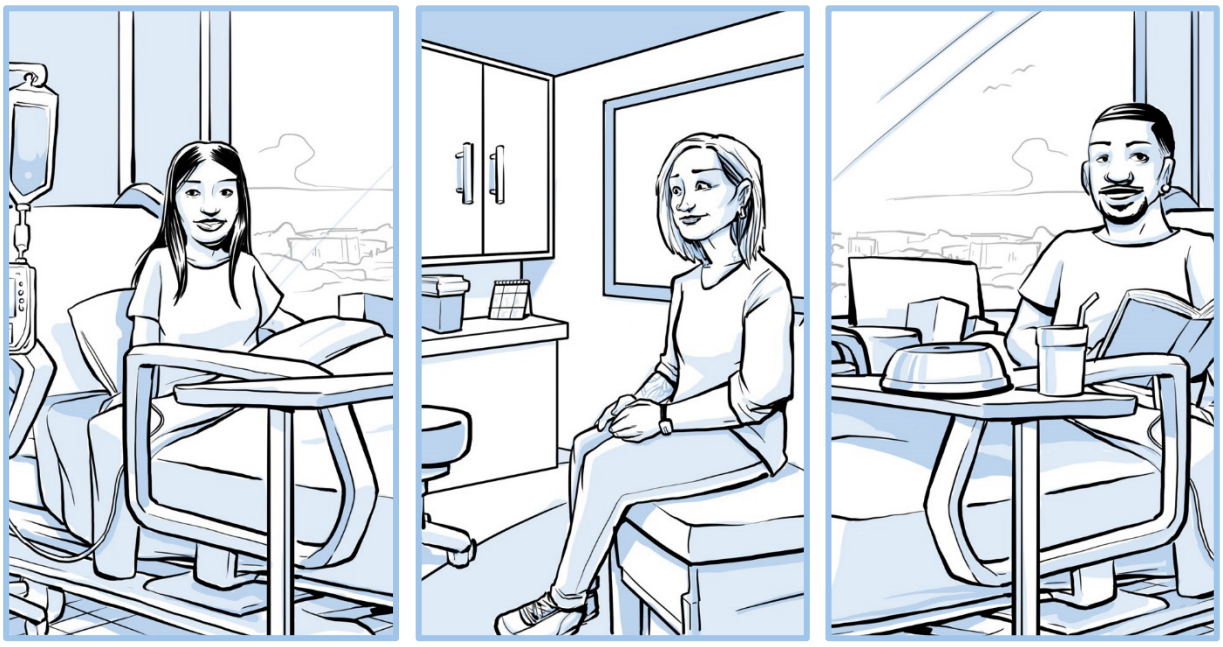


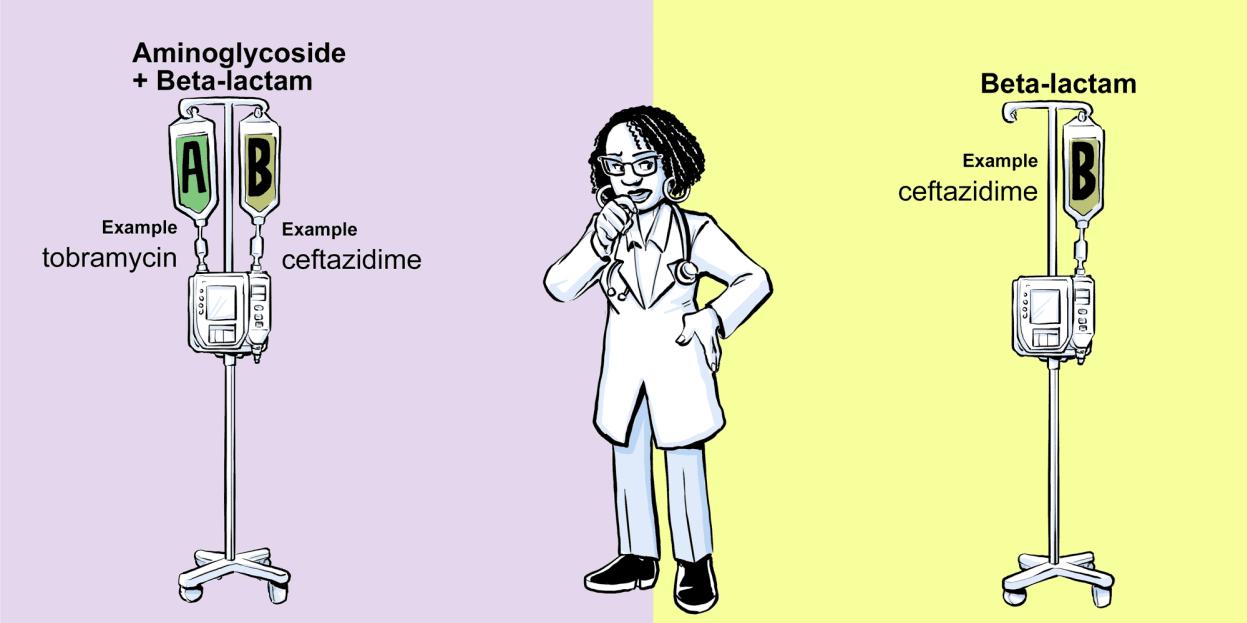
The STOP360 Research Study

This study is about treatments for pulmonary exacerbations.

You are invited to join the study.

Reviewing this document can help you decide if you want to say yes or no.

Scan code to view this information online at envisionconsent.org/stop360



This study

We want to improve how we treat pulmonary exacerbations from Pseudomonas.

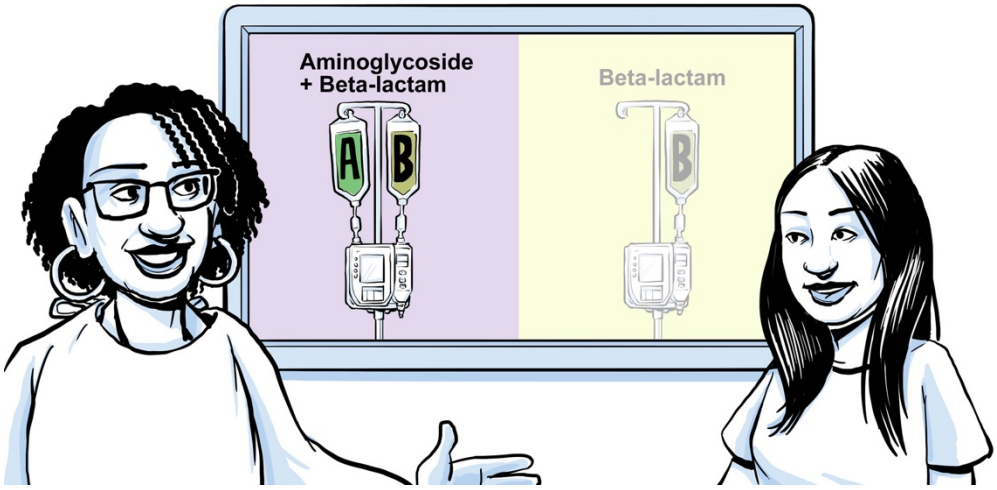
Doctors usually treat this with two antibiotics together:

1. Aminoglycosides, such as tobramycin, are a type of antibiotic that may cause kidney injury, hearing loss, or balance issues.
2. Beta-lactams, such as ceftazidime, are a different type of antibiotic that do not cause these specific problems.

Now the cystic fibrosis community wants to know:

- Can beta-lactams alone treat the exacerbation without the added risks of aminoglycosides?

We are doing this research study to answer that question.



Study treatment

If you join the study, you will get one or two IV (intravenous) antibiotics to treat your exacerbation.

A computer will randomly assign half of the people in the study to get two antibiotics and half of the people to get one antibiotic.

