The PFF Patient Registry is a major resource designed to accelerate progress in pulmonary fibrosis research. We’ve seen a tremendous response from the research community and are eager to assist them in answering key questions about PF.

Kevin R. Flaherty, MD, MS
Steering Committee Chair
PFF Patient Registry and PFF Care Center Network
Pulmonary fibrosis (PF) is a complex group of over 200 debilitating lung diseases. While more than 200,000 Americans are living with PF, each case is unique and much about the disease remains largely unknown.

The Pulmonary Fibrosis Foundation (PFF) is committed to improving the lives of people with pulmonary fibrosis and leading research to faster diagnoses, better treatments, and a cure. Knowledge is the first step in understanding how to positively impact so many living with PF.

In 2015, the PFF took a crucial step by developing a comprehensive research tool with the launch of the PFF Patient Registry and Biorepository. This unparalleled resource tracks de-identified data and blood samples from more than 2,000 patients nationwide. Collections are performed through the PFF’s Care Center Network to ensure standard procedures for maximum data integrity.

We are pleased to share this PFF Patient Registry Report, which illustrates the knowledge that can be achieved through this unique research resource. To date, more than 23 abstracts and manuscripts have been developed using Registry data at no cost to researchers. And the PFF’s annual $2.5 million investment in the Registry has already yielded research projects valued at $31 million.

But there is more work to be done. We invite you to join us in support of the next phase of the Registry, which will launch in 2020. Your gift to the PFF Patient Registry will enable us to expand patient enrollment and provide even greater access to investigators studying PF.

We are grateful to the scientists, researchers, and clinicians who helped us identify the need and design for the PFF Patient Registry. We are especially thankful to the patients who enrolled in the Registry, making it possible for us to come ever closer to a world without pulmonary fibrosis.

George Eliades, PhD
Chair, Board of Directors

William T. Schmidt
President and CEO

DEAR FRIENDS,

Sincerely,
In pulmonary fibrosis, scar tissue builds up in the walls of the lungs’ air sacs. Eventually, this makes it hard for oxygen to reach the bloodstream and circulate throughout the body. Low oxygen levels and scar tissue combine to cause coughing and shortness of breath, particularly during walking, exercise and—eventually—everyday activities.

PF’s main symptoms—shortness of breath, fatigue, a dry cough that doesn’t improve—are similar to those of other lung diseases, which often delays correct diagnosis and treatment.

PF generally progresses over time and there is currently no cure, although medications are available that may slow its pace.

There are several causes of PF:

- **Drug-induced** – Some medications used to treat cancer, abnormal heart rhythms, and inflammatory conditions can damage the lungs.
- **Radiation-induced** – Chest radiation used to treat lymphoma, Hodgkin’s disease, or cancers of the breast, lung, and other organs can cause lung injury.
- **Autoimmune** – Connective tissue diseases like rheumatoid arthritis, lupus, and Sjögren’s syndrome can attack the lungs.
- **Environmental** – Lung damage can result from breathing in mold spores, bacteria, or animal proteins.
- **Occupational** – Lung injury and scarring can develop after lengthy exposure to inorganic dusts like asbestos, silica, coal dust, and beryllium.
- **Idiopathic** – This refers to those diseases that primarily affect the lungs and have no known causes. Idiopathic pulmonary fibrosis (IPF) is the most common idiopathic disorder, but other examples include non-specific interstitial pneumonitis, cryptogenic organizing pneumonia, and desquamative interstitial pneumonia.

“We never forget that there is a real person behind every statistic in the PFF Patient Registry, and that knowledge drives us forward every day.”

**Cathie Spino, ScD**
Director of Statistical Analysis of Biomedical and Educational Research (SABER)
School of Public Health, University of Michigan

**PULMONARY FIBROSIS BY THE NUMBERS**

- **200+** Types of PF
- **200,000+** People live with PF in the U.S.
- **1 in 200** Over age 70 are living with IPF
The Registry has encouraged me to become a patient advocate in the fight against PF. It makes me feel like I am contributing as an active partner in research, because we as patients have the most to gain and the most to lose.

Rick Rudell
Patient, PFF Ambassador, and Support Group Leader
SEARCHING FOR ANSWERS

As a retired naval pilot who then worked in a paper mill for 20 years, Rick Rudell of Virginia Beach, Virginia, can’t help but wonder if occupational exposures caused or aggravated his IPF. “In the Navy, I investigated aviation accidents with the belief that you will find the cause if you look hard enough, even when a plane has crashed into the ocean,” he says. “I’m hoping that’s what will happen with the Registry: that there will be a few other people who had similar occupational exposures or other similarities that will lead investigators to an ‘a-ha moment’.”

