

PFF 2020

PULMONARY FIBROSIS FOUNDATION

NOVEMBER 2017

STRATEGIC PLAN: PFF2020

Pulmonary Fibrosis
FOUNDATION

DEAR FRIENDS,

It is with a deep sense of pride that we're pleased to share with you the "Pulmonary Fibrosis Foundation Strategic Plan: PFF2020." The first of its kind for the Pulmonary Fibrosis Foundation (PFF), this plan takes a forward-thinking approach through the year 2020 at our vision for growth and how our role should drive, support, and impact the growing needs of the entire pulmonary fibrosis (PF) community.

This is truly an exciting and transformational time for the PFF. As we look back at many accomplishments in a relatively short period of time, we understand that there is more important work yet to tackle. In order to adapt purposefully to the changing pulmonary fibrosis landscape, we recognize the need to take measured, yet bold steps forward to achieve our mission. The creation of this strategic plan demonstrates the steadfast commitment and collective insight that propels us to continually strive towards making a difference in the lives of all those who are affected by PF.

With gratitude, we would like to acknowledge that the "Pulmonary Fibrosis Foundation Strategic Plan: PFF2020" was developed from an inclusive process of strategic planning that began in 2015. The Plan was coordinated by the Strategic Planning Committee, comprised of Board members David McNinch and George Eliades, PhD, PFF advocate and advisor Martin Attwell, and many members of the PFF professional staff. Further, we would like to express appreciation to Bain & Company for their generous support and coordination



throughout this process to ensure that the plan development identified the most appropriate set of strategic priorities for sustained growth and impact. Those priorities were discussed as the sole focus of the Board of Directors retreat in early 2016 and the Plan was formally approved by the Board in February of 2016.

Our ultimate pursuit is to realize a world without PF. Whether your role is related to research, patient care, patient and family support, fundraising, or advocacy, it is with your actions that we can make a difference together. We hope you will review the principal goals and objectives outlined in the Plan and join us in creating an exciting future for the PFF.

A handwritten signature in black ink that reads "William T. Schmidt".

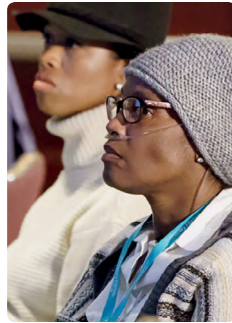
WILLIAM T. SCHMIDT

PRESIDENT AND CHIEF EXECUTIVE OFFICER

A handwritten signature in black ink that reads "George Eliades".

GEORGE ELIADES

CHAIR, BOARD OF DIRECTORS



Imagine being told you have a little-known disease for which the causes are unknown. Imagine going home and looking online to discover that there is no cure for what you have — pulmonary fibrosis (PF). It's a disease that kills about 40,000 each year and yet most people have never heard of it.

Many PF patients feel alone and overwhelmed when they are first diagnosed. They need someone to help them find their way through this terrible disease, and the Pulmonary Fibrosis Foundation (PFF) is there to guide them. Our mission is to mobilize people and resources to provide access to high-quality care and lead research for a cure so that people with pulmonary fibrosis will live longer, healthier lives. By actively engaging the PF community, the PFF has developed essential programs for patients, caregivers, and health care professionals to give them a greater understanding of PF and support while living with the disease.

“When you get diagnosed, you don’t know which end is up. I looked at all avenues to see if somebody could help me make sense of things. I felt like the Lone Ranger.”

VALERIA HATCHER / PFF AMBASSADOR

The Foundation has taken major steps forward in the past few years, empowering our community and investing in research to find a cure. We are building on these successes with the “Pulmonary Fibrosis Foundation Strategic Plan: PFF2020,” our vision for the future that maps out strategies for fighting this disease and creating a brighter tomorrow for those affected by PF.

Now imagine a world without pulmonary fibrosis.

With your support, together we can make that happen.

WHAT IS PULMONARY FIBROSIS?

A FAMILY OF DISEASES

Pulmonary fibrosis (PF) is a family of more than 200 different lung diseases that look very much alike. They fall into an even larger group called “interstitial lung diseases (ILD).” The word “pulmonary” means lung and “fibrosis” means scar tissue, so in its simplest sense, pulmonary fibrosis means scarring in the lungs.

Scar tissue builds up in the walls of the air sacs of the lungs. Eventually, the scar tissue makes it hard for oxygen to get into the blood. Low oxygen levels (and the stiff scar tissue itself) can cause coughing and shortness of breath, particularly when walking and exercising.

Certain forms of PF are progressive and worsen over time. Every individual diagnosed has a unique experience with the disease, and there is no standard or expected clinical course. Some people with PF remain stable for extended periods of time; yet others may experience a rapid progression of symptoms; while others may experience a stepwise deterioration over time, fluctuating between periods of stability and worsening symptoms.

“I started out knowing nothing about the disease when my son was diagnosed. Just being able to go online to the PFF website and gather information and find a support group is invaluable.”

MOTHER OF A PATIENT / PFF SUMMIT SURVEY

DIFFICULTY OF DIAGNOSIS

Doctors find it challenging to accurately diagnose PF. Many patients are diagnosed years after the onset of symptoms. While there are multiple types of PF, the differences between them are not yet fully understood and the causes are still unknown. It is thought that certain autoimmune diseases, exposure to airborne toxins, undergoing radiation treatment, taking certain medications, and genetics could be involved in developing PF. Sometimes doctors are able to identify a specific cause, but when one is not found it is called “idiopathic pulmonary fibrosis,” or IPF. When the cause is unknown, it can be very frustrating for patients and their families.

A definitive diagnosis requires a multi-disciplinary approach to exclude other known causes and may require a lung biopsy – an invasive, expensive, and sometimes painful procedure. Adding to the difficulty is the limited awareness of the disease and the fact that it often impacts patients in underserved populations. By the time most patients are diagnosed, the disease has often progressed.

TREATMENT

With no known cure for IPF, one of the more common types of PF, the disease is often fatal within three to five years of diagnosis. The good news for people living with PF is that researchers are studying new ways to halt its progression, and there are treatments designed to specifically manage the symptoms of the disease, including pulmonary rehabilitation and supplemental oxygen. Lung transplantation is an option for a select group of patients with PF, but it remains an option for only a minority of patients.