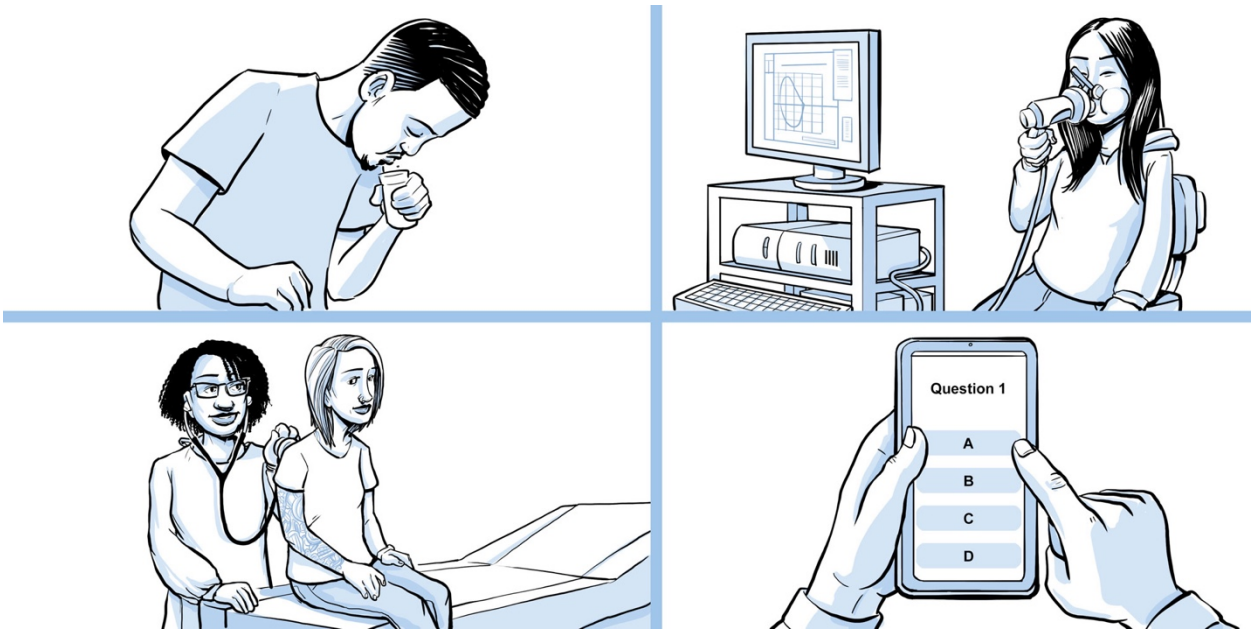
You will have a 50/50 chance of getting either:

2 Antibiotics Beta-lactam + Aminoglycoside *example: ceftazidime + tobramycin*	or	**1 Antibiotic** Beta-lactam *example: ceftazidime*

Both treatments will be done the same way:

- You will get the antibiotics for about 14 days.
- Your IV treatment can be done in the hospital or at home. You and your care team will know which treatment you are getting.
- You will be asked not to take oral or inhaled antibiotics that work against Pseudomonas from your first visit until your second visit in about four weeks. This includes ciprofloxacin and tobramycin, such as TOBI.

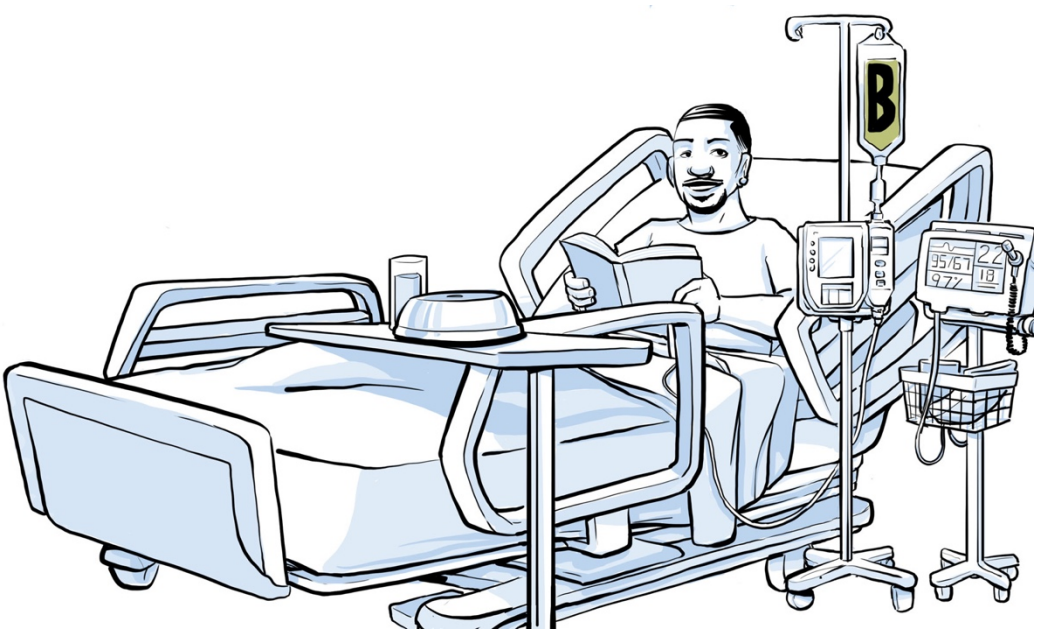
If you do not join the study, your care team will work with you to decide which antibiotics to use. Doctors usually treat pulmonary exacerbations with a beta-lactam and an aminoglycoside together for about 14 days.



