

## Instructions for Commercial Product Access for Clinical and Pre-Clinical Research

Failure to provide complete and accurate information may result in delay or rejection of requests. Genentech may need additional information to fulfill requests to ensure requests comply with applicable laws and regulations.

### Purchasing product:

1. This form and these instructions are subject to change. Please obtain the latest version at: <https://www.gene.com/contact-us/customer-service/ordering>. If you have questions, contact Genentech Customer Service at [csclinicaltrials-d@gene.com](mailto:csclinicaltrials-d@gene.com).
2. Complete the Commercial Product Access for Clinical and Pre-Clinical Research Request Form and email it to Genentech via [csclinicaltrials-d@gene.com](mailto:csclinicaltrials-d@gene.com). Please allow up to 10 business days for Genentech to review the request.
3. Product orders must be placed within 6 months of the approval of your request. Order quantity must be within the approved limit(s). If additional product is required, another Request Form must be submitted.
4. Commercial product must be purchased from an approved distributor and will be shipped by Genentech. Approved distributors can be found on <https://www.gene.com/contact-us/customer-service/ordering>.

### Important Guidelines:

- **Licensure to Handle Genentech Product:** Researchers or Contract Research Organizations (CROs) requesting to purchase commercial product for research purposes must provide valid and appropriate state license information.
- **Institutional Approval:** Researches who do not have a [clinicaltrials.gov](https://clinicaltrials.gov) reference number must provide a study design and Institutional Review Board protocol number.
- **Ability to Audit:** Genentech may audit facilities receiving Genentech commercial product.
- **No Ex-U.S. Shipment:** Research studies must be conducted within the United States of America.
- **Product Availability:** Product availability is not guaranteed at time of order. Please be aware that shipment of product may be delayed.
- **Product Returns:** Expired product may be returned in accordance with Genentech's Product Return Policy. Please contact Genentech Customer Service at (800) 551-2231 for the current policy.
- **Distributor Change:** Contact Genentech at [csclinicaltrials-d@gene.com](mailto:csclinicaltrials-d@gene.com) if you plan to switch between approved distributors.

## Commercial Product Access for Clinical and Pre-Clinical Research Request Form

Failure to provide complete and accurate information may result in delay or rejection of requests. Genentech may need additional information to fulfill requests to ensure requests comply with applicable laws and regulations.

### Ship-To Facility Information (CRO or Purchasing Entity)

First Name: Last Name:  
Facility Name: State License #:  
Street Address: City:  
State: Zip Code:  
Phone: Email:

### Authorized Distributor (See: <https://www.gene.com/contact-us/customer-service/ordering>)

Distributor:

### Sponsor Contact Information

First Name: Last Name:  
Company Name: Company URL:  
Street Address: City:  
State: Zip Code:  
Phone: Email:

### Product Requested

Name / Strength:			NDC:	QTY:
Name / Strength:			NDC:	QTY:
Name / Strength:			NDC:	QTY:
Do you anticipate multiple shipments for this request?	Yes	No	If yes, how many?	
Will any of this product be shipped outside the U.S.?	Yes	No		
Is this request for research previously approved by Genentech?	Yes	No	If yes, request number:	

### Study Information

Study Title:  
Intended Start Date: Intended End Date: ClinicalTrials.gov Number:  
Site Location(s):  
Study Objective:

### Additional Study Information (Complete this section if this research is not registered on ClinicalTrials.gov)

Study Type (Check all that apply)  
Analytical:      Structural      Functional/PK/PD      Institutional Review Board:  
Clinical:      Phase I      Phase II      Phase III      Phase IV      Protocol Number:  
Target Enrollment (Number of Participants):

### Is the request in connection with a study to develop a biosimilar and seek approval via the U.S. FDA?

Yes      No      By checking YES, you certify that the Study Administrator is an eligible product developer, as defined under the CREATES Act, and that you have requested sufficient quantities of the applicable product to conduct testing to support a biosimilar application to FDA.

If yes, Name of Manufacturer that is developing biosimilar:

### Attestation by Sponsor or CRO

I certify that the information submitted in this request is truthful and accurate and that I hold the applicable licenses, registrations, and permits to handle the requested product and/or conduct research in accordance with applicable laws, regulations, and standards.

Attested by:      Sponsor      CRO  
Name:      Date:  
Title:      Email:

Submission of this request to Genentech does not establish any legal or contractual arrangement by or between the requestor and Genentech or otherwise establish any legal or other right of the requestor to receive product from Genentech. Genentech reserves the right to rescind, revoke, or amend this program at any time without notice.