

It's about

TIME.



DEAR FRIENDS,

We are pleased to share this second Pulmonary Fibrosis Foundation (PFF) Registry Annual Report, which highlights recent progress in pulmonary fibrosis research using Registry data. As we continue enrollment and enhance the Registry, we are eager to inform the community of our plans.

Last fall, we announced PRECISIONS, a groundbreaking clinical trial that will use clinical data and blood samples from the Registry. Now getting underway, PRECISIONS marks the first time a pharmacogenomic approach has been used in an IPF clinical research trial.

We recently joined forces with Bristol Myers Squibb and several industry partners to form the PROLIFIC Consortium, a new collaboration to develop tests to identify important biomarkers in patients with pulmonary fibrosis. Researchers will use samples from the Registry's biorepository.

The PFF continues to share Registry data at no cost to academic investigators. To date, 38 research projects, including eight using blood samples, have been approved. Without the Registry, these studies would have required tens of millions of dollars in funding.

Under the new, more inclusive name Pulmonary Fibrosis Foundation Registry, we will reopen enrollment this year. We will also add an online direct-to-community feature so that a broader group of people can submit their data.

For the first time, we will hear not just from current patients but also from caregivers, family members, and those patients who have received a lung transplant. Participants in all categories will be able to engage with the Registry remotely, an important feature during this time of COVID-19, when many medical studies are on hold.

As we prepare to cross this new frontier of pulmonary fibrosis research, we invite you to join us in supporting this priceless asset to our community. A financial gift to the Registry will help to ensure its continuation and expansion. Thank you for your commitment to helping us unlock new treatments and a cure for pulmonary fibrosis.



George Eliades, PhD
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It's about **FINDING A CURE.**

Pulmonary fibrosis (PF) is a complex group of more than 200 debilitating lung diseases. Even though over 200,000 Americans currently live with PF, doctors are still learning a great deal about this disease, including the best ways to diagnose and treat it. There is currently no cure.

In PF, scar tissue builds up in the walls of the lungs' air sacs. When the scarring becomes severe, the lungs struggle to bring life-sustaining oxygen to the bloodstream. Breathing becomes a constant challenge. For all too many people with PF, premature death is the result.

PF symptoms include coughing, shortness of breath, and fatigue. These symptoms are often mistaken for asthma, chronic obstructive pulmonary disease (COPD), or even the natural results of aging. Making a prompt and accurate diagnosis is challenging, because PF symptoms are not specific to the disease. Early treatment can delay and lessen symptoms, and some clinical trials have shown that current therapies can extend patients' lives.

The majority of people with PF have idiopathic pulmonary fibrosis (IPF), which means that no cause can be identified. In other cases, the

cause can be linked to certain medications, radiation therapy, autoimmune diseases, or environmental or occupational exposures.

WHAT IS THE PFF REGISTRY?

The PFF Registry is an important observational research tool. That means we record patients' experiences with pulmonary fibrosis during both routine and emergency treatment to learn all we can about the disease. The Registry is the first nationwide research study and biorepository that lets researchers explore what treatment strategies work best for patients and to find new ways to diagnose, treat, and potentially cure PF.

By collecting participating patients' data, blood samples and high-resolution CT scans over time, we will increase our understanding of what a typical disease course might be in PF. Researchers also use the Registry to study diagnostic and predictive biomarkers. Doctors will be able to use this information to improve PF treatment and patients' quality of life. Observational research like the Registry complements interventional research. Clinical trials, a type of interventional research, are needed to directly compare one treatment to another.

PFF BY THE NUMBERS

1 in 200

OVER AGE 70 ARE
LIVING WITH IPF

50,000

NEW CASES OF PF PER
YEAR IN THE U.S.



“

My outlook started to change when I found the Pulmonary Fibrosis Foundation website. At last I had hope. I learned that not everyone dies in 3-5 years and in fact some people live significantly longer.

”

Sandy Gallagher

Idiopathic Pulmonary Fibrosis Patient
PFF Registry Participant

SANDY GALLAGHER: TAKING TIME FOR HERSELF

Sandy Gallagher of Charlottesville, Virginia, has always been the kind of person who puts other peoples' needs ahead of her own: driving elderly neighbors, baking cookies for bake sales, making quilts to donate for charity. Her life changed in January 2018, when she was diagnosed with IPF.