Study activities

This study will take about six hours of your time over six weeks.

- There will be a second in-person visit in four weeks.
- You will get extra medical tests and answer questions about your health.
- You will get paid up to $202.50 for your time and effort.



Benefits and risks

Medication

It is possible that a beta-lactam alone can treat your pulmonary exacerbation without the side effects that come with an aminoglycoside. But if you only get a beta-lactam, your exacerbation might not improve as much as if you got both a beta-lactam and an aminoglycoside.

Medical tests

There can be discomfort from some of the medical tests, such as the pulmonary function test and sputum collection. These discomforts are the same as when you do these tests at your regular CF clinic visits.



Your decision

How do you decide if this study is right for you?

Some people join the study, and some people don't. People can have reasons for both wanting to join and not wanting to join.

Here are a few things that people sometimes think about:

Someone might want to join if they:

- Want to contribute to CF research.
- Want to help the CF community learn about antibiotic use for exacerbations.
- Are comfortable with the risks of this study.

Someone might not want to join if they:

- Do not have time for extra study visits and questions.
- Prefer to choose their antibiotic treatment with their care team.
- Are uncomfortable with the risks of this study.

No matter what you choose, your CF team will support your decision. You can talk more with the research team to make a decision that is right for you.

If you decide to join, you can stop being in the study at any time for any reason and your CF team will support your decision. If we learn new information that could change your decision, we will share this with you.

Now, you have the basic information. To help decide if you want to say yes or no, you can:

Ask questions.
The research team can help you decide.

Talk to people you trust.
Family, friends, or your care team can help you decide.

Learn more.
The detailed information can help you decide.

Schedule

The study will take about six hours of your time over six weeks.

This includes two in-person visits and one phone call.

Start

Visit 1 2 – 3 hours

- Medical and personal information
- Health questions
- Physical exam
- Pulmonary function test
- Sputum collection
- Urine collection
- Pregnancy test (if applicable)

Randomization

The computer will randomly assign you to get one or two antibiotics.

Treatment

You will start IV antibiotic treatment. You will continue treatment for about 14 days.

Week 1

Health questions 10 minutes

You will answer questions on a phone or tablet.

Treatment

You will continue IV antibiotic treatment.

Week 2

Health questions 10 minutes

You will answer questions on a phone or tablet.

Treatment

After about 14 days, you will stop IV antibiotic treatment.

Week 3

No study activity

Week 4

Visit 2 1 – 2 hours

- Health questions
- Physical exam
- Pulmonary function test
- Sputum collection
- Urine collection

Week 5

No study activity

Week 6

Phone call 30 – 60 minutes

You will have a follow-up phone call.

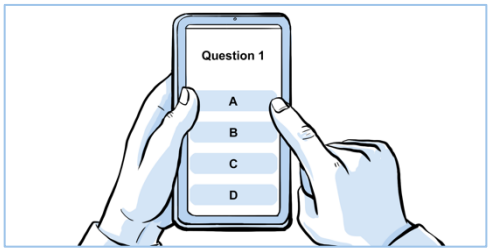
Health questions 10 minutes

You will answer questions on a phone or tablet.

