ASTHMA PATIENT-CENTERED RESEARCH TRAINING

Asthma and Allergy Foundation of America

WITH FUNDING BY PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI) CONTRACT #2207-AAFA

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PLEASE TAKE YOUR PRE-SURVEY PRIOR TO THE START OF TRAINING TODAY.

INTRODUCTION

Welcome to the Asthma Patient-Centered Research Training. This workshop was created by the Asthma and Allergy Foundation of America (AAFA) with grant funding from the Patient-Centered Outcomes Research Institute (PCORI).

The **Asthma and Allergy Foundation of America (AAFA)**, a nonprofit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to improving quality of life for people with asthma and allergic diseases through education, advocacy, and research. The organization offers resources and advocacy for people affected with asthma and allergies, healthcare providers, and policymakers. AAFA's goal is for those with asthma and allergies to live life without limits.

The **Patient-Centered Outcomes Research Institute (PCORI)** is an independent nonprofit, non-governmental organization located in Washington, DC, and authorized by Congress in 2010. PCORI's goal is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policymakers make informed health decisions. The organization provides grants to fund comparative effectiveness research (CER), as well as supporting work that will improve the methods used to conduct such studies.

Training Introductions

- Name
- What do you like to do?
- Do you have asthma? Or, are you a parent, friend, or caregiver of someone with asthma?
- What do you want to get out of today?
- Something special about you?

Training Topics

- Introductions
- Overview of Asthma
- Asthma Research
- Clinical Research
- Comparative Effectiveness Research
- Patient-Centered Outcomes Research Institute (PCORI)
- Asthma Articles – How to find out more!

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Training Agenda

- Registration & Pre-survey
- Introductions
- Overview of Asthma
- Break
- Clinical Research & Research Process
- Research Match Game
- Break
- More about PCORI
- Research Expert
- Post-survey & Lunch

Asthma is a life-long illness affecting millions of Americans. Currently, this illness can be treated but not cured. People who have asthma must make daily decisions on how best to deal with their condition. These decisions include which medications to take and when, which healthcare provider to see, and what treatments are best for them. In today's training, you will learn about asthma, clinical research, asthma research priorities, and how patients can become involved in shaping the agenda for future research.

This training was designed to provide you with the following:

- Information about asthma and asthma research
- Questions to ask experts about asthma and research
- How to participate in the research process
- Resources to help you make decisions about the treatment and control of asthma
- How to review asthma publications and websites that provide accurate information

Who is the Pretend family and why are they included in the training?

The Pretend family is just that, pretend. The father is Marcus, age 42; the mother is Candice, age 38; the children are Tabitha, age 12, Jay, age 8, and Samantha, age 15 months. They were created to help make this training patient-focused. (Candice the mother will be your guide during the training.)

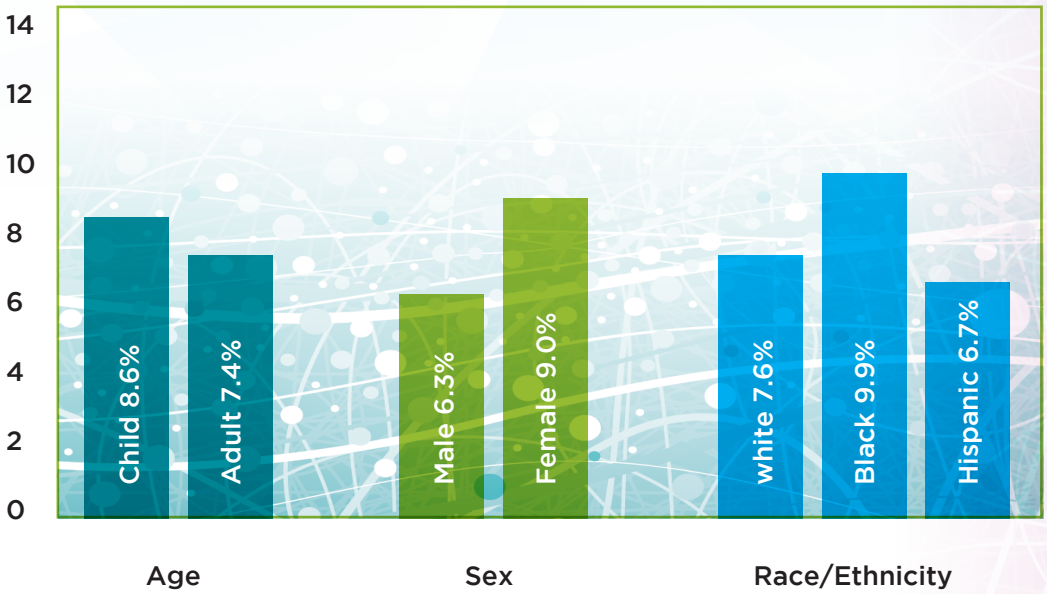
The Participant Manual includes information and facts about asthma, space to write your own notes, a resource list, and a glossary of terms. The glossary includes definitions of words, terms, and abbreviations to help you better understand today's training. (Terms defined in the glossary will appear in italics in your manual.)

Before talking about research, we will begin with an overview of asthma to make sure everyone has the latest information about the disease.

What is asthma?

Asthma is a *chronic disease* that affects the airways in the lungs. During an asthma attack, airways become inflamed, making it hard to breathe. Asthma attacks can be mild, moderate, or serious—even life threatening. A chronic disease is a long-standing illness that cannot be cured, only treated. The graph below shows the age, gender, and race/ethnicity of people in the United States with asthma. The rate of asthma is higher in children, females, and blacks.

Current Asthma Prevalence Percents by Age, Sex, and Race/Ethnicity, United States, 2014



Source: National Health Interview Survey, National Center for Health Statistics, Centers for Disease Control and Prevention

https://www.cdc.gov/asthma/asthmadata.htm

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What causes asthma symptoms?

Asthma *symptoms* are caused by difficulty getting air out of the airways due to *bronchoconstriction*, airway wall thickening due to overuse of these muscles, swelling inside the airways, and increased *mucus* in the airways.

What are the symptoms of asthma?

Asthma symptoms include coughing (especially at night), *wheezing* or noisy breathing, shortness of breath, chest tightness, pain or pressure, and increased mucus in the lungs. An increased rate of breathing can sometimes be associated with asthma, especially in children. Often, exercise will make asthma symptoms worse and may be the only *trigger* for asthma in some people. Sometimes signs of *allergies*—such as a runny, stuffy nose—happen before or during problems with asthma.

What are the triggers of asthma?

Triggers of asthma symptoms vary from person to person. Common triggers include: nasal or lung infections such as colds, flu, or *pneumonia*; allergies to *dust mites*, cockroaches, pets, or *pollen*; tobacco smoke exposure; exercise; stress; strong smells and air pollution. People with asthma can usually report some of their triggers.

