About clinical trials and medical research opportunities

What is medical research?

Any potential new medication or medical device must first be tested in human medical research studies (also known as a "clinical trials") before it can be prescribed more broadly to patients.

The goal of clinical trials is to learn if a potential new medication or medical device (the "investigational product") is safe and how well it works.

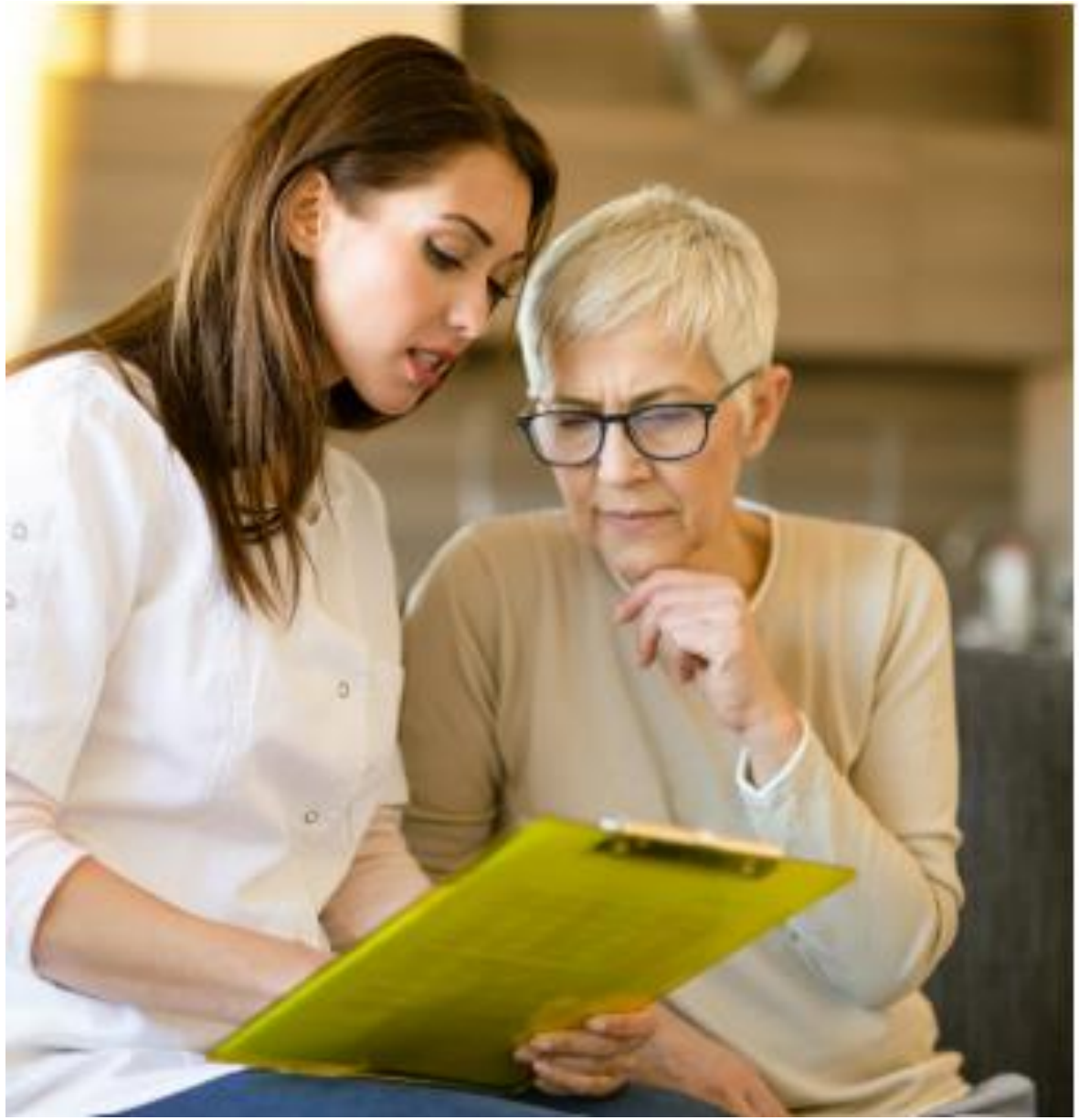
If an investigational product has been successful in clinical trials, pharmaceutical and biotechnology companies submit the trial results to regulatory agencies, to seek approval for their product to be prescribed to patients.

Are clinical trials safe?

Researchers must follow very strict rules to ensure the safety and well-being of everyone taking part in a clinical trial. Clinical trials are carefully monitored by various regulatory agencies such as:

- US Food and Drug Administration (FDA) in the United States
- European Medicines Agency (EMA) in Europe
- Other Ministries of Health or regulatory authorities in countries around the world.