Pharmaceutical companies have started to invest in PF treatments, and the pipeline is promising. Two FDA-approved drugs are now on the market (Esbriet®, Ofev®) for IPF, with an additional 13 drugs in clinical trials. Drug development activity for non-IPF patients is just beginning.

LEADING THE CHARGE

As one of the largest nonprofit funders of pulmonary fibrosis (PF) research, the Pulmonary Fibrosis Foundation (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 insidious disease. Doing so will require the commitment of many, and we are proud to grow beyond our grassroots network to create a global community of PF leaders working together to drive awareness and advocacy. One recent study estimates that idiopathic pulmonary fibrosis (IPF) affects 1 out of 200 adults over the age of 65 in the United States. This is why it is more urgent than ever for the PFF to push forward with our mission.

OUR MISSION

The Pulmonary Fibrosis Foundation mobilizes people and resources to provide access to high-quality care and leads research for a cure so people with pulmonary fibrosis will live longer, healthier lives.

“As the leading advocate for the pulmonary fibrosis community, we are dedicated to advancing the care of people living with these deadly diseases.”

GREGORY COSGROVE, MD / PFF CHIEF MEDICAL OFFICER



JOIN US

The PFF is focused on continuing to be the trusted leader in the fight against PF by taking an active role in bringing people, programs, and resources together to spread awareness and find a solution for this disease. It will take everyone working together to create a different outcome for those with PF. We hope you will join us in the fight.

WE'RE ALREADY MAKING PROGRESS

The PFF has made extraordinary strides toward its mission by developing signature programs that benefit patients, caregivers, and health care professionals. We have demonstrated particular success in three target areas:

- Raising Awareness
- Providing Disease Education
- Funding Research

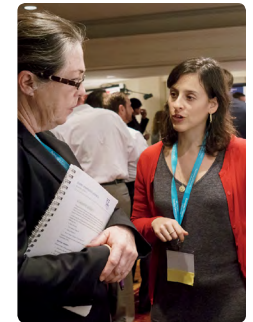
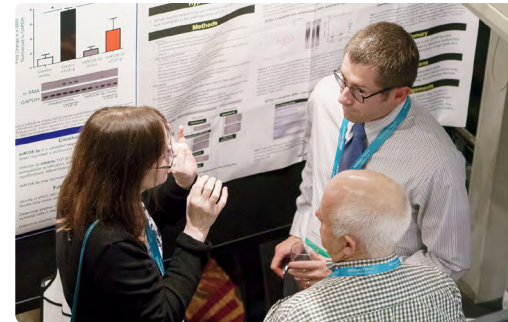
LEADING THE CHARGE

WE'RE ALREADY MAKING PROGRESS (cont.)

Raising Awareness

Awareness is critical to supporting patients, increasing essential research funding, and ultimately finding a cure for any disease, but it is even more important for a rare disease like PF. Joining with those impacted by the disease, the PFF has made a concentrated difference in spreading awareness in the broader community by introducing new initiatives and expanding existing programs.

- **GLOBAL PULMONARY FIBROSIS AWARENESS MONTH** — Each September, people all over the world come together to engage in advocacy, fundraising, and awareness initiatives.
- **PFF PATIENT COMMUNICATION CENTER** — The first comprehensive resource for the PF community with a dedicated call center providing the most up-to-date information about PF and the Foundation (844.TalkPFF or pcc@pulmonaryfibrosis.org)
- **PFF AMBASSADOR PROGRAM** — A personal and dynamic way to provide greater understanding of the disease and support those living with PF by empowering patients, caregivers and health care professionals to become spokespersons for the Foundation
- **SUPPORT GROUP LEADER NETWORK** — A forum for volunteer PF support group leaders to connect, exchange ideas, learn from one another, and discuss best practices for use at their meetings



Providing Disease Education

The premier patient resource for those with PF, the Foundation is committed to expanding knowledge about the disease by providing educational materials and opportunities for the PF community to learn from and connect with leading specialists.

- **PFF SUMMIT** — Our biennial health care conference provides a collaborative environment where a multi-faceted group of world-renowned experts, physicians, researchers, allied health professionals, industry representatives, patients, caregivers, and family members exchange ideas and information.
- **PFF CLINICAL TEAM** — We established a clinical team of experts, including a chief medical officer, to maximize our expertise and impact.
- **PFF DISEASE EDUCATION WEBINAR SERIES** — We created a series of webinars facilitated by a variety of experts and specialists from the field to help groups and individuals learn more about PF.
- **EDUCATIONAL MATERIALS** — Printed and digital educational materials are available for patients, caregivers, family members, and health care professionals to learn more about pulmonary fibrosis.

LEADING THE CHARGE

WE'RE ALREADY MAKING PROGRESS (cont.)

Funding Research

The Foundation has raised funds specifically to support research, which is an important vehicle to continue the vital work needed to eradicate this deadly disease. These funds have allowed the PFF to:

- award more than \$4 million in sponsorships and research and program grants;
- provide 19 awards resulting in more than \$95 million in subsequent NIH funding;
- design and fund the first all-cause pulmonary fibrosis patient registry to understand and advance the care of patients with PF; and
- establish the PFF Care Center Network (CCN) to ensure that best practices are in place for the care of PF patients throughout the community.

Other Significant Achievements

- We saw revenue increase by nearly 250% from 2011 to 2015.
- We secured a **FOUR-STAR CHARITY NAVIGATOR** rating and were designated as an accredited charity with the **BETTER BUSINESS BUREAU** to ensure “best in class” operational management and stewardship of contributions.
- We began exploration of the creation of a Therapeutics Network.
- We supported patients and provided information during the first Expanded Access Program for new therapies for IPF.
- We engaged the US Food and Drug Administration (FDA) in a discussion about the need for new treatments for PF patients.



The Pulmonary Fibrosis Foundation mobilizes people and resources to provide access to high-quality care and leads research for a cure so people with pulmonary fibrosis will live longer, healthier lives.

The PFF will continue to deliver in these areas, but now is the time to do more...

In order to build on these successes, the PFF examined what we're doing right and what we need to do to achieve more. Through the strategic planning process, we developed a plan through the year 2020 that clarifies our vision, sets goals for achievement, establishes five strategies for reaching these goals, and discusses desired outcomes and metrics for measuring success.

OUR VISION FOR THE FUTURE

As part of the strategic planning process, the Pulmonary Fibrosis Foundation (PFF) articulated what we want to achieve through the year 2020:

People living with pulmonary fibrosis (PF) will live longer, healthier lives.