How is asthma defined?

Asthma is a chronic, inflammatory disease of the airways that causes *airway obstruction* due to constriction of the smooth muscles that surround them, *inflammation* or swelling on the inside of the airway, and increased airway sensitivity or *hyperresponsiveness*.

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What happens in the body when you have an asthma attack?

Several things happen in the lungs during an asthma attack: Muscles on the outside of the airways become tightened, squeezing the airways closed; inflammation of the lining inside the airways occurs; extra mucus collects in the swollen airways; and the small air sacs at the end of the airways where *oxygen* and *carbon dioxide* exchange, called *alveoli*, are filled with trapped air.

The lining of the airways breaks down causing changes in the *cells* and *cilia* that normally protect the airways. The lungs of someone with not well controlled asthma can experience serious changes. Taking regular controller medications can reverse these ill effects, but if the patient stops taking their medications, airway lining breakdown will reoccur.

Are there healthcare guidelines for diagnosis and treatment of asthma?

The U.S. Guidelines for the Diagnosis and Management of Asthma, written by the National Asthma Education and Prevention Program (NAEPP) Coordinating Committee, were last updated in 2007. The full report—Expert Panel Report 3 (EPR-3)—can be accessed on the National Heart, Lung, and Blood Institute website at **https://www.nhlbi.nih.gov/health- pro/guidelines/current/asthma-guidelines/full- report**.

The Global Initiative for Asthma (GINA) guidelines were updated in 2016. These guidelines can be accessed on the GINA website at **http://ginasthma.org/2016-gina- report-global- strategy-for-asthma-management- and-prevention/**.

Both sets of guidelines are lengthy documents and may be difficult for someone without a medical background to understand. That said, these public documents have a huge amount of information for those who are interested. They include information on childhood and adult asthma, severity and control of asthma, asthma education, and the treatment of asthma.

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What are the signs that asthma is not well controlled?

The red flags of asthma are warning signs that asthma is not well controlled. These red flags include an increase in asthma symptoms such as coughing, chest tightness, and shortness of breath. Another sign that asthma control is worsening is an increased need for rescue or quick-relief medication (more than 2–3 times per week for symptoms). When rescue medication does not last a full 4–6 hours and doses need to be repeated more often, immediate medical attention is needed. Another indicator of asthma control that patients may not think about is how many times per year they require *steroids* (prednisone or Medrol) to control asthma symptoms. Limitation of activities due to asthma symptoms is also a warning sign. All of these red flags should be discussed with a healthcare provider.

What are the major types of asthma medications?

The two major types of asthma medications are called *controllers* and *rescue* (or *quick-relief*) *medications*. Controllers are usually prescribed to take daily for the prevention and control of asthma. Rescue or quick-relief medications (*albuterol* is most common) are used for symptoms.

It is very important to use asthma medications exactly as they are prescribed. It may be hard to take medications when you are not having symptoms, but not taking them can lead to changes in the airways that cause asthma symptoms. Prevention is the key!

Every patient with asthma should have a written treatment plan given to them by their healthcare provider. This plan should list controller and rescue medications and tell when to take them. It should also tell the patient what to do if symptoms are not controlled. This part of the plan is called an asthma action plan.

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What are the goals of asthma treatment?

It is important for every patient with asthma to think about what they want out of their asthma medications. This should be the patient's goal for treatment. Asthma is a long-standing disease and it is important for patients to link specific asthma treatments with successful asthma control. It is important to talk to your healthcare provider about what you need from your asthma treatment. Many patients, for example, would like to be able to exercise without symptoms. Your healthcare provider should know your goals for treatment and whether or not they are being met.

The asthma guidelines referred to earlier also list general goals for asthma treatment. These goals include preventing asthma symptoms, minimizing the use of rescue medications (twice weekly or less for symptoms), normal lung function measures, normal activity, patient satisfaction with asthma care, prevention of asthma attacks, no need for emergency department visits or hospitalizations, preventing loss of lung function, and the right medications with few or no side effects. Your healthcare provider should consider these goals when treating you for asthma.

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ASTHMA RESEARCH

Why is asthma research important?

Asthma research is necessary to discover and create new treatments for asthma. Researchers are also attempting to learn the different causes of asthma in the hope of someday finding a cure. They look at the effects of asthma on patients to determine the course and trends of the disease. Recently, researchers found that different types of patients have different varieties of asthma, and that the best treatments for these patients may vary. Researchers look at asthma patients of different races or ethnicities, genders, and ages to try to determine the best treatments for each type of patient. Sometimes researchers compare one type of treatment to another. While investigating a treatment, researchers may come up with ideas for new research and treatments.

Is there a ranking system or prioritization of what research is important?

Deciding which asthma research is of greatest importance at a given time can be tricky. In 2002, researchers discovered that different populations were experiencing different outcomes. It became important to discover the cause of these differences, to find ways to educate people about and help reduce these differences, and to indicate those at highest risk and improve asthma treatment in these populations.

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What are the differences in ethnic and income groups with regards to asthma rates and symptoms?

As a result of asthma research of the trends discovered in 2002, research on asthma *disparities* in urban environments was given highest importance in 2012. It was discovered that asthma continues to affect minority and low-income groups more frequently—that African American and Latino children who live in low-socioeconomic urban areas have higher asthma rates and more symptoms and deaths than white children. Researchers found that the imbalance in asthma rates and symptoms continued to increase despite overall improvement in asthma treatments.

Researchers also identified factors that contributed to these differences. They concluded that the type of healthcare treatment, poor housing with increased exposure to asthma triggers, and environmental stress were all causes. These conclusions have led to additional research on how to minimize disparities in asthma rates and symptoms in different populations.

What are asthma outcome measures?

When conducting asthma research, *outcome measures* (evaluation of the results of the study) must be defined prior to starting research. In the past, outcome measures were created only by expert researchers. These measures included blood testing of the *allergy antibodies* (IGE), asthma control questionnaires, number of asthma attacks in a set time period, emergency department visits, asthma medication use, and *spirometry* testing. More recently, asthma research has started looking at treatment measures reported by patients. These patient-reported outcome measures (PROMS) focus on patients' *quality of life* and may reveal new information to researchers.

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Do different types of healthcare providers recommend different types of asthma treatment?

Variously trained healthcare professionals will treat asthma differently. *Pulmonary* or allergy/asthma providers usually follow the asthma guidelines discussed earlier. These guidelines are based on evidence from research. A *naturopath* doctor may look at viral infections or toxic loads in the body and the effect on a patient's overall health, including asthma. A nutritionist may look at inflammatory foods a patient is eating that may have led to inflammatory *illnesses* like asthma. Unfortunately, there is limited evidence on the recommendations from the naturopath and nutritionist. New asthma research is now looking at alternative methods of treatment, but to date, nothing has been found that works as well as treatment based on the established asthma guidelines. Talk to your healthcare provider about any alternative treatments you have used or are thinking about using, and always ask if there are research studies showing that the treatment may be beneficial, or at least, not harmful.

