

## Summary of Clinical Trial Results

### A study to look at the long-term outcomes of people with COVID-19 pneumonia

See the end of the summary for the full title of the study.

#### About this summary

This is a summary of the results of a clinical trial (called a 'study' in this document) – written for:

- Members of the public.
- People who took part in the study.

The study started in October 2020 and ended in June 2022. This summary was written after the study had ended.

No single study can tell us everything about a person's recovery after illness. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other long-term follow-up studies of people who had COVID-19 pneumonia.

- **This means that you should not make decisions based on this one summary – always speak to your doctor if you have any questions.**

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#### Glossary

- COVID-19 = coronavirus disease 2019

#### Thank you to the people who took part in this study

The people who took part in this study have helped researchers answer important questions about their health over time after being hospitalized because of COVID-19 pneumonia.

## Key information about this study

### Why was the study done and who took part?

- This study was done to understand the long-term effect on people's health, quality of life, and ability to think after they were hospitalized with COVID-19 pneumonia (an inflammation in the lungs).
- People began this study after leaving the hospital and finishing a previous study of COVID-19 pneumonia during their hospitalization.
- During this study, researchers looked at people's health, quality of life, and ability to think every 3 months for a total of 1 year.
- This study included 173 people in 3 countries.

### What were the results?

- Most people's health and wellness did not get worse during the year after being in the hospital for COVID-19 pneumonia.
- The lung texture (how the lung looks) and lung function (how the lung works) of most people who took part in this study got better over time. Some of the people who had problems in their lung texture or lung function at the start of the study were not back to normal after a year.
- Most people's quality of life did not get worse and often improved during the study. Some of the people still had tiredness, coughing, and shortness of breath.
- A small group of people in the study who had trouble remembering, learning new things, concentrating, or making decisions about their everyday life at the start of the study still had problems at the end of the study.

## 1. General information about this study

### Why was this study done?

About 20 out of every 100 people who get COVID-19 (also called 'coronavirus disease 2019') will develop inflammation in the lungs called pneumonia, which makes it hard to breathe. About 5 out of these 20 people will develop a more severe COVID-19 illness that causes other organs in the body, like the kidneys, to not work normally. COVID-19 may affect people differently. Some people have health problems for a short time or no problems at all after COVID-19. Other people have continued problems with their lungs and health for a long time.

In 5 studies called 'COVACTA', 'REMDACTA', 'MARIPOSA', 'COVASTIL', and 'EMPACTA', researchers treated adults who had been hospitalized with COVID-19 pneumonia. These studies looked to see how different medicines worked and how safe they were in people with COVID-19 pneumonia.

In this study, called '**LOPAC**', some of the adults who took part in 1 of the 5 previous COVID-19 studies agreed to be checked for an additional year to see how their health and wellness changed over time.

## What were the study medicines?

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There were no study medicines in this study. Researchers did not look at the effect of medicine for COVID-19 pneumonia in this study.

## What did researchers want to find out?

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Researchers wanted to look at people's health and wellness after they were hospitalized for COVID-19 pneumonia. They wanted to see how people's lung texture and function, quality of life, and ability to think changed over time.

### The questions that researchers wanted to answer were:

1. Did people's lung texture (how the lung looks) or lung function (how the lung works) change after being hospitalized with COVID-19 pneumonia?
2. Did people see any differences in their quality of life?
3. How did people's ability to think change after COVID-19 pneumonia?