“Now I’m learning to take care of myself first,” she says. “Not in a selfish way, but in a way that is mindful of my need for rest and quiet.”

Her initial reaction to her IPF diagnosis was shock and fear: “I started to plan for the end of my life.

I cleaned out closets, wrote my will, and planned my funeral.” Her outlook started to change when she found the PFF website. “At last I had hope,” she says. “I learned that not everyone dies in 3-5 years and in fact some people live significantly longer.”

Today, as a PFF Registry participant, Gallagher contributes data and biosamples each time she visits her University of Virginia pulmonologist. She also has enrolled in five clinical trials—so far. “I take part in every research study I can,” she says. “Maybe that information won’t help me, but it may help someone else, maybe my children or grandchildren.”

It's about **PATIENTS.**

KEN VELLA: RETHINKING RETIREMENT



When accountant Ken Vella and his wife Eileen retired from the corporate world and moved from the Chicago area to South Carolina in 2013, they looked forward to the warm weather and

slower-paced lifestyle. By 2014, he had developed a dry cough that his physician diagnosed as seasonal allergies. Over the next several years, the cough continued, eventually accompanied by wheezing and shortness of breath, but his doctor stood by the allergy diagnosis. Eventually, Vella had an appointment with another provider in the practice who recognized a serious problem and sent him for an immediate chest x-ray.

By the time Vella's official IPF diagnosis came in January 2018, he knew major lifestyle changes were in order. He sold the small CPA firm he had founded and he and Eileen moved to Wake Forest, North Carolina, where he now receives his IPF care at Duke University.

Fortunately, Vella has not experienced any IPF-related exacerbations, and medications have stabilized his pulmonary function. "I try to make the best of every day," he says. "I am able to swim laps and be quite active. Although I often get tired in the afternoons, I feel refreshed after napping."

RICK RUDELL: HOLDING HIS OWN



Not much has changed for IPF patient Rick Rudell since he was featured in the PFF Registry's 2019 Annual Report. And when you have a chronic, life-limiting disease, that's a good thing, he says.

The PFF Ambassador and support group leader from Virginia Beach, Virginia, is still a candidate for a lung transplant and sees his pulmonologists regularly throughout the year. Although he's had some disease progression the past year, Rudell says it hasn't slowed him down. In early 2020, he was diagnosed with obstructive sleep apnea, a diagnosis that had the unexpected effect of helping improve his quality of life. "My CPAP machine makes me feel so much better," he says. "This way, I know that for at least 8 hours each night I'll be comfortable and my lungs will get plenty of oxygen."

PFF REGISTRY BY THE NUMBERS

2,003

PATIENT
VOLUNTEERS

OVER
3,600

PATIENT-YEARS
OF DATA

PROLIFIC

What if proteins in your blood known as biomarkers could give your doctor information about what your future with PF might be? And what if the presence or absence of a biomarker could predict whether a specific medication would help you? That's the promise of precision medicine.



It's also the goal of PROLIFIC Prognostic Lung Fibrosis Consortium, a new group created by the PFF and Bristol Myers Squibb Company to facilitate drug development. Peter H. Schafer, PhD, of Bristol Myers Squibb, explains that PROLIFIC is needed because, until now, companies haven't had a way to share basic scientific information with competitors. Pharmaceutical companies currently develop proprietary versions of laboratory tests for drugs in development. "It doesn't really make sense for

each company to develop its own tests," he says. "It's more efficient for us to combine efforts to develop tests we all can use."

PROLIFIC members will use PFF Registry data and biosamples to create and validate their shared laboratory tests. They have decided to focus on 12 different biomarkers:

- Epithelial damage (CYFRA 21-1, SP-D, CA-19-9, CA-125, KL-6)
- Fibrosis (MMP-7, TN-C, POSTN)
- Inflammation (CCL 18, CXCL13, sICAM-1)
- Thrombosis (PAI-1)

These biomarkers have been chosen for their potential to predict the disease course of PF and how well a drug will work in a specific individual. The biomarkers may also be useful for comparing results across different clinical trials, which could speed regulatory approval.