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What is research?

According to the Merriam-Webster online dictionary, research is a careful or diligent search; a studious inquiry or examination aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws; or, the collecting of information about a particular subject.

From this definition, we see that we all do research daily—to verify things we hear or find information about things we need, for example. We do not usually go about this using a scientific or experimental method, but we are all familiar with the search for information. We might ask friends or family, check the Internet, or talk to a healthcare provider in our search for answers.

What is the Food and Drug Administration (FDA)?

The *Food and Drug Administration* is a federal agency within the U.S. Department of Health & Human Services. This agency is responsible for protecting public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, *biological products*, and medical devices. The FDA is also responsible for advancing public health by helping to promote innovations that make medical products more effective, safer, and more affordable. Finally, the FDA is in charge of helping the public get the accurate, science-based information needed for the use of medical products and food that maintain and improve health.

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What is clinical research?

Clinical research is the study of health and illness in people. Researchers may do clinical research to explore the cause of a disease or a set of symptoms, to test if a treatment will help with a symptom or condition, or to learn how a certain behavior affects people's health. Researchers may want to compare one treatment to another or look at how a treatment affects different types of people.

Clinical research is called many different things. Some of the various terms used to describe clinical research are *clinical trials*, clinical studies, medical trials, studies, research, trials, and *protocols*.

Clinical research tests new ways to prevent, detect, or treat disease. These treatments can be new drugs or combinations of drugs, new surgical procedures or tools, or new ways to use existing treatments. Clinical trials can also test other aspects of care, such as ways to improve quality of life for people with chronic illnesses.

What is the National Institutes of Health (NIH)?

The National Institutes of Health, a part of the U.S. Department of Health and Human Services, is the nation's medical research agency that is making important discoveries to improve health and save lives. Thanks in large part to NIH-funded medical research, Americans today are living longer and healthier. The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems, and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH invests nearly $32.3 billion annually in medical research for the American people. There are 27 institutes and centers at NIH. Most asthma research funding and initiatives come out of the National Heart, Lung, and Blood Institute (NHLBI).

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What is the difference in medical research and medical treatment?

	Clinical/Medical Research	Medical Treatment
Intent	Answers specific questions through research involving numerous research volunteers.	Addresses the needs of individual patients.
Intended Benefit	Generally designed and intended to benefit future patients.	Intended to benefit the individual patient.
Funding	Paid for by drug developers and government agencies.	Funded by individual patients and their health plans.
Timeframe	Depends on research protocols.	Requires real-time decisions
Consent	Requires written informed consent.	May or may not require informed consent.
Assessment	Involves periodic and systematic assessment of patient data.	Based on as-needed patient assessment.
Protections	Protected by government agencies, institutional review boards, professional standards, informed consent, and legal standards.	Guided by state boards of medical practice, professional standards, peer review, informed consent, and legal standards.
Certainty	Tests products and procedures of unproven benefit to the patient.	Uses products and procedures accepted by the medical community as safe and effective.
Access to Information	Considered confidential intellectual property.	Available to the general public through product labeling.
Release of Findings	Published in medical journals after clinical research ends.	Individual medical records are not released to the general public.

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What reasons might people have not to trust clinical research?

In the past, research was sometimes conducted without patients' consent. Today, patients must be informed regarding the risks and benefits of participation in clinical trials/research prior to participation. They must sign a document called an *informed consent*. Sometimes people may not know why they do not trust researchers; they just know that bad things have happened in the past.

What are the steps of medical research designated by the FDA?

The steps of medical research as designated by the FDA are pre-investigation, investigation, and post-investigation. During the pre-investigation *phase*, the problem to be researched is identified, existing information is collected and evaluated, and *research objectives* and *hypotheses* are specified. Then *study subjects* are selected, a *study design* is created, the research plan is written, and research tools are developed. During the investigation phase, pre-testing is done, and often times, a small pilot study is conducted to work out any issues prior to the start of the full study. Then the principal trial begins and results are collected. The handling of lack of response to treatment and other ethical issues is conducted on an ongoing basis.

Finally, the results are examined. In the post-investigation phase, results are analyzed and interpreted. The results are then distributed in medical journals and at scientific meetings.

What are the major types of clinical research?

The two main types of clinical research are clinical trials and *observational studies*. These types of research will be discussed in further detail.

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What is a clinical trial?

A well-designed clinical trial is the best way to prove that a treatment or medical approach works. In a clinical trial, participants receive specific treatments or *interventions* based on a research plan (also called research *protocol*). These interventions can be a medical product such as a drug or device, a procedure such as a surgery, or changes to the participants' behavior such as diet or exercise. A comparison is made between a new drug, procedure, or change in behavior to a standard one that is already in use, or between a new medication and *placebo* (a pill or *inhaler* that appears like the medication but contains no active ingredients).

Comparative studies look at the differences and similarities between interventions or medications that are already available (such as comparing one type of asthma inhaler to another). When a new product or approach is being studied, it is usually not known whether it will be helpful, harmful, or no different than available alternatives (including no intervention or treatment). Researchers try to determine the safety and effectiveness of the intervention by measuring certain outcomes in participants.

What are the phases of clinical trials?

PHASE I

Purpose: Find out whether a medical approach (e.g., drug, *diagnostic* test, device) is safe, identify side effects, and figure out appropriate doses.
Number of participants: typically fewer than 100.

PHASE II

Purpose: Begin testing whether a medical approach works, continue *monitoring* for side effects, and gather information for designing a large, phase III trial.
Number of participants: typically 100–300.

PHASE III

Purpose: Prove whether a medical approach works and continue monitoring side effects.
Number of participants: as many as needed or are able to enroll—can be 1,000 or more.

PHASE IV

Purpose: While a medical approach is being marketed, continue gathering information on its effects.
Number of people: thousands.

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What is an observational study? Are there different types of observational studies?

In an observational study, researchers observe participants rather than conducting experiments or testing new treatments. This type of study helps researchers understand a situation and come up with ideas that can later be tested in a clinical trial. Observational studies help to find connections—between medications and symptoms, for example—but cannot prove that one thing causes another.

The following is a list of different types of observational studies:

CASE STUDY/CASE SERIES

A detailed description of one or more patients. By documenting new and unusual cases, researchers start to generate hypotheses about causes or *risk factors*.

ECOLOGICAL STUDY

Compares the rate (occurrence) of a disease or condition for specific groups of people, such as towns in different climates or with different average incomes.

CROSS-SECTIONAL STUDY

A snapshot of many people at one moment in time. These studies can show how common a condition is and help identify factors associated with it.

