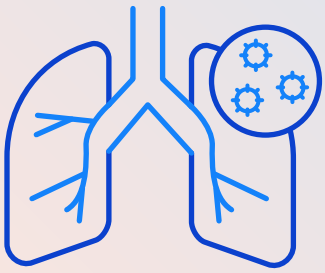
What do COPD clinical studies mean for me?

If you live with chronic obstructive pulmonary disease (COPD) or provide care for a loved one who does and are considering **participating in a clinical study**, you are in the right place. To help you feel prepared, find out more about clinical studies by exploring the sections below.

This is a co-created resource by F. Hoffmann-La Roche Ltd and the Global COPD Focus Group which included the following patient organisations; GAAPP, SLHP, EFA, AAOKenya, APEPOC, HSAACI and Lung Union Austria. The content is non-promotional and does not make specific reference to the availability or the use of a medicine.



Why is research important in COPD?

Currently, there is no cure for COPD. Without research there is no progress, and without progress there is no chance of a better treatment and care solutions, and ultimately a potential cure.

Treating COPD and making lifestyle changes, can help people to breathe better and live an improved quality of life. Everyone is unique and each person will experience a treatment differently. More research, focusing on the needs of people living with COPD and their loved ones, is necessary to find personalised solutions to – **slow, stop or even prevent progression of COPD.**

Clinical studies can improve people's lives by helping us understand COPD and how to treat it. For many, the chance that research may lead to new COPD treatments which can benefit the COPD community is very important.

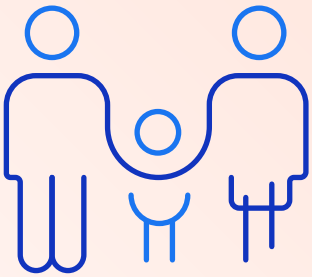
What is a clinical study?

New medications and therapies are tested through clinical studies (also known as clinical trials or research). These often involve volunteers (i.e. people with and without COPD) who take the new medication, usually compared to either an available treatment, or a treatment that appears real but has no effect, called a *placebo* or control.

Clinical studies are well regulated and monitored to ensure participants' safety and understanding of the goals and design of the study. You have the right to leave the study at any time you wish.

Data, or information, are collected from all participants to determine the effectiveness and safety of the medication.

Watch a short video about clinical studies here.



Why do clinical studies matter to me, my family, and the COPD community?

Clinical studies help researchers and companies create important medicines you might use every day. These studies empower you work to with your healthcare team to make decisions about your COPD and get check-ups and care.

In COPD, clinical studies aim to:

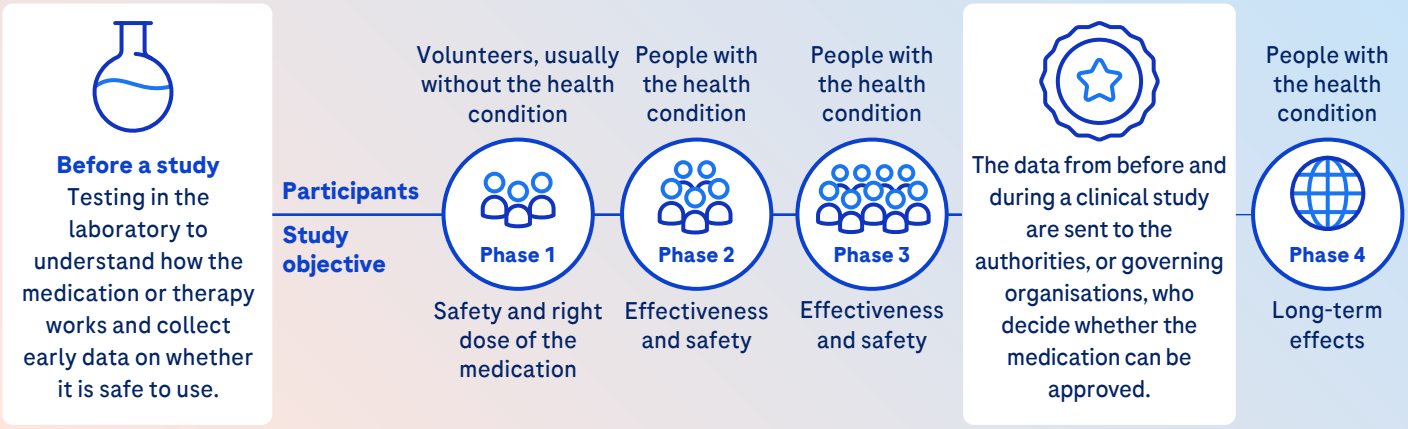
understand more about COPD, symptoms, and exacerbations (or flare-ups), how it affects people differently, and the interaction between COPD with other breathing-related conditions, through the setting of study goals (or *endpoints*).