PROLIFIC MEMBERS

- | | | |
|--------------------------------|-----------------------------|---------------------------------|
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| • Galapagos | • OptiKira LLC | • Three Lakes Foundation |
| | • Pliant Therapeutics, Inc. | |

It's about **RESEARCH.**

As one of the largest nonprofit funders of PF research, the PFF forges meaningful collaborations with the nation's top research institutions, industry partners, and government agencies with the shared goal of finding a cure for this devastating disease.

PRECISIONS CLINICAL TRIAL

Biomarkers play a critical role in PRECISIONS, the first-ever clinical trial to apply the principles of precision medicine to the diagnosis and treatment of IPF. PRECISIONS (for **P**rospective **t**reatment **E**fficacy in IPF **u**sing **g**enotype for **N**ac **S**election trial and Molecular Endophenotyping in Idiopathic Pulmonary Fibrosis and Interstitial Lung Diseases study) has received a \$22 million grant from the National Institutes of Health and additional support from the Three Lakes Foundation. Additionally, PRECISIONS will rely on PFF Patient Registry data and biosamples.

"Personalized medicine is the approach of selecting the best therapy for an individual patient, the therapy that is most likely to aid them and at the same time least likely to cause any harm," explains co-principal investigator Fernando Martinez, MD, MS. "PRECISIONS is the first time the principles of personalized medicine will be applied and tested in an interventional study of pulmonary fibrosis patients."

PRECISIONS has three main goals:

- 1** Determine whether N-Acetyl-cysteine (NAC) is an effective treatment for people with IPF who have a gene variant known to play a role in lung immunity. NAC is inexpensive and already available over the counter as a supplement.
- 2** Develop blood tests to help distinguish IPF from other lung diseases with similar symptoms. These tests could identify molecular signatures linked with IPF, eventually perhaps being able to predict an individual's disease course and response to therapy.
- 3** Identify subtle differences in the genetic code that influence an individual's risk of developing IPF, which may help monitor high-risk people even before they show symptoms.

“PRECISIONS literally could not happen without the PFF Registry, from the guidance of the PFF leadership team to the PFF Care Center Network sites where PRECISIONS research will occur, to the very committed and engaged patients in the Registry that have agreed to join. The Registry has been integral to this study from the outset.”

Fernando J. Martinez, MD, MS

Weill Cornell Medicine and New York-Presbyterian Weill Cornell Medical Center

”



Behind the Scenes: **A ROBUST INFRASTRUCTURE**

The PFF Registry is a complicated entity that requires a robust infrastructure to gather the scientific data that will lead the best and brightest researchers to vital discoveries about how best to diagnose, treat, and even prevent or cure PF.

CARE CENTER NETWORK

The PFF Care Center Network is a growing group of medical centers that have the necessary resources and specialized staff to provide high-quality care to people with PF. Experts in pulmonary medicine, rheumatology, radiology, pathology, and nursing who specialize in interstitial lung disease make up the care team at each PFF Care Center.

Additionally, the Care Center Network forms the infrastructure of the initial PFF Registry. Registry patients receive their care at a PFF Care Center so that trained coordinators oversee data collection to protect the Registry's integrity.

SABER

The Registry is managed by the Data Coordinating Center at the Statistical Analysis of Biomedical and Educational Research (SABER) at the University of Michigan. SABER provides the computer infrastructure and houses the Registry's clinical database and biosamples. SABER also coordinates researchers' access to Registry data and sends out biosamples to researchers as needed.

Additionally, SABER data scientists work with researchers to hone their ideas and verify that the Registry data can support the proposed study. Support from SABER data scientists continues throughout the research process, up to and including preparing manuscripts for publication.



We record participants' experiences with PF to learn all we can about the disease and how to treat it. Participants don't have to change their medications or how often they see their physician. The Registry follows thousands of participants for as long as they are able to participate. This means huge amounts of patient data are available to researchers who are eager to answer key questions about PF.