CASE-CONTROL STUDY

A group of people who have a condition is compared to a control group of people who do not. Possible causes or risk factors can emerge.

COHORT STUDY

A large group of people is observed over time. Some eventually develop a disease or condition. Researchers can learn how often a condition occurs and find possible causes or risk factors.

What type of study provides the best evidence?

Randomized controlled trials (RCT) prove whether a treatment or intervention works. Meta-analyses and systematic reviews combine multiple randomized controlled trials to provide additional evidence of benefit. Most treatment guidelines use the evidence and conclusions from randomized controlled trials, meta-analyses, and systematic reviews to make recommendations for treatment.

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Why are clinical studies done?

Clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases. Specific reasons for studies include: evaluation of one or more interventions (such as drugs, medical devices, approaches to surgery, or radiation therapy) for treating a disease, syndrome, or condition; finding ways (medicines, *vaccines*, or lifestyle changes) to prevent the initial development or recurrence of a disease or condition; evaluating one or more methods aimed at identifying or diagnosing a particular disease or condition; examining methods for identifying a condition or the risk factors for that condition; exploring and measuring ways to improve comfort and quality of life through *supportive care*.

Who conducts clinical research?

Clinical studies are led by a researcher called the principal investigator (PI). There is typically a *research team*, which may include physicians, nurses, social workers, and other healthcare professionals.

Clinical research is usually *sponsored* or paid for by either *pharmaceutical* companies, academic medical centers, voluntary groups, nonprofit organizations, federal agencies (like the NIH, PCORI, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs), healthcare providers, and other individuals.

What type of plan is used to make sure research is done properly?

A clinical study is conducted according to a research plan known as the *research protocol*. The protocol is designed to answer specific research questions and ensure the health of participants. Protocols usually include the following information: reason(s) for conducting the study; who may participate in the study (the *eligibility criteria*); the number of participants needed; a schedule of tests, procedures, or drugs and their dosages; length of the study; and what information will be gathered about the participants.

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Who can participate in clinical research?

Clinical studies have rules that are listed in the research protocol outlining who can participate. Some studies seek participants who have the illnesses or conditions that will be studied; some studies are looking for healthy participants; and some studies are limited to a predetermined group of people asked by researchers to enroll. The factors that qualify someone for participation in a clinical study are called *inclusion criteria*. The factors that disqualify someone from participation are called *exclusion criteria*. Inclusion and exclusion criteria are based on characteristics such as age, gender, the type and stage of a disease, previous treatment history, and other existing medical conditions.

How are people that participate in clinical research protected from harm?

Researchers use a process called informed consent to provide potential participants with information about the clinical trial that allows them to decide whether to enroll in the study. It also guides continued participation in the study. The informed consent is intended to protect participants and should provide them with enough information to understand the risks and benefits of participation in the trial.

Is informed consent a contract?

An informed consent document must be signed by a participant before joining a research study to show that they were given information on the risks, potential benefits, and alternatives. The informed consent document is not a binding contract and participants may withdraw from the study at any time for any reason.

What is an institutional review board (IRB)?

An *institutional review board* is a group of doctors, researchers, professors, and members of the community who review research proposals to ensure that every study is ethical and that the rights and welfare of the participants are protected. This includes making sure that risks are minimized and reasonable in relation to any potential benefits. The IRB reviews and approves or disapproves the research study protocol and informed consent documents.

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Do you want to participate in clinical research?

Participating in a clinical study contributes to medical knowledge. The results of these studies can make a difference in the care of future patients by providing information about the benefits and risks of *therapeutic*, *preventative*, or diagnostic products or interventions. Clinical trials provide the basis for the development and marketing of new drugs and medical devices. The safety and effectiveness of the study may not be fully known at the time of the trial. Some trials may provide participants with the possibility of receiving direct medical benefits, while others may not.

Trials may involve some risk of harm or injury to the participant, though it may not be greater than the risks related to routine medical care or disease progression. If trials are IRB approved, the IRB has decided that the risks of participation have been minimized and are reasonable in relation to the benefits. Trials may require participants to have additional procedures, tests, and assessments based on the study protocol. These requirements are described in the informed consent document. A potential participant should discuss any issues with members of the research team and/or with his or her usual healthcare provider.

How do you find clinical studies or trials to participate in?

If you are interested in participating in asthma clinical trials, ask your healthcare provider, contact a local asthma specialist or asthma academic center, speak to your local AAFA chapter or go to the AAFA website at **www.aafa.org**, go to the PCORI website at **http://www.pcori.org/get-involved**, or go to ClinicalTrials.gov at **https://clinicaltrials.gov/ct2/search/index**.

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COMPARATIVE EFFECTIVENESS RESEARCH

What is comparative effectiveness research?

Comparative effectiveness research (CER) is research that compares drugs, medical devices, tests, or surgeries to determine which treatment or intervention is most effective. Sometimes this is done by reviewing existing research and then grouping information about the benefits and harms of each treatment. Researchers also conduct new research comparing two treatments or interventions to see which works best. This type of research informs patients, healthcare providers, health insurance plans, and others on the most effective treatment for a specific condition, and even for a selected population with a condition.

This approach to research has not been widely used in healthcare in the U.S. because of the expense of funding and development. Pharmaceutical companies and medical device companies have generally been involved in funding research for new medical treatments and products. They primarily fund research to prove the safety and effectiveness of products that they have invented or purchased rights to develop.

How is comparative effectiveness research different?

CER is designed to inform healthcare decisions by providing research results (or evidence) on the effectiveness, benefits, and harms of different treatment options. In this approach, treatments are compared to see which work the best.

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How are patients included in the research process?

CER has most recently been developed and funded by the Patient-Centered Outcomes Research Institute (PCORI). This organization has made it a priority to include *patient partners* that have the condition being researched as one of the first steps when selecting project research teams. Patient partners participate in the complete process, including offering suggestions on what to include in the research proposal, where and how funding will be obtained, the recruitment of participants for the study, the implementation of the research, patient data (results) collection, and analysis of patient results from the study, distribution (dissemination) of results, and public support (advocacy) for research recommendations to include influencing policy making at local, state, and national levels.

What are the benefits of comparative effectiveness research?

The benefit of CER is that it offers the best and most accurate information about treating a patient's illness or condition. CER reports do not tell healthcare providers which treatment to use, but they are tools to help the patient and health provider understand the facts about different treatment options and make the best decision about which treatment is right. Also, CER helps patients become better informed, which is extremely important in a long-standing illness like asthma.

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

What is the Patient-Centered Outcomes Research Institute (PCORI)?

The Patient Protection and Affordable Care Act of 2010 created PCORI to fund and promote comparative clinical effectiveness research (CER). PCORI was started to assist patients, clinicians, health insurance plans, and policy-makers in making informed health decisions. PCORI emphasizes the voice of the **patient** in assessing healthcare options. Their mission statement commits to producing and promoting high-integrity research guided by patients, caregivers, and the community.

