CROHN'S
&COLITIS
FOUNDATION

2018 Annual Report

Better Together

We're accelerating the pace of our fight against inflammatory bowel disease with the help of our powerful community of scientists, healthcare providers, policy makers, and—of course—patients and caregivers.

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A Message from Our Leadership

2018 was a year of major new initiatives and expansion across our research investments, advocacy efforts, and patient, caregiver, and professional education programs.

Better Together

Over 50 years ago, our founders joined together with shared goals and a common vision. In the years since, the winflammatory bowel disease (IBD) community has grown exponentially; together, we have made tremendous progress toward achieving our mission. Our many accomplishments are proof that we are better together. We are the largest community of IBD patients and caregivers in the country, engaged in the fight against Crohn's disease and ulcerative colitis, and it is together that we can achieve a world without IBD.

In 2018, with your help and support, we saw critical advances in our mission programs and introduced major new initiatives focused on the expansion and acceleration of our research investments, along with increased focus on our critical education, support, and advocacy efforts.

To date we have invested over $350 million in critical research, which has resulted in tremendous progress, including significantly improving patient quality of life and moving us closer to cures. In the last 10 years alone, we have funded essential research in key areas, with multimillion-dollar investments across multiple institutions. In our drive toward better treatments and cures, we are accelerating research on a variety of fronts by breaking down traditional barriers to patients, data, and collaborations. In 2018, research partners in academia and the pharmaceutical industry gained access to an unprecedented amount of biosamples, along with extensive data collected from thousands of patients through our unique IBD Plexus platform. This important platform will cut years off the research process, and will dramatically accelerate the pace of scientific investigation for our partners.

We are also seeing our longer-term investments paying off in very significant ways—in fact, we are on the cusp of major breakthroughs that will have a real impact on patients' lives:

- **Our Pediatric RISK Stratification study yielded consequential data to advance our understanding of Crohn's disease.** We are working to translate the discovery of biomarkers into a risk diagnostic tool to enable providers to predict complications and help make therapeutic decisions at diagnosis.

- **Through the Genetics Initiative, we have helped identify 240 genes associated with IBD, and continue to identify new genetic mutations with links to the diseases.** This past year, we investigated a new gene mutation that increases the risk of ulcerative colitis, opening the door to new therapies.

- **Our investment in microbiome research has enabled an understanding of the bacteria and viruses that live in our system.** These discoveries are making possible the development of treatments, such as live bacterial cocktails, that can be given to patients to help rebalance their microbiome, and potentially put their disease into remission.

> **To date we have invested over $350 million in critical research, which has resulted in tremendous progress, including significantly improving patients' quality of life and moving us closer to cures.**

While these advancements are critical, we recognize that they do not provide the full answer. We cannot rest on our laurels; there are new areas and new domains that must be investigated, and we are putting important stakes in the ground around issues such as environmental triggers, including psychological stress; we are exploring how stress-related brain changes might impact the course of the disease; and we are understanding the role of diet to develop dietary strategies to help manage IBD.

In this era of rapidly advancing science, we would be seriously remiss if we didn't look beyond the traditional approaches to identify research opportunities that could be applied to advance our mission and accelerate the pace of IBD research.

- Two new Foundation efforts—IBD Ventures and our IBD Innovate conference—are designed to break down traditional barriers by supporting commercial enterprises that have the **potential to bring transformative, novel products to IBD patients in the near future.**

- In 2018, we held a Biomarker Summit to bring together key stakeholders in our search for reliable disease markers, **and we are supporting research into novel technologies,** including the development of unique biosensors, designed to track disease progression and make predictions about flares.

Each step of the way, we aim to inspire and engage the community in our work and mission. We invite patients and caregivers to sit at the table as we design education programs and set our research agenda. They stand by our side as we advocate for important public policy that creates a better world for all IBD patients. It is due to our volunteer-fueled advocacy efforts that step therapy reform—legislation that removes barriers to getting the right treatment in a timely fashion—was passed in Minnesota and Ohio in 2018. We have also significantly increased our advocacy efforts on the national level.

Research has shown that an empowered and resilient patient has better outcomes, receives better care, and has an improved quality of life. As such, we place great emphasis on building shared decision-making—a central element of our IBD Qorus quality of care initiative—as well as other tools and resources. Our goal is to provide the resources, knowledge, and support that patients need to navigate this challenging disease journey.

These are just a few of our many accomplishments. As you read through this annual report, please know that each and every one of you played an important part in these achievements. We could not do this without you. Remember: **together we are better.**

Michael Osso

Michael Osso
President & CEO

John Crosson
Chair, Board of Trustees

Putting Patients First

Our Goal:
Empowering the IBD Community

How we're reaching it:
By increasing support and education for patients and caregivers, while providing them with the tools they need to take charge of their care. We are proactively fighting alongside the IBD community to ensure they have access to the treatments they need.

