

# The Leaflet

## Folia Health



### About the Leaflet

Learn more about the ins and outs of Folia and all of its offerings. Each issue will also include a medical digest and a profile of a current Folia user.



### New this month: Canopy Series

This season, we are all about research! We put together the questions you have been asking and created a really cool opportunity to contribute to research which will enhance your knowledge.

Social Media



@foliahealth



## Introducing: Peter



This quarter, we are excited to introduce Peter, our Director of Engineering. Peter currently lives in Texas with his girlfriend, Mari, and during the workday, codes and takes meetings with the company of his dog, Julie.

Peter was an original member of the Folia team, and joined because he believes in Folia's positive mission. His favorite part of his job is the interesting challenges that arise with the engineering aspect of Folia's platform. He enjoys working with the team because he knows everyone is doing something different, but they bring their skills to the table to contribute together. If he could do any other job at Folia, he would take on the role of Data Analysis.



Outside of the office, Peter enjoys running and going on hikes. An average Saturday for Peter typically involves a run with Mari, and a fun dinner somewhere in his new town. His favorite TV shows are Curb Your Enthusiasm and the Great British Baking Show.

# This Quarter's Latest News

Little insights into whats been happening at Folia!

## Canopy Series

This season, we have been all about asking questions.

Specifically, asked you what questions you have! We compiled the results from the surveys that have been completed, and came up with general questions that can be answered by tracking your health.

At the end of Canopy Series, you will receive a report that answers these questions and shows how other people are utilizing Folia to track their symptoms and treatments. Are you curious how other individuals with your condition are managing their treatment options? This is the type of question that we aim to answer through this research series.

If you are on a diagnostic odyssey and don't yet have a diagnosis, don't worry! We will provide you an opportunity soon to have your questions answered.

## Sjögren's Awareness Month

April is Sjögren's Syndrome awareness month. We have such a wonderful community of individuals with Sjögren's, and we will be sharing their stories on our blog all month.

If you have a story you would like to share, we would love to feature you. You can have any diagnosis, be a caregiver, or be on a diagnostic odyssey - we love learning from everyone.

# Community Spotlight

The things they don't tell you about participating in a clinical trial.

What if you grew up knowing you wouldn't live to 50? How would you make a decision to join a clinical trial to potentially elongate your life? These thoughts and decisions aren't foreign to individuals with Cystic Fibrosis.

In 2017, researchers stated that the median predicted survival age for individuals born between the years of 1993 and 1997 with Cystic Fibrosis would live to 31 years old.

## Jennifer's Story

Jennifer was diagnosed with CF at age 37, and was born in 1965. To say she is defying the odds is an understatement.

When Jennifer was born a mere 58 years ago, they didn't know about her genetic mutation of CF. In fact, doctors and researchers didn't know CF could be a product of a genetic mutation. Over the course of her first 37 years, Jennifer experienced various symptoms, but no one was able to put them together and recognize a root cause of her experiences.

At the age of 11, she had scoliosis surgery - a Harrington rod was placed in her back to fix the curvature of her spine. Nowadays, doctors are understanding a link between scoliosis and CF. After her surgery, she started experiencing pancreatic issues. Her doctor thought he fused a nerve to the pancreas during her

scoliosis surgery. To address this issue, she was put on a diet to help manage pancreatic insufficiency. This is another telltale sign of CF - yet it would be many years before a pulmonologist put the pieces together and recognized she has CF.

Jennifer's clinical trial journey hasn't always been positive, yet she continues to advocate for their participation. With one trial treatment, she became diabetic. With another, she experienced a severe infection. Yet, she continues to partake in whatever she can, and she has fun while doing it. During one trial, she was inpatient at the hospital on the cardiac floor. She created a walking club for any patient on the floor who needed to walk the halls.

Most recently, Jennifer has been exploring clinical trials for Colonoscopies. Recent research suggests "The risk for colorectal cancer in adults with cystic fibrosis is 5–10 times greater than the general population, and even higher for people with CF who receive a lung or other solid organ transplant". However, getting a colonoscopy is no easy feat for patients with CF. It involves a 5 day prep period, and last time Jennifer did this, her experience was less than optimal.



