

IIS Portal User Guide - Investigator

December 18, 2023

IIS Portal - Requirements

We support the following types of Investigator Initiated Studies:

- Clinical studies of approved and investigational uses of Genentech medicines, including medicines approved by the FDA or still in development (i.e. interventional studies phase I to IV).
- Clinical observational studies, real world evidence (i.e. non-interventional studies)
- Clinical studies requesting Roche/Genentech medicines only

IIS Portal - Requirements

- Potential sponsor-investigators should discuss their concepts with their MSL prior to submission into the portal
- Areas of Strategic Interest and IIS Portal link are on the IIS Page:

<https://www.gene.com/medical-professionals/investigator-initiated-studies>

How a Potential Sponsor-Investigator Submits a Proposal into the IIS Portal

IIS Portal - Study Area



Login

OPTIONAL: Click on the LOGIN button if you have an account

New Study

1

Study Area

2

Principal Investigator Details

3

Study Details

4

Study Products & Support

5

Request Summary

Choose your Area of Study *

Roche Diagnostics

Studies using Roche Diagnostics products

Roche Pharma

Genentech

Studies using Genentech Pharma products

Ensure that Genentech is selected

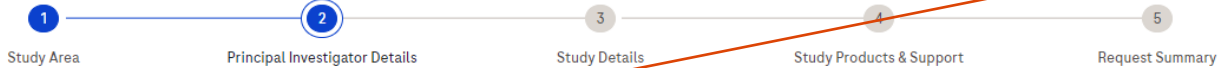
Click on the Start Submission button

Start Submission

IIS Portal - Principal Investigator Details

New Study

Area of Study: Genentech



The request may be submitted by the potential sponsor-investigator or may be delegated

Are you submitting this study on behalf of an investigator

Yes No

Principal Investigator Details

Academic Title/Salutation *

Academic Title

First Name *

First Name

Last Name *

Last Name

Country *

United States

Complete all required fields on the page before clicking on Next Step

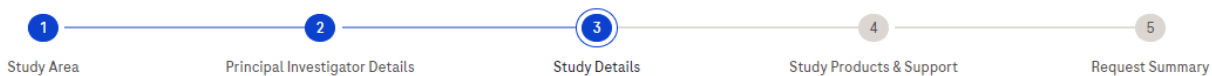
Cancel Submission

Next Step

IIS Portal - Study Details (1/2)

New Study

Area of Study: Genentech



Study Details

Title *

Therapeutic Area *

Length of study recruitment (in months) *

Length of study (in months incl. recruitment and any follow up periods) *

Length of study recruitment (in months) must be less than Length of Study

Length of study (in months including recruitment) - enter the number of months it will take to complete the study

Cancel Submission

Previous Step

Next Step

IIS Portal - Study Details (2/2)

of Patients / Sample size *

Enter sample size

How many sites will be involved? *

Single Country / Single Site Single Country / Multi Site Multi Country / Multi Site

Will the study be using an Investigational Medicinal Device? *

Yes No Maybe

Name of the person at Roche/Genentech with whom you have already discussed your proposal idea (e.g. MSL)


Enter the name of the person

Description *

Please describe the scientific questions and rationales that will be answered with the study. Please include as much of the following information as possible: Brief Study Synopsis, Overview/Hypothesis, Background/Rationale, Study Objectives, Study Endpoints, Inclusion/Exclusion Criteria, Target Population, Statistical Considerations, and Treatment Plan, and any translational/corrolative studies. Please apply (if possible) the PICO Framework: Population, Intervention, Control, Outcome(s).

Alternatively, upload your synopsis containing the above information below

Enter the Description

 Add files. File size must not exceed 5MB.

CONTINUED FROM PREVIOUS

If selecting Multi Site, a free text field will open to enter the number sites

Description - you may type in the description OR upload a separate document that includes the necessary items listed per the instructions

Complete all required fields before clicking on Next Step

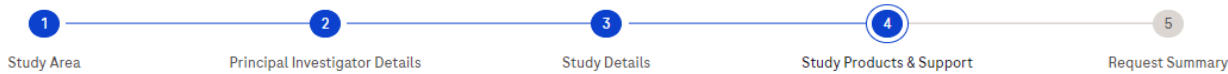
You can go to the previous page or cancel your submission at any time

Cancel Submission

Previous Step

Next Step

IIS Portal - Study Products and Support (1/3)



Select all the Roche/GNE medicinal products included in the study.

Study Products & Support

Roche/Genentech Medicinal Products

Will your study involve Roche/Genentech Medicinal Products? *

Yes No

Select all Roche/Genentech Medicinal Products *

<input type="text" value="atezolizumab"/> <input type="button" value="x"/>	<input type="checkbox"/>	Please check the box if you request Roche/Genentech to supply the product	<input type="button" value="x Remove"/>
<input type="text" value="tiragolumab"/> <input type="button" value="x"/>	<input checked="" type="checkbox"/>	Please check the box if you request Roche/Genentech to supply the product	<input type="button" value="x Remove"/>

[+ Add more](#)

Did you find all the Roche/Genentech Medicinal Products you were looking for? *

Yes No

Select all Roche/Genentech Medicinal Products *

<input type="text" value="Type product"/>	<input type="checkbox"/>	Please check the box if you request Roche/Genentech to supply the product	<input type="button" value="x Remove"/>
---	--------------------------	---	---

Box should be checked if requesting Genentech to provide product for the study.