Kevin Flaherty, MD, MS

Steering Committee Chair

PFF Registry and PFF Care Center Network





What Sets the **REGISTRY APART**

This large, all-cause PF Registry launched in 2015, completing the first phase of its enrollment with 2,003 patients in 2018. Patients typically remain in the Registry for the rest of their lives, or until they receive a lung transplant.

THE REGISTRY COLLECTS IMPORTANT DATA FOR EACH PATIENT LIKE:

- Demographic information
- How each diagnosis was made
- Test results, including pulmonary function tests
- Medication use, including side effects
- Patient-reported quality-of-life data
- Medical outcomes such as hospitalization, lung transplantation, and death

- Opportunity to volunteer blood samples for research and biomarker exploration
- High-resolution CT (HRCT) scans are uploaded for researcher access

PFF REGISTRY BY THE NUMBERS

79

DISTINCT DISEASES
ACROSS SIX
CATEGORIES

300+

INDIVIDUAL DATA
ELEMENTS
COLLECTED PER
PATIENT



Every minute counts with PF, so the faster we can go from an idea for a study to answering a question or moving a new drug into the clinic, the better. This efficiency in expediting research is the Registry's great value proposition because it means we, as funders, can maximize our resources to help the PF population even more.

Dana Ball

Executive Director
Three Lakes Foundation





PFF Scholars: **FUNDING THE FUTURE OF RESEARCH**

PFF Scholars is a program that provides financial support and mentorship to promising early-career PF researchers. Scholars use data and biosamples from the PFF Registry to conduct original research.

The hope is that, at the end of their two-year grant, each PFF Scholar will be better equipped to obtain funding from the National Institutes of Health (NIH) and other important funding organizations to continue their cutting-edge PF research.

PFF Scholar John Kim, MD, of the University of Virginia, is focusing on whether the amount of polyunsaturated fatty acids a person has in their blood may turn out to be a potential risk factor in whether or not they later develop interstitial lung disease. "My central hypothesis, based on my preliminary data, is that higher plasma levels of omega-3

fatty acids will be associated with less disease severity and progression in adults with IPF," he says.

Additionally, Dr. Kim is intrigued by emerging methods to detect early levels of lung inflammation and fibrosis, long before a diagnosis of PF would be made. "Are there risk factors that might be linked to these early imaging abnormalities?" he says. "If we could find factors that we can link to early lung injury and identify those who might be more at risk for developing interstitial lung disease in the future, perhaps we could intervene early to prevent PF."

The PFF is committed to helping promising physician-scientists launch their research careers via the Young Scholars program.



As a young researcher, I deeply appreciate the participation of patients and their families. We are trying to understand and explore outcomes that are meaningful to patients, and we can only make progress with patient participation, so we're very grateful.

John Kim, MD, MS
Rector and Visitors
of the University of Virginia



It's about **THE FUTURE.**

With the answers to many key questions about PF seeming more within reach than ever before, it's important to reflect upon the impact each of the Registry's 2,003 enrollees has had on scientific progress. But it's also important to note that already a quarter of these patients have left the Registry in less than three years. While some have been fortunate enough to receive a lung transplant, many of these patients have died since joining the Registry.

Therefore, the Registry is on the brink of an aggressive expansion. In the near future, patient enrollment will reopen for the clinical component at 68 PFF Care Centers. Meanwhile, data collection will continue from those who remain.

And, for the first time, the Registry will include a direct-to-community feature to begin collecting data not only from patients but also lung transplant recipients, caregivers, and family members. What's more, direct-to-community participants need not be affiliated with a PFF Care Center Network medical center. This change will allow even greater geographic diversity by including responses from people in areas that may be rural or underserved.

New at the helm is Junelle Speller, Vice President of the PFF Registry. She brings extensive experience working with other types of patient registries and has participated in one herself.

She is joined at the PFF by three new, highly respected pulmonologists who have joined as senior members of its medical team. The new team members are: Dr. Amy Hajari Case of Piedmont Healthcare (Atlanta), Dr. Sonye Danoff of the Johns Hopkins University School of Medicine (Baltimore), and Dr. Joyce Lee of the University of Colorado Anschutz Medical Campus (Aurora).