Study activity details

These tests and procedures help us learn if one antibiotic works just as well as two antibiotics.

Medical and personal information
We will review your medical chart and collect information from you, such as your sex at birth, date of birth, and race. We will also ask about your medical history including illnesses and medications. If blood tests are done as part of your clinical care, we will record the results from those tests.



Health questions
You will be asked questions about your health, life, hearing, and balance.

During in-person visits, you will answer questions on a paper form.

On weeks 1, 2, and 6, you will answer questions using an app that you download on your own phone or tablet.

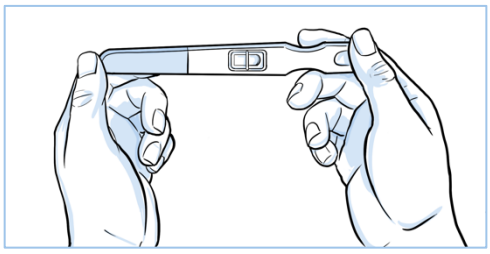
- The questionnaire app is made by the company Medidata.
- The app will require you to enter your name, email address, and phone number, and to agree to its terms of use.
- You will receive text message reminders to complete the question forms.
- If you do not want to or cannot download the app, you can still be in the study.

Physical exam
You will have a physical exam, including height and weight.

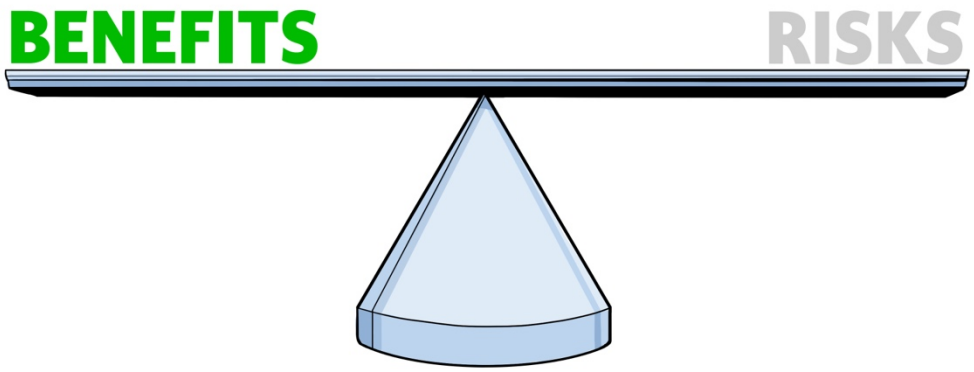
Pulmonary function test
If it has been more than three days since your last test, your lung function will be measured. You may be asked to take a bronchodilator, such as albuterol, before doing the pulmonary function test. Your results will be shared with you and your care team.

Sputum collection
If you can cough up sputum, a sample will be collected and stored for future research.

Urine collection
We will collect and store a urine sample for this study and future research.



Pregnancy test
Anyone who can potentially become pregnant will have a pregnancy test at the first study visit. The test must be negative because the treatment options may not be appropriate during pregnancy. Your results will be shared with you and your care team.

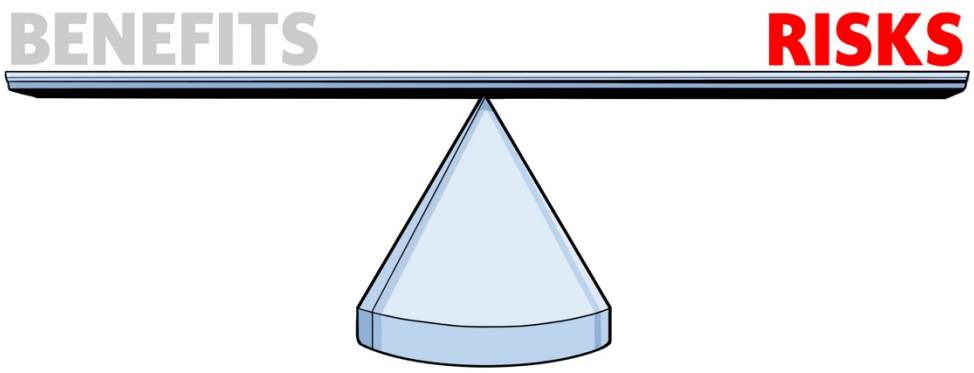


Benefits

Potential benefits for you
The standard treatment for exacerbations is two antibiotics (beta-lactam and aminoglycoside). In this study, you might get a beta-lactam alone. This may treat your exacerbation without exposure to the risks of an aminoglycoside.