Now on continuous oxygen, Rick visits his pulmonologist at Duke University several times per year for follow-up care and evaluation for lung transplant. After each visit, his test results get added to the Registry. He also completes quality-of-life questionnaires at each visit for the Registry. Rick has had one acute exacerbation since being diagnosed with IPF in early 2016. If he has another one, all of that data will be entered into the Registry, adding to what is known about disease management and patient outcomes.

His wife, Martha, uses her background as an administrative assistant to create spreadsheets of Rick’s weight, medications, and other data, collecting them all into a neat binder for trips to Duke, where she takes notes at all his appointments. “While I’m considered his caregiver, Rick’s faith, courage, and positive attitude give me strength and hope daily,” she says.

Now a PFF Ambassador and support group leader, Rick finds that participating in the Registry has given him a new sense of purpose.

WHAT THE REGISTRY MEANS TO PATIENTS

The PFF Patient Registry is an observational research tool. That means 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 will follow thousands of participants for as long as they are able to participate. This means huge amounts of patient data will be made available to researchers.

Observational research is not designed to answer questions about whether one treatment is better than another—that is the purpose of clinical trials. The Registry is helping to answer other important questions like:

- What factors determine who should take anti-fibrotic treatments?
- How does the use of supplemental oxygen change the risk of being hospitalized?
- How do hospitalizations affect survival?
- What role does patient race play in survival?
PRECISIONS is a proposed multicenter study that will evaluate biomarkers to aid in the diagnosis of pulmonary fibrosis. It will also perform a first-of-its-kind pharmacogenomic clinical trial for patients with IPF, thereby introducing precision medicine. As a principal investigator, I knew the PFF Registry was key to the success of the project. Studies such as PRECISIONS may be impractical without the Registry’s expert clinical and investigative groups, funding from both non-federal and federal sources such as the National Heart, Lung, and Blood Institute, and a large number of patients with diverse PF disorders who have been recruited and characterized in a systematic fashion with stored biologic samples and consent for future research.

Fernando J. Martinez, MD, MS
Weill Cornell Medicine and New York-Presbyterian
Weill Cornell Medical Center
The PFF Patient Registry is a nationwide research study and biorepository that enables researchers, for the first time, to explore what treatment strategies actually work best for patients and to find new ways to diagnose, treat and potentially cure pulmonary fibrosis. It's the most expansive, multicenter registry with longitudinal data that will increase our understanding of PF’s natural history and more thoroughly assess diagnostic and predictive biomarkers.

This large, all-cause PF registry launched in 2015. The first phase of enrollment of 2,000 patients was completed in July 2018. Patients remain in the Registry for the rest of their lives, or until they receive a lung transplant.

The PFF Patient Registry includes:
- Patient demographics
- How each diagnosis was made
- Test results, including pulmonary function tests
- Medication use
- Patient reported quality-of-life data
- Medical outcomes such as hospitalization, lung transplantation and death
- Opportunity to volunteer blood samples for research and biomarker development

Key features highlight the PFF Patient Registry’s potential to rapidly advance our knowledge of PF:

Geographic diversity – Registry patients receive multidisciplinary care at 42 centers nationwide that represent the current standard of care.

Biorepository – De-identified HRCT reports and blood samples are available for nearly 90 percent of patients and tied back to individual records.

Longitudinal data – This will help illuminate the natural history of the diseases that cause PF.

Real-world experience – Data entered into the Registry reflect the usual care of practice which can complement data from clinical trials, which are highly protocolized.

Infrastructure – The Registry can facilitate clinical trial enrollment because nearly 90 percent of patients have self-identified as wanting to participate in relevant trials.

Easy-to-use interface – Well-designed dashboards provide near real-time updates on the Registry, make the data clearer by providing visualizations of important information, and allow users to interact with the data and look at specific sub-groups of interest.

Cost-effectiveness – Over a one year period, the PFF’s $2.5 million investment in the Registry yielded 17 research projects valued at $31 million. This demonstrates a substantial return and illustrates the research stimulus that can be achieved with continued investment in the Registry.

PULMONARY FIBROSIS BY THE NUMBERS

- 3% to 20% of people with PF have another family member with PF
- 42 PFF CARE CENTER NETWORK SITES MONITOR PATIENTS IN THE REGISTRY
- 50,000 new cases of PF per year in the U.S.
When patients receive their diagnosis, they naturally ask what they can expect to happen in the future. It’s difficult to tell them that we currently have no way to predict the course of their disease. The only way we can realistically answer that question is if we follow large numbers of patients with PF, identify, and then validate predictive tools or biomarkers. This is now possible thanks to the PFF Patient Registry!