## What kind of study was this?

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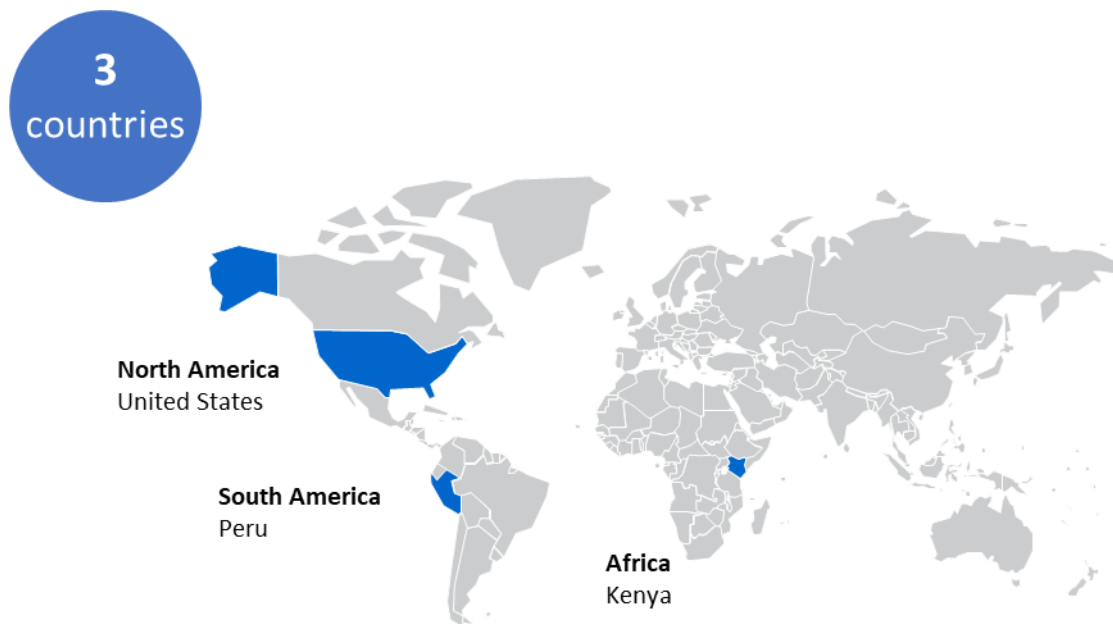
This study was a '**non-treatment, observational study**'. This means that the study doctors looked at people's health and wellness over a year. **This study did not look at the effects of any medicines.**

This study was a '**long-term follow-up study**'. This means that this study looked at people for 1 year after they were hospitalized with COVID-19 pneumonia and had finished a previous study of COVID-19 pneumonia during hospitalization.

## When and where did the study take place?

The study started in October 2020 and ended in June 2022. This summary was written after the study had ended.

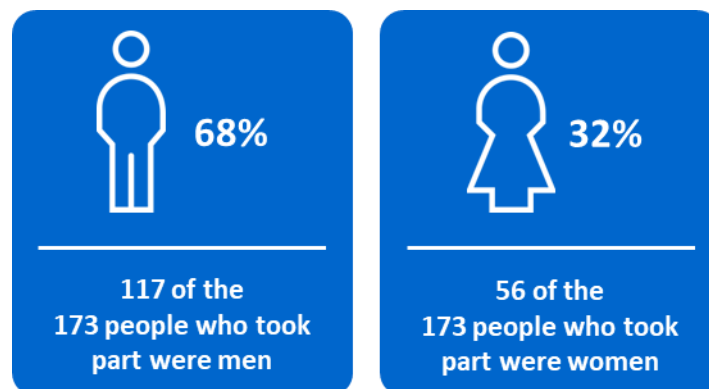
The study took place at 29 study centers in 3 countries (Kenya, Peru, and the United States). This map shows the countries where this study took place.



## 2. Who took part in this study?

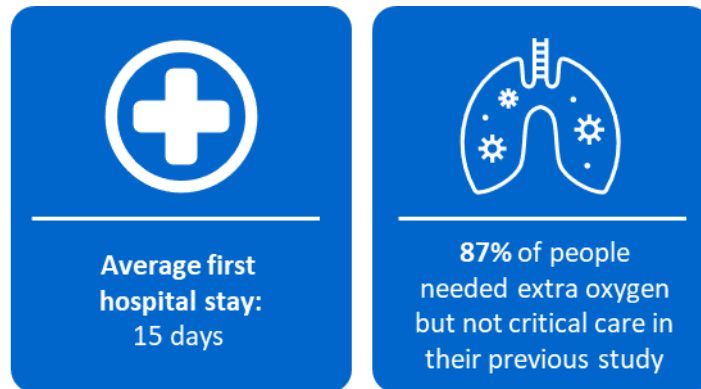
A total of 173 people took part in this study after they were hospitalized with COVID-19 pneumonia.

People who took part in the study were between 26 and 82 years of age; 117 of the 173 people (68%) were men and 56 of the 173 people (32%) were women.