"Camp Oasis Changed My Life"

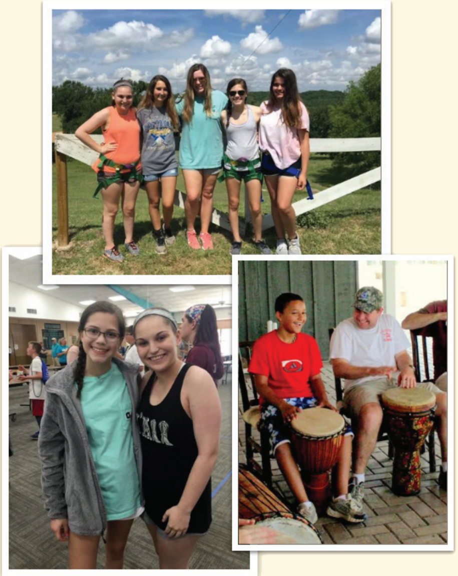
60% of campers returning from Camp Oasis, our summer camp for kids with IBD, describe it as life-changing. Marni Goldman, now 16, found her tribe—and a new attitude about her disease— during her very first visit.

When I was 7 years old, my mom called me down from my bedroom to watch a video. It was about Camp Oasis, a sleepaway camp for kids with Crohn's disease or ulcerative colitis. She thought I might be interested in going to the camp—which started in just three weeks—but she wanted it to be my choice. I hadn't even finished watching the promo video before I said, "Mom, I have to go there!"

Still, I was scared when we first arrived; I wouldn't let go of my mom's leg. I'd never been away from my parents overnight, but right away I met a girl named Sabrina. Within five minutes, we clicked. It was her second summer at the camp, so she knew everything and stuck with me. We have been friends ever since. We still talk every day, even though we only get to see each other twice a year.

Camp Oasis really did change my life. Since everybody there has either Crohn's or colitis, it's easy to relate to each other. You don't have to worry about saying, "I have to run to the bathroom," because everyone knows what that's like. At a regular camp they might say, "Can you wait five minutes?" but you can't. But everyone there understands the struggle. I'm 16 now, so this will be my last year as a camper, and then I'll hopefully get to be a Leader-in-Training. Once I'm 19, I'll be able go back as a counselor. From the first time I was there, that's what I wanted to do.

It's hard to put into words what Camp Oasis has done for me, because I just love it so much. It's given me a more positive outlook about my condition. During the year, I can be really negative about my Crohn's; when I get home from camp, and for months after, my whole outlook changes. I'm positive. I'm like, "Let's tackle this head on." Just being with people who understand changes everything.



Top: Marni (second from right) at Camp Oasis with friends Sabrina Fugua, Morgan Mercer, Kylie Allred, and Victoria Spruill. Bottom left: Marni (left) with friend Sabrina before leaving camp. Bottom right: Campers enjoying musical activities.

A Comprehensive Approach

We're here to support patients and caregivers in all areas and at every stage of their disease journey.

Our aim at the Crohn's & Colitis Foundation is to ensure patients and caregivers receive the education and support they need to build resilience and to live their best lives," says Catherine Soto, director of patient education and support at the Foundation. "Every patient is at a different point in their life and at a different stage of their disease journey. Whether they're just beginning to try to understand their disease, making new decisions, seeking different treatment options, or searching for help with the psychosocial impact of IBD, it's important that we are able to offer the resources they need."

2018 saw an increase in the size and scope of the resources we provide, including new information about the financial management of IBD and additional mental health support.

Mental health and emotional support

No patient or caregiver should feel isolated or remain uninformed; that's what drives our efforts to create multiple avenues for connection and emotional support. "Our Crohn's & Colitis Community website is a space in which both patients and caregivers can hear each other's stories in discussion forums, ask questions to experts, and join online support groups," says Soto. These monthly, web-based groups are varied, and most often consist of four 90-minute sessions led by an expert facilitator. Each week, these support groups focus on a specific IBD topic, such as the basics of IBD, medical management, nutrition issues, and more. In 2018, participation in all live support programs increased by 168%.

Educational opportunities

In 2018, many patients and caregivers attended live, in-person education events. Additionally, our educational webcasts and videos garnered over 200,000 views. Our focus is to meet people wherever they are—from cities to rural areas and every place in between—as well as to offer in-depth information from experts that people can watch in their own homes. "But education and support aren't just about experts sharing information. Another important approach has been to embed patient stories into a range of educational materials. This has allowed us to address topics of interest from the patient's perspective," says Soto.

Financial management of IBD

"When you have a chronic illness like Crohn's or ulcerative colitis, you have to become a savvy manager of costs and of your health," says Laura Wingate, senior vice president, education, support & advocacy. You also have to become an expert in health insurance issues, and act as your own or your loved one's advocate. That's the driving force behind our improved suite of financial resources, which helps patients and caregivers find available financial assistance for ostomy supplies or medications, information about co-pay accumulator programs, tips on what to do if you're denied insurance coverage, and much more.

Equal Partners in Care

IBD Qorus, our quality-of-care initiative, helps patients and providers to make more informed healthcare decisions together.

Donald Lum, MD

When Donald Lum, MD, a gastroenterologist in Portland, Oregon, is about to see a patient in his clinic, he first checks their patient-reported survey on the IBD Qorus dashboard. "I look for what their number one concern is that day, which allows me to really zero in on what my patient needs," he says.

IBD Qorus is the Crohn's & Colitis Foundation's expanding national program that aims to improve the quality of care delivered to patients. It works to not only empower patients to become better advocates for themselves, it also encourages and enables clinicians to share best practices with their peers via a collaborative Learning Health System. But it all comes back to the patient–clinician relationship.

> I look for what their number one concern is for today, which allows me to really zero in on what my patient needs.

“A younger patient might tell me that coming in for infusions every eight weeks doesn’t work for their lifestyle, or that a certain medication is too expensive, which is something I might not have thought of before IBD Qorus,” says Lum, “So together, we look for other options.” IBD Qorus is helping to prove that when patients are actively involved, the delivery of care is inevitably better.

The IBD Qorus Collaborative in Las Vegas, Nevada

2018 by the Numbers:

11,704	Questions from patients, caregivers, and providers through our IBD Help Center
237,476	Unique views of our live and archived IBD education webcasts and videos
9,041	Patients and caregivers hosted at live education events
21%	Increase in attendance of patients and family members at in-person support groups from 2017

Our Goal:

To Leverage Our Major Research

How we're reaching it:
By taking what we've learned and building on key findings.

What We've Learned—and What's Up Next

Since our inception, the Crohn's & Colitis Foundation has been firmly committed to funding research that has the potential to change the lives of people with IBD. In 2018, we continued to support ongoing studies that are yielding fruitful results, while also investing in new endeavors that hold the promise of uncovering unique treatments and tools. Here's a look at some of the most exciting research findings of 2018, as well as a glimpse into the not-so-distant future.

In pediatrics... We made several key breakthroughs with our RISK Stratification Study, the largest-ever patient study of pediatric Crohn's disease.

- We expanded on findings reported in a 2017 paper published in The Lancet that identified a predictive model for complications requiring surgery in pediatric Crohn's disease. The original research was based on patient follow-up for at least three years. We now have additional information, attained by following this group for two more years. This is particularly important in helping us to **understand long-term outcomes, and to help us to support pediatric patients who are entering adulthood.**
- We discovered that levels of the blood protein **COL3A1—a type of gene that helps make collagen—was significantly higher among patients who ultimately went on to develop small intestinal strictures** (narrowings in the small intestine). This research was published in the journal Clinical Gastroenterology and Hepatology in September 2018.
- We published a prospective study in the American Journal of Gastroenterology in October 2018 examining the impact of early-life environment on Crohn's disease progression. We used data from 1,119 Crohn's subjects, recruited from our RISK inception cohort, and found that pediatric **Crohn's patients who had been breastfed were less likely to develop complications,** such as strictures, while maternal smoking during pregnancy was associated with an increased risk of hospitalization and surgery.

In 2019, we'll be expanding our search for blood-based biomarkers, analyzing hundreds of thousands of them in an attempt to identify potential protein signatures and signals that can be used as powerful diagnostic and screening tools in the future. Our hope is to use this information to help identify, in a minimally invasive manner, the approximately 20% of pediatric patients who rapidly progress to complicated disease requiring surgery.

In genetics... Our years of investment in genetics research has paid off. This has helped identify over 240 genetic mutations that are now associated with IBD.

- In 2018, we continued this momentum by investigating C1orf106, a gene that, when mutated, raises the risk of developing ulcerative colitis. This gene is particularly interesting because it's involved in stabilizing the adherens junction, which is the glue between the cells that line the gut. When this is altered, it can cause defects in the gastrointestinal barrier, allowing substances from the gut to leak into the bloodstream and trigger symptoms of ulcerative colitis. **These findings pave the way for future research into new therapies that can restore or prevent the leaky gut in ulcerative colitis by targeting this gene or the protein it generates.**

- Researchers participating in our Genetics Initiative also discovered that increased levels of plasminogen activator inhibitor-1 (PAI-1)—a substance in the body involved in normal blood clotting—may be a crucial reason why some IBD patients don't respond to the standard, first-line therapy of anti-TNF drugs. The study, published in early 2019 in the journal Science Translational Medicine, demonstrates that **patients with severe disease had high levels of PAI-1.** The researchers also found that when PAI-1 was pharmacologically inhibited, both inflammation and damage to the lining of the digestive tract improved in mice with severe colitis. Researchers at Washington University are attempting to create molecules to block PAI-1 in the body, in the hope that it will one day develop into a potent drug. To support these efforts, the Foundation established a collaboration with a drug discovery company that will provide specialized expertise in therapeutics development. This aims to further advance the discovery of potent PAI-1 inhibitors, in partnership with our academic researchers.

In lifestyle... The Foundation helped launch crucial research in this area in 2018.

Patients and clinicians have always known that stress undoubtedly impacts IBD, but so far the mechanism for this has proved elusive. Last year, the Foundation led the way in this historically under-funded area by supporting two new studies focusing exclusively on psychological stress.

- At UCLA, researchers are evaluating changes in the composition of the gut microbiome and its metabolic byproducts (metabolites) in response to perceived stress. They are also monitoring the brain imaging of patients with IBD in an attempt to correlate specific markers of brain–gut communication with symptoms. We hope that this will yield more information about **who is most susceptible to disease flares when exposed to psychological stress.**

- The second study—being conducted at the University of Alabama at Birmingham—focuses on the role of early-life stress in the development and progression of IBD. These researchers are examining a specific blood-based vascular biomarker that is known to be elevated in early-life stress. The first part of the study focuses on how early-life stress impacts gut inflammation and the overall immune system. The second part will involve collecting blood samples from pediatric IBD patients who have also undergone robust neuropsychological evaluations, in order to check levels of this blood-based vascular biomarker. Once researchers have a better sense of patient stress levels, they will be monitored to **establish whether stress leads to more severe disease or more frequent flares.**

  Both studies are still in the patient recruitment stages, with plans to begin collecting data in 2019.

Diet Matters

A new study compares the Mediterranean diet

Diet is a much-talked-about topic within the IBD community, with both patients and physicians wondering about its role in the management of both Crohn's disease and ulcerative colitis. That's why the Crohn's & Colitis Foundation is using a grant from the Patient-Centered Outcomes Research Institute (PCORI) to look at two different diets and their ability to manage symptoms in patients with Crohn's disease. "Patients want to know what to eat, and we struggle with what to tell them," explains lead investigator James Lewis, MD, a professor of medicine and epidemiology at the Perelman School of Medicine at the University of Pennsylvania.

The study randomizes patients for 12 weeks, allocating them to either a Mediterranean-style diet, which focuses on foods such as olive oil, low-fat dairy, fish, fruits, vegetables, and beans, or the Specific Carbohydrate Diet (SCD), a more restrictive way of eating that eliminates all refined or processed foods, as well as carbohydrates, such as soy, lactose, sucrose, grains, and starchy vegetables like potatoes, okra, and corn.

"In the absence of better data, I have usually recommended the Mediterranean diet to patients, prepared from fresh ingredients, because it has been shown to have other health benefits, such as reducing the risk of heart disease. And there are theoretical reasons why it should work for patients with inflammatory bowel disease," says Lewis. "The SCD diet was first used many years ago to treat celiac disease, until doctors eventually realized that gluten was the culprit that caused inflammation and symptoms in celiac disease." There is some preliminary research to suggest that the SCD diet may be helpful in treating inflammatory bowel disease as well.

During the 12-week trial, patients eat food prepared by an outside vendor for the first half and make their own meals for the second. "We think it's important for people to learn how to follow these plans on their own," explains Lewis. Researchers gauge results through subjects' self-reported physical symptoms as well as by measuring certain biomarkers for inflammation, such as C-reactive protein (measured via a blood test) and calprotectin (measured in stool).

Lewis says all data will be collected by the end of 2019. "Hopefully, this research will give us some answers," he adds. "Right now, we don't have a good gestalt of how restricted patients' diets actually need to be. This study, along with other work being done in the field, could help change that."

Top: James Lewis, MD, professor of medicine and epidemiology at the Perelman School of Medicine at the University of Pennsylvania.

A Mediterranean-style meal full of fresh vegetables, fish, and olive oil.

Gerard Honig, PhD

Exploring the Microbiome

What's going on in IBD patients' guts can yield important clues about disease triggers and how to overcome them.

An ecologist with a bucket of pond weeds can deduce myriad details about the setting from which those plants were collected: water temperature, oxygen levels, even the site's proximity to woodlands and agricultural fields. A similar principle applies to the trillions of bacteria, fungi, viruses, and other microorganisms, known as the gut microbiome, that live in the gastrointestinal (GI) tract.

"We know that there are certain patterns in the composition and abundance of gut bacteria and in their metabolic products that are characteristically observed in people with IBD," says Gerard Honig, PhD, the Crohn's & Colitis Foundation's associate director of research innovation. Those patterns are beginning to provide important clues about how a patient's disease might progress. Eventually, researchers may even be able to use them to predict who will get IBD in the first place.

In addition to learning more about how the microbiome might affect IBD development or trigger a flare, several projects that are supported by the Crohn's & Colitis Foundation's Microbiome Initiative are exploring whether information about the gut's ecosystem could help clinicians provide a more personalized approach to treatment.

> **One of the promising advances in this area involves analyzing the microbiome.**

"One of the promising advances in this area involves analyzing the microbiome and using it to make predictions about which patients are going to respond to which drugs," says Honig. In May 2017, Cell Host & Microbe published results of such a study that was funded, in part, by the Crohn's & Colitis Foundation. Investigators identified two species of bacteria common to the GI tracts of IBD patients that responded well to vedolizumab, a type of drug called a monoclonal antibody, which helps to regulate the immune system by targeting specific proteins. This drug is usually only considered after treatment with an anti-TNF drug has failed; if doctors knew ahead of time who would benefit from vedolizumab, they could prescribe it to those patients straight away.

In another Crohn's & Colitis Foundation–funded project, investigators at Vedanta Biosciences are developing a living cocktail (essentially a super probiotic) that floods the gut with beneficial microbes that are vigorous enough to outcompete species found in patients with Crohn's and colitis. "The microbiome in a person's gut," explains Honig, "is not static; it might change in response to diet, medication, aging, illness and infections, and, possibly, swallowing the right type of beneficial bacteria."

Such work builds on the Foundation's decade-long commitment to microbiome research. It's particularly exciting to see the field evolving from basic discovery to the kinds of clinical applications that could directly improve patient health. "There is widespread conviction in science and industry that this could be a new paradigm in human health," says Honig.

Scientist Spotlight

Efi Kokkotou's groundbreaking research is paving the way for new IBD treatments.


Efi Kokkotou, MD, PhD, ScD

When it comes to inflammatory bowel disease, drug treatment is often elusive. While many patients respond to standard therapies, such as biologics, about half of all patients either don't respond initially or experience loss of response to these medications. That's why Efi Kokkotou, MD, PhD, ScD, associate professor of medicine at Beth Israel Deaconess Medical Center and Harvard Medical School, has made it her life's mission to find a drug that will help the majority of patients.

Thanks to a recent grant from a partnership between the Crohn's & Colitis Foundation and Pfizer's Centers for Therapeutic Innovation (CTI), Kokkotou is on her way. "About a decade ago, I identified a potential target molecule, melanin concentrating hormone (MCH), that's been implicated in the origin of inflammatory bowel disease," she explains. Kokkotou's groundbreaking research found that people who over-express this molecule are more likely to ultimately develop IBD. "MCH promotes inflammation and the release of cytokines that in turn break down epithelial, immune, and stroma cells," she says. This in turn leads to the onset of IBD.

> **"I identified a potential target molecule, melanin concentrating hormone, that's been implicated in the origin of inflammatory bowel disease."**

Now Kokkotou is working with scientists from Pfizer CTI to evaluate the potential of MCH as a therapeutic target for IBD. Kokkotou is inspired by the millions of adults worldwide who struggle with IBD. "We either need to find a drug that will help 80 or 90% of patients, or match available drugs to people by using personalized medicine," she stresses, noting that about 70% of people with Crohn's disease and 30% with ulcerative colitis ultimately end up undergoing surgery. The goal: to find effective disease-modifying drugs that prevent the progression of the disease and induce sustained remission.

2018 by the Numbers: Reaping the Returns

209	20,000	29,000	59%
Scientific papers published, thanks to research we funded	Patients' data stored in IBD Plexus, our information exchange platform that's poised to become the largest research database for Crohn's disease and ulcerative colitis in the world	Patients' biosamples in IBD Plexus—a 58% growth from launch in late 2017	Increase in our number of hospital or clinical partnerships, which reflects the growth in our institutional sponsorships, pool of volunteers, and interest in our support and educational programs

Speeding Toward Cures

Our Goal:

Accelerate the Pace of Change

How we're reaching it:
By creating unique partnerships with academics and commercial entities that bring together the best minds in IBD research.

An Innovative Strategy

Breaking down barriers to progress

Non-profit organizations don't traditionally designate a portion of their funding to support the work of commercial entities, but that's precisely what IBD Ventures—formerly known as the Entrepreneurial Investing Initiative—is largely about. Funding recipients for this program are selected based on the likelihood that they'll be able to bring a novel drug, diagnostic test, or device to market in the foreseeable future. "The goal is to select and fund the right product opportunities that, if successful, will have a meaningful impact for patients in the shortest amount of time possible," says Andres Hurtado-Lorenzo, PhD, the Crohn's & Colitis Foundation's senior director of translational research.

Through IBD Ventures, the Foundation is currently supporting several unique projects that aim to benefit IBD patients quickly. The hope is that, in the not-too-distant future, patients could have access to:

- A live bacterial cocktail that slows or stops disease progression
- A blood test that predicts whether a patient is at high or low risk for aggressive disease
- New drug treatments that work by inhibiting enzymes that are elevated in people with IBD

Imagine Living Better with IBD

Innovative tools have the potential to change lives

Our ultimate vision is a future free from Crohn's disease and ulcerative colitis. In the meantime, we're funding a number of unique projects that are poised to help patients gain access to products, tools, and treatments that will make their lives better.

Imagine... wearing a bracelet that warns you of an impending flare

One day you might be able to do just that, thanks to scientific developments in sweat-sensing technology. Researchers have already figured out how to detect a variety of substances that are secreted in sweat. By measuring glucose, for example, someone with diabetes can monitor their blood sugar level (though this technology is still being perfected).

Shalini Prasad, PhD, is leading a team at the University of Texas, Dallas, that believes a similar strategy can be applied to people with IBD—and she's determined to prove it. "The goal is to capture sweat in real time—you wouldn't have to exercise or be sweating profusely—to measure inflammatory biomarkers in it, alert a patient about any changes, and enable them to make some informed decisions about their treatment," she explains.

Imagine... swallowing a pill that sends information about your disease status to your smartphone

You already use your phone to check the weather, the stock market, and so much more; why not get alerts about the state of your GI health? First, you'd have to swallow a capsule that's loaded with sensors. That capsule is exactly what Timothy Lu, MD, PhD, and his colleagues at MIT are in the process of developing.

While so-called capsule endoscopy already exists, it currently simply contains a tiny camera that isn't always appropriate to use for people with Crohn's, especially those with developed strictures. The capsule that Lu's group is perfecting is being specifically created for use by IBD patients. If they're successful, not only will such a capsule provide a visual glimpse of the digestive tract, it will also be used to predict disease flares, thanks to its numerous sensors that detect inflammatory markers and gases that are associated with changes in disease activity.

Imagine... taking a simple blood test and learning about how your disease will progress

When someone finds out that they have breast, colon, or prostate cancer, they can take a test that analyzes their tumor and provides information about their risk of recurrence. Those results, in turn, allow them to make important treatment decisions. Do they need the most extensive type of surgery? Is it safe to opt out of chemotherapy or radiation?

Patients who are newly diagnosed with IBD have similar questions about how aggressively—or not—they should be treating their disease, but right now it's mostly a guessing game. That may soon change, thanks to a new blood test called PredictSURE IBD™. According to research conducted in Europe, 91% of people who had multiple relapses within 12–18 months of taking the test had been correctly identified by the test as being in the high-risk group. We are currently funding a study to find out whether this tool will be equally accurate when used on Americans with IBD.

Meetings of the Minds

Connecting healthcare providers, researchers, and innovators

Educating healthcare professionals and connecting clinicians, researchers, and industry leaders are crucial parts of our mission. 2018 was a banner year for the Crohn's & Colitis Foundation in this area, as we hosted three significant conferences, all of which were brand new and brought together participants from across IBD research, clinical, and commercial communities that might not ordinarily work together.

Key moments from the first annual Crohn's & Colitis Congress.

Crohn's & Colitis Congress®

We partnered with the American Gastroenterological Association to produce the first annual Crohn's & Colitis Congress. This brought together more than 1,300 clinicians, researchers, and others who have dedicated their careers to advancing the field of IBD, getting to cures, or improving the care of patients. Multidisciplinary panel discussions and specialized workshops were among the highlights. "The audience was diverse, as were the topics. We covered best practices and research innovations, as well as lifestyle and psychosocial issues," says Caren Heller, MD, MBA, the Crohn's & Colitis Foundation's chief scientific officer.

IBD Innovate

This brand-new symposium is yet another way that the Foundation is striving to support the discovery and development of novel products that have the potential to address the unmet needs of patients with IBD. In this symposium, we highlighted research related to the development of novel products that have the potential to dramatically change the lives of people with IBD, addressed challenges and opportunities for IBD product development, and brought together some of the top innovators in IBD. Attendees included top researchers from biotech companies and academia that are supported by IBD Ventures, as well as representatives from many other interesting companies and startups. Poster sessions included such pioneering products as a home toilet that tracks disease activity and a topical treatment for ulcerative colitis.

IBD Biomarker Summit

The Foundation convened representatives from biotech companies, pharmaceutical manufacturers, academic researchers, and top-level officials from the FDA all of whom joined forces at this working meeting. The focus: determining what it will take to accelerate development of IBD biomarkers, which are quantifiable, measurable indicators of disease. "We don't have a lot of robust biomarkers, and we need to come together to overcome the next hurdle in order to move forward in precision medicine," says Hurtado-Lorenzo. "None of us can do it alone."

2018 by the Numbers:

1,300
SPARC IBD participants across nine sites, whom researchers will follow to understand their response to treatments and how to predict this response or their loss of response

$23.8M
Invested in over 250 new and continuing projects at over 100 U.S. and international institutions

304
Applications reviewed for investigator-initiated grants, and 53 new ones funded

1,300
Clinicians, researchers, and other IBD leaders who attended our first annual Crohn's & Colitis Congress®

Building Powerful Partnerships

Our Goal:

Uniting Stakeholders to Care and Cure

How we're reaching it:
By engaging patients and supporters, soliciting major donors, and keeping the momentum going strong.

Reaching New Heights

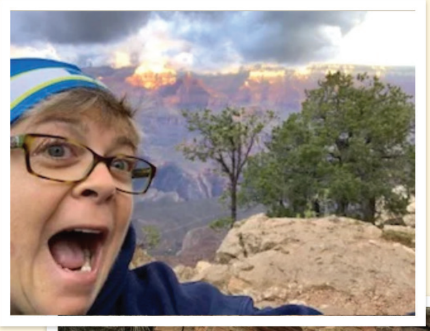
The Crohn's & Colitis Foundation is constantly striving to engage patients and supporters through a variety of new and diverse events. In 2018, our Team Challenge program offered its first official hike option, with a select group of participants joining us for a hike through the Grand Canyon. For long-time Team Challenge participant, Lori Dunbar, it was the perfect way to celebrate a milestone birthday and raise money for a cause that's near and dear to her heart.

Back in 2006, I saw a flyer for a Team Challenge half marathon in Napa, California, and thought, why not?

In reality, there were plenty of good reasons not to push myself. Just a few years earlier, surgeons had removed five feet of my colon, and 17 years of taking steroids had taken such a toll on my joints that I had pins in my hips. But I needed something to strive for. I ended up becoming really close to everyone on my virtual training team, and when I crossed the finish line, I was ecstatic.

That half marathon wasn't my first introduction to the Crohn's & Colitis Foundation: I'd been involved with the New Jersey chapter since I was diagnosed with Crohn's as a teenager (I'm now the NJ Chapter board president). It wasn't my first athletic event with the organization, either; I've led a Take Steps walk team for as long as I can remember. But I wanted something to work toward. There are so many who have this disease and are so sick that they can't leave their houses—but I can. That's a main driver.

I've since completed more than 35 Team Challenge events, but a few years ago I got artificial hips and had to give up running the half marathons (though I continue walking in them). Still, when I heard that Team Challenge was heading to the Grand Canyon for the first time, I knew I had to be part of it.



Top: Lori Dunbar at a Grand Canyon overlook the morning after the hike. Bottom: Lori and her hiking group on the hike down the Bright Diamond Trail.

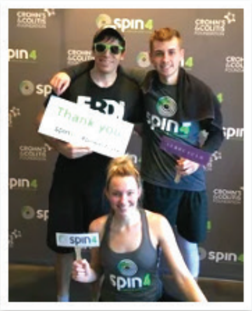
I was 49—my husband gleefully points out that I'll turn 50 this year—and I've always wanted to visit the Grand Canyon. The event was the perfect opportunity to make it happen. I got to check something off my bucket list, do it with my Team Challenge friends, and raise money for something near and dear to my heart.
Because of my joint problems, I settled on the gentlest of the three options: the South Rim Adventure, which entailed hiking a nine-mile round trip.

In the Grand Canyon, being immersed in beauty and these incredible surroundings, you can't help but be in awe. The people I was with were amazing. You get kind of transported to a different place where nothing else matters—you're part of this family, where you can talk about anything and everything. I didn't guard my words, didn't guard myself. I could talk about my health, my feelings. I was my truest self. The level of intimacy and vulnerability in this place of incredible beauty was life altering.

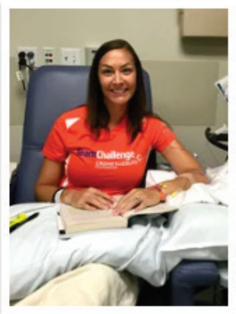
Prior to doing that first half marathon and getting involved with Team Challenge, I hardly told anyone about my Crohn's diagnosis. I tried to mask everything. Since then, my voice is large. I travel a lot for work, and on the airplane I typically wear a Team Challenge jacket, or a t-shirt that says, "Ask me about my Crohn's disease." One of my goals is to raise as much awareness as I can.

Inspiring and Engaging the Entire IBD Community

Since our inception in 1967, the Crohn's & Colitis Foundation has been dedicated to improving the lives of people with IBD, but we know that we can't do it alone. Our non-profit, volunteer-fueled organization thrives because we bring the voices of our IBD patient and caregiver community to the table in all our initiatives.



Social media



Awareness/ fund-raising events

Patient support

Patient engagement in research

Legislative reform

Social media

12 Million

In 2018, we had **12 million** impressions on Facebook, as well as **8.4 million** people reached and **405,000** engaged users who were looking to discover more about living with Crohn's disease or ulcerative colitis and find inspiring patient stories.

25,080

We shared information about living better with IBD, with more than **25,000** Twitter followers, an increase of **12.5%** from the previous year.

66%

Our presence and impact on Instagram grew by **66%**, and we had over **164,000** engagements with our content, an increase of **76%** from 2017.

CROHN'S & COLITIS FOUNDATION

2.8 Million

Our flagship site, www.crohnscolitisfoundation.org, received more than **2.8 million** visits in 2018, as more patients and caregivers turned to us for help, advice, and support.

Awareness/fund-raising events

60,000

We proved that we're better together by encouraging patients and supporters to connect at 108 Take Steps community walks across the country in 2018. Approximately **60,000 participants** joined together to walk for cures.

54%

We showed more patients and supporters that raising funds can be fun: **54%** of spin4 crohn's & colitis cures participants were new to the organization in 2018.

$25 Million

Over 922 Team Challenge participants crossed the finish line in half marathons, bike races, and other events. We exceeded the **$25 million** mark in funds raised since the inception of Team Challenge.

