I am

the key to finding new treatments for cystic fibrosis.



Cystic Fibrosis Foundation

| Adding *tomorrows* every day.

Help us discover and develop potential new treatments for cystic fibrosis.

Learn

Ask

Join

DEAR FRIENDS,

For more than 50 years, the Cystic Fibrosis Foundation has dedicated itself to advancing cystic fibrosis (CF) research, treatment and care. Since the CF Foundation was established in 1955 by devoted parents who wished to improve the lives of their children, we have made tremendous progress in treating this disease.

You are the key to continuing this progress. People with CF who join clinical trials are among our most important contributors to the CF research effort. You play a critical role in the development of new treatments and the search for a cure.

Clinical trials that test potential new drugs and therapies in people with CF are a major part of CF research. Drugs that are now widely used in the treatment of CF—such as Pulmozyme®, Cayston®, TOBI®, azithromycin and hypertonic saline—would not be available to *all* people with CF if a *small group* of people with CF had not first taken part in clinical trials.

We are now testing more potential drugs in clinical trials than ever before, including new therapies that target the basic defect that causes CF. To help these drugs move swiftly from the research and testing stages into the hands of patients who need them, we need more people with CF to take part in clinical trials. Without volunteers—without people like you—research and progress are not possible.

We invite all people with CF and their families to **learn** more about clinical research, **ask** their doctors and CF care center teams for information about clinical trials and **join** in the effort to develop new treatments by volunteering for clinical trials.

By participating in clinical trials, you help our community continue to move forward so that everyone with CF can live healthier and longer lives.



ROBERT J. BEALL, Ph.D.
President and Chief Executive Officer
Cystic Fibrosis Foundation

Learn

LEARN ABOUT CF CLINICAL TRIALS

The CF Foundation and CF care centers are ready to help people with CF and their families understand clinical trials.

CF care centers are places of support, where the doors to CF treatment and research are open to all. Care centers use the talents of many health experts—including doctors, nurses, researchers, respiratory and physical therapists, dietitians and social workers—to give the best care to people with CF. Ongoing efforts to improve care and develop potential new treatments are always under way.

New drugs to treat CF are available only after they are tested by people with CF in a series of clinical trials. Results from clinical trials must be submitted to the U.S. Food and Drug Administration (FDA) and meet strict standards before a new drug is approved.

PATIENT SAFETY IS THE MOST IMPORTANT ASPECT OF EVERY CF CLINICAL TRIAL.

- Many laws and regulations control the testing of new drugs in clinical trials. These regulations help ensure that clinical trials are as safe as they can be. The FDA must approve the clinical trial design before any new drug is tested in people.
- Each CF care center has an Institutional Review Board (IRB) to protect the rights of people who take part in clinical trials. The IRB must review and approve each trial before it involves any participants.
- All CF Foundation-approved clinical trials are closely reviewed by a Data Safety Monitoring Board (DSMB). This is a neutral, independent group of experts in research, biostatistics, safety and CF care. The role of the DSMB is to protect the safety and welfare of volunteers taking part in CF clinical trials and to make sure trials are done safely and ethically. The DSMB reviews activities before, during and after each trial.

“Participating in clinical trials does involve time, but you give time to what’s important to you. It’s been a wonderful experience.”

NICOLE FAULK, WHOSE 7-YEAR-OLD DAUGHTER CAPRI HAS CF AND IS TAKING PART IN A CLINICAL TRIAL



“I am proud of my role as a participant in clinical trials. Even when a drug does not continue to the next phase of testing, researchers still learn from the clinical trial so that they can make a better drug in the future.”

JOAN, A 50-YEAR-OLD MARKET RESEARCH CONSULTANT WITH CF, WHO HAS BEEN MARRIED FOR MORE THAN 20 YEARS



ASK YOUR CF CARE CENTER TEAM ABOUT CLINICAL TRIALS

Potential new drugs are being tested at care centers all over the United States by people with CF of all ages. Your CF care center is a great source for news about current CF research.

Most CF care centers have a research team in charge of clinical trials. The research doctors (usually called "investigators") and research coordinators can provide you with information about current clinical trials and answer all your questions.

The research team asks people with CF to join clinical trials and work closely with them throughout the clinical trial process. Be sure to ask your doctor, nurse or a research team member to keep you informed—new trials are always being added.

You can find more information on the CF Foundation website, www.cff.org, including an online search tool to help you find CF clinical trials in your area. The tool allows you to narrow your search—for example, by age, lung function or type of therapy—and provides information on specific clinical trials that you can then discuss with your CF care team.

TO FIND A CLINICAL TRIAL:

- Visit **www.cff.org/Find**.
- Call the CF Foundation's toll-free Clinical Trials Hotline, **1-877-823-5646** (1-877-8CF-JOIN).

Ask

Join

JOIN THE SEARCH FOR NEW TREATMENTS AND A POTENTIAL CURE

Today, there are more opportunities than ever before to join clinical trials that test potential new antibiotics, enzymes and other drugs that could improve the lives of people with CF.

Because CF affects a relatively small group of people, those with CF cannot simply count on "someone else" signing up to test much-needed potential CF drugs. We hope that everyone will consider taking part in clinical trials to help find new and better treatments for CF.

After you've learned more about CF clinical trials, you will work with the team at your CF care center to explore trials you might consider joining. Not every trial will be right for you. Your team will help you find out if you or your child is eligible to participate in a specific trial. The team will also explain the potential benefits and risks of each clinical trial and what you will need to do to join a trial.

JOINING A CLINICAL TRIAL IS A PERSONAL DECISION. YOUR RIGHTS AS A PARTICIPANT WILL BE RESPECTED.

- Taking part in CF research is always your choice. Choosing not to participate will not affect the routine care you receive at your CF care center.
- You will be given full details about the possible benefits and risks of joining any CF clinical trial. You can ask as many questions as you want before you make a decision.
- You must give your informed consent before enrolling in a trial.
- If you are a parent, you must give your consent for your child to participate.
- Your identity and medical information will be kept private, in keeping with the law.
- You can stop taking part in a clinical trial at any time, for any reason.

“I’ve been involved in CF clinical trials literally from the week I was diagnosed as a child. Since turning 18, it’s been my decision whether to join trials. As I see it, ‘If not me, who?’”

BRIAN, 22, COLLEGE STUDENT AND CLINICAL TRIALS VOLUNTEER



"There are many promising new drug therapies for cystic fibrosis currently in development. Any one of these—or a combination—could have a profound impact on the lives of those with cystic fibrosis. You are the key to helping us discover and develop potential new treatments for CF. Together we are adding tomorrows every day."

ROBERT J. BEALL, Ph.D.
President and Chief Executive Officer
Cystic Fibrosis Foundation



TO LEARN ABOUT PARTICIPATING IN A CLINICAL TRIAL:

- Visit **www.cff.org/Find**.
- Call the CF Foundation's Clinical Trials Hotline, **1-877-823-5646** (1-877-8CF-JOIN).

THE FOLLOWING WEBSITES OFFER GENERAL INFORMATION ABOUT CLINICAL TRIALS:

- The CF Foundation: **www.cff.org/research**
- The National Institutes of Health (NIH): **www.clinicaltrials.gov** and **www.nhlbi.nih.gov/childrenandclinicalstudies**
- The Food and Drug Administration: **www.fda.gov/oashi/clinicaltrials**

My Care Center Contacts

Cystic Fibrosis Foundation

Adding *tomorrows* every day.

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CYSTIC FIBROSIS FOUNDATION
APPROVED BY THE EDUCATION COMMITTEE

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