Gregory P. Cosgrove, MD
PFF Chief Medical Officer
PULMONARY FIBROSIS RESEARCH

The Registry is designed to support observational research projects. It can also supplement and expedite prospective research projects.

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<thead>
<tr>
<th>WITHOUT THE PFF PATIENT REGISTRY</th>
<th>WITH THE PFF PATIENT REGISTRY</th>
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<tbody>
<tr>
<td>Researcher must build clinical trial infrastructure to collect and analyze data for each trial</td>
<td>This infrastructure already exists, including best-in-class statistical support from SABER at the University of Michigan</td>
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<tr>
<td>Difficult and time-consuming to recruit large numbers of patients from a broad geographic area</td>
<td>Access to data from 2,000+ patients nationwide, nearly 90% of whom wish to participate in new clinical research</td>
</tr>
<tr>
<td>Controlled circumstances in which patient data are collected only as specified in the trial design</td>
<td>“Real-world,” standard-of-care data collection provides insights into actual diagnostic and treatment practices</td>
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<tr>
<td>Snapshot in time</td>
<td>Longitudinal data and trends will emerge from ongoing data collection</td>
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<tr>
<td>Limited focus on the patient experience to date</td>
<td>Includes ongoing patient-reported outcome data</td>
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<tr>
<td>Inter-institution collaboration may or may not occur</td>
<td>Collaboration is enhanced by centralized Registry structure and requirement that each research project include at least one Registry researcher</td>
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PFF PATIENT REGISTRY BY THE NUMBERS

- **80** DISTINCT DISEASES ACROSS SIX CATEGORIES
- **OVER 4,000** PATIENT YEARS OF DATA
- **OVER 300** INDIVIDUAL DATA ELEMENTS COLLECTED
There is no question that the Registry allows us to impact the lives of our patients and future patients in a positive way because it allows us to ask and perhaps answer essential questions in PF.

Ayodeji Adegunsoye, MD, MS
University of Chicago
The PFF invites interested clinical and translational investigators to utilize Registry data. Researchers can access the Registry upon submission and approval of a research proposal. The PFF currently reviews research proposals three times per year.

One researcher who has used the Registry’s data is Ayodeji Adegunsoye, MD, MS, a University of Chicago pulmonologist. Most recently, he presented an abstract based on Registry data at the 2019 American Thoracic Society international conference. Dr. Adegunsoye and his colleagues assessed racial differences in Registry participants at baseline, including demographics, disease severity, and survival patterns. They concluded that PF diagnoses occurred a decade earlier in Blacks compared to Whites. They also found that connective tissue disease-associated interstitial lung disease was four times more prevalent in Black patients compared to White patients. Finally, one-year mortality and transplant-free survival did not differ among racial subgroups.

In addition to shedding new light on national demographic patterns in PF, this study also validated earlier work by Dr. Adegunsoye in which he reached similar conclusions using data from his own institution. Dr. Adegunsoye also is using the Registry in a prospective study that examines the impact of race on genetic predisposition to the pulmonary honeycombing seen in late-stage PF.

The Registry is managed by the Data Coordinating Center at the Statistical Analysis of Biomedical Education and Research (SABER), University of Michigan. SABER data scientists work with applicants to hone their ideas and to confirm that the Registry data can support the proposed study. Their support continues throughout the research process, up to and including preparing manuscripts for publication.

As of June 30, 2019, Registry-based research includes 17 studies — six of which have gone from abstract to manuscript development. Four are using biosamples or imaging from the Registry. Selected abstracts and manuscripts in progress include:

- Patient Characteristics Associated with Anti-Fibrotic Medication Use in the PFF Patient Registry
- Analysis of Chest CT in IPF: Protocols and Timing of Imaging Studies in the PFF Patient Registry
- Presence of Biopsy and Geographic Region Predict Discussion at Interstitial Lung Disease Multidisciplinary Conference
- Lipoproteins in Interstitial Lung Disease
- Impact of Pirfenidone on Quality of Life

For more information and to submit a PFF Registry research proposal, visit www.pffpatientregistry.org or email ccn@pulmonaryfibrosis.org. Both academic and industry researchers are welcome to apply. Investigators who are not members of a Registry team must include a Registry investigator as a collaborator on their proposal.
REGISTRY INFRASTRUCTURE

The PFF Care Center Network is a growing group of medical centers with expertise in accurately diagnosing and treating people living with PF. These centers have the necessary resources and specialized staff to provide high-quality multidisciplinary care.