As the PFF Registry expands, PF patients from anywhere in the U.S. will be able to participate virtually for the first time.

PFF REGISTRY BY THE NUMBERS





“

I hope my participation in the PFF Registry can ultimately help other patients understand and plan for what their disease may bring. How do you learn to live a fairly productive life when you have a progressive disease and there's no playbook on what to expect? By filling out quality-of-life questionnaires for the Registry, I want to provide enough data points so that healthcare providers can help their patients work through their struggles.

”

Ken Vella

Idiopathic Pulmonary Fibrosis Patient

PFF Registry Participant, PF Support Group Leader

It's about **COMMUNITY.**

The PF patient journey is difficult and can feel isolating. Every person diagnosed with pulmonary fibrosis has a unique experience with the disease. Some patients remain in a stable condition for years, while others experience rapid deterioration. Most patients find themselves having both good days and bad days.

Many people with PF find the uncertainty of not knowing what will happen with the disease to be extremely challenging. And it's not easy when spouses or other family members find themselves transformed into caregivers. The PFF helps many find and create their own PF communities to support each other through life's ups and downs.

Physicians currently have no way to predict the course of any individual case of PF, but the PFF Registry is working to change that.

For the first time, caregivers and lung transplant recipients can participate in the Registry to help us better understand the patient experience.

By following large numbers of PF patients over time, we are already learning more about the best way to care for patients, including symptom management, quality-of-life concerns, and more.

What's more, family members and caregivers can also participate in the next phase of the Registry by providing quality-of-life information about both the patient and their own experiences. As more people contribute data, a clearer picture of life in a PF family will emerge.



When my father was diagnosed with pulmonary fibrosis years ago, we called the PFF. The Foundation was just in its infancy, but they gave us all the information they had. Fifteen years later, they've grown and evolved and have created an important community and scientific resource. That's why PFF is one of my top philanthropic causes and has been for over a decade.

Chuck McQuaid

The Chuck and Monica McQuaid
Family Foundation





This is an exciting time for the Registry as PFF prepares for a major relaunch.

The improved Registry will include:

- Reopened and expanded patient enrollment plus enrollment of caregivers and families
- Updated protocol to answer more questions about PF
- Extended follow-up period through December 2023
- Simplified clinical data recording
- Coordinated direct-to-community registry to examine PF's effects on patients, caregivers, and families across all care settings
- Increased engagement via additional email communications and surveys on health and quality-of-life topics.

Sign up to receive enrollment information when the expanded Registry goes live!

bit.ly/registrynews

Contact Jennifer Mefford, Senior Director, Corporate Partnerships, at jmefford@pulmonaryfibrosis.org to discuss corporate sponsorship of the PFF Registry.

In order for the Registry to reach its full potential, this multimillion dollar effort must reopen to patient enrollment to repopulate as patients leave the Registry due to death or transplant. Planning and fundraising are underway for the next phase of the Registry. Your gift to the PFF Registry will enable us to expand patient

enrollment and provide even greater access to investigators as they progress toward finding for a cure for PF.

The PFF gratefully acknowledges Genentech, a member of the Roche Group, as Founding Partner of the PFF Registry.

**\$3.5
MILLION**

NEEDED ANNUALLY
TO OPERATE THE
REGISTRY

\$1,250

COST PER PATIENT
PER YEAR

\$600

COST PER BLOOD
COLLECTION SAMPLE
FOR ITS USABLE
LIFE

\$150

COST TO ADD EACH
HRCT TO THE IMAGE
LIBRARY



The science of interstitial lung disease is advancing because of collaborative efforts of the patient community, industry, academia, advocacy groups, and the government all working together to try to find new approaches and treatments that will help patients. We were very proud to be the Founding Partner for the PFF Registry. Our commitment to it continues and we hope to be able to provide additional support as the Registry moves into its next phase.