Potential benefits for others
Learning which antibiotic approach is best for outcomes and risks may benefit people with CF in the future.

About 730 people with CF will take part in this study at approximately 70 hospitals and clinics around the United States, Canada, and Europe. Once the study is completed, we will let you know how to get a summary of the results.



Risks

Main risk

The main risk in this study is that if you get a beta-lactam alone, you may not improve as much as if you get both antibiotics.

- You and your care team will know which IV antibiotics you are getting. Your care team will be monitoring your progress while you are on the antibiotics. They can make changes to your care if necessary.
- The CFF Data and Safety Monitoring Board will be following along as the study is being conducted to monitor safety.

Antibiotics

Both types can cause an allergic reaction, including a severe allergic reaction with swelling in the throat or difficulty breathing. Both types also have their own specific risks.

Antibiotics	Associated risks
Aminoglycosides Example: tobramycin	The risks include kidney injury, hearing loss, ringing in the ears, balance problems, and, rarely, muscle weakness. These problems may develop gradually after repeated use but can be permanent and are sometimes severe.
Beta-lactams Example: ceftazidime	The risks are temporary and include abdominal pain, diarrhea, nausea and vomiting, decreased white blood cells, decreased platelets, and skin rashes.

Study activities
Many of the study activities are the same as those done at standard clinic visits and have the same minimal risks.

Study activities	Associated risks
Sputum collection	Coughing up sputum may cause temporary shortness of breath.
Pulmonary function test	Pulmonary function testing can cause temporary wheezing, shortness of breath, and lightheadedness.
Health questions	Sometimes people may feel uncomfortable answering certain questions. If this happens, please talk to the research team about why that question is being asked. If you are still uncomfortable, you do not have to answer the question.
Medidata app	To complete the questions, you will need to download an app that will take up space on your phone. Medidata is a separate company from our research team and makes the app. Information about how Medidata uses your information is found in their terms of use. There could be privacy risks associated with using the app. Read Medidata's privacy notice if you'd like to learn more.
Sharing personal information	There is a small chance that someone could access your study data, including your personal information or online responses, without permission.

This study may also have unknown risks.

Withdrawal from study

- You can stop being in the study at any time for any reason.
- You could also need to be removed from the study for unexpected reasons.

Payment and costs

Payment
You will be paid up to $202.50 for the time and effort it takes to complete study visits and question forms. We will give you separate information about how you will be paid.

You will be paid after each completed activity as follows:

Enrollment Visit	$90
Week 4 Visit	$60
Week 6 Phone Call	$30
Completion of electronic question forms (up to 3 total)	$7.50 each (up to $22.50)