And so, Jennifer continues to contribute to research by participating in any and every study she can qualify for. Here is advice Jennifer has for anyone considering participating in a trial:

This is your opportunity to better the experience for the next generation.

You will learn something new every time you participate in something new, and this is priceless.

Sometimes it is hard to not know exactly how you are contributing to the study, but that's okay! If you are okay with not knowing, then you won't be disappointed.

Be open to doing whatever they need you to do. If they need to take labs, be okay with that.

Being part of a trial is so life changing because you are doing something to leave your little mark on the planet. It may not feel like it, but you are.



## DeAnna's Story

DeAnna was diagnosed with CF at 6 months, when she was classified as “failure to thrive”. She went through the motions of having CF for the first 22 years of her life without a hitch. Then, the hospitalizations began. They started happening yearly, and then every few months, as her lung function deteriorated. As a mom to young children, her lung function plummeted to 32%. She was evaluated for a lung transplant, but decided against it.

Her last ditch effort to save her lung function before having a lung transplant as the only option was to join a clinical trial for the Tobi Podhaler. Thus began her almost 20 year journey participating in various clinical trials. Since enrolling in her first trial, DeAnna’s lung function has increased from 32% to 58%.

When DeAnna joined her first trial, she wasn’t expecting much of anything out of it. She was simply going through the motions because she was so sick. She needed accountability, and the trial provided that, as well as additional care. She didn’t necessarily believe in what she was doing, but soon she found herself becoming increasingly invested. The care coordinator helped her to build relationships with a network of providers, and this is what it’s all about.

Now that DeAnna has participated in a variety of trials, her thoughts have changed. She believes that without clinical trials, she wouldn’t be here today.

Here is DeAnna's advice for anyone who is considering participating in a clinical trial:

Do it. For yourself - see what is out there, what might work for you. Do it for others - help your fellow person who cannot be in a trial.

This is how drugs come to market. Not only will you be able to help in that sense, but you will also garner connections and a community at local centers.

There is no downside to joining other than time invested in the study. Realistically, you can always quit, but you are going to get a more accurate understanding of where you are in the scheme of your condition. You will also get better care because you have more eyes on you.

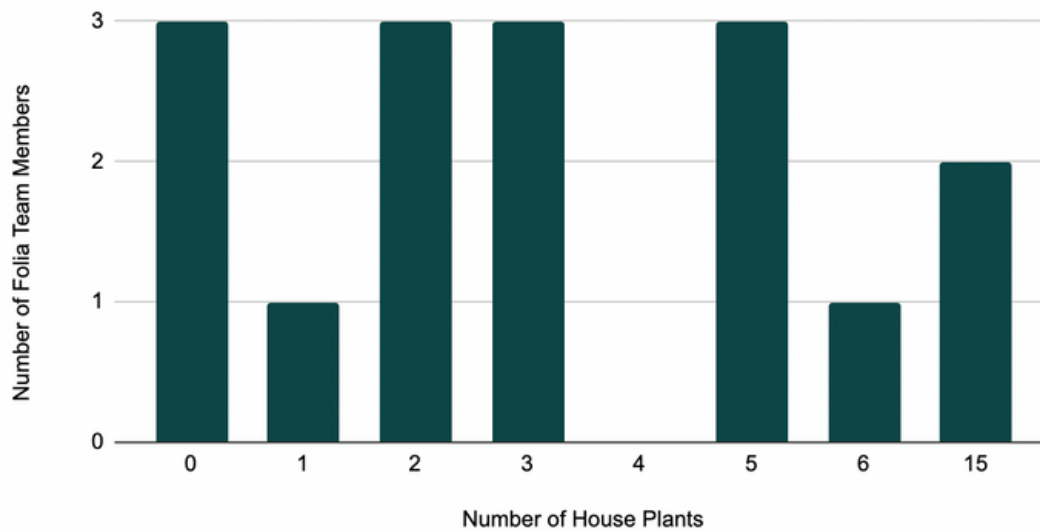
If anything, she wishes she could go shout it to the world. Join a trial and contribute to research!





