



WELCOME



Around noon each day, a stack of white cardboard boxes piles up outside the door to our lab. Inside each box is a frozen sample of microbes ready to make their way to a clinic and, ultimately, into a person whose life has been halted by disease.

These boxes serve as daily reminders of the hundreds of doctors, technicians, donors, and all the infrastructure that has been created to make sure that these treatments are available to patients who need them.

Recently, a young woman named Jessica visited our office. Eighteen months earlier, she had received a fecal transplant from an OpenBiome stool donor. Our team gathered in the board room to listen as she described the pain and fear of life with *C. difficile* fighting to make it from meetings to the bathroom on time, losing a quarter of her body

weight, and growing too weak to bathe or climb steps alone, as round after round of antibiotics failed to cure the infection. She was 29 years old, newly married, in a new job, and afraid she was going to die.

She was the first patient in her city to get a fecal transplant. As curious hospital staff crowded in to watch the procedure, her physician infused 250 mL of stool into her colon. Bacteria in that infusion out-competed the *C. difficile*, and the infection was eliminated. By the next day, she had started to feel normal again.

In 2016, we sent 10,997 treatments out our door for patients with antibiotic-resistant *C. difficile*. We also partnered with dozens of clinical researchers on 22 studies exploring new ways to fight disease using our own gut microbes.

At the end of the year, we took a big step towards ensuring that patients will continue to have safe access to this treatment in perpetuity. We signed an agreement to work with Finch Therapeutics towards FDA approval of an FMT treatment. The decision will allow us to execute on our mission at a

level we couldn't have imagined when we first set out to fill an urgent gap. Now, we hope to help bring patients the next generation in FMT care, and secure its availability in the long run. If successful, OpenBiome will have a dedicated resource stream to support our platform for translational research and lay the groundwork for future advances in patient care. For more on the move, please see www.openbiome.org/finch-collaboration.

In this report, we take stock of the progress that we and our partners have made in using the gut microbiome to protect and restore human health. We also strive to remember what's behind the numbers, and what's waiting inside each white box: a community of microbes that could mean all the difference to someone who needs it.

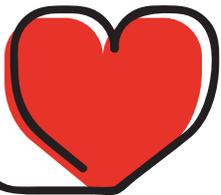
Thank you for your support and your engagement with OpenBiome.

10,997
treatments sent in 2016
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C. difficile.



James Mark Smith

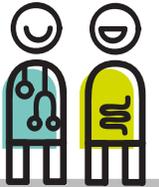
JAMES AND MARK



“Your work is **meaningful,** significant, and life-changing.”

“Prior to my fecal transplant in late September of 2015, I was subject to unbelievable amounts of extremely expensive and unhealthy antibiotics for 3 months as well as several ER visits to simply exist. I was never able to exist more than 4 days off antibiotics before the infection returned in an amplified form each time. I am profoundly thankful to OpenBiome and my doctor. Your work is meaningful, significant, and life-changing.”

- TINA



PATIENT TESTIMONIAL

TREATING PATIENTS

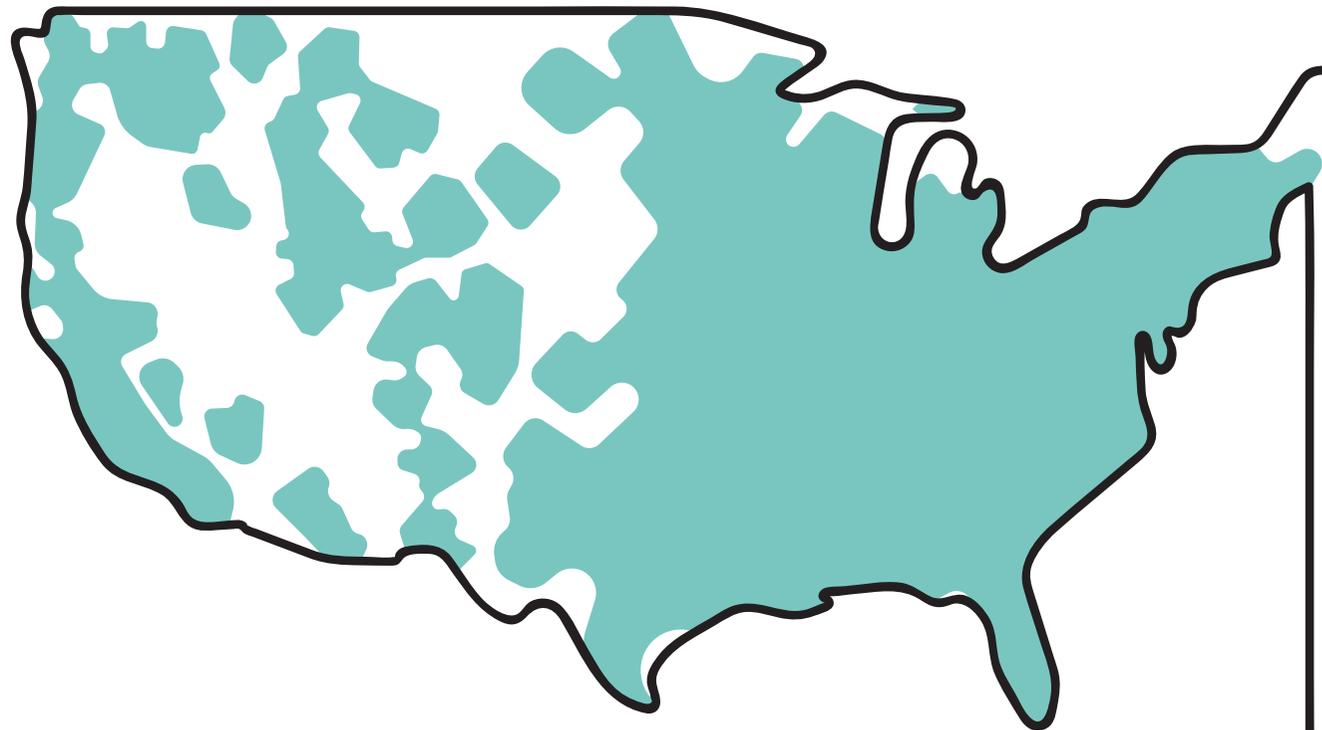
20,000
treatments shipped just after
the new year