address unmet medical needs for people living with COPD, their loved ones and healthcare professionals with effective and safe innovative solutions to slow, stop, or even prevent progression of COPD.

improve health, wellbeing, and quality of life for people living with COPD, and their loved ones through *holistic care*.

The clinical study process

Every new medication or device goes through many development stages, known as phases of clinical studies, each with different goals, before it can be approved for use. Data, or information, found at each phase determines whether research continues. Once the medication is approved and available, it will continue to be studied to investigate any potential modifications, and long-term effects.



Clinical study key terms

Inclusion/exclusion criteria	Key features of the study population researchers use to enrol people on to a clinical study. If a person has certain features that could interfere with the results, they will be excluded from the study.
Exacerbations	A 'flare-up', 'lung attack' or period when your breathing is worse than usual and may worsen without treatment.
Informed consent form	A form you sign confirming you understand what the clinical study is about, your role and commitment to participate. It includes information on the study treatment, and alternative treatment options.
Primary endpoint	Main study goal to ensure what is being investigated is meaningful for people living with COPD, their loved ones and healthcare professionals involved in COPD.
Study drug	Medication being assessed in the clinical study.
Standard of care	Treatment already available in the healthcare system.
Placebo	A medication that has no effect, used to test if another medication works.
Washout period	The time in between stopping current medication and starting the new medication. This ensures any benefits in the clinical study are due to the study drug.
Treatment administration	When and how you are given the medication.
Holistic care	Care that encompasses all aspects of a person's well-being, including physical, emotional, and social.
Comparative study	A type of study where one group of participants receive the study medication, and other groups receive either the standard of care or placebo to compare how effective and safe the study medication is.
Randomised	When participants are put into different groups, without knowing which, at the start of the study. Different groups may receive different amounts (doses) of the study medication or placebo.
Blinded/ double-blinded	In a blinded study, participants are unaware of what treatment group they have been allocated to. In a double-blinded study, both the researcher and participant are unaware of what treatment group participants have been allocated to.
Efficacy	When the study drug or therapy produces the intended effect, or result, within a clinical study.
Side effects	The effect a medication has in addition to its intended effect. Side effects can be beneficial or harmful.
Adverse events	A harmful or undesirable effect from a medication.
Pseudonymised data	Data collected in a format that cannot be linked back to the individual participating.
Patient reported outcomes	A measure of the participant's health and experience of their illness and treatment as reported by them.
Open label	A type of study where both the clinical study team and participants are aware of the medication being given.

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What should my family and I expect to happen during a clinical study?

Recruitment

Initial contact between clinical study team and you, healthcare providers, or patient advocacy organisations or support groups (e.g. through advertising, social media, study registries).

Informed consent

Legal document including information about the clinical study and personal involvement, along with a consent form which confirms your understanding and voluntary agreement to participate following review of this information.

Pre-screening

Answering questions by questionnaire or during appointment, to help researchers decide if you and the clinical study are a good fit.

Screening

Tests to see if you meet the study *inclusion criteria*. This may include: lung function tests, questionnaires, an exercise test, scans, and a chest x-ray.

Enrolment and study group assignment

Confirmation of enrolment as a participant in the clinical study followed by assignment to study groups to receive either the study drug, standard of care or placebo.