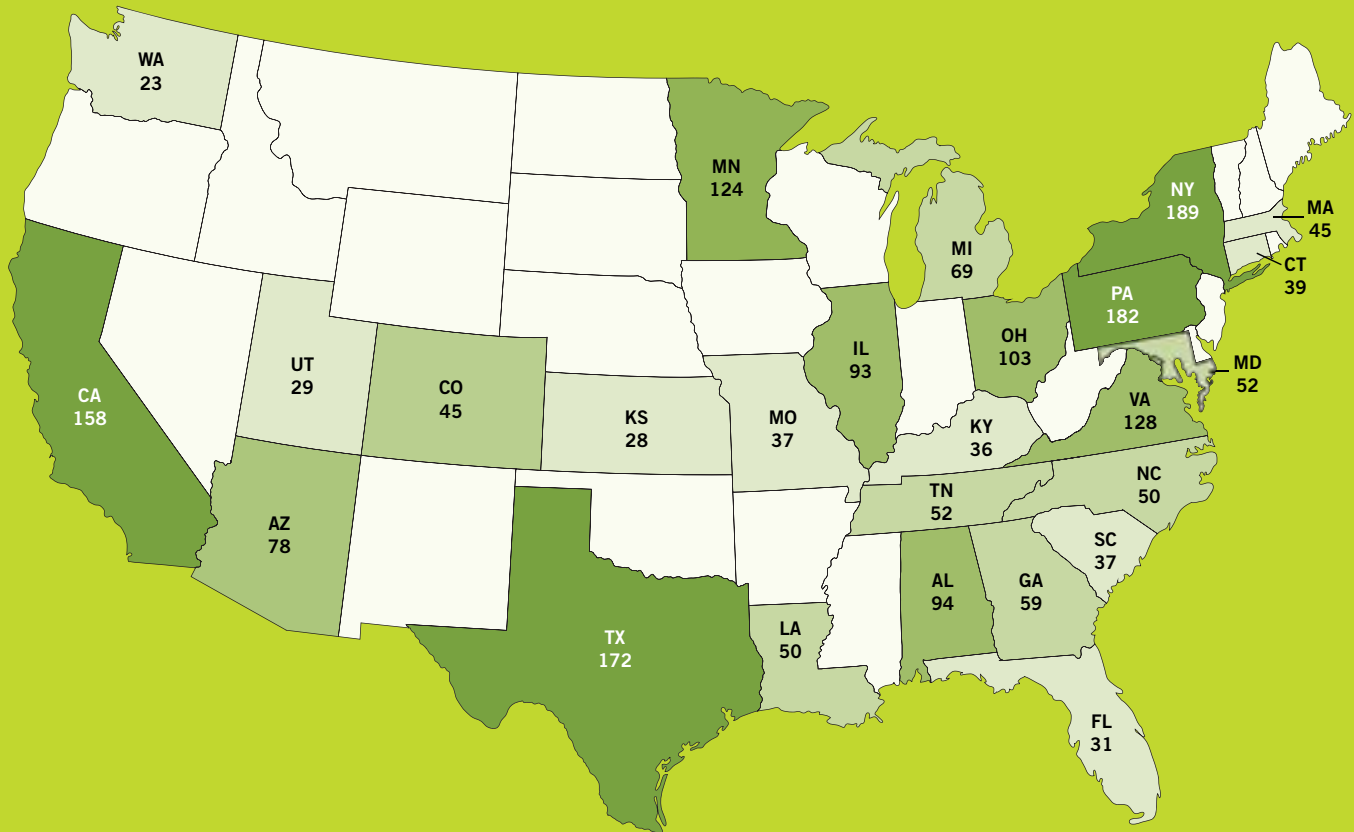
John Stauffer, MD

Principal Medical Director, Genentech, Inc.



PFF Registry Metrics

ENROLLMENT BY STATE



Patient Reported Outcomes (PRO)
Records

23,489

Forced Vital Capacity (FVC)
Measures

12,217

Diffusing Capacity of the Lungs for
Carbon Monoxide (DLCO) Measures

10,082

Average Months
Since Enrollment

37.7

High Resolution CT Scans
Received

2,104

Blood Sample
Collections

1,627

Distinct Diseases
in the Registry

79

Data Elements

300

Donated Blood
Samples

81%

Agreed to
Future Research

89%

Data updated August 6, 2020

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