Age range: 26 to 82 years old

All the people in this study were previously hospitalized with COVID-19 pneumonia.



The average time from when people finished the previous COVID-19 study to when they started this study (LOPAC) was 5 months.

People could take part in this study if:

- They were 18 years of age or older.
- They had taken part in 1 of the 5 previous studies that looked at how different medicines worked and how safe they were in people with COVID-19 pneumonia.

People could not take part in the study if:

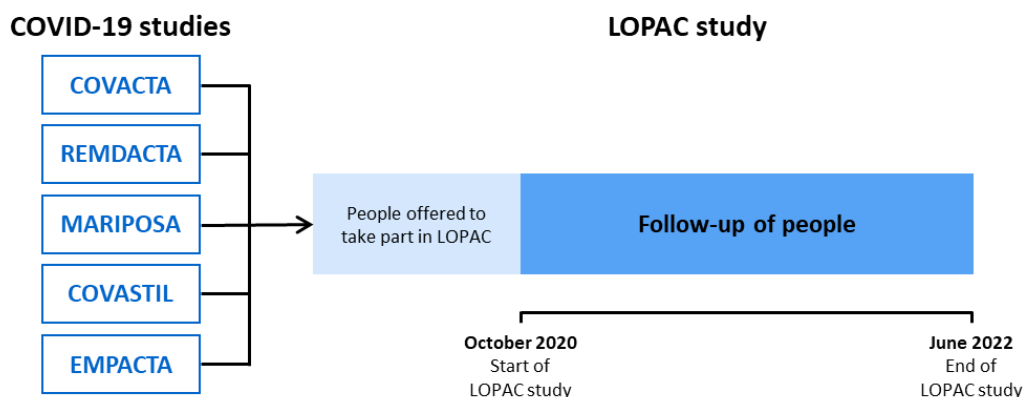
- They decided to take part in another study that looked at the effect of medicines.
- They had any serious medical condition that made it dangerous for them to take part in this study.

### 3. What happened during the study?

Adults who took part in 1 of the 5 COVID-19 studies (COVACTA, REMDACTA, MARIPOSA, COVASTIL, and EMPACTA) could keep getting health and wellness check-ups in this study (LOPAC).

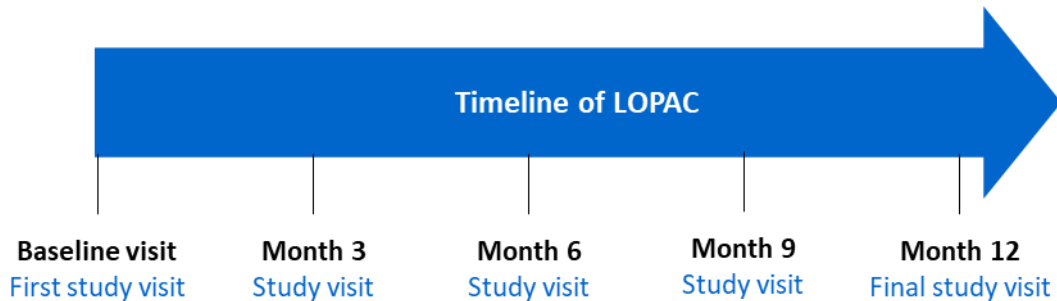
The researchers looked at how well people recovered up to 1 year after they were hospitalized for COVID-19 pneumonia.

This picture shows what happened during the study.



People visited the study researchers every 3 months for a total of 5 appointments over 1 year.

This picture shows the timeline of the study.

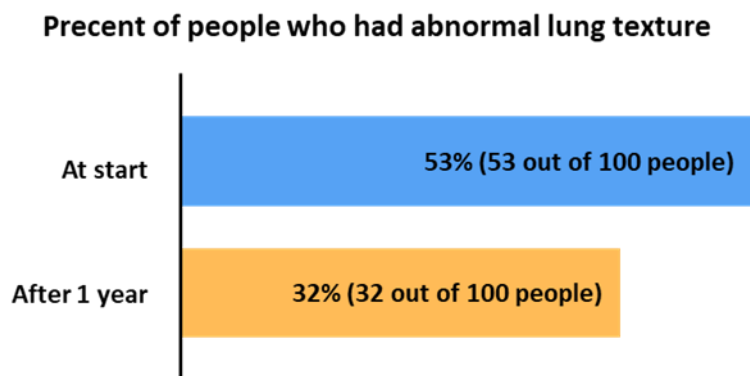


#### 4. What were the results of the study?

**Question 1:** Did people’s lung texture (how the lung looks) or lung function (how the lung works) change after being hospitalized with COVID-19 pneumonia?

Researchers looked at chest scans of people after they were hospitalized with COVID-19 pneumonia. These scans gave a very detailed picture of a person’s **lung structure and texture**.

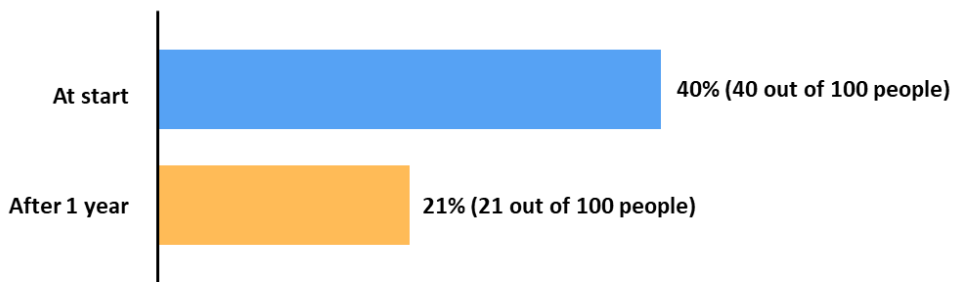
At the start of the study, about half of the people had abnormal lung texture. After 1 year, most people’s lung texture did not get worse. At the end of the study, about one-third of people had abnormal lung texture.



In the study, researchers also did tests to look at how well people’s lungs were working. These breathing tests measure how much air is in the lungs and how well a person breathes in and out. When results of the breathing tests are lower than normal, it means that **lung function** is decreased.

- At the start of the study, about 40% of people had decreased lung function.
- After 1 year, 21% of people had decreased lung function.

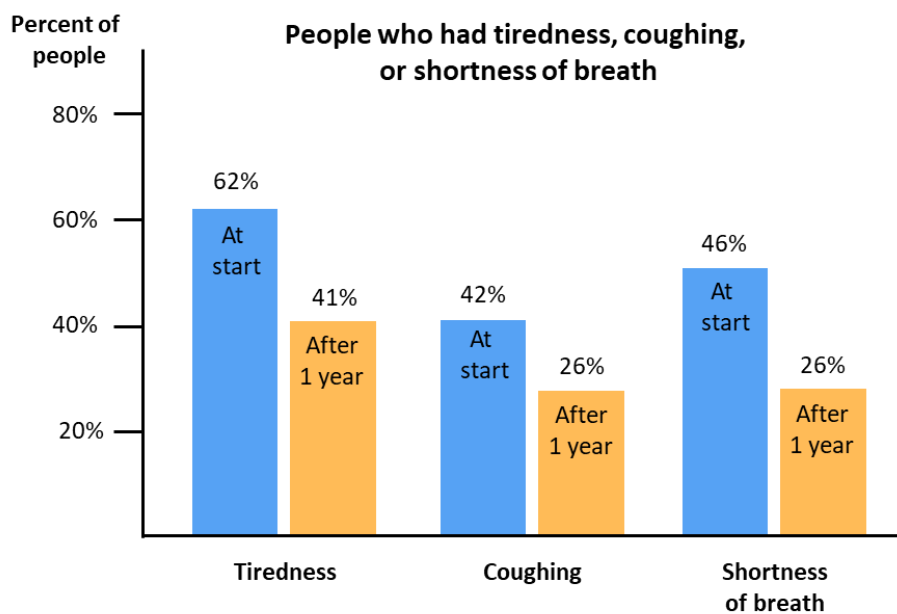
**Percent of people with decreased lung function**



**Question 2: Did people see any differences in their quality of life?**

Researchers also collected information about people’s quality of life. People in the study completed forms that asked questions about how they felt, if they had any issues with their breathing, and how well they could do their usual activities.

