

# A long-term follow-up study of patients with coronavirus (COVID-19) associated pneumonia

<b>Submission date</b> 23/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/03/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

There is limited evidence on the long-term effects of COVID-19 infection. This is due to the recent onset of the pandemic and, therefore, there has not been an opportunity to study patients who have recovered from the infection.

Previous studies suggest that hospitalized patients had residual disease and that this phenomenon may not apply only to critically ill patients. In addition, there have been reports of cardiovascular injury, which may increase the risk of myocardial infarction. Some neurological consequences, such as numbness, paresthesias, and confusion have been reported. The UK National Health Service, in March 2020, predicted that 45% of COVID-19 patients who had been hospitalized will need ongoing medical care, 4% will require inpatient rehabilitation, and 1% may permanently require acute care.

This study will follow patients with COVID-19 associated pneumonia, who have participated in or are participating in Genentech/Roche sponsored studies, for approximately 12 months after hospital discharge or end of the parent study. The study aims to understand the long-term consequences of resolved COVID-19 associated pneumonia.

### Who can participate?

Patients with COVID-19 associated pneumonia, who have participated in or are participating in one of the following Genentech/Roche sponsored studies: COVACTA, REMDACTA, MARIPOSA, COVASTIL, or BACC Bay.

### What does the study involve?

Patients will provide consent to participate prior to the first assessment of this study (the Baseline visit). This Baseline visit will occur as soon as possible after the patient completes day 60 or discontinues from the parent study. Study visits will occur approximately every 3 months for approximately 12 months, therefore visits will take place at the Baseline visit and 3, 6, 9, and 12 months after. During this study, physical exams, nasopharyngeal swab, CT scans, echocardiograms, lung function testing, blood samples, questionnaires, and walking tests will be used to assess the patients.

Throughout the study, patients will conduct weekly home lung function monitoring using a handheld spirometry device. Data stored in the spirometry device will be uploaded via a smart device (such as a smartphone). Both devices will be provided by the Sponsor.

In addition, patients will be invited to use an optional wearable device (such as a smart watch), provided by the Sponsor, on a continuous basis to capture daily activity and sleep patterns for the duration of the study. Data stored in the wearable device will be uploaded via a smart device. At the end of this study, patients will be required to return the devices.

What are the possible benefits and risks of participating?

There are no additional study drugs or other treatments beyond standard care that will be provided as a result of taking part in this study, therefore no additional risks or benefits are anticipated.

Where is the study run from?

Genentech, Inc (USA)

When is the study starting and how long is it expected to run for?

From August 2020 to March 2022

Who is funding the study?

F. Hoffmann-La Roche Ltd (USA)

Who is the main contact?

global-roche-genentech-trials@gene.com

## Contact information

### Type(s)

Public

### Contact name

Mr Clinical Trials

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

ML42746

## Study information

**Scientific Title**

Long-term follow-up study of patients with COVID-19 associated pneumonia who participated in a designated Genentech/Roche sponsored study or Genentech/Roche supported investigator-initiated placebo-controlled or active-controlled study

**Acronym**

LOPAC

**Study objectives**

To assess long-term outcomes in adult patients who were hospitalized with COVID-19 associated pneumonia.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 23/09/2020, Advarra IRB (6940 Columbia Gateway Dr #110, Columbia, MD 21046, USA; +1 410-884-2900; no email available), ref: Pro00046520

**Study design**

Phase IV multicenter observational follow-up study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

COVID-19 pneumonia, COVID-19 (SARS-CoV-2 infection)

**Interventions**

To assess long-term outcomes in adult patients who were hospitalized with COVID-19 associated pneumonia. Participants will be recruited from Genentech/Roche sponsored studies or any supported Genentech/Roche independent investigator studies for COVID-19 associated pneumonia. Participants will be followed up for pulmonary, cardiac, cognitive, and quality of life outcomes every three months over 12 months. In addition, any encounters with health care professionals/visits at health care facilities outside of the visits scheduled within the study will be recorded.

**Intervention Type**

Other

**Primary outcome(s)**

1. Lung texture analysis of high-resolution computed tomography (HRCT) scan of the chest at baseline, 3, 6, 9, and 12 months
2. Lung function measured using pulmonary function tests at baseline, 3, 6, 9, and 12 months
3. Cardiac function measured using echocardiography at baseline, 3, 6, 9, and 12 months
4. Healthcare resource utilization measured using hospitalization, emergency room visits, urgent care/unscheduled visits, physical therapy, and rehabilitation, in addition to other relevant information collected between baseline, 3, 6, 9, and 12 months
5. Patient-reported health-related quality of life, cognitive function, and respiratory symptoms, measured by the Short Form 36 Question Health Survey Version 2 (SF-36v2), Euro-QoL-5D-5-L (EQ-5D-5L), Living with Idiopathic Pulmonary Fibrosis Symptoms Questionnaire-Modified (L-IPF-M), and Montreal Cognitive Assessment (MoCA) at baseline, 3, 6, 9, and 12 months

### **Key secondary outcome(s)**

1. Peripheral blood biomarkers measured using circulating markers of inflammation, fibrosis, coagulation, or other emerging exploratory markers of disease biology, as appropriate at baseline, 3, 6, 9, and 12 months
2. SARS-CoV-2 infection measured using symptom guided nasopharyngeal swab for COVID-19 real-time polymerase chain reaction (RT-PCR) between baseline, 3, 6, 9, and 12 months
3. Progression or long-term sequelae of COVID-19 disease measured using patient records at baseline, 3, 6, 9, and 12 months
4. Physical fitness measured using the Six-minute walk test (6MWT) and Borg Scale of Perceived Exertion (optional) at baseline, 3, 6, 9, and 12 months
5. Continuous activity and sleep tracking (optional) captured by a wearable device (such as a smart watch) between baseline and 12 months
6. Prevalence and incidence of COVID-19 antibodies measured from blood samples at baseline, 3, 6, 9, and 12 months

### **Completion date**

30/03/2022

## **Eligibility**

### **Key inclusion criteria**

1. Informed consent by any patient capable of giving consent, or, when the patient is not capable of giving consent, by their legal/authorized representative
2. Aged  $\geq 18$  years at the time of providing informed consent
3. Able to comply with the study procedures, in the investigator's judgment
4. Participated in any Genentech/Roche sponsored study or any supported Genentech/Roche independent investigator study for COVID-19 associated pneumonia (Note: Includes patients who completed or discontinued early from these studies)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Sex**

All

**Key exclusion criteria**

1. Participation in an interventional study at the time of enrollment or plans to enroll in an interventional study during this study
2. Any serious medical condition or abnormality of clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study

**Date of first enrolment**

29/10/2020

**Date of final enrolment**

31/03/2021

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

Genentech, Inc

1 DNA Way

South San Francisco

United States of America

90404

**Sponsor information****Organisation**

Genentech, Inc

**Funder(s)****Funder type**

Industry

**Funder Name**

Genentech, Inc

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes