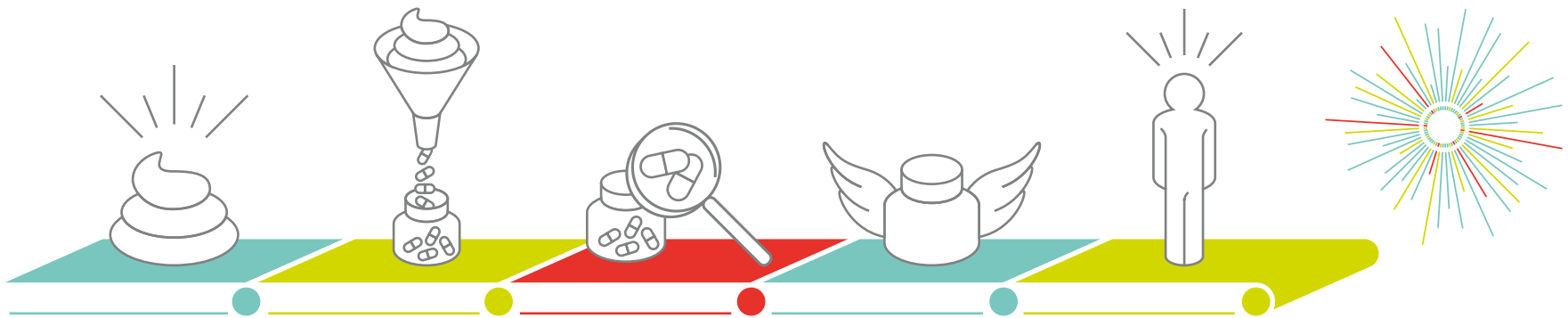


OpenBiome Annual Report 2015



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Welcome



Media Highlights

In 2015, OpenBiome was featured in

[The New York Times](#), [Fast Company](#),

[CNN](#), [the BBC](#), [The Washington Post](#),

and other news outlets around the

world. Our work was also shared

through radio appearances on NPR, the

Australian Broadcasting Corporation,

and others, and featured in multiple

educational documentaries about the

gut microbiome.

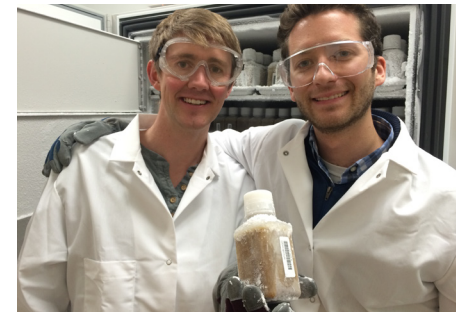
What an incredible year we had in 2015! The theme of the year was undoubtedly “growth” as we transitioned to a national-scale stool bank, growing our **hospital network from 169 to 517** and growing our **team from 14 to 41**.

Throughout all of this growth, we’re very pleased to say that our team was able to remain entirely focused on our mission of enabling safe access to fecal microbiota transplantation and catalyzing research into the human microbiome.

On the access side of things, the team enabled a **record-breaking 7131 FMT treatments** over the course of the year. The number of lives touched is humbling – especially after recognizing that each of these patients has a story like the one on page 2 of this report. Beyond providing treatments, though, our team removed a huge barrier to access by introducing the **FMT Capsule G3** formulation at the end of the year. We’re thrilled that, for the first time ever, FMT capsules are broadly available in the clinic, eliminating a huge barrier to access: the colonoscopy.

Our Research team has also been hard at work. Throughout the course of the year, we launched **11 ground-breaking clinical trials** to investigate the role of the microbiome in diseases like ulcerative colitis, Crohn’s disease, and pouchitis. These studies are only the beginning as we have dozens more similar studies in the works – all focused on learning how we can engineer the microbiome to improve human health.