Is PCORI doing asthma research?

PCORI approved $23 million for eight asthma research studies to reduce disparities in asthma burden and outcomes in 2013. AAFA was given a patient engagement grant to help asthma patients understand and participate in patient-centered outcomes research, which is how this training was developed. Multiple asthma research studies have been and are continuing to be funded by PCORI. All of these studies have patient partners.

How can you become involved in PCORI?

Visit PCORI's website (**http://www.pcori.org/**) to find ways to become involved. Patients can suggest a patient-centered research question, provide input on current studies, become a merit reviewer, join an advisory panel, participate in PCORI asthma events, and even become a PCORI ambassador.

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Can you believe everything you read or hear about asthma?

You cannot trust that everything you read or hear about asthma is accurate. Sometimes news writers pick just one part of a research report conclusion to talk about rather than the complete report. In addition, news writers want to pick a topic that will interest people, and in doing so, sometimes facts are exaggerated. As a good *consumer* of asthma information it is important to know which sources you can use to confirm or deny what you hear and read.

What are good resources for information about asthma?

At the end of your Participant Manual there is a list of federal resources and agencies, professional organizations, and other relevant associations, organizations, and coalitions, all of which are excellent resources for accurate information about asthma, diagnosis of the condition, different treatment options, and the effects of these treatments.

The example given in the presentation accompanying this manual used the *Cochrane Review* (**http://www.cochranelibrary.com/**) to find research information about different treatments for asthma.

How can you use the Internet to find accurate information?

A web browser (Google, for example) can be used to locate different topics regarding asthma. As we already discussed, not all information on the Internet is accurate. The list of resources included in the back of your manual will help guide you to websites that should provide accurate information. It is a good rule to always confirm the information you read on the Internet with your healthcare provider, which will also lead to good conversations about what you are interested in with regards to your asthma treatment.

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RESEARCH EXPERT

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CONCLUSION

PLEASE COMPLETE YOUR POST-SURVEY AND RETURN IT TO THE TRAINING STAFF.

ASTHMA & RESEARCH TERMS GLOSSARY

Adverse event: An unfavorable change in the health of a participant, such as abnormal laboratory findings, that happens during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.

Airway obstruction: A partial or complete blockage of the airway.

Albuterol: A bronchodilator (airway-opening) medication for quick relief of asthma symptoms. May be taken in aerosol or tablet form.

Allergen: A substance (such as a food or pollen) that your body perceives as dangerous and therefore causes an allergic reaction.

Allergy: An immune response to a substance or condition produced by the release of histamine or histamine-like substances by effected cells. May result in sneezing, runny nose, hives, coughing, wheezing, and other symptoms.

Allergy antibodies: Produced by the immune system in response to allergens. Usually causes an allergic reaction resulting in symptoms such as a runny nose, scratchy throat, or itchy skin. See also *histamine*.

Alveoli: Small, thin-walled sacs located at the ends of the smallest airways in the lungs where the exchange of oxygen and carbon dioxide takes place.

Antibiotic: Medication used to treat infection caused by bacteria. Antibiotics do not protect against viruses and do not prevent the common cold.

Anticholinergic (also called cholinergic blockers or "maintenance" bronchodilators): This type of medicine relaxes the muscle bands around the airways, opening the airways and letting more air out of the lungs to improve breathing. Anticholinergics also help clear mucus from the lungs.

Antihistamine: Medication that stops the action of histamine, which causes allergy symptoms such as itching and swelling.

Anti-inflammatory: Medication that reduces inflammation (swelling in the airway).

Asthma: A disease of the airways or branches of the lungs (bronchial tubes) that carry air in and out of the lungs. Asthma causes the airways to narrow, the lining of the airways to swell, and the cells that line the airways to produce more mucus. These changes make breathing difficult and cause the feeling of breathlessness. Common symptoms include coughing, shortness of breath, wheezing, chest tightness, and excess mucus production.

Bacteria: Infectious organisms that may cause sinusitis, bronchitis, or pneumonia.

Baseline characteristics: Data collected at the beginning of a clinical study for all participants and for each comparison group. These data include demographics (such as age and gender) and study-specific measures (for example, systolic blood pressure or prior antidepressant treatment).

Beta 2-agonists: A bronchodilator medication that opens the airways of the lungs by relaxing the muscles around the airways that have tightened (bronchospasm). These medications may be short-acting (quick-relief) or long-acting (control) medications. Short-acting beta 2-agonists are used to relieve asthma symptoms when they occur.

Breath sounds: Lung sounds heard through a stethoscope.

Breathing rate: The number of breaths per minute.

Bronchial tubes: Airways in the lungs that branch from the trachea (windpipe).

Bronchioles: The smallest branches of the airways in the lungs which connect to the alveoli (air sacs).

Bronchitis: Inflammation of the bronchial tubes that usually results in bronchospasm and coughing.

Bronchoconstriction: Narrowing of the airways caused by contraction of the smooth muscles that surround them.

Bronchodilator: A drug that relaxes the muscle bands that tighten around the airways with asthma. Bronchodilators can also help clear mucus from the lungs.

Bronchospasm: The tightening of the muscle bands that surround the airways, causing the airways to narrow.

Carbon dioxide: A colorless, odorless gas that is formed in the tissues and delivered to the lungs to be exhaled.

Case study: A type of observational study in which a detailed description of one or more patients is given to allow researchers to form hypotheses about causes or risk factors of the condition.

Case-control study: A type of observational study in which a group of people who have a condition is compared to a control group of people who do not.

Cell: The basic unit of all living organisms.

Chronic disease: A disease that can be controlled, but not cured.

Cilia: Hair-like structures that line the airways in the lungs and help to clean out the airways.

Clinical trials: Research programs conducted with patients to evaluate a new medical treatment, drug, or device. The purpose of clinical trials is to find new and improved methods of treating different diseases and special conditions.

Cohort study: A type of observational study in which a large group of people is observed over time. This allows researchers to learn how often a condition occurs and find possible causes or risk factors.

Comparative effectiveness research (CER): Research that compares drugs, medical devices, tests, or surgeries to determine which treatment or intervention is most effective.

Condition: The disease, disorder, syndrome, illness, or injury that is being studied. According to **ClinicalTrials.gov**, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.

Consumer: A person who purchases or utilizes a good or service.

Contraindication: A reason not to use a course of treatment or medication.

Controlled trial: A type of clinical trial in which observations made during the trial are compared to a standard called the control. The control may be observations of a group of participants in the same trial or observations from outside the trial (from an earlier trial, for example, which is called a historical control).

Controller medication: A medication taken long-term for prevention and control of asthma and asthma symptoms.

Corticosteroid: A type of steroid hormone used to treat inflammation.