Study visits and monitoring

During the study data will be collected through assessments (tests) on how you are responding to the treatment. For some clinical studies, telehealth and at-home nursing visits can make participation easier, particularly for those unable to travel to a clinical study site.

Analysis

Study results will be collected, analysed, interpreted and shared.

End of study and interviews

Sharing of clinical study findings. Interview opportunity for you to share any feedback, and potentially an invitation to participate in any follow up studies. These help researchers understand effects not measured in the study and help with the design of future studies.

Clinical studies are conducted under very strict safety controls, and you will be regularly monitored. You can leave the study at any point for whatever reason, even after signing the informed consent form.

What will happen with my data?

Your data are essential to achieve the aims of the clinical study. It shows how you react to a medication.

Data are collected continuously throughout the study in many different forms (e.g. tests, questionnaires, blood samples).

Your results (data) are combined with data from other participants, to understand how many people may benefit from treatment and how many experience unwanted side effects.

These large amounts of *efficacy* and safety data are analysed to show the effect of the medication didn't happen by chance.

With your consent, your anonymised data could also become part of community registries, to improve understanding and help people living with COPD.

What are the advantages and disadvantages for me and my family in joining a clinical study?

Take time before deciding to join a clinical study. There are several positives of participating and other factors including potential risks to consider. It is important you choose **what is right for you.**

Possible advantages

Access to free, regular monitoring and *holistic care* (e.g. counselling/ psychological support)

Access to new medicines or treatment unavailable outside of a clinical study

Access to mobile nursing and/or at-home care

Regular access to healthcare professionals to answer your questions

Contributing to scientific advancements and improving quality of life of the COPD community

Contributing to the design of future clinical studies

Reimbursement for your time and travel

Possible disadvantages

Stopping your current medication (i.e. washout period)

Receiving medication or placebo that is no better or worse than what is already available

Having side effects

Experiencing information overload and feeling overwhelmed

Not experiencing any personal benefit

The study may end if several people drop out or if early findings support ending the study

Additional time and travel commitments (due to regular assessments)

For further information on COPD clinical studies, watch here.

What questions should I ask my doctor if I want to participate in a clinical study?

- Are there any clinical studies that I can join?
- Where can I find out about clinical studies that are happening now?
- What is in it for me and my family?
- Will my family and I be reimbursed for study participation related costs e.g. travel?
- How can I learn more about different clinical study participation opportunities?
- Who do I reach out to if I have any questions or need advice?

If your doctor offers you a place on a clinical study, consider asking the following questions:

Study purpose and logistics:

What is the purpose of the clinical study?

How long will the clinical study last?

How much time will I need to give to the study? Is there flexibility so I can fit appointments around my daily responsibilities?

How much time will each study visit take?

How will study visits be organised?

What assessments are involved as part of screening?

Can a family member, friend or caregiver attend study visits with me?

Treatment:

Will I have to change my lifestyle, diet, or other activities?

Will I have to stop taking my current medication(s)?

What is the treatment you are investigating?

What are the treatment side effects?

How will potential side effects be addressed or managed?

Monitoring and support:

How will I be monitored or checked on throughout the study?

Will I be able to meet or contact other study participants?

Does the study offer emotional or psychological support?

What happens if my condition gets worse during the study?

What if I want to leave the study?

Data protection and post-study:

Will the results be shared with me after the study? How?

What impact will the study have on my long-term treatment?

How will my data, privacy, and confidentiality be protected during the study?

Who can I speak to if I have further questions?

Who should my family and I speak to if we want more information on clinical studies?

Speak to the clinical study team, your doctor, healthcare provider or local COPD community organisation (if available), for more information on available clinical studies or if you have any questions about joining a clinical study.

Websites like ClinicalTrials.gov contain all current and future studies in COPD and include study details and results.

With thanks to the Global COPD Focus Group consisting of members of the following patient groups: GAAPP, SLHP, EFA, AAOKenya, APEPOC, HSAACI and Lung Union Austria.

Roche funded the production of this document, and it was co-created with representatives of the Global COPD Focus Group and COPD Community.

One linked video in this document is not Roche owned has been sourced from the American Lung Association.