To transform this hope into reality and focus our efforts, we chose four key visionary statements and set corresponding strategic goals and initiatives to achieve each one. We identified these visions and goals using survey feedback we received from the PF community, including input from medical experts and people affected by the disease.

“Success would be expanding the understanding of this disease to a greater majority and making sure that the patients are getting the best treatment and medicine for this illness. The Foundation can be instrumental in stepping in where there are vacancies or lapses in the patient’s plan of care.”

PF RESEARCHER / PFF SUMMIT SURVEY

1

vision → Every patient is diagnosed quickly and receives the highest quality care

goal → Decrease time to diagnosis to less than six months and continuously improve and reassess evidence-based care guidelines

INITIATIVES

- Expand the PFF Care Center Network to educate community providers and enhance appropriate and timely referrals
- Continuously improve and reassess evidence-based guidelines and identify outcomes using the PFF Care Center Network and the PFF Patient Registry

2

vision → Our understanding of PF is increased, and we have better diagnostics and treatments

goal → Ensure the level of development in PF therapeutics and diagnostics is sustained or improved

INITIATIVES

- Enroll 2,000 patients into the PFF Patient Registry
- Leverage the resources from the PFF Patient Registry to enhance internal and external research priorities, expand our understanding of PF with meaningful scientific contributions and publications, and ensure best practices become the standard of care
- Prioritize research programs identified by the Research Advisory Forum to accelerate our understanding of PF
- Develop a Therapeutics Network to increase patient participation in clinical trials

OUR VISION FOR THE FUTURE

3

vision → The community is mobilized to deliver information, participate in research, and provide access to high-quality care

goal → Ensure that the PF community has reasonable access to high-quality care, research, and information

INITIATIVES

- Engage and educate patients, caregivers, and families
- Educate policy makers on high-impact topics
- Educate health care providers
- Engage the non-PF affiliated community
- Expand network of affiliated CCN providers so that 90% of patients have reasonable access to expert care within two hours of their homes



4

vision → Growing streams of sustainable revenue are available to support the developing needs of the PF community

goal → Execute a development program that on average grows revenue by 15 percent per year

INITIATIVES

- Design a comprehensive, donor-centric development program
- Build an earned income program to diversify revenue

Let's take action.

Through these priority initiatives, together we can advance our research, outreach, and advocacy agenda. “Pulmonary Fibrosis Foundation Strategic Plan: PFF2020” outlines five strategies the Foundation will put into action to help power these initiatives and meet our goals. These strategies include the PFF Care Center Network, the PFF Patient Registry, a Therapeutics Network, Advocacy, and Fundraising. By participating in our efforts in these five areas to ensure these programs reach their full potential, you can help us achieve our vision for 2020, that people living with pulmonary fibrosis will live longer, healthier lives.

STRATEGY 1:

PFF CARE CENTER NETWORK

Working Together to Improve Patient Outcomes

The Pulmonary Fibrosis Foundation (PFF) is dedicated to its vision that every patient is diagnosed quickly and receives the highest quality care. As part of that commitment, over the past three years the PFF has worked with the pulmonary fibrosis (PF) medical community to establish the PFF Care Center Network, where people with PF can find experienced medical professionals who understand their disease and support services to improve the quality of their lives. The CCN provides regional educational support on diagnosis, treatment, and clinical trials.

Following two rounds of a competitive application process, the CCN has now increased to 40 sites across the United States. By continuing to expand the CCN and developing partnerships within their local communities, we will enhance awareness, educate providers, and ensure that the best practices identified through the PFF Patient Registry become the standard of care in the CCN and local communities. In doing so, we aim to decrease the time to an accurate diagnosis of PF to fewer than six months.

“[The CCN] will help spread knowledge for all patients with this disease so that we can strive to have continuity of care across the country and the world and quicker diagnosis and treatment of PF.”

REGISTERED NURSE / PFF SUMMIT SURVEY

WHAT IS IT?

The PFF Care Center Network is a growing group of medical centers with experience and expertise in treating patients with fibrotic lung disease that are dedicated to improving the lives of those living with PF. Disease management can be complex. The CCN is comprised of sites that have the necessary resources for patients to obtain medical expertise and specialized staff to fully manage the disease. CCN sites embrace a multidisciplinary approach that delivers comprehensive patient care. Experts in pulmonary medicine, rheumatology, radiology, and pathology specializing in interstitial lung disease comprise the care team at each CCN site.

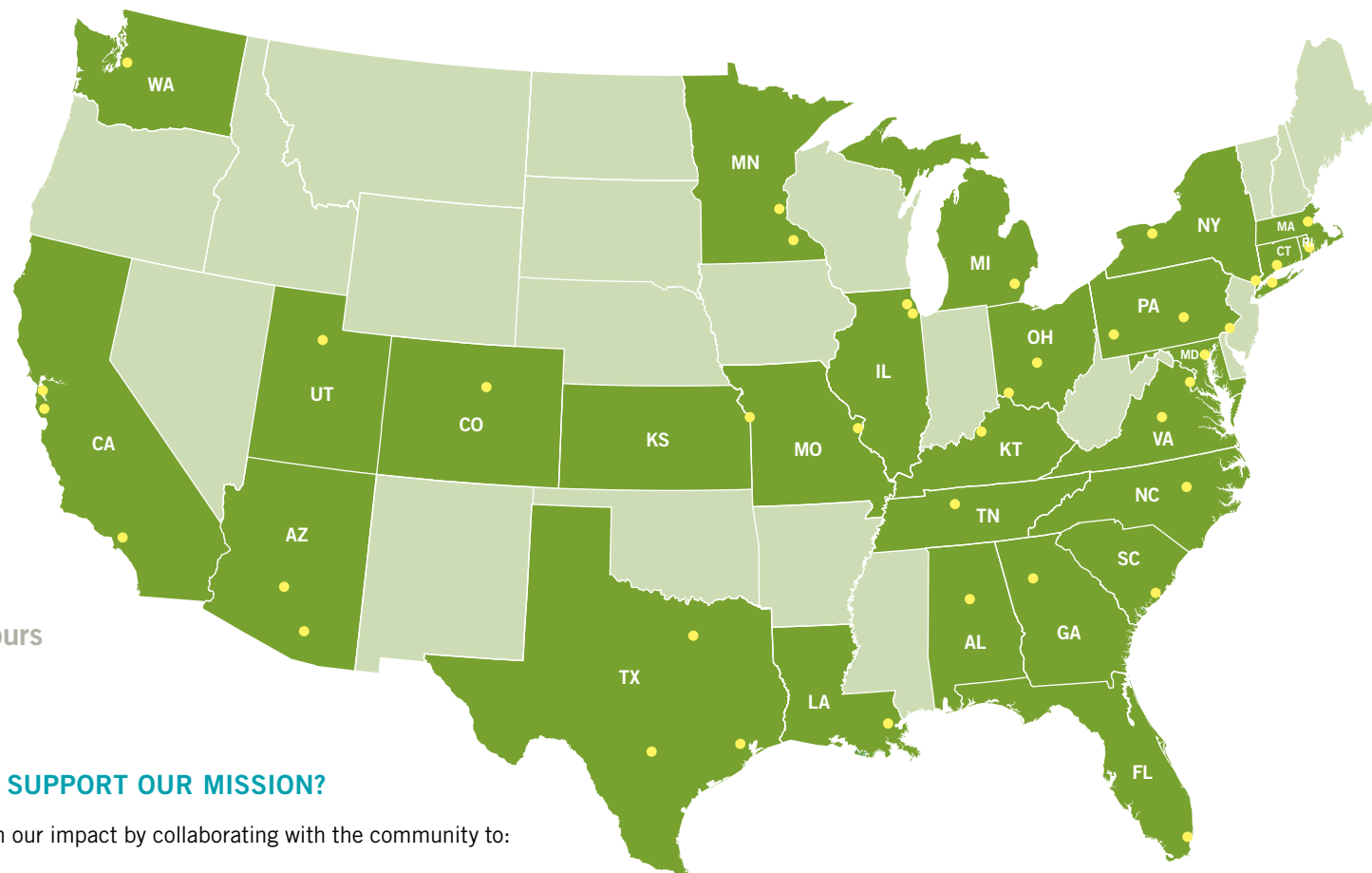
WHY IS IT IMPORTANT?

Because of the CCN's multidisciplinary approach, patients benefit from a more accurate diagnosis, recommendations for continuing care, assistance in delivering essential social services, and the opportunity to participate in collaborative research. Each patient is considered and treated individually.

CCN sites work with the Pulmonary Fibrosis Foundation to actively engage their local PF communities and promote quality of life, instructional, and research objectives with their activities. The sites are involved with other PFF Signature Programs and provide PF support groups to allow local communities to connect with and learn from others impacted by the disease.

Our current network has 40 CCN sites

78% of patients in metropolitan statistical areas* are within two hours of a current CCN site



HOW DOES IT SUPPORT OUR MISSION?

CCN sites broaden our impact by collaborating with the community to:

- identify patients with PF earlier,
- provide access to specialized care and cutting-edge research, and
- enhance awareness and understanding of PF.

CCN GOALS

- 1 Diagnosis: Reduce time to accurate diagnosis of PF
- 2 Quality of care: Ensure patients have access to high-quality care within two hours of their homes through the expansion of the CCN and their partners within the community
- 3 Research: Facilitate research within the CCN and Registry to enhance our understanding of PF and expedite efficient clinical trials to identify effective therapies

● CCN SITE LOCATION

*Two-hour driving distance defined as 120 miles; analysis only includes population living within MSAs (86% of total US population). Metropolitan statistical areas (MSAs) defined by the Office of Management and Budget (OMB) include population centers with over 50K residents and their adjacent communities.

Source: PFF, US Census Bureau

STRATEGIES TO MEET CCN GOALS

Engaging Community Practices

In order to reach all patients more effectively and efficiently, the CCN sites will develop partnerships with community-based health care professionals to share information and expertise. We proposed a hub-and-spoke model whereby the PFF Care Center Network site stands as the hub and the nearby community practices radiate out from the center like spokes on a wheel, with a two-way flow of communication connecting each one to the hub. This will facilitate our efforts on four fronts.

- **EDUCATE:** Our short-term vision is for the PFF to link community practices to PFF Care Center Network sites via a hub-and-spoke model to increase awareness of pulmonary fibrosis and the PFF's resources. In the long term, we envision using this established line of communication to educate community practices about evidence-based care so that best practices become the standard, enabling high-quality local care.
- **DIAGNOSE:** We want to create collaborative relationships between community practices and CCN sites and encourage community practices to refer patients to nearby CCN sites when appropriate to expedite diagnosis and treatment planning.
- **TREAT:** In the short term, treatment will be provided at CCN sites in collaboration with their partners in the community. Our long-term vision is to educate and empower physicians in the community to diagnose and treat patients via evidence-based guidelines.
- **COORDINATE:** In the short term, the PFF will coordinate ongoing care and research by providing treatment in consultation with CCN experts and facilitating referrals to Network sites for specialized care (e.g., lung transplants) and trial recruitment.

CCN Expansion

Our current Network has 40 sites. About 78 percent of patients in metropolitan statistical areas (MSAs) are within two hours of a current site. By adding 10 CCN sites that target the largest unserved MSAs by population, we can increase our reach to 90 percent of the population. We can also accomplish this expansion via collaboration with community practices.

“The PFF Care Center Network provides the opportunity for patients to receive specialized disease management and participate in clinical research aimed at improving outcomes for patients with pulmonary fibrosis.”

KATHLEEN O. LINDELL, PHD, RN / PFF BOARD OF DIRECTORS
VICE CHAIR AND MEDICAL ADVISORY BOARD MEMBER.