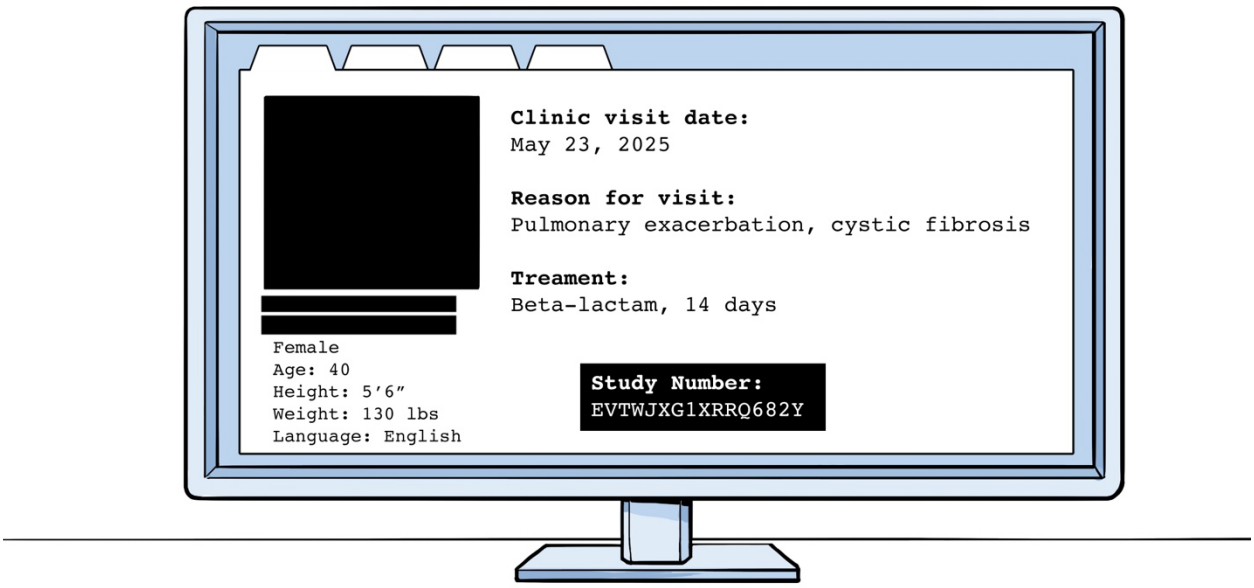
If you agree to join the study, but are found to be ineligible, you will be paid $30.

Payment considerations

- The payments from this study may be taxable. Study sites are required to report to the IRS payments totaling $600 or more made to anyone in any one year. Reimbursements such as parking, mileage, or childcare do not count towards the $600 limit and will not be taxed as income.
- If you are receiving supplemental security income (SSI), Medicaid, or Medicare, you can receive up to $2,000 per calendar year as payment for study participation without affecting your eligibility for these benefits. Please ask your research team for details and let your research team know if you have any questions or concerns about this.

Costs

- Your study-related expenses such as parking, mileage (at the current federal business mileage rate), meals, or childcare for visits that are not part of your standard CF care will also be reimbursed if you provide receipts or documentation.
- Standard phone data rates may apply for using the Medidata app.
- You will not be billed for procedures done only for research.
- Your insurance company will be billed for your usual medical care including antibiotics and related tests.



Privacy

Protecting your privacy

We will label your information with a study number. The list that links a person's name to their study number will be stored separately. We will store all your research records on secure computers. We will not use information that identifies you if this research is published.

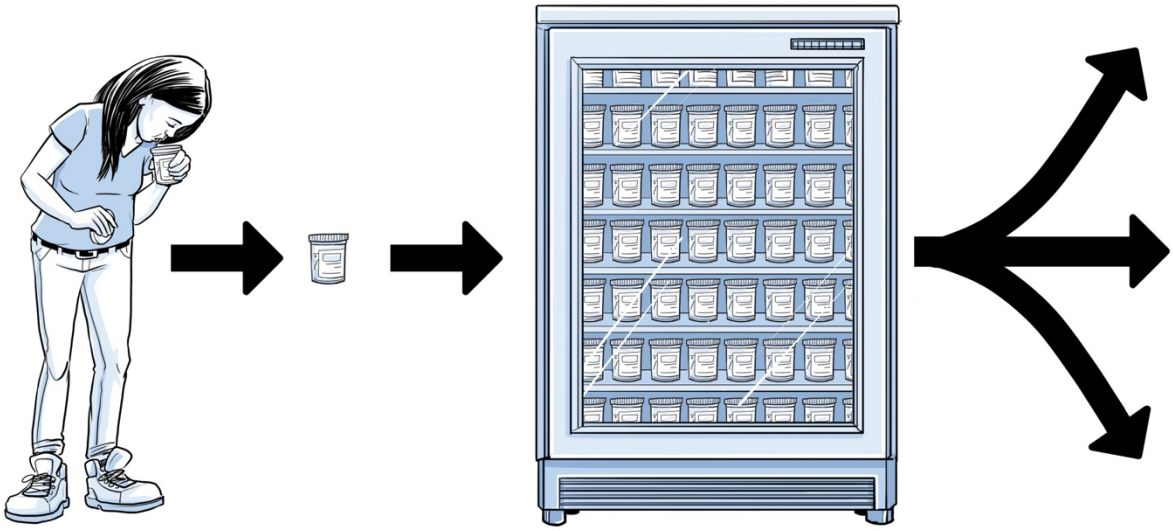
Clinical data

Clinical data collected about you during the study will be included in your medical record because the research involves your care.