Cross-over design: A type of intervention model (design). Describes a clinical trial in which groups of participants receive two or more interventions in a particular order. For example, a two-by-two cross-over design involves two groups of participants. One group receives drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. Participants "cross-over" to the other drug during the trial. All participants receive drug A and drug B at some point during the trial, but in a different order depending on the group to which they are assigned.

Cross-sectional study: A type of observational study. A snapshot of many people at one moment in time is examined to determine how common a condition is and help identify factors associated with it.

Dander, animal: Tiny scales shed from animal skin or hair. Dander floats in the air, settles on surfaces, and is a major part of household dust. Cat dander is a common cause of allergic reactions.

Data: Facts and statistics collected together for reference or analysis. In research, data is collected, observed, or created for purposes of analysis to produce research results.

Decongestant: Medication that shrinks swollen nasal tissues to relieve symptoms of nasal swelling, congestion, and mucus secretion.

Dehydration: Excessive loss of water.

Diagnostic: Relating to or used for the diagnosis of a disease, illness, or problem.

Diaphragm: The major muscle used for breathing, located at the base of the lungs.

Disparity: A great difference.

Double blind masking: A type of masking in which two or more parties involved in the clinical trial do not know which participants have been assigned which interventions. Typically, the parties include the investigators and participants.

Dry powder inhaler (DPI): A device for inhaling respiratory medications that come in powder form.

Dust mites: Microscopic bugs that live in household dust and are a common trigger for allergies. See also *allergen*.

Dyspnea: Shortness of breath.

Ecological study: A type of observational study that compares the occurrence of a disease or condition for specific groups of people—such as towns in different climates or with different average incomes.

Eligibility criteria: The key standards that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria include both inclusion

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criteria and exclusion criteria. For example, a study might only accept participants who are above or below certain ages.

Enrollment: The number of participants in a clinical study. The "estimated enrollment" is the number of participants that the researchers need for the study.

Exacerbation: An increase in the severity of a disease or its symptoms—asthma worsening or an asthma attack.

Exclusion criteria: The factors (or reasons) that prevent a person from participating in a clinical study.

Exercise-induced asthma: Asthma that is made worse when exercising.

Exhalation: Breathing air out of the lungs.

Expanded access: The use of an intervention outside of a clinical trial for people with serious or life-threatening conditions that do not meet the trial criteria.

Factorial design: A type of intervention model (design). Describes a clinical trial in which multiple interventions are evaluated in a single study, either independently or together, in order to investigate treatment interactions.

Family-based study: A type of observational study that focuses on relatives to determine genetic factors associated with a condition.

Food and Drug Administration (FDA): An agency within the U.S. Department of Health and Human Services. FDA is responsible for protecting the public health by making sure that human and veterinary drugs, vaccines, and other biological products, medical devices, the Nation's food supply, cosmetics, dietary supplements, and products that give off radiation are safe, effective, and secure.

Funder type: Describes the organization that provides funding or support for a clinical study. Support may include providing facilities, expertise, or financial resources. Organizations listed as sponsors and collaborators for a study are considered the funders of the study. There are four types of funders: National Institutes of Health; other U.S. federal agencies (the Food and Drug Administration, Centers for Disease Control and Prevention, U.S. Department of Veterans Affairs, for example); industry (such as pharmaceutical and device companies); and all others (including individuals, universities, and community-based organizations).

Health services research: A field of investigation that studies how things like social factors, organizational processes, health technologies, and personal behaviors affect access to and quality of healthcare, and ultimately the health and well-being of individuals, families, and communities.

HEPA (high-efficiency particulate air filter): A filter that removes particles in the air by forcing it through screens containing microscopic pores.

Histamine: A naturally occurring substance that is released by the immune system after being exposed to an allergen. When you inhale an allergen, special cells called mast cells located in the nose and lungs release histamine. Histamine then attaches to receptors on nearby blood vessels, causing them to dilate (enlarge). Histamine also binds to other receptors located in nasal tissues, causing redness, swelling, itching, and changes in the secretions.

Holding chamber: See *spacer*.

Human subjects review board: A group of people who review, approve, and monitor the clinical study protocol. Their role is to protect the rights and welfare of human research subjects

participating in a study. The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed. Also known as an institutional review board (IRB) or ethics committee.

Humidification: The act of moisturizing the air with molecules of water.

Hyperresponsiveness: Increased sensitivity of the airway to stimuli causing bronchoconstriction.

Hyperventilation: Excessive rate and depth of breathing.

Hypothesis: An idea or theory about research outcomes that has not yet been proven.

Immune system: The body's defense system that protects against infections and foreign substances.

Inclusion criteria: The factors (or reasons) that allow a person to participate in a clinical study.

Indication: A symptom that suggests medical treatment is necessary—a reason to use treatment.

Inflammation: A response in the body that may include swelling and redness.

Informed consent: A process used by researchers to communicate with potential and enrolled participants about a clinical study. As part of the informed consent process, researchers provide all important information about the study so potential participants can decide whether to enroll or continue to participate in the trial. The informed consent ensures that potential participants understand the risks and potential benefits of participating in the study and the alternatives to the research being conducted. Enrolling in, and staying in, a clinical study is completely voluntary. Because giving consent to participate in research is not a contract, participants may leave a study at any time. The goal of the informed consent process is to protect participants. It begins when a potential participant first asks for information about a study and continues throughout the study until it ends. The researcher and potential participant will have discussions that include answering the participant's questions about the research. However, all important information about the study must also be given to the potential participant in a written document that is clear and easy to understand. The informed consent document is reviewed and approved by the institutional review board before the document is given to potential participants. Generally, a person must sign an informed consent document to enroll in a clinical study.

Inhalation: Breathing air into the lungs.

Inhaler: See *metered dose inhaler (MDI)*.

Institutional review board (IRB): A committee of doctors, researchers, professors, and community members that approve, monitor, and review research proposals to protect the rights and welfare of participants.

Intervention: A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either under investigation or already available. Interventions can also include noninvasive approaches, such as surveys, education, and interviews.

Intervention model (design): The general design of the strategy for assigning interventions to participants in a clinical study. Types of intervention models include single group design, parallel design, cross-over design, and factorial design.

Intervention name: The intervention being studied.

Intervention type: The general category of the intervention being studied. Intervention types include drug, device, biological/vaccine, and procedure/surgery, among others.

Interventional study (or clinical trial): A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Investigational new drug: A drug or biological product that is used in a clinical trial but has not been approved by the Food and Drug Administration (FDA). (The drug is either unavailable for prescription or is available but has not been approved by the FDA for the use being studied.)

Investigator: A researcher involved in a clinical study. Related terms include Site Principal Investigator, Site Sub-Investigator, Study Chair, Study Director, and Study Principal Investigator.