$18.7 Million

We celebrated our successes and planned for the future at galas, golf tournaments, and other special events across the country, generating **$18.7 million** in the process.

Patient support

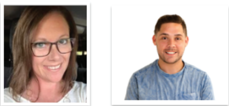
8,332

We continued to ensure that no one has to fight IBD alone: **8,332** patients and family members attended in-person support groups in 2018.

1,144

We gave **1,144** kids with IBD the chance to connect with others just like them at Camp Oasis, our co-ed residential summer camp, across 12 campsite locations in 2018. We awarded 487 camp scholarships based on family need.

Patient engagement in research



173,994

We encouraged patient participation in research. In 2018, there were **173,994** interactions with our Clinical Trials Community's educational resources, which aim to increase awareness of clinical trials and educate patients and healthcare providers.

34

We launched the Clinical Trials Ambassador Program and trained **34** ambassadors who are available to connect with patients interested in participating in clinical trials.

Legislative reform

216

Thanks to the efforts of our dedicated volunteers, **step therapy reform passed in Minnesota and Ohio**. In 2018, 216 volunteers attended in-person advocacy days in front of Congress (Day on the Hill) and state legislatures.

1,351

We grew our Advocacy Network volunteer list and received **1,351** responses to an Advocacy and Access to Care Survey, which will inform our public policy priorities.

Ross Maltz, MD

Partners for Policy Change

With the help of advocacy volunteers, we're pushing hard for legislative reform that puts patients first.

When Ross Maltz, MD, diagnoses a child with Crohn's or ulcerative colitis, he works with the family to identify what they believe to be the ideal treatment for their particular case. Whether the patient will actually get to use that medication right away, however, is often unclear. "I always add the caveat that I have no idea what the insurance company is thinking, but will fight for what is best for the patient," says Maltz. In an effort to contain costs, insurance companies frequently insist that patients try a cheaper treatment and fail to improve sufficiently on it before agreeing to cover a more expensive drug. This protocol, known as step therapy or "fail first," puts patients at risk for uncontrolled symptoms and irreversible disease progression.

Maltz's patients face better odds than most. At Nationwide Children's Hospital in Columbus, Ohio, this pediatric gastroenterologist has four staffers who help him appeal coverage decisions, and they often go through multiple rounds to get patients the medications they need. However, such staffing is rare, and many providers are forced to alter their treatment recommendations to satisfy insurers.

> **No patient should have to go through trials of the wrong medication in order to get the appropriate, originally prescribed medication.**

To even the playing field, the Crohn's & Colitis Foundation has been campaigning for federal and state laws designed to strengthen the appeal process, so that patients can access the treatments they need in a timely manner. On more than one occasion, says Maltz, an insurance company has demanded that he use outdated treatment protocols, which means that those patients end up missing out on treatments that could help them dramatically.

As part of a coalition of patient advocacy groups, the Foundation has been educating lawmakers about the importance of step therapy reform, crafting model legislation, and testifying in state legislatures across the country.

After years of hard work, 2018 marked some notable achievements. Thanks to over 200 volunteers (including Maltz) who participated in our state advocacy efforts, step therapy reform legislation passed in Ohio and Minnesota. Any step therapy policy in those state-regulated plans must now be medically sound and come with a clear, quick appeals process. More bills are being passed in states across the nation, and the federal bill is steadily advancing.

Having lived with Crohn's for two decades himself, Maltz has both personal and professional stakes in these victories. "I'm very excited that we achieved step therapy reform in Ohio and Minnesota," he says. "But we have a lot more to do. There are many more states with step therapy reform bills currently being considered, and I hope in the next year or so we can get a federal bill signed into law."

2018 by the Numbers:

$11M

Generated thanks to the efforts of 60,000 participants at Take Steps community walks across the country

33%

Increase in proceeds raised from spin4 crohn's & colitis cures events across the country since 2017

$3.4M

Grant from The Leona M. and Harry B. Helmsley Charitable Trust to expand IBD Qorus, our quality-of-care initiative designed to improve patient outcomes by standardizing treatment

$136M

Increase in the amount of federal funds that will be devoted to IBD research in 2019, thanks to the Foundation's advocacy efforts

Financials and Supporters

More than 80 cents of every dollar the Crohn's & Colitis Foundation spends goes to research, education, or support services.

Where the Money Goes

IBD Plexus
A massive research exchange platform that allows researchers to dramatically accelerate their work by tapping into biosamples and extensive data already collected from over 20,000 patients

Environmental Triggers Initiative
Funding for research on environmental factors—such as viruses, psychological stress, and diet—that may contribute to IBD

IBD Ventures
A funding mechanism dedicated to supporting novel product-oriented research and development

Microbiome Initiative
A consortium of the country's top IBD researchers who are studying the ways in which intestinal microbiota contribute to Crohn's disease and ulcerative colitis

Pediatric RISK Stratification Study
An ongoing, multi-center study that follows over 1,000 children with Crohn's disease, which aims to identify factors that predict developing disease with complications requiring surgery