We’re immensely proud of the hard work our team has accomplished in 2015. Moving ahead into 2016, we’re excited about the new challenges and opportunities we face as we seek to further unlock the power of the microbiome to improve health. We’ll be moving into a new facility, further expanding our clinical footprint, and engaging in even more ground-breaking microbiome research.



Thank you for your support and engagement with OpenBiome,

James and Mark

James Burgess
Executive Director

Mark Smith
President, Research Director

Patient Testimonial

“After many years of “living by the toilet,” I was diagnosed properly to have Clostridium difficile.

The treatment I had to have, and ultimately did have, was the FMT. Imagine my dismay, after coming so far, to find I might have to query each of my distant relatives or acquaintances just to find somebody to poop on cue for me.

Then my infectious disease doctor told me about a unique group he’d heard of that operates from MIT called OpenBiome.

Today, I feel worlds better. I have better control over my stool. I have no diarrhea. That cannot be said enough: I have no more diarrhea. I am still working on getting back 9 years of a lost life. I am 51 today. I was 42 years old when I was first diagnosed with cancer and when the diarrhea began. I have a lot of living yet to do, living of a life that I had thought was nearly over, and is now just beginning again.

My life is beginning again because I had the opportunity to have a fecal transplant from a stranger who came to my aid.”

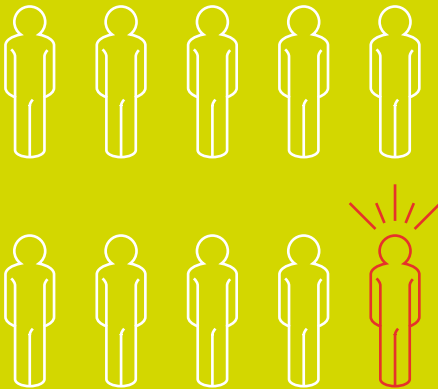


Treating *C. difficile*



Goal for 2015: Treat 1 in 10 patients

In January 2015, we set an ambitious goal to treat 1 in 10 patients suffering from intractable *C. difficile* infections, a target that would enable us to begin changing the epidemiology of this disease. We met our goal by mid-June.



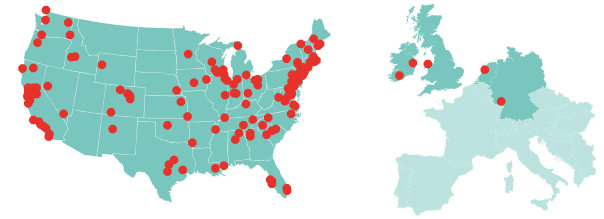
Domestic Footprint

With 517 OpenBiome clinical partners across all 50 U.S. states, 94% of the U.S. population now lives within a 2-hour drive of a FMT provider. This wide-reaching network of clinicians is vital to our mission of expanding safe access to FMT, as we strive to ensure that distance does not pose a barrier to patient access. By the end of the year, 7,131 treatments had gone out our door.

International Footprint

OpenBiome also aimed to expand its operations and support overseas. In 2015, we shipped 56 treatments internationally to facilities in Ireland, the United Kingdom, and Germany.

In August, OpenBiome launched a new partnership with the APC Microbiome Institute at the University College Cork in Ireland to bring fecal microbiota preparations to patients in Europe suffering from recurrent *C. difficile* infections.



Clinical Figures

2015 (green) vs. 2014 (red)

790 lbs of stool processed



7,131 treatments provided



348 clinical partners added



\$121.3M in savings to the U.S. healthcare system*



*Each FMT saves the U.S. healthcare system a conservative estimate of \$17,016 in direct costs. Konijeti GG, Sauk J, Shrime MG, Gupta M, Anathkrishnan AN. Cost-effectiveness of Competing Strategies for Management of Recurrent *Clostridium difficile* Infection: A Decision Analysis. Clin Infect Dis. 2014 Jun; 58(11):1507-14

What is *C. difficile*?

Clostridium difficile is the most common hospital-acquired infection in the U.S. It results from a disruption to the normal community of bacteria that live in our guts, usually following antibiotics. Treating *C. difficile* can be challenging: the first step is to try antibiotics, but 1 in 5 patients will find that their infection returns. After trying antibiotics a second time, 2 in 5 patients will still be sick. For those patients, a fecal transplant works 80-90% of the time.

What is a fecal transplant?

A fecal microbiota transplant (FMT) is a medical procedure in which stool from a healthy human donor is infused into the colon of a patient, most often by colonoscopy, enema, or a plastic tube inserted through the nose leading to the intestines. This year, OpenBiome also introduced FMT pills.

Every year, about 41,000 patients suffer from *C. difficile* infections that keep recurring, even after multiple rounds of antibiotics. FMT is now the standard of care for treating these patients, and so we targeted supplying treatments at a rate that would reach 10% of these patients each month.

We surpassed this goal by mid-year, shipping over 700 units in June alone!

Catalyzing Research



OpenBiome is **supporting 50% of all U.S. clinical trials** investigating the use of FMT for disease beyond *C. difficile*. OpenBiome's portfolio includes 11 studies that are enrolling patients and encompasses 50% of all registered clinical trials for FMT in the U.S.

Overview

The use of FMT to cure *C. difficile* infections is just the beginning; researchers in the lab and the clinic are working to unlock a new class of therapies that improve human health by modulating the communities of bacteria that live within us. The microbiome has been linked to a range of diseases, from inflammatory bowel diseases such as Crohn's and ulcerative colitis, to metabolic disorders such as obesity and Type II diabetes.

Fecal transplantation is often the point of departure for understanding how the microbiome can affect these diseases, and through the material and services we provide, OpenBiome serves as a platform connecting scientists across studies and disciplines.

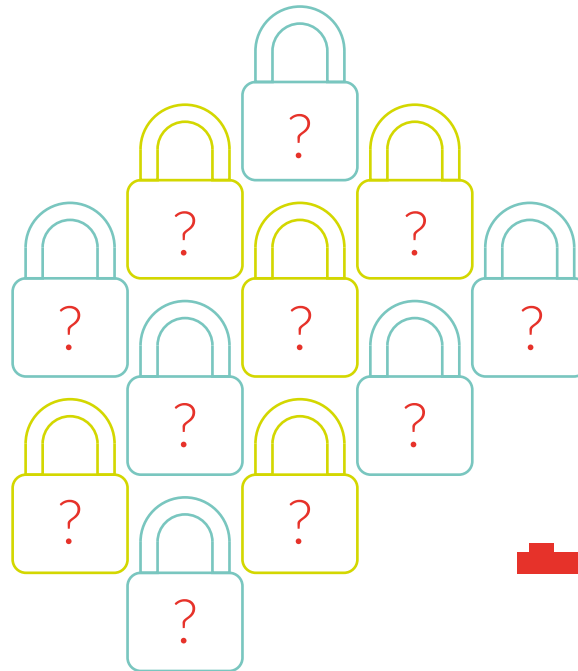
Publishing Impact

OpenBiome team members collectively published 15 manuscripts in peer-reviewed journals such as the *Journal of Law and the Biosciences and Microbiome*, engaging with the academic community on best practices for universal stool banking. We also presented eight abstracts at four prominent gastroenterology and infectious disease conferences.

Notably, OpenBiome's Chief Medical Officer, Dr. Zain Kassam and Dr. Jessica Allegretti, a gastroenterologist at Brigham and Women's Hospital, delivered a prize-winning oral presentation at United European Gastroenterology Week in October reporting on the results of our encapsulated FMT dose-finding study, which was also led by Dr. Monika Fischer, professor of medicine at Indiana University.

Update on STOOL Study

Although FMT is the standard of care for treating recurrent *C. difficile* infection, there is still much to learn about the long-term safety profile of this therapy. In the spring of 2015, OpenBiome began enrolling patients in the first prospective, longitudinal safety study of FMT in recurrent *C. difficile* patients. Titled "Safety of fecal microbiota transplantation: OpenBiome outcomes and longitudinal follow-up (STOOL)," this multi-center study is enrolling patients at eight sites in the U.S., and will follow participants for one year after their procedure.



Patient Testimonial

“Writing to share the miracle procedure fecal microbiota transplantation. This saved my husband’s life after many times in Kaiser. One breakdown after another. Called into palliative care meeting with family members to put him into comfort hospice. I, being wife of 50 years said “not yet.” The following month the procedure was done. Total success! Since, after 8 months and increased improvement – not even a sniffle. He’s doing very well.

I’m amazed and thankful – very grateful that there was a remedy. Maybe he’ll make it to 100 – Life is precious.”



Quality & Safety



Only 2.8% of prospective donors pass our clinical exams and screening.



Pre-Screen Survey

Over 10,500
Potential Donors

Clinical Assessment

Laboratory Investigations

Donor Assessment

Our Clinical Assessment and Safety team, under the leadership of Clinical Program Director Dr. Majdi Osman, MD MPH, continued to refine our Donor Assessment protocol. Less than 3% of stool donor candidates pass our clinical evaluation and become OpenBiome donors.

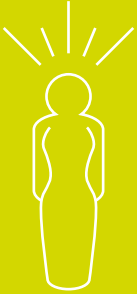
Safety

OpenBiome submitted data on a 1,406 multi-center patient cohort the largest in the field by an order of magnitude, to Digestive Disease Week (DDW), the pre-eminent digestive disease conference. This submission, which reported on the safety and efficacy record of FMT in these real-world applications, was ranked in the top 10% of abstracts.

Clinical Education

In 2015, we began a push to expand our clinical education program. As a first step, and as part of our sweeping packaging changes, checklists to guide clinical staff through every step of FMT administration are now included with each treatment unit.

Spotlighted Initiatives



Capsules

In December, we made fecal transplantation by pill widely available for the first time. This long-awaited treatment option will help drive forward not only treatment of recurrent *C. difficile* infection, but also advances in our ability to explore FMT for other diseases and conditions.

Patients, practitioners, and the press have all responded enthusiastically to FMT capsules. The release of FMT Capsule G3, as they're called, was covered by the New York Times, Fast Company, the Washington Post, and WBUR, Boston's NPR affiliate radio station.

One dose of 30 pills yielded an initial cure rate of 70% and an aggregate cure rate of 94% when patients took a second course.

While colonoscopy still has the highest cure rate, capsules provide an alternative to the high costs and procedure-related risks associated with colonoscopies or upper endoscopies.

FMT Capsules G3 will also accelerate research breakthroughs in the treatment of chronic conditions for which long-term FMT maintenance therapies could help manage the patient's disease. Asking patients to come in for repeated colonoscopies or upper endoscopies to treat their chronic condition is expensive, time-consuming, and not a realistic option for many individuals. By making repeated treatments more tolerable, FMT Capsules G3 may reduce barriers to care for chronically ill patients.

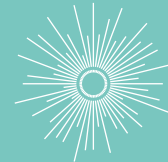
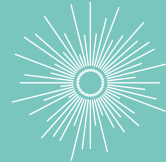
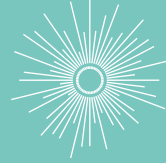
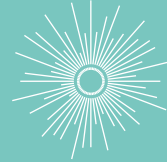
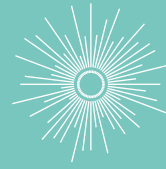
PersonalBiome

This fall, OpenBiome pilot launched PersonalBiome, a biobanking service that allows individuals to freeze and preserve a sample of their healthy microbiome. First featured in [The New York Times](#), PersonalBiome allows individuals to bank their healthy microbial community in one of OpenBiome's three treatment formats. If they require a fecal transplant in the future, patients can then use their own stool sample to repopulate their microbiome.

OpenBiome launched PersonalBiome to serve individuals who are at an increased risk of developing *C. difficile*, such as patients who are severely immunocompromised or expecting surgery. OpenBiome will work closely with hospitals and clinics to extend PersonalBiome to this vulnerable patient population.



Clinical Partner Testimonial



“It is really important information. The more I read, the more I have compassion for people with C. Diff. Treatment can really be life changing. Thanks for ALL you and your staff are doing. I look back and remember what I thought when I heard our department was going to store “frozen poop.” My attitude has since changed and I want others to be educated on this very effective treatment.”

-Technician, South Carolina

About OpenBiome: History & Team

Mission & History

OpenBiome's mission is to expand safe access to fecal microbiota transplantation for patients suffering from recurrent *C. difficile* infection and to catalyze research into the human microbiome. Founded in 2012 in the Alm Lab at the MIT, OpenBiome aims to reduce the practical barriers to providing FMT and enable translational research investigating new applications of microbiome-based therapies.

Legal

The Microbiome Health Research Institute, Inc. (d/b/a "OpenBiome") is a 501(c)(3) nonprofit organization incorporated in the State of Massachusetts.

Board of Directors

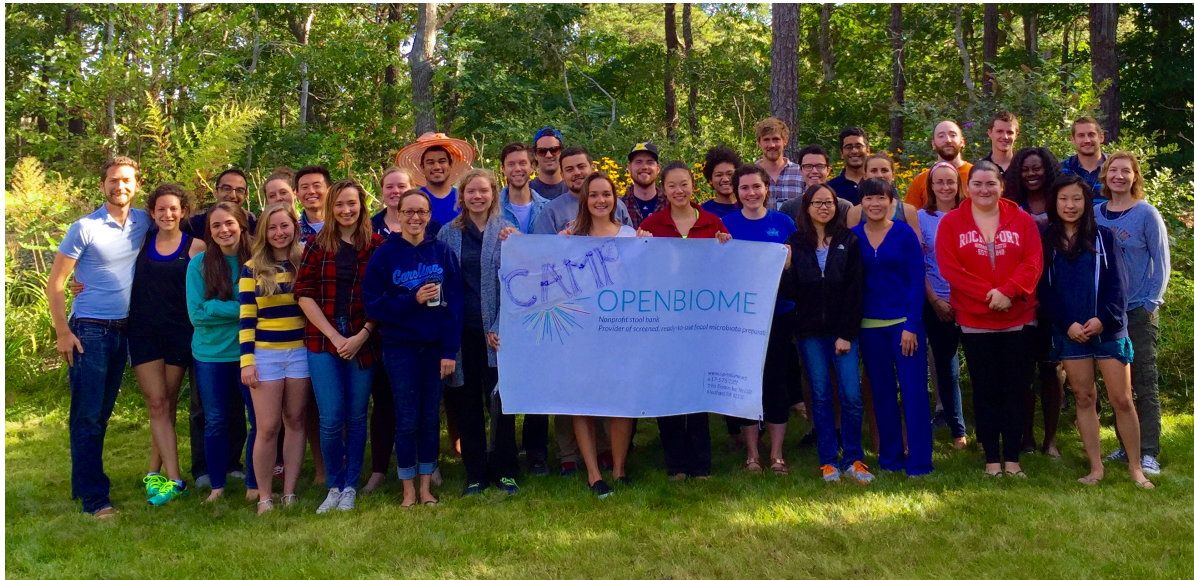
The Board of Directors of OpenBiome is composed of the following individuals:

Mark Smith, PhD	Neil Rasmussen
James Burgess	Jane Williams, MD
Jim Burnham	Elliot Mattingly
Eric Alm, PhD	



Majdi Osman, MD MPH

Majdi Osman is OpenBiome's Clinical Program Director, overseeing the clinical safety and donor programs. Majdi is an Internal Medicine physician who trained at University College London and completed his Master's in Public Health at the Harvard T. H. Chan School of Public Health on a Frank Knox Fellowship. He previously worked at the World Health Organization and taught and practiced medicine throughout Africa. Majdi co-founded YBank, a nonprofit dedicated to adolescent health. His research focuses on infectious diseases, quality improvement and clinical safety, which has informed his oversight of OpenBiome's rigorous donor screening program, and has aided in communications with partner physicians.