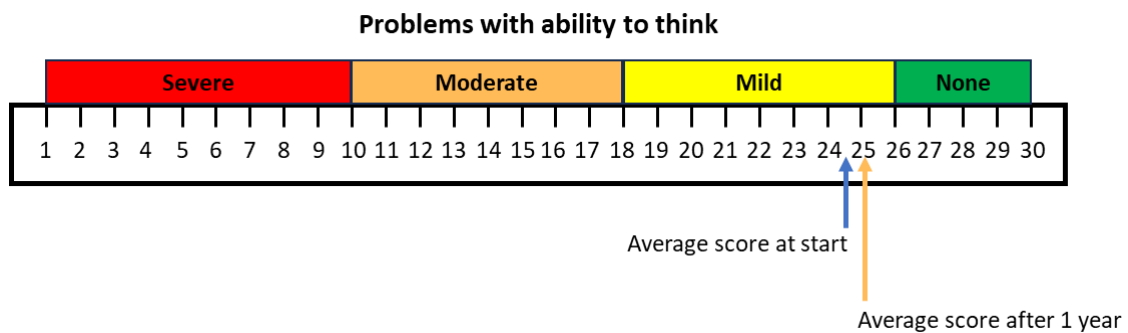
- On average, people’s quality of life did not get worse and often improved during the study.
- Most people’s tiredness, coughing, and shortness of breath got better over time.
  - A small group of people who had tiredness and problems with breathing at the start of the study also had problems after 1 year.



### Question 3: How did people’s ability to think change after COVID-19 pneumonia?

Researchers asked people a series of questions that looked at their memory, language, concentration, and ability to learn new things. The answers were scored on a scale from 1 (worst) to 30 (best). A score of 26 and above is considered as normal.

- People’s ability to think did not get worse during the study.
- A small group of people in the study who had trouble remembering, learning new things, concentrating, or making decisions about their everyday life at the start of the study still had problems at the end of the study.



This section shows only the key results from this study.

## 5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happen during a study and are thought to be related to the study medicine.

Because this study did not look at the effects of any medicines, any side effects recorded were related to the study tests.

### Serious side effects

A side effect is considered ‘serious’ if it is life-threatening, needs hospital care, or causes lasting problems.

There were no serious side effects due to the study tests.

### Most common side effects

There were no side effects due to study tests.

### Other side effects

There are no data on other side effects from this study.



## 6. How has this study helped research?

The information presented here is from a single study of 173 people after they were hospitalized with COVID-19 pneumonia. These results helped researchers learn more about people's long-term health and wellness after being hospitalized with COVID-19 pneumonia and as they recovered from the disease.

Although many people got better over time, some of the people continued to have problems with their lungs, quality of life, or ability to think at the end of this 1-year study.

The data from this study suggest that some people struggle with their health after COVID-19 pneumonia. More information is needed to understand why problems with long-term health and wellness continue for some people.

No single study can tell us everything about a person's recovery after illness. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from results from other follow-up studies looking at long-term outcomes of COVID-19.

- **This means that you should not make decisions based on this one summary – always speak to your doctor if you have any questions.**

## 7. Are there plans for other studies?

At the time of writing this summary, no other studies looking at the long-term recovery after COVID-19 pneumonia are planned.

## 8. Where can I find more information?

Some of the study data were presented at a scientific meeting. If you would like to find out more about the results of the study, the full title of the abstract is: "12-Month Follow-up Study of Patients After Hospitalization for COVID-19." The authors are Ivan O. Rosas, James A. McKinnell, Reena Shah, and others. The abstract was presented at the American Thoracic Society (ATS) International Conference (C66 Viral Infections, Covid, And Beyond); May 19-24, 2023, Washington, DC, United States.

### Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit <https://forpatients.roche.com/en/About.html> and click Contact Us to directly contact Roche for questions

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own medicines:

- Speak to the doctor in charge of your medicines.

### **Who organized and paid for this study?**

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This study was organized and paid for by Genentech, Inc (a member of the Roche Group), who have their headquarters in South San Francisco, California, United States.

### **Full title of the study and other identifying information**

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The full title of this study is: “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”

The study is known as **LOPAC**

- The protocol number for this study is: ML42746, including data from long-term follow-up substudy of ML42528