These government agencies are responsible for the rules and regulations on the conduct of clinical trials.



What are the risks?

The side effects of an investigational product are not always known. Researchers must tell you about any known risks and also discuss the potential for unknown risks before you decide whether to take part in a clinical trial.

Most side effects are minor and merely unpleasant. However, sometimes side effects can be more serious or even life-threatening. The risks vary, depending on the product being tested.

Clinical trial participants can stop taking part in a trial at any time and for any reason.

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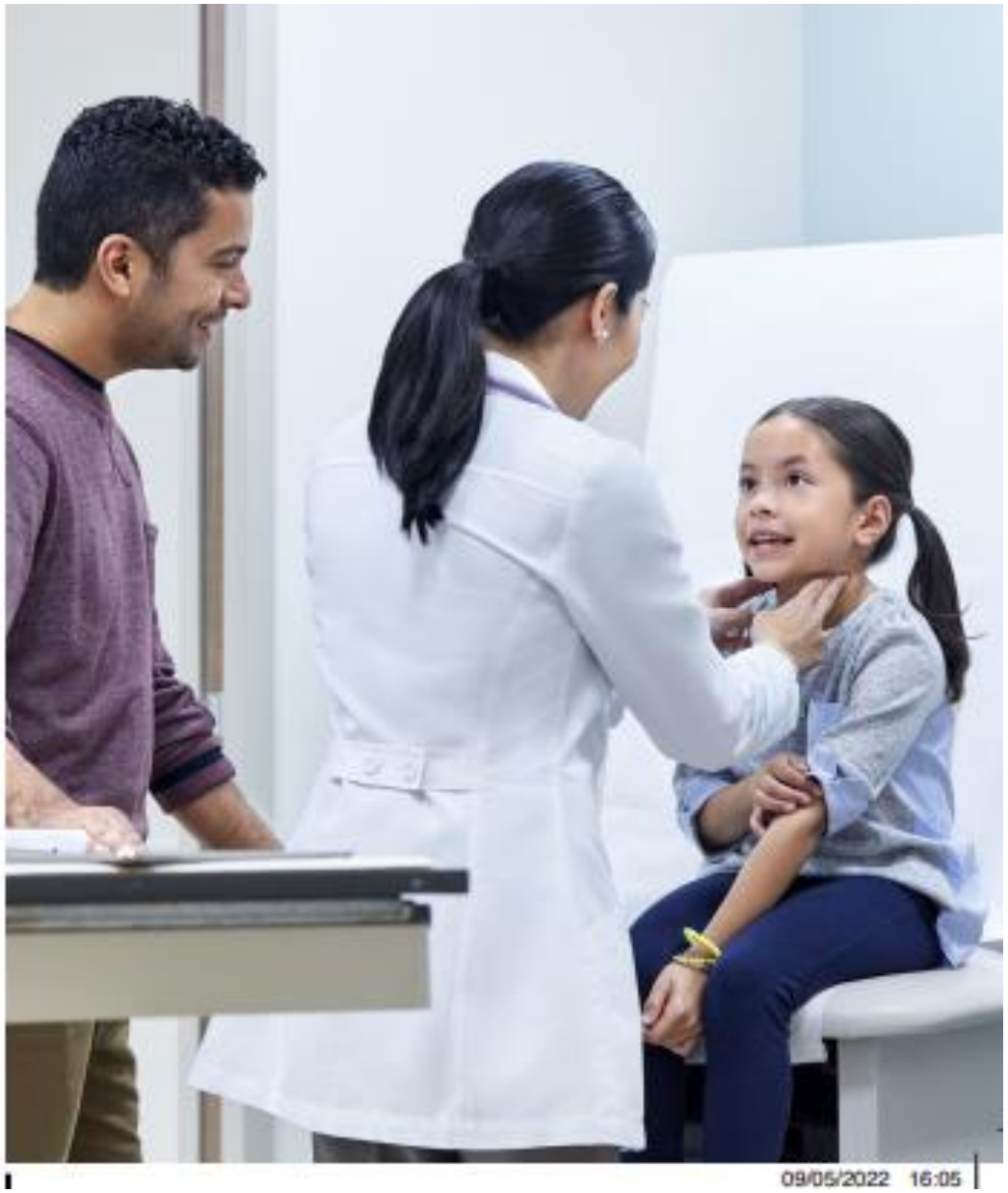
Institutional Review Boards and Ethics Committees

Institutional Review Boards (IRBs) and Ethics Committees (ECs) are responsible for reviewing proposed and ongoing clinical trials to make sure there are appropriate steps in place to protect the rights and welfare of participants. They are made up of scientists, doctors, and other experts, as well as lay members of the community.