About OpenBiome: Financials

As of December 31, 2015

Statement of Financial Position

Assets

Current assets:	
Cash	\$ 441,090
Accounts receivable	635,594
Inventory	461,521
Prepaid expenses	<u>18,593</u>
Total Current Assets	<u>1,556,798</u>
Furniture and equipment, net	195,825
Security deposit	<u>35,500</u>
Total assets	<u>\$ 1,788,123</u>

Liabilities and net assets

Current liabilities:	
Accounts payable	\$ 104,639
Accrued expenses	<u>49,677</u>
Total Current Liabilities	<u>154,316</u>
Net assets:	
Unrestricted	<u>1,633,807</u>
Total net assets	<u>1,633,807</u>
Total liabilities and net assets	<u>\$ 1,788,123</u>

Major Donors from 2015

Rasmussen Family Foundation - \$225,000

Anna-Maria & Stephen Kellen Foundation - \$100,000

Alex Algard - \$30,000

Statement of Activities

Unrestricted operating revenue and support:

Sales of product (net of discounts)	\$ 2,323,950
Commercial research sales	576,001
Shipping and handling fees	382,597
Less cost of sales	<u>(854,675)</u>
Gross profit on sales	2,427,873
Major donation	355,000
Other donation	<u>12,871</u>

Total unrestricted operating revenues and support **2,795,744**

Operating expenses:

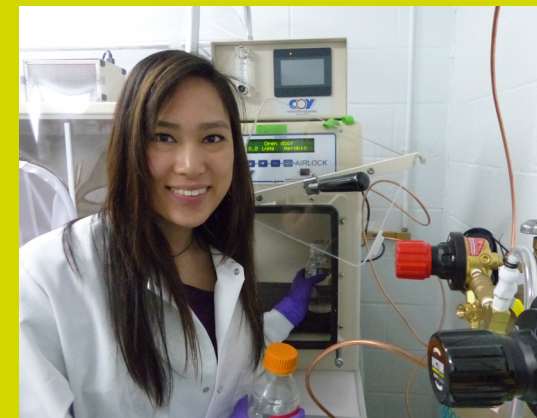
Program	939,046
General and administrative	585,571
Fundraising	<u>8,394</u>

Total operating expenses **1,533,011**

Change in net assets **1,262,733**

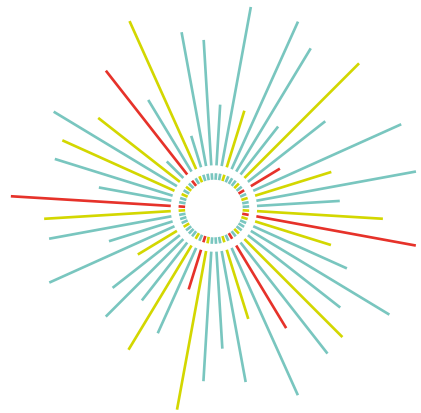
Net assets, beginning of year 371,074

Net assets, end of year **\$ 1,633,807**



Elaine Vo, PhD

Elaine joined OpenBiome as the Lead Research Scientist, and then Research and Development Program Director, at OpenBiome. Bringing an extensive background in molecular biology and microbial ecology, Elaine has overseen research and development, informing the design of our FMT capsules and advancements across our biomanufacturing pipeline. Elaine holds a PhD in Integrative Biology from the University of California-Berkeley, where she studied what drives variation in vertebrate gut microbiota, and how that variation is associated with host condition.



OPENBIOME