatically assigns a temporary tracking number. ...TEMP-000331
3. Please complete the following mandatory fields marked with an *:

- **General Information node:**
  - Study Title
  - Primary Product
  - Therapeutic Area
  - Indication to be Studied
  - Type of Support Requested
  - Pediatric Study

- **Personnel node:**
  - Primary Investigator First & Last Name
  - Primary Investigator Email
  - Sponsor/Institution Name
  - Country

- **Proposal node:**
  - Overview/Hypothesis
  - Background/Rationale

- **Acknowledgement node**

**NOTE:** All non-mandatory fields are not required for an IDEA review by Roche, however you are free to complete if you wish.
IDEA Submission by Requester
General Information Node

- Study Title
- Primary Product
- Therapeutic Area
- Indication to be Studied
- Type of Support Requested
- Pediatric Study

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

The application saves automatically when you navigate to a new page.
IDEA Submission by Requester
Personnel Node

If you have previously completed your user profile, you can copy the information by clicking “Copy My Profile” (see below under TIP how to complete your profile)

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

To complete your profile go to the profile button, select Profile and complete all the necessary field to have a complete profile.
1 IDEA Submission by Requester
Proposal Node

- Overview/Hypothesis
- Background/Rationale
IDEA Submission by Requester

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

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 ▲.
2 | PROPOSAL Submission
If the IDEA is of interest to Roche, you will be invited to submit a full PROPOSAL which needs to contain your CV, a detailed budget (if funding is requested) and/or detailed information on the drug product(s) (if drug product is requested).

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.
2 PROPOSAL submission

Log in

If Roche is interested in the IDEA, you will most likely have been informed verbally by the Roche representative and you will receive an e-mail notification with a deep link to the IDEA submission. There are 2 ways to access the submission:

1. Via deep link from the e-mail (easiest way):
   - Click on the deep link provided in the e-mail
   - Log into the system with your user name and password
   - This will open the submission immediately

2. **PROPOSAL submission**

   Log in

   2. **Via URL**
      - Go to [https://go.roche.com/IIS](https://go.roche.com/IIS)
      - Upon log in, you will be directed to your Dashboard
      - There are two ways how you can open the submission:
        1. Using the message ‘1 Proposal Requiring Information’ from your Task List or
        2. Via Tracking Number listed under My Projects
PROPOSAL submission
Overview of required fields

Complete all the remaining mandatory fields marked with an *

- **General Information node:**
  - Disease Area
  - Multi Site Study (yes/no)
  - Number of Sites
  - Number of countries
    - If >2 countries, choose the countries participating in the study

- **Personnel node:**
  - Primary Investigator Phone Number
  - Sponsor/Institution Address
  - Sponsor/Institution City & Postal Code
  - Attach CV

- **Proposal node:**
  - First Patient In / Activity Start Date
  - Length of Recruitment (in months)
  - Length of Study (in months)
  - Trial Design/Model (choose all that apply)
  - Study Phase
  - Sample Size
  - Attach Budget (if funding is requested)

- **Scientific Summary node**
  - Primary & Secondary Objectives
  - Primary & Secondary Endpoints
  - Inclusion & Exclusion Criteria
  - Population
  - Sample Size/Statistical Power
  - Treatment Plan

- **Oncology Analysis node** (if Oncology study only)
  - Malignancy Type
  - Malignancy Stage
  - Correlative Study

- **Requested Product node** (if Product is requested)
  - Primary Product confirmation
  - Any additional Product requests

There are additional fields that do not have an *. These are optional and at the discretion of the Requester if completed or not.

The system also allows to add photos or insert a word document in the Scientific Summary node.
PROPOSAL submission
General Information Node

- Disease Area
- Multi Site Study (yes/no)
- Number of Sites
- Number of countries
- If >2 countries, choose the countries participating in the study
2 PROPOSAL submission
Personnel Node

If a profile has previously been completed, then use the Copy My Profile functionality to complete the missing fields (see below under how to complete your profile):
- Primary Investigator Phone Number
- Sponsor/Institution Address
- Sponsor/Institution City & Postal Code
- Attach CV

If you wish to inform us on other study personnel that will be part of the study team, please do so by choosing + Add Personnel. This is optional.

To complete your profile go to the profile button, select Profile and complete all the necessary field to have a complete profile.
PROPOSAL submission
Proposal Node

- First Patient In / Activity Start Date
- Length of Recruitment (in months)
- Length of Study (in months)
- Trial Design/Model (choose all that apply)
- Study Phase
- Sample Size
- Attach Budget (if funding is requested)
PROPOSAL submission
Scientific Summary Node

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

- Primary & Secondary Objectives
- Primary & Secondary Endpoints
- Inclusion & Exclusion Criteria
- Population
- Sample Size/Statistical Power
- Treatment Plan
2 PROPOSAL submission
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 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
PROPOSAL submission
Attachments Node

This node will show all the attachments (at a minimum the CV) that have uploaded either during the IDEA submission or now during the PROPOSAL submission.

To upload additional documents:
1. Choose Actions
2. Select New Supporting Documents
3. Upload document
4. Choose the correct Attachment Type
5. Select Post
This node will only be needed, if the IDEA was submitted by Roche on your behalf. Select that you agree with terms and conditions.

To check if no information is missing, check the nodes bar. Any node that has information missing will be missing the check mark in the circle. Go to the node, complete the information and save (under Actions).
PROPOSAL submission

Once all fields are completed and all required documents uploaded submit Proposal
1. Choose Actions
2. Select Submit Proposal

Submission confirmation is projected on the screen, click ok. In addition, and an e-mail notification is sent to you

Log out of the system:
1. Click on the user logo
2. Choose Logout
The system will now check if all fields are completed. If anything is missing an error message will pop up on the screen indicating all the missing fields:

Go back to the different nodes and complete the missing information and re-submit.
3 | PROTOCOL Submission
If the PROPOSAL has been approved by Roche, you will be invited to provide us with a PROTOCOL. Depending on the requirements in your country, Roche may request the PROTOCOL to be submitted through the IIS Portal. Upon receipt of the PROTOCOL, Roche will proceed with a cross functional review consisting of members from Clinical Operations, Medical, Biostatistics, Safety Science, Drug Supply and Regulatory functions. Once the PROTOCOL is approved, Roche can initiate the signature of the Agreement (contract).
If Roche has approved the PROPOSAL, you will have receive an e-mail notification requesting the Protocol with a deep link to the submission.

Log in via deep link from the e-mail:

- Click on the deep link provided in the e-mail
- Log into the system with your user name and password
- This will open the submission immediately

Thank you for submitting the above mentioned Proposal. We are happy to inform you that your Proposal has been approved and we invite you to submit your draft protocol to us via this link https://staging.environpharma.com/env_roche/visitracker/portal/login.xhtml?login=ISR.
If you used the link in the e-mail, the submission will automatically open in the new node called Protocol. Otherwise, open the submission via your **Task List: Protocol Requested**

1. **Attach** the Protocol
2. Go to **Actions** and select **Submit Protocol**