	2016	2017	2018	2019	2020
NETWORK EXPANSION	<ul style="list-style-type: none"> Establish 40 CCN sites Develop CCN's Ambassador program 	<ul style="list-style-type: none"> Identify additional CCN site locations to reach 90% goal Start initial training of Ambassadors 	<ul style="list-style-type: none"> Consider establishing accreditation process for CCN sites Initiate PFF Ambassador outreach to community Begin community integration with pilot group of CCN sites 	<ul style="list-style-type: none"> Expand pilot program of community site integration 	<ul style="list-style-type: none"> Initiate integration of pulmonary rehabilitation centers with pilot group of CCN sites
PRIORITY COMMUNITY OUTREACH (TO)	<ul style="list-style-type: none"> Community pulmonologists 	<ul style="list-style-type: none"> Pulmonary/cardiac rehabilitation centers 	<ul style="list-style-type: none"> General practitioners / Nurse practitioners 		
MEASUREMENT & MONITORING		<ul style="list-style-type: none"> Conduct baseline knowledge, attitudes, beliefs, and practices (KABP) survey 	<ul style="list-style-type: none"> Field and analyze survey 	<ul style="list-style-type: none"> Integrate feedback 	<ul style="list-style-type: none"> Conduct audit of program effectiveness
SITE PARTICIPATION INCENTIVES		<ul style="list-style-type: none"> Develop point of view on economic value of site participation 	<ul style="list-style-type: none"> Implement alternate participation model 		

PATH TO 2020: KEY CCN ACTIVITIES

To ensure we focus our efforts in the right direction, the PFF developed a PFF Care Center Network action plan that maps out key activities and the timeline necessary for reaching our goals. Envisioning the process in stages, the plan identifies the actions we must take each year from 2016 to 2020 in order to achieve success.

“We see the CCN as a way to build bridges outward to raise awareness of PF and aid in the care of patients with pulmonary fibrosis.”

KEVIN R. FLAHERTY, MD, MS / STEERING COMMITTEE CHAIR,
PFF CARE CENTER NETWORK AND PFF PATIENT REGISTRY

KEY CCN METRICS

By following these steps and documenting our results, we will hold ourselves accountable. We have set five key metrics with corresponding targets to measure and track our progress.

- 1 Percent of patients in metropolitan statistical areas within a two-hour radius of a CCN site or affiliated partner
Target: 90 percent
- 2 Time to diagnosis
Target: Less than six months
- 3 Each site identifies “spokes” with whom they actively collaborate
Target: Five each site, 200 for the total Network
- 4 “Spoke tracker” to measure quality of collaboration with satellite sites
Target: Will be determined after satellite sites are established
- 5 Adherence to diagnostic and treatment guidelines
Target: 75% adherence to guidelines

STRATEGY 2:

PFF PATIENT REGISTRY

The First Step to a Cure

The Pulmonary Fibrosis Foundation (PFF) is leading the charge to find a cure for pulmonary fibrosis (PF), and the first step is to increase our knowledge of the diseases that impact the lives of so many. To achieve this, the Foundation sought input on unmet needs from PF clinicians, scientific leaders, and the patient community. It became clear that the absence of a large nationwide patient registry and biorepository was keeping researchers from taking critical steps toward a cure. In response, the Foundation introduced the PFF Patient Registry, a first-of-its-kind PF research study that will generate a database of anonymized medical information collected at participating PFF Care Center Network sites from at least 2,000 patients. Together, the CCN and the Registry will significantly improve research relating to PF diagnosis, treatment, and an eventual cure. In the spring of 2016, the Registry enrolled its first patient.

The PFF Patient Registry will enable us, for the first time, to understand what treatments work best for patients and to find new ways to diagnose, treat, and potentially cure pulmonary fibrosis.

WHAT IS IT?

The PFF Patient Registry will be a comprehensive research tool available in the fight against PF. All data entered into the Registry will come through a CCN site, ensuring standard collection procedures and controls for maximum data integrity. The de-identified information includes the patient's age and gender, details on how the diagnosis was made, medical tests results, medications taken, and medical outcomes such as hospitalization, transplantation, and death.

Participants may choose to contribute blood samples to a biorepository that will store samples for use in future research. When combined with the information in the Registry, these samples have the potential to help scientists find new causes of PF, identify means of determining whether treatments are working, improve the ways doctors monitor the progression of the disease, and help discover new treatments.

WHY IS IT IMPORTANT?

Research is the pathway to a cure for PF. This combination of data from so many patients, including those with less-studied forms of PF, will generate an unparalleled resource for future research into treatments and provide data for improving and reassessing evidence-based care guidelines.

HOW DOES IT SUPPORT OUR MISSION?

This initiative will:

- increase our understanding of PF,
- enable better diagnostics and treatments, and
- advance our vision to ensure every patient is diagnosed quickly and receives the highest quality care.

Across these objectives, we aim to use our Registry to learn about patient sub-groups.

What we can study:

Investigate the causes and progression of disease

Develop, test, and validate biomarkers (measurable indicators of the presence or status of a disease)

Assess effectiveness of all treatments and understand variations in outcomes

How this will impact patients:

Support research and encourage targeted investment in drug development

Enable faster diagnosis of PF patients
Identify those most likely to progress and require early treatment

Develop evidence-based care guidelines to enable higher quality care of PF patients

REGISTRY GOALS

- 1 Collect longitudinal data from more than 2,000 patients by 2020 and develop a lower-cost approach to data collection to build greater scale
- 2 Provide database access for research into causes, progression, treatment effects, and outcomes
- 3 Use Registry data to continuously improve and reassess evidence-based clinical guidelines

“I explain [to patients] that the PFF Care Center Network will be linked with the PFF Patient Registry, where de-identified data will be saved and used for research. The Registry is very valuable in terms of gathering data for research, as well as helping to show in numbers just how widespread pulmonary fibrosis really is.”

VOLUNTEER / PFF SUMMIT SURVEY

STRATEGIES TO MEET REGISTRY GOALS

The PFF Patient Registry will evolve over the next five years to collect many types of data.

- In the short term, our efforts will focus on CCN sites to establish serial collection of annotated samples and electronic medical records at each patient visit.
- In the long term, we will diversify data sources by including patient-reported outcomes via wearables data and partnerships with other organizations. We will also incorporate electronic medical records from community sites and computerized tomography scans from community providers.

HOW WILL THE REGISTRY BE USED?

All data included in the PFF Patient Registry will be used to foster research to better understand PF, drive toward a cure, and improve the lives of those living with PF. See the chart above.