# Folia Fun: Who has the biggest green thumb?

How many house plants does each member of the Folia team have?



## Individual winners:

Most house plants



Paula

Paula (15+) and Hiba (too many to count)



Hiba

Least house plants



Bella

Bella and Carlos (0)



Carlos

It runs in the family!

Liz's kids have a herbs, cacti, and wildflowers.



Liz

# What Is A Clinical Trial?

## Understanding the current clinical trial landscape

As of April 6, 2023, there were a total of 447,979 registered clinical trials occurring around the world (1). Since 2000, the number of registered studies has increased exponentially, and as science and technology continue to develop, the sky's the limit.

But what does it mean to join a clinical trial? Will you suddenly become a lab rat? We are here to help break it down, so you can better understand what it might be like to participate in a clinical trial.



## Development of a treatment in the USA

The drug development process is long and drawn out, and is built in a way to keep humans safe. Step 1 of developing a treatment is **Discovery and Development**. Scientists will start researching everything they can about this new treatment in a laboratory. They test molecular compounds, explore new technologies, and draw insights into whatever they are discovering and trying to treat. Then, they reach Step 2, **Preclinical Research**. This is when a treatment undergoes laboratory and animal testing, so scientists can get a basic understanding of safety of the treatment. Once the treatment passes this step, it moves on to Step 3: **Clinical research**. This is the step we will be focusing on, as humans are introduced to the treatment. After a period of clinical research, the treatment goes

through Step 4 - FDA review - where the FDA reviews all of the data from the trials, and decides whether to approve or deny the treatment. If approved, the treatment will move to Step 5 - FDA Post Market Safety Monitoring. The FDA will continue to monitor the safety of the treatment once it is on the market and available to the public (2).

## What does this phase mean?

Say you are eligible to participate in a phase 2 clinical trial. This sounds exciting, but what does it actually mean? Each phase of a clinical trial is designed to uncover as much about the treatment/drug as possible, in as wide of a variety of individuals as possible.



A **Phase 1 Clinical trial** has about 20-100 individuals with the targeted condition. On average, the study lasts several months, and the main objective is to understand the safety and dosage of the treatment. If a treatment passes phase 1 - 70% of treatments do - then it moves on to Phase 2. A **Phase 2** study will have up to several hundred people with the condition, and the study will last anywhere from several months to two years. The goal of this phase is to understand the efficacy and side effects. About 33% of treatments pass phase 2 and move on to phase 3.

A **Phase 3** study has between 300 to 3,000 volunteer participants with the condition. The study will take about 1 - 4 years, and the purpose of this phase is to understand the efficacy of the

treatment, and to monitor adverse/bad reactions. About 25-30% of treatments make it to **Phase 4**, and the population is expanded to several thousand individuals. The focus remains on the safety and efficacy of the treatment. Once all of the clinical trial steps are complete, the data is compiled and sent to the FDA for review (3).

### Decentralized trials?

You might be familiar with the term “decentralized trials”. A fully decentralized trial is one where all procedures are done at home. A fully centralized trial is one where everything is done at the research site. Anything between these two opposites is considered a hybrid trial (4). Some drug companies might team up with an app (such as Folia!) to help them design a fully decentralized or hybrid trial. When considering participating in a clinical trial, this will be a major consideration, as centralized clinical trials require travel to and from the trial site.



# Folia Logo Contest!

In the last few months, we have been modifying the logo for each season. Whether it is adding a snowman for winter, or a flower for spring, we are enjoying seeing the variations of our Folia sprout.

This spring, our logo was created Dan's son, Aiden. We loved his creativity so much that we want to hold a Folia logo contest.

You can decorate our logo and submit your art for a chance to win \$100.

Please go to our website at [www.foliahealth.com/logocontest](http://www.foliahealth.com/logocontest) to learn more.



Folia Community - you are wonderful, and we love hearing from you!

If you have any feedback, ideas for future stories, or want to be featured in a future edition of The Leaflet, please do not hesitate to reach out!

You can contact us via email - [info@foliahealth.com](mailto:info@foliahealth.com), on intercom, or through social media - [@foliahealth](https://www.instagram.com/foliahealth) on all platforms.