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 PFF Patient Registry. All 2,000+ Registry participants receive their medical care at a PFF Care Center. In this way, consistent and accurate data collection by trained site coordinators protects the Registry’s integrity.

THE PFF CARE CENTER NETWORK

68 Sites Nationwide and Growing

- Registry Enrollment Sites
- Additional Care Center Network Sites
I always emphasize to researchers that they can come with an idea and receive outstanding statistical support from inception to publication. So not only do they have the Registry’s longitudinal data and banked biospecimens, they have an impressive support team to extract data and assist with its analysis.

Mary E. Strek, MD
Chair, Ancillary Studies Committee
PFF Patient Registry
The Registry is an example of a critical open-access resource containing phenotypic clinical data and biospecimens that can be leveraged by investigators to enhance recruitment and retention of patients for clinical trials, as well as support ancillary or independent mechanistic studies to better understand the etiology of pulmonary fibrosis.

James P. Kiley, PhD
Director of the Division of Lung Diseases
National Heart, Lung, and Blood Institute
The concern of all of us at the PFF is that just building the Registry isn’t enough—we need additional funding to ensure that this critical resource helps us reach our ultimate goal of improved outcomes for our patients.

Andrew H. Limper, MD
Chair, PFF Medical and Scientific Advisory Committee

In order for the Registry to reach its full potential, it must reopen to patient enrollment to repopulate as patients leave the Registry. Planning and fundraising are underway for the next phase of the Registry, which will launch in 2020.

Your gift to the PFF Patient Registry will enable us to expand patient enrollment and provide even greater access to investigators as they search for a cure for PF.

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

We are proud to support the PFF Patient Registry to help advance science and have a positive impact on the pulmonary fibrosis community.

Benjamin Kramer, MD
Vice President for U.S. Medical Affairs at Genentech
<table>
<thead>
<tr>
<th>SITE</th>
<th>PRINCIPAL INVESTIGATOR</th>
<th>LOCATION</th>
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<tbody>
<tr>
<td>University of Alabama at Birmingham</td>
<td>Dr. Tracy Luckhardt</td>
<td>Birmingham, AL</td>
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<tr>
<td>Dignity Health St. Joseph’s Hospital and Medical Center</td>
<td>Dr. Rajat Walia</td>
<td>Phoenix, AZ</td>
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<tr>
<td>University of Arizona</td>
<td>Dr. Sachin Chaudhary</td>
<td>Tucson, AZ</td>
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<tr>
<td>University of California at Los Angeles</td>
<td>Dr. Stephen Weigt</td>
<td>Los Angeles, CA</td>
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<tr>
<td>University of California at San Francisco</td>
<td>Dr. Paul Wolters</td>
<td>San Francisco, CA</td>
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<tr>
<td>Stanford Health Center</td>
<td>Dr. Joshua Mooney</td>
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<td>National Jewish Health</td>
<td>Dr. Tristan Huie</td>
<td>Denver, CO</td>
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<tr>
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<td>Dr. Mridu Gulati</td>
<td>New Haven, CT</td>
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<td>Baltimore, MD</td>
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<td>Dr. Todd Nevins</td>
<td>Baltimore, MD</td>
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<td>University of Michigan</td>
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<td>Mayo Clinic</td>
<td>Dr. Teng Moua</td>
<td>Rochester, MN</td>
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<td>University of Minnesota Medical Center</td>
<td>Dr. Hyun Kim</td>
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<td>The Ohio State University</td>
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<td>Penn State Milton S. Hershey Medical Center</td>
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<td>Dr. Maryl Kreider</td>
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<td>Dallas, TX</td>
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<tr>
<td>The University of Texas Health Science Center at Houston</td>
<td>Dr. Rodeo Abrencillo</td>
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<td>Dr. Anoop Nambiar</td>
<td>San Antonio, TX</td>
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<td>Dr. Mary Beth Scholand</td>
<td>Salt Lake City, UT</td>
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<tr>
<td>University of Virginia Health Systems</td>
<td>Dr. Tessy Paul</td>
<td>Charlottesville, VA</td>
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<tr>
<td>Inova Fairfax Hospital</td>
<td>Dr. Christopher King</td>
<td>Falls Church, VA</td>
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<tr>
<td>University of Washington Medical Center</td>
<td>Dr. Ganesh Raghun</td>
<td>Seattle, WA</td>
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</table>
Registry data allow us to better understand the impact of PF on patients. Of the 2,003 patients enrolled, there have been:

- **644** Hospitalizations
- **534** Emergency Room Visits
- **225** Acute Exacerbations

The PFF Registry is a dynamic, real-time dataset. These metrics will typically grow over time. Data current as of 6.30.19.
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*As of June 30, 2019