Irritants: Things that bother the nose, throat, or airways when they are inhaled (not an allergen).

Leukotriene modifier: A drug that blocks chemicals called leukotrienes in the airways. Leukotrienes occur naturally in the body and cause tightening of airway muscles and production of excess mucus and fluid. By blocking leukotrienes, leukotriene modifiers decrease these reactions.

Masking (or blinding): A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions. Types of masking include single blind masking, and double blind masking.

Medical history: A list of a person's previous illnesses, present conditions, symptoms, medications, and health risk factors.

Metered dose inhaler (MDI): A small aerosol canister that releases a mist of medication. This drug can be breathed into the airways. Many asthma medications are taken using an MDI.

Mold: Parasitic, microscopic fungi with spores that float in the air like pollen. Mold is a common trigger for allergies and can be found in damp areas such as a basement or bathroom, as well as outdoors in grass, leaf piles, hay, mulch, or under mushrooms.

Monitoring: To observe and check the progress of something over a period of time.

Mucus: A material produced by glands in the airways, nose, and sinuses. Mucus cleans and protects certain parts of the body, such as the lungs.

Nasal spray: Medication used to help prevent and treat nasal congestion or nasal allergy symptoms. Available by prescription or over-the-counter in decongestant, corticosteroid, or salt-water solution form.

Naturopathic medicine: Emphasizes natural techniques such as diet and exercise for treating disease rather than drugs or surgery.

Nebulizer: A machine that changes liquid medicine into fine droplets (in aerosol or mist form) that are inhaled through a mouthpiece or mask. Nebulizers can be used to deliver bronchodilator (airway-opening) drugs such as albuterol and Atrovent, as well as anti-inflammatory or steroid medicines (Pulmicort Respules). A nebulizer may be used instead of a metered dose inhaler (MDI). It is powered by a compressed air machine and plugs into an electrical outlet.

Non-steroidal: Anti-inflammatory medication that is not a steroid. See also *steroid*.

Nutritionist: A person who studies nutrition.

Observational study: A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions (as in an interventional study).

Observational study model (design): The general design of the strategy for identifying and following up with participants during observational studies. Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

Open label: Describes a clinical trial in which masking is not used. This means that all parties involved in the trial know which participants have been assigned which interventions.

Other adverse event: An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect. It also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Outcome measure: A planned measurement described in the protocol that is used to determine the effects of interventions on participants in a clinical trial. For observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment. Types of outcome measures include primary outcome measure and secondary outcome measure.

Oxygen: The essential element in the respiration process that sustains life. This colorless, odorless gas makes up about 21% of the air.

Parallel design: A type of intervention model (design). Describes a clinical trial in which two or more groups of participants receive different interventions. For example, a two-arm parallel design involves two groups of participants. During the trial, participants in one group receive drug A "in parallel" to participants in the other group, who receive drug B.

Participant flow: A summary of the progress of participants through each stage of a clinical study, by study group. This includes the number of participants who started, completed, and dropped out of the study.

Patient partners: Members of the research team who also have the condition being studied. They participate in the complete research process, including the proposal and funding, recruitment of participants, implementation of the study, and analysis of the research results.

Peak expiratory flow rate: A test used to measure how fast air can be exhaled from the lungs.

Peak flow meter: A small hand-held device that measures how fast air comes out of the lungs when a person exhales forcefully. This measurement is called a peak expiratory flow (PEF) and is measured in liters per minute (lpm). A person's PEF may drop hours or even days before asthma symptoms are noticeable. Readings from the meter can help the patient recognize early changes that may be signs of worsening asthma. A peak flow meter can also help the patient learn what triggers his or her symptoms and understand what symptoms indicate that emergency care is needed. Peak flow readings also help the doctor decide when to stop or add medications.

Personal best PEF (peak exploratory flow): The highest peak flow number a person can achieve when symptoms are under good control. The personal best PEF is the number to which all other peak flow readings will be compared. In children, peak expiratory flow rates are based on how tall the child is. Therefore, the personal best peak expiratory flow will change as growth occurs. A child's

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personal best peak expiratory flow should be re-determined approximately every 6 months or when a growth spurt has occurred.

Pharmaceutical: Relating to the manufacturing and sale of medicinal drugs.

Phase: Food and Drug Administration (FDA) descriptions of the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants. There are five phases. Phase 0: Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies). Phase 1: Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted. Phase 2: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared to similar participants receiving a different treatment (usually an inactive substance called a placebo or a different drug). Safety continues to be evaluated, and short-term adverse events are studied. Phase 3: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. Phase 4: Studies occurring after FDA has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the study sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

Placebo: A substance that does not contain active ingredients and is made to be physically indistinguishable (looks and tastes identical) from the actual drug being studied.

Pneumonia: An infection of the lungs that can be caused by bacteria, a virus, or fungus.

Pollen: A fine, powdery substance released by plants and trees that is a common trigger of allergies. See also *allergen*.

Pollen and mold counts: A measure of the amount of allergens in the air. The counts are usually reported for mold spores and three types of pollen: grasses, trees, and weeds. The count is reported as grains per cubic meter of air and is translated into a corresponding level (absent, low, medium, or high).

Preventative: Relating to or used for the prevention of a disease, illness, or problem.

Primary outcome measure: The planned outcome measure in the protocol that is the most important for evaluating the effects of an intervention. Most clinical studies have one primary outcome measure, though some may have more.

Primary purpose: The main reason for a clinical trial. Types of primary purposes are treatment, prevention, diagnostic, supportive care, screening, health services research, basic science, and other.

Principal investigator (PI): The person who is responsible for the scientific and technical direction of the entire clinical study.

Productive cough: A "wet" cough that may involve coughing up mucus.

Protocol: The written description of a clinical study that includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Publications: Published scientific articles or abstracts about a clinical study. A publication reference, also called a citation, may be submitted to **ClinicalTrials.gov** at any time.

Puffer: Alternate term for inhaler or metered dose inhaler.

Pulmonary: Relating to the lungs.

Pulmonary function tests (PFTS) (also referred to as lung function tests): A test or series of tests that measure many aspects of lung function and capacity.

Pulse oximetry: A test in which a device that clips on the finger measures the oxygen level in the blood.

Quality of life: The standard of health, comfort, and happiness of a person or group.

Randomized controlled trial: A clinical trial in which participants are randomly assigned to an experimental or control group to compare the intervention being studied to an established standard (the control).

Rescue medication: A medication used for the quick relief of asthma symptoms.

Research objective: Describes what the research is trying to achieve and provides direction for the project.

Respiration: The process of breathing which includes the exchange of gases (oxygen and carbon dioxide) in the blood, the taking in and processing of oxygen, and the delivery of carbon dioxide to the lungs for removal. See also *inhalation* and *exhalation*.

Risk factor: A characteristic that increases a person's chance of developing a disease.