If product is not listed in the field above, click NO here and add the product manually.

Box should be checked if requesting Genentech to provide product for the study.

You can go to the previous page or cancel your submission at any time

[Cancel Submission](#)

[Previous Step](#)

[Go to Summary](#)

IIS Portal - Study Products and Support (2/3)

Non Roche/Genentech Medicinal Products

Will non-Roche/Genentech Medicinal Products be involved in the study? *

Yes No

List all non-Roche/Genentech Medicinal Products involved in the study *

Enter any non-Roche/GNE product in here

Support

Are you requesting financial support? *

Yes No

Please enter total budget amount that you are requesting from Roche/Genentech *

Financial - check YES if budget is being requested from Genentech. Include the total budget amount and currency (USD)

For the Total Budget Amount, there are no commas, so a million is 1000000. Type USD for currency

Do you request other type of support from Roche/Genentech? *

Yes No

You can go to the previous page or cancel your submission at any time

Cancel Submission

Previous Step

Go to Summary

IIS Portal - Study Products and Support (3/3)

Do you request other type of support from Roche/Genentech? *

Yes No

Please specify: *

E.g.: correlatives, labs, assays, diagnostics, etc...

Enter the type(s) of support

Do you receive support from other sources (e.g., government entities, other pharma collaborators, etc.)?

Yes No

Is this a pediatric study (including studies with pediatric & adult patients)? *

Yes No

Will you be including a Roche/Genentech Diagnostics Assay or Solution? *

Yes No

Check YES if other support is being requested from Genentech and enter details in text field.

Check YES if receiving support from other sources and enter names of other sources

Pediatric studies may include both adult and pediatric patients (under 18 years old)

Complete all required fields before Go to Summary

You can go to previous page or cancel your submission at any time

Cancel Submission

Previous Step

Go to Summary

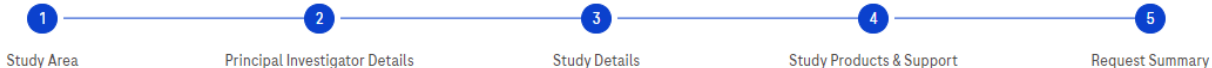
IIS Portal - Request Summary (1/2)

A Study of Gamma Radiation Exposure of ~85Gy +/- Super Soldier Serum

Area of Study: Genentech

Export as a PDF

The study can be Exported as a PDF before it is submitted.



Investigator Details

First Name
Bruce

Last Name
Banner

Country
United States

Academic Title/Salutation
Dr

Name of Institution
Avengers University

Business Phone Number
+1 1154136286

The study can still be edited at this time by clicking on Edit Submission

Edit Submission

Submit Study

IIS Portal - Study Products and Support (2/2)

Do you receive support from other sources (e.g., government entities, other pharma collaborators, etc.)?

Yes,
Stark Enterprises

Is this a pediatric study (including studies with pediatric & adult patients)?

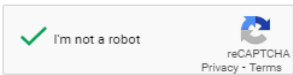
No

Will you be including a Roche/Genentech Diagnostics Assay or Solution?

No

Agree to [Privacy Statement](#)*

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 Form. I, the study investigator or his/ her duly authorized delegate, attest that Roche/ Genentech has not unduly influenced submission of this IIS Idea.*



Must check boxes:

- “Agree to Privacy ...”
- “By accepting this ...”
- “I’m not a robot”



Click on Submit Study to complete the submission

Edit Submission

Submit Study

IIS Portal – Reminders & Contact Information

- Potential sponsor-investigators should discuss their concepts with their MSL prior to submission into the portal
- Once the submission has been completed, the Submitter will receive a notification via email
- A PDF file of the submission will be attached to their email notification
- The Submitter may email the PDF to their MSL or Genentech contact
- *For any questions, email us directly at: USA.IISPortal@gene.com*

IMPORTANT PRIVACY NOTICE:

- If you are a resident of a U.S. state that provides certain data protection rights with respect to Roche/Genentech's processing of your personal information, a description of the personal information collected and processed by Roche/Genentech and each of your rights under such laws concerning your personal information can be found at: <https://www.roche.com/us-privacy-policy> (Roche US) and <https://www.gene.com/privacy-policy> (Genentech, Inc.).

The background of the image is a vibrant, multi-colored microscopic view of plant tissue, likely showing various cell structures and vascular bundles. The colors range from bright cyan and green to deep purple and magenta. A large, solid dark blue rectangular area is superimposed over the center of the image, serving as a background for the text.

Genentech

A Member of the Roche Group