What is it like to take part in a clinical trial?

The first step is finding out all about the trial before deciding whether you want to take part. This process is called informed consent. If you agree to take part, researchers will see if you are eligible to participate during a process called screening, which may involve some medical tests and assessments. Different trials have different requirements.

In randomized clinical trials, you will be assigned at random (meaning you cannot choose) to receive either the investigational product, a standard medication, or placebo. A placebo looks like the investigational product but contains no active medicine. Including placebo in certain trials is important to provide more certainty that any effect seen with the investigational product is definitely attributable to the product.



As a trial participant, how am I protected?

Informed consent

Researchers are required to provide you with complete information about the trial before you decide whether to participate. This process is called getting informed consent. You should not agree to participate in a trial unless you understand all the details in the Informed Consent Form (ICF). You can ask questions if you are not sure about anything.

All potential trial participants must be given information about:

- the purpose of researching the investigational product
- the amount of time they will be in the trial
- the possible risks and benefits of taking part
- what other procedures or treatments are available
- the privacy of their medical records (although the researchers, IRBs/ECs, and regulators may review them)
- what treatments are available if they become sick or hurt because of taking part, and who will provide payment for any needed treatment
- the contact information for the person who can answer questions about the trial.

If you agree to take part after reading and understanding all the information, you will need to sign the ICF. Even after signing, you can leave the trial at any time and for any reason without penalty.

Why do people take part in clinical trials?

Some people participate in clinical trials to contribute to medical research and to help doctors find new ways to help patients. Others take part because they hope to receive investigational medications, devices, or procedures because their condition is not responding to standard treatment. However, there is no guarantee that an investigational product will work.

It is important that all kinds of people are represented in clinical trials. This is because certain conditions and medications may affect people differently based on their age, sex, race/ethnicity, and their genes.

Without clinical trials, improvements to current treatments and medical technologies would not be possible.

What questions should I ask before deciding to take part in a clinical trial?

- *What kinds of tests and assessments will I have to take?*
- *What are my other treatment choices?*
- *How often will I have to visit the researcher or clinic?*
- *Will I have to stay in the hospital overnight?*
- *What are the side effects of the investigational product?*
- *What kind of follow-up will I receive?*
- *Will I be paid to take part? Will I be reimbursed for travel expenses?*
- *Do I need health insurance?*

How can I find out more?

Ask your doctor if there are any clinical trials that might be right for you.

More information about current clinical trials can be found at http://www.clinicalresearch.com/aware.

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CHINOOK STUDY

THE WINDWARD PROGRAM

Do you have severe asthma?

If so, you may be interested in taking part of the CHINOOK study.

Airway Remodeling Study for Severe Asthma

ClinicalTrials.gov Identifier: NCT03953300

The aim of the study is to further evaluate an already approved medication called Benralizumab and how it might further help treat severe eosinophilic asthma.

Research Study sponsored by: AstraZeneca

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Who can join?	What is involved in participating?
✓ Are 18-70 years, ✓ Are currently NOT a smoker, ✓ Have been diagnosed with asthma requiring continuous treatment.	✓ Attend appointments to have tests and assessments with study doctor/team, ✓ Come to clinic to receive the study treatment.

Please contact study site, for more information:

Lisa LaRiccia BSN RN
Clinical Trial Educator II
Phone: 727-218-7971
Email: lisa.lariccia@iqvia.com

Airway Remodeling Study for Severe Asthma

ClinicalTrials.gov Identifier: NCT03953300

CHINOOK STUDY
THE WINDWARD PROGRAM

Do you have patients with severe asthma? The aim of the study is to further evaluate an already approved medication called Benralizumab and how it might further help treat severe eosinophilic asthma.

Inclusion Criteria	Exclusion Criteria
✓ Are 18-70 years,	✓ Ex-smokers < 12 months,
✓ Are currently NOT a smoker,	✓ Previously received Benralizumab,
✓ Have been diagnosed with asthma requiring continuous treatment with ICS plus LABA,	✓ Receipt of any marketed or investigational biologic within 4 months or 5 half-lives,
✓ A high blood eosinophil count (determined at screening visit).	✓ Clinically important pulmonary disease other than asthma.

Please refer potential patients to study site, or for more information:

KU Medical Center
Dr Mario Castro
Contact the Research Coordinator,
Laurin Brown RRT at
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E: lbrown37@KUMC.edu

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