Secondary outcome measure: A planned outcome measure in the protocol that is not as important as the primary outcome measure but is still of interest in evaluating the effect of an intervention. Most clinical studies have more than one secondary outcome measure.

Serious adverse event: An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above.

Single blind masking: A type of masking in which one party involved in the clinical trial—either the investigators or participants—does not know which participants have been assigned which interventions.

Single group design: Describes a clinical trial in which all participants receive the same intervention.

Sinuses: Air pockets inside the bones of the head and face that link to the nose.

Sinusitis: Inflammation of the sinuses resulting in symptoms such as a runny or stuffed nose and facial pain.

Spacer (sometimes called holding chambers): A chamber that is used with a metered dose inhaler to help the medication get into the airways better. Spacers also make metered dose inhalers easier to use.

Spirometry: A basic pulmonary function test that measures how much and how fast air moves out of the lungs.

Sponsor (lead): The sponsor is the organization or person who oversees the clinical study and is responsible for analyzing the study data.

Sponsor-investigator: The person who both initiates and conducts the clinical study.

Sputum: Mucus or phlegm.

Steroid: Medication that reduces swelling and inflammation. Comes in pill, injected, and inhaled forms. Also called corticosteroid.

Study arm: A group of participants in a clinical study who receive the same intervention.

Study design: The investigative methods used in the clinical study. For interventional studies, these include primary purpose, intervention model (design), masking (or blinding), and allocation.

Study record: An entry on **ClinicalTrials.gov** that contains summary protocol information about a clinical study, such as recruitment status, eligibility criteria, contact information, and in some cases, summary results.

Study subject: A research participant that is examined and observed by researchers.

Study type: Describes the nature of a clinical study. Study types include interventional studies (or clinical trials), observational studies, and expanded access.

Supportive care: Patient care focused on the prevention or treatment of symptoms, side effects, and emotional and social issues related to a disease and its treatment.

Symptom: What is experienced as a result of a disease or illness, like pain, cough, or shortness of breath.

Theophylline: A long-term control medication that opens the airways and helps prevent and relieve bronchospasm.

Therapeutic: Relating to or used for the treatment of a disease, illness, or problem.

Time frame, outcome measure: The points in time at which an outcome measure is assessed. These times are planned before the clinical study starts and are listed in the protocol.

Title acronym: The acronym or initials used to identify a clinical study, if provided. For example, the title acronym for the Women's Health Initiative is WHI.

Trachea: The main airway (windpipe) supplying air to both lungs.

Treatment: Medical care given for a disease, illness, or injury.

Triggers: Things that cause asthma symptoms or make them worse.

Vaccine: A shot that protects the body from a specific disease by stimulating the body's own immune system.

Wheezing: The high-pitched whistling sound of air moving through narrowed airways.

Federal Resources and Agencies

Agency for Healthcare Research and Quality (AHRQ) at **https://www.ahrq.gov/**

AHRQ National Quality Measures Clearinghouse at **https://www.qualitymeasures.ahrq.gov/**

AHRQ National Guideline Clearinghouse at **https://www.guideline.gov/**

Centers for Disease Control and Prevention (CDC) at **https://www.cdc.gov/**

Centers for Disease Control and Prevention – National Center for Environmental Health (NCEH) at **https://www.cdc.gov/nceh/default.htm**

Centers for Medicare & Medicaid Services (CMS) at **https://www.cms.gov/**

ClinicalTrials.gov at **https://clinicaltrials.gov/**

Department of Health and Human Services (DHHS) at **https://www.hhs.gov/**

Department of Housing and Urban Development (HUD) at **https://portal.hud.gov/hudportal/HUD**

Environmental Protection Agency (EPA) at **https://www.epa.gov/**

Food and Drug Administration (FDA) at **http://www.fda.gov/**

Health Resources and Services Administration (HRSA) at **https://www.hrsa.gov/index.html**

National Center for Health Statistics (NCHS) at **https://www.cdc.gov/NCHS/**

National Institutes of Health (NIH) at **https://www.nih.gov/**

National Institute of Allergy and Infectious Diseases (NIAID) at **https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-institute-allergy-infectious-diseases-niaid**

National Heart, Lung, and Blood Institute (NHLBI) at **https://www.nhlbi.nih.gov/**

National Library of Medicine (NLM) at **https://www.nlm.nih.gov/**

National Quality Measures Clearinghouse (NQMC) at **https://qualitymeasures.ahrq.gov/**

Occupational Safety and Health Administration (OSHA) at **https://www.osha.gov/**

Patient-Centered Outcomes Research Institute (PCORI) at **http://www.pcori.org/**

Professional Societies

American Academy of Allergy, Asthma & Immunology (AAAAI) at **http://www.aaaai.org/conditions-and-treatments/allergies/food-allergies**

American Academy of Family Physicians (AAFP) at **http://www.aafp.org/home.html**

American Academy of Pediatrics (AAP) at **https://www.aap.org/en-us/Pages/Default.aspx**

American Association for Respiratory Care (AARC) at **http://www.aarc.org/**

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American College of Allergy, Asthma & Immunology (ACAAI) at **http://acaai.org/allergies/types/food-allergy**

American College of Physicians (ACP) at **https://www.acponline.org/**

American Osteopathic Association (AOA) at **http://www.osteopathic.org/Pages/default.aspx**

American Thoracic Society (ATS) at **http://www.thoracic.org/**

Association of Asthma Educators (AAE) at **http://www.asthmaeducators.org/**

National Association of School Nurses (NASN) at **http://www.nasn.org/**

Other Relevant Associations, Organizations, and Coalitions

Alliance for Health Reform at **http://www.allhealth.org/**

American Lung Association (ALA) at **http://www.lung.org/**

American Public Health Association (APHA) at **http://www.apha.org/**

Association of State and Territorial Health Officials (ASTHO) at **http://www.astho.org/**

Asthma and Allergy Foundation of American (AAFA) at **http://www.aafa.org/**

Brookings Institution at **https://www.brookings.edu/**

National Academies of Science, Engineering & Medicine – Health & Medicine Division at **http://www.nationalacademies.org/hmd/**

Health Information and the Law at **http://www.healthinfolaw.org/federal-law**

National Association of County & City Health Officials (NACCHO) at **http://www.naccho.org/**

National Association of State Medicaid Directors (NASMD) at **http://medicaiddirectors.org/**

National Conference of State Legislatures (NCSL) at **http://www.ncsl.org/**

National Governors Association (NGA) at **https://www.nga.org/cms/home.html**

National Health Council (NHC) at **http://www.nationalhealthcouncil.org/**

National Network of Public Health Institutes (NNPHI) at **https://nnphi.org/**

National Quality Forum (NQF) at **http://www.qualityforum.org/Home.aspx**

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Asthma and Allergy
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