	2016	2017	2018	2019	2020
MILESTONES	<ul style="list-style-type: none"> Decide on 2020 target number of patients 	<ul style="list-style-type: none"> 2,000 patients enrolled with biological samples 	<ul style="list-style-type: none"> Start collecting other patient-reported data Start collecting community data 		<ul style="list-style-type: none"> Additional patients enrolled with biological samples
REGISTRY OPERATIONS	<ul style="list-style-type: none"> Decide publication format and cadence 	<ul style="list-style-type: none"> Collaborate with patient-reported data collection organizations 	<ul style="list-style-type: none"> Develop lower-cost collection methodology Utilize data warehousing to tie the Registry to other sources 	<div style="border: 1px solid red; padding: 5px; display: inline-block;"> A lower-cost approach will enable us to increase the scale of the Registry in the long term. </div>	<ul style="list-style-type: none"> Capture data from multiple points of care
FUNDING	<ul style="list-style-type: none"> Secure funding for serial collection of samples 	<ul style="list-style-type: none"> Develop a business plan to sustain the Registry 	<ul style="list-style-type: none"> Implement business plan to sustain the Registry 		
MEASUREMENT & MONITORING	<ul style="list-style-type: none"> Ongoing tracking of patient enrollment, samples collected, and publications released 				

PATH TO 2020: KEY REGISTRY ACTIVITIES

The PFF developed a Registry action plan that details milestones and key operational and fundraising activities we must undertake over the next five years to reach our goals in 2020.

“The Registry database is something the community has needed for a long time. You hear all the stories, but now we’ll have the data collected in a standardized way for accurate and meaningful analysis. That will make recruitment for clinical trials easier, help develop effective therapies, and provide researchers with valuable data.”

TERENCE HALES / PFF BOARD OF DIRECTORS MEMBER, PF FAMILY MEMBER

KEY REGISTRY METRICS

To hold ourselves accountable, we set four key metrics with corresponding targets to measure our progress.

- 1 Number of patients enrolled
Target: 2017: 2,000 patients; 2020: 6,000 patients
- 2 Number of biological samples collected
Target: 2017: 1,800 samples; 2020: 5,400 samples
- 3 Number of publications released by 2020
Target: 10 publications
- 4 Completeness of records
Target: 95 percent

STRATEGY 3:

THERAPEUTICS NETWORK

Driving Toward a Cure

As the PFF Patient Registry advances our goals for better diagnostics and treatment, the Therapeutics Network (TN) drives us toward a cure. Observing the impact that similar initiatives have had on other diseases, the Pulmonary Fibrosis Foundation (PFF) Board of Directors approved exploration into the creation of a Therapeutics Network, an ambitious initiative to facilitate drug development. In collaboration with a contract research organization experienced in the field, the PFF identified short and long-term priorities to establish a TN. We decided to focus on a short-term initiative that would have an early impact, demonstrate value to the field, and foster additional partnerships within the PF community. The TN is currently one of our unfunded initiatives.

WHAT IS IT?

A therapeutics network supports drug development to discover and advance new therapies to treat and cure disease via clinical trials. The PFF's Therapeutics Network will establish an environment to sustain continued and enhanced investment in IPF treatments and to develop an evidence base to support therapy used in other types of PF. The TN could enhance drug evaluation in three ways:

- Advise on clinical trial protocols
- Recruit and train sites and support patient recruitment
- Collaborate with manufacturers to conduct novel and efficient clinical trials

“[We need to] be more aggressive in developing and guiding treatments for patients.”

PF PATIENT / PFF SUMMIT SURVEY

WHY IS IT IMPORTANT?

In 2015, two drugs were approved for the treatment of IPF (Esbriet® and Ofev®). There are presently 13 potential PF therapies in the pipeline. The number of patients required to support Phase III trials is expected to increase from about 2,000 in 2015 to about 6,000 in 2018 if the current trial design is utilized, limiting the number of candidates that can be effectively evaluated. Novel and efficient trials designs are required to evaluate all potential candidates to treat PF.

HOW DOES IT SUPPORT OUR MISSION?

The TN will improve outcomes for those living with PF by mobilizing resources to improve the level of development in therapeutics and facilitate patient participation in clinical trials.

THERAPEUTICS NETWORK GOAL AND STRATEGIES

The TN will create an environment to efficiently evaluate therapies and interventions for the treatment of all forms of PF.

- The PFF met with eight partners to understand and assess the value of a TN. Pharmaceutical companies enthusiastically received the proposed initiative, as did our two CCN and Registry partners that have completed Phase III studies.
- We will draft a proposal for collaboration with the PFF and future partners.

PATH TO 2020: KEY THERAPEUTICS NETWORK ACTIVITIES

The PFF identified potential areas of impact to direct action plans for this developing initiative. These will include defining trial protocols, enrolling sites, recruiting patients, supporting site operations, and conducting post-marketing trials.

STRATEGY 4:

ADVOCACY

Providing Hope for a Better Tomorrow

Raising awareness of a rare disease is challenging. It takes an extraordinary amount of time, perseverance, and community involvement to inform the world about a disease when most people are unaware of its existence. The key to raising the profile of pulmonary fibrosis (PF) is the exceptional programming that forms the backbone of the Pulmonary Fibrosis Foundation (PFF). We engage in multipronged awareness initiatives that extend beyond the patient and caregiver community to reach health care providers, researchers, legislators, and the public. In recent years, the Foundation has successfully mobilized people and resources to educate, connect, and support the PF community. We will continue to build on these efforts to advocate for a cure and provide hope for a better tomorrow.

WHAT IS IT?

The formula for a world without pulmonary fibrosis is a mixture of awareness, education, and research. Advocacy is key to achieving all of these.

“By speaking about their individual experiences with pulmonary fibrosis, PFF Ambassadors promote disease awareness, share up-to-date information, and provide hope and inspiration to the PF community.”

COURTNEY FIRAK / PFF DIRECTOR OF PROGRAMS



WHY IS IT IMPORTANT?

Our programs enhance awareness of pulmonary fibrosis and provide education to anyone seeking a greater understanding of PF or support while living with the disease. We continue to advocate for important research initiatives that push toward finding a cure.

HOW DOES IT SUPPORT OUR MISSION?

Our Advocacy initiative mobilizes the community to deliver information, participate in research, and provide access to high-quality care so people with PF will live longer, healthier lives.

KEY ADVOCACY PROGRAMS

The PFF's core programming advances global awareness, provides resources, and promotes disease education. As discussed in the section detailing our progress on pages 5 and 6, the PFF has a range of successful key advocacy programs that further our mission, including the **PFF Ambassadors**, the **Support Group Leader Network**, **Global Pulmonary Fibrosis Awareness Month**, the **PFF Patient Communication Center**, the **PFF Summit**, and the **PFF Disease Education Webinar Series**. In addition, we've expanded **PFF Daughters**, a program that began with the Coalition for Pulmonary Fibrosis focusing on daughters of PF patients. The volunteer program has evolved to provide opportunities for the entire family to advocate for improved care and to raise awareness about the disease.