Medidata app

The Medidata app will collect your name, email address, and mobile phone number but will not share your personal information. The only data shared with the research team are your responses to the questions. Data entered into the app is encrypted.

There are some reasons why we may be required to share the information you give us with others. The most common reason for this is to make sure the research is done safely and legally. This is explained more in the Health Insurance Portability and Accountability Act (HIPAA) authorization.



Future research

Your data and samples will be stored.
We may share your data and samples (urine and sputum) with other researchers for future CF research.

- Your data will be stored on secure servers at Seattle Children's Hospital. We will keep your data indefinitely.
- Your samples (urine and sputum) will be stored in the Cystic Fibrosis Foundation (CFF) specimen bank. We will keep your samples indefinitely or until they are used up.

Your data and samples can be shared.

- This information will be coded so future researchers will not be able to identify you.
- This will only be shared with researchers who have approval from their Institutional Review Board (IRB) and the CFF.
- For-profit companies will need the same approval before any data or samples will be given to them.
- You will not be told that your data or samples are used for future research, and you will not be given individual results.

- If any new therapies, products, or procedures are developed from your data or samples, you would not receive any money.
- Results from research studies using your data or samples may be published in medical journals or presented at scientific meetings, but your name and other identifying information will not be used.

CFF Patient Registry data
You previously enrolled in the CFF Patient Registry, a database that contains information about the clinical care of people with CF (such as hospitalizations and medications).

- We will use your CFF Registry identification number (ID) to link your clinical care information in the registry (past, present, and future) to your stored samples and data from this research study.
- Your CFF Registry ID may also be used to link data from this study with other studies that you enroll in.

What if you change your mind about sharing your data or your samples?

If you change your mind during the study, please tell the research team. If you change your mind after the study is over, you may contact the CFF at biorepository@cff.org. Your data and samples will no longer be shared but what has already been shared with researchers may continue to be used.

Contact

Problems and questions
Please contact the research team if you think you are injured as the direct result of this study or experience any medical problems, or if you have questions, concerns, or complaints about the study.

- The study site will provide treatment or refer you for treatment if needed.
- Your insurance company would be billed for the treatment.
- The study site makes no commitment to provide free medical care or other compensation for injury from your participation in this study. But you will not lose any of your legal rights or release anyone involved in the study from responsibility for mistakes.

Emergencies and hospitalization
If you seek emergency care or go to the hospital, you should tell the doctor there that you are in this research study.

The Advarra Institutional Review Board (IRB) has reviewed this study.
If you have any questions about your rights as a research participant, contact the IRB using the information below. Please reference Pro00064313 when contacting the Study Subject Adviser.

Mail Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044

Phone 877-992-4724

Email adviser@advarra.com

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

If you have more questions, talk with your research team.

Glossary

Term	Definition
Bronchodilator	An inhaled medicine that relaxes the airways in the lungs to improve breathing.
Cystic Fibrosis Foundation	A non-profit organization that sets the standards for care of people with CF and provides funding for research and improvement of CF care.
Data and Safety Monitoring Board	A group of people, including community members, who review an ongoing study to determine if it is safe to continue the study.
Encrypted	Information converted into a code that protects it from being read by someone who does not have permission.
Institutional Review Board	A group of people who determine if a research study protects the rights and well-being of study participants. Participants cannot be enrolled until the IRB approves the study.
Intravenous	Giving medications into a vein (commonly the arm) through a small plastic tube that is inserted using a needle.
Pseudomonas	Bacteria found in the lungs of some people with CF that can cause pulmonary exacerbations.
Pulmonary exacerbation	Worsening respiratory symptoms, such as cough, sputum production, and/or decrease in PFT results.
Randomly	By chance. Like the flip of a coin.
Sputum	Mucus or phlegm in the lungs that can be coughed up.