Welcome to the Genentech Investigator Initiated Studies (IIS) Portal

Are you ready to propose a concept idea? To get started, please discuss your concept with your Medical Science Liaison (MSL). For general inquiries or if you do not yet have an MSL, please email us at: usa.iisportal@roche.com

1. IIS Portal login

If Genentech is interested in your concept idea, you will receive an email inviting you to complete your proposal application. If this is your first time using the IIS Portal, you will also receive an email with an activation link to complete your user profile.

2. Completing the application for proposal

1. Upon login, you will be directed to your Dashboard
2. Open the application by selecting the Tracking Number found in the email sent to you from your MSL
3. Complete the required fields, which are marked with an asterisk (*)

Refer to the Investigator Checklist for guidance
Review prepopulated data and complete required fields

General Information node:
- Amount Requested (for funding requests only)
- Multi-Site Study
- Number of Sites
- Number of Countries

Personnel node:
- Institution/Sponsor Address
- Primary Phone Number
- PI CV (upload using link on screen)

Please click the blue for more instruction on the information needed in each field.
Review prepopulated data and complete required fields (continued)

Proposal node:
- First Patient in/Start Date
- Length of Recruitment (in months)
- Length of Study
- Trial Design/Model
- Study Phase
- Sample Size
- The budget can be added, but is not required at this time

Scientific Summary node:
- Primary Objectives
- Secondary Objectives
- Primary Endpoints
- Secondary Endpoints
- Inclusion Criteria
- Exclusion Criteria
- Population
- Statistical Considerations
- Treatment Plan
- References

Optional: Submit one document on the Attachments node that contains all the information requested here. Be sure to write “see attached” in each of the fields.
Review prepopulated data and complete required fields (continued)

Oncology Analysis node:
This will only appear if oncology is selected as the therapeutic area; fields marked with an * are required
- Malignancy Type
- Malignancy Stage
- Does this study involve a correlative study?

Requested Product node:
The Product/Compound selected on the General Information node will appear in the table; click the edit icon to enter the details
1. Select whether or not a placebo is required
2. Click the check mark to add this to the table
3. To add additional products, click Add Row
Review prepopulated data and complete required fields (continued)

Planned Publications node:
Applicable if known at time of submission

1. Click **Add Journal/Congress** to open the Search Target window
2. Enter the name or first few letters of the journal or congress you wish to add and click Search (add TBD if you are unsure of the target)
3. Select from the list and click **Add**
4. If your target does not appear, there is a link to enter manually

5. The publication will now appear in the Journal/Congress table
6. Select the **Publication Type** from the drop-down menu
7. Add the anticipated publication date
8. Click the check mark to save
9. Repeat to add additional publications
Investigator Guide

3 Review prepopulated data and complete required fields (continued)

Attachments node:
1. Use attachments for project documentation including the scientific summary (if applicable), and any additional supporting documentation
2. Upload a new document by selecting **New Supporting Material** from the **Actions** menu
3. Select the attachment type from the drop-down menu, choose the file from your computer, and click **Post**
4. Repeat to add additional documents
5. Upload a new version of a document by clicking the gear icon. The system will save all document versions for the audit trail

Acknowledgment node:
- Please read these terms and conditions carefully. You must agree to all the terms and conditions before submission
- Once you have read the terms and conditions, select **I Agree** from the drop-down to confirm acknowledgment
Submit Proposal

Once all the required information has been entered, select **Submit Proposal** from the Actions menu.

- If you attempt to submit with required data missing, a new window will open that lists the fields requiring information and an exclamation point will appear in the table of contents next to the node or nodes that require additional data.

Proposal Under Review

- Upon submission, the application will be locked from further editing and you will receive a notification confirming the submission.
- The application status will change to **Proposal Evaluation**.
- Your proposal will be reviewed by the Study Review Team (SRT).
- Once approved, your MSL will contact you with any feedback and invite you to submit your protocol.
Submit Protocol

1. To open the submission
   - Select **Protocol Requested** to open your Workbench; find the correct application and double-click to open
   - Double-click the tracking number under **My Projects**
2. Click **Attach File** for both Protocol and Budget
3. Click the Actions menu and select **Submit Protocol**

Protocol Under Review

- After you submit your protocol and budget, it will be reviewed by the SRT
- Your MSL will contact you with any feedback through the protocol review process
- Your MSL will notify you once it is approved
- Any revisions to your protocol can be sent directly to your MSL outside of the IIS Portal

Refer to the **Investigator Checklist** for guidance