MEETING PATIENT NEEDS

In order to change systems on behalf of patients and families, we must understand the practical needs of the patients and keep them at the center of our focus. The PFF is dedicated to identifying the areas of highest need, providing resources to meet them, and advocating for improved patient outcomes.

- **Misdiagnosis**—When the symptoms of PF begin, misdiagnosis is almost universal. Asthma, chronic obstructive pulmonary disease, heart disease, obesity, aging, sleep apnea, or a sedentary lifestyle are often wrongly identified as the cause. On average, people living with PF are not diagnosed with interstitial lung disease (ILD) for more than a year after the onset of symptoms.
- **Access to care**—Once diagnosed, PF patients often do not receive optimal care, including adequate oxygen prescriptions; appropriate pharmacologic therapy; and timely referral for pulmonary rehabilitation, an ILD center, or a lung transplant program. Patients often face barriers to accessing subspecialty pulmonary care, regardless of their insurance coverage, and their access to other forms of health care.
- **Managing symptoms**—People living with PF suffer from breathlessness and chronic cough, leading to poor quality of life and social isolation. Patients experience many barriers to accessing home and portable oxygen equipment, which often limits activity for many of them.

ADVOCACY GOALS

Our goal for 2020 is that 90 percent of the pulmonary fibrosis community will have access to high-quality care, research, and information.

We will be successful if we can:

- engage and educate patients, caregivers, and families;
- educate policy makers on high-impact topics;
- educate health care providers about pulmonary fibrosis, PFF resources, and high-quality care; and
- engage the non-PF affiliated community to build awareness and partnerships.

STRATEGIES TO ACHIEVE ADVOCACY GOALS

The PFF will advance change by educating policy makers, focusing on high-impact topics.

- In the short term, the PFF will conduct an assessment and develop infrastructure to support an Advocacy program. The PFF will develop partnerships with other advocacy groups focused on high-impact areas that will further research and disease awareness.
- Between now and 2018, the PFF will determine a funding and engagement strategy to enhance our interactions with the National Institutes of Health (NIH). Other medium-term targets are to improve access to, and reimbursement of, pulmonary rehabilitation programs and supplemental oxygen.

“[The PFF] shines a light on a disease that few have heard of.”

PATH TO 2020: KEY ADVOCACY INITIATIVES

INITIATIVE	DESCRIPTION	TARGET AUDIENCE	ADVOCACY GOALS			
			ENGAGE PATIENTS/ FAMILIES	EDUCATE HCPs	EDUCATE POLICY- MAKERS	ENGAGE NON- PF AFFILIATED COMMUNITY
GOVERNMENT ADVOCACY	<ul style="list-style-type: none"> Educate policy-makers about most critical PF issues Partner with like-minded groups to increase our share of voice 	<ul style="list-style-type: none"> Federal stakeholders: Centers for Medicare and Medicaid Services (CMS), NIH, FDA 			✓	✓
PFF AMBASSADORS	<ul style="list-style-type: none"> Develop PFF Ambassadors to serve as spokespeople for the PF community 	<ul style="list-style-type: none"> PF and non-PF community 	✓	✓	✓	✓
CONFERENCES	<ul style="list-style-type: none"> Develop PFF awareness at relevant conferences 	<ul style="list-style-type: none"> PF community 	✓	✓		
PFF SUMMIT	<ul style="list-style-type: none"> Improve biennial Summit for greater PF education/awareness 	<ul style="list-style-type: none"> PF community 	✓	✓		
SUPPORT GROUP LEADER NETWORK	<ul style="list-style-type: none"> Provide forum for support groups to interact and exchange best practices 	<ul style="list-style-type: none"> PF volunteer support groups 	✓			
PFF DAUGHTERS	<ul style="list-style-type: none"> Develop volunteer program that serves as a gateway for individuals to become affiliated with the PFF 	<ul style="list-style-type: none"> PF and non-PF community 	✓		✓	✓

“[Being a PFF Ambassador] is a small way of paying back everything the PFF has done for me surrounding my transplant. I’m out there actually walking the pavement and knocking on doors to drum up support for patients and for the Pulmonary Fibrosis Foundation. I encourage people to take their meds, do the rehab, and see their doctors – my main message is one of hope.”

DOUG JONES / PFF AMBASSADOR, PF PATIENT

STRATEGY 5: FUNDRAISING

Changing the Future

Philanthropy powers the Pulmonary Fibrosis Foundation's (PFF) drive toward a cure. It has fueled the successes we've experienced thus far and will propel us forward in new directions for the future. Every dollar raised increases awareness of pulmonary fibrosis (PF), provides resources and support to those living with the disease, and expands the research that improves outcomes for tomorrow. Together, we're changing the future for those affected by PF.

WHAT IS IT?

Eradicating this deadly disease requires resources. The PFF is dedicated to raising the funds needed to push forward and funding the important initiatives outlined in our strategic plan. Stewardship of these funds is critically important. **The PFF has secured a Four-Star Charity Navigator rating and has been designated as an accredited charity with the Better Business Bureau to ensure “best in class” operational management and stewardship of contributions.** From 2011 to 2015, the PFF grew revenue nearly two and a half times to support the pulmonary fibrosis community. In addition to supporting programs, these funds allowed the PFF to award more than \$4 million in research grants and sponsorships and provide 19 awards resulting in more than \$95 million in subsequent funding from the National Institutes of Health.



The Pulmonary Fibrosis Foundation is a 501(c)(3) nonprofit organization.

“I see the CCN and Registry as key to future breakthroughs.”

RESPIRATORY THERAPIST / PFF SUMMIT SURVEY

WHY IS IT IMPORTANT?

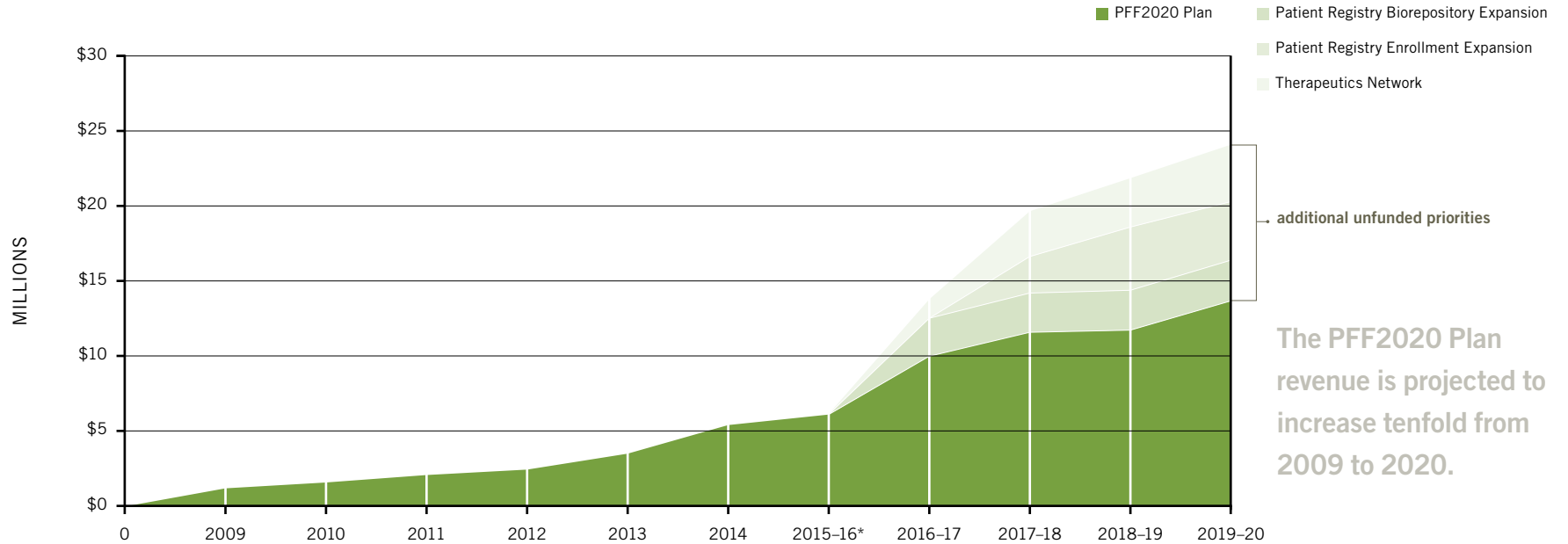
The generosity of donors brings us ever closer to finding new treatments and, ultimately, a cure. The funds we've raised have helped us develop, launch, and expand advocacy initiatives and groundbreaking programs, such as the PFF Care Center Network and the PFF Patient Registry.

Opportunities abound for individuals and organizations wishing to make a significant impact. Funds are needed to expand enrollment in the Registry, which will allow for a more thorough understanding of the disease and potential treatments; conduct serial collections of DNA from individuals enrolled in the Registry, which will allow for a greater understanding the role genetics play in the progression of the disease; and launch a Therapeutics Network, which will facilitate the development of a wide range of novel treatments options.

FUNDRAISING GOALS

- 1 Develop growing streams of sustainable revenue, both contributed and earned income, to support the needs of the PF community
- 2 Build an effective fundraising program that fully supports all programming set forth within the current strategic plan and all future initiatives currently under consideration
- 3 Significantly increase the Foundation's fundraising capacity by expanding current streams of revenue, identifying new opportunities, maximizing individual giving, increasing donor retention, and improving fundraising efficiencies
- 4 Execute a development program that on average grows revenue by 15 percent per year

REVENUE GROWTH PROJECTIONS BY FISCAL YEAR



NOTE: In 2015, the PFF changed its fiscal year to end June 30. *Unaudited

STRATEGIES FOR ACHIEVING FUNDRAISING GOALS

We will grow our development program by continuing to work closely with all of our stakeholders. Over the coming months, we will continue to develop:

- An individual giving program that allows donors to better recognize the impact of their gifts
- An expanded community events program that better supports the work of the hundreds of people across the country holding events to honor or remember family and friends impacted by PF
- A more comprehensive annual fund that makes it easier for stakeholders to support the community, featuring improved communications and new opportunities for recurring, workplace, and matching gifts
- A global partnership approach that allows businesses and individuals to sponsor research, education, advocacy, and fundraising initiatives in a way that meets their individual needs

- A planned giving program for families wishing to leave a lasting legacy
- Signature events across the country including Broadway Belts for PFF! — an annual fundraiser featuring performances from some of Broadway’s most recognizable performers, and the Breathe Benefit, a fundraising gala that will engage the entire PF community in a night of celebration
- Virtual events, such as Global Pulmonary Fibrosis Awareness Month and Giving Tuesday, that will allow members of the community to lend their support when they are unable to participate in person

We will pursue partnerships with educational partners, industry leaders, and other community organizations to support the PFF’s mission and programs highlighted in the Strategic Plan. Revenue-generating activities will include fees associated with participating in the PFF Registry, continuing medical education (CME), market research, content licensing, and our online store, Shop PFF.

MAKE AN IMPACT

Every year, about 50,000 families receive news that a loved one has been diagnosed with IPF, one of the more common types of PF. Those families are often scared, overwhelmed, frustrated, and confused. The Pulmonary Fibrosis Foundation wants to change that. By developing the ambitious but desperately needed plan for 2020, the PFF is taking an active role in finding a cure and supporting patients and their families impacted by the disease. We are fulfilling upon important programs that require support from the entire community — engagement with our volunteers, funding from donors, and awareness generated by all involved in the PF community. With success in each of these areas, the Foundation has an opportunity to remove barriers and realize change.

Pulmonary Fibrosis FOUNDATION



The time is now.

As we move forward to achieve our goals and execute the strategies detailed in this report, we urge you to give today. Whether that means that you are giving of your time or money, the Foundation needs YOU. **Together, we imagine a world without pulmonary fibrosis and together, we will make a difference.**

Call **844.TALKPFF** (844.825.5733) or visit pulmonaryfibrosis.org to learn more, get involved, or make a gift.

“We discovered the PFF after my father’s battle with this horrible disease ended, but my experience and relationship with this fabulous Foundation was just beginning. Since his passing, I have helped to organize several awareness events and fundraisers. We see our hard-earned dollars going towards raising awareness, support, and ultimately a cure. We are proud to help the PFF in any way we can and encourage so many others to do the same!”

KATHY PETRAK / VOLUNTEER

WE THANK YOU FOR YOUR SUPPORT.

230 EAST OHIO STREET SUITE 500 CHICAGO, ILLINOIS 60611

Pulmonary Fibrosis
FOUNDATION