780 Fecal Microbiota Transplantation (FMT) providers

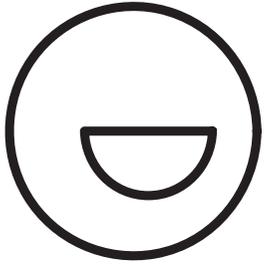
In 2016, 271 medical centers joined our FMT provider network, bringing the total to 780 healthcare facilities around the US. 60% of our partners worked with OpenBiome to offer FMT for the first time. With this expansion, 99% of the U.S. population now lives within a 4-hour drive of an FMT provider, and 97% lives within a 2-hour drive.

20,000 treatments

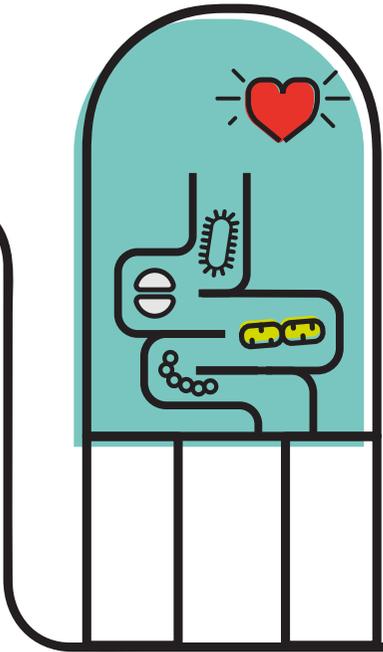
OpenBiome sent out 10,997 FMT treatments to clinicians in 2016, surpassing our 2015 total by more than 50%. Overall, FMT from OpenBiome treated an estimated 12% of severe or antibiotic-resistant *C. diff* infections in the U.S. in 2016.



99% of the U.S. population is within a 4-hour drive of an FMT provider (coverage shown) and 97% lives within 2 hours



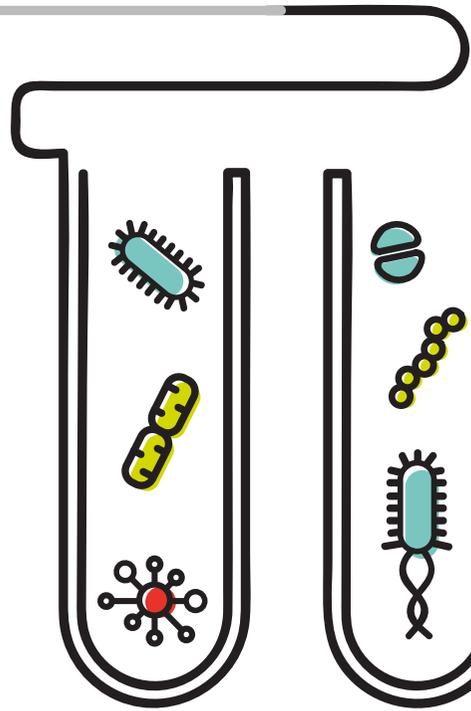
“I can’t imagine what drew you all into this business, but I am eternally **grateful**,”



“*C. diff* is such a sneaky rascal that very few realize how debilitating and confining it is. I can’t imagine what drew you all into this business, but I am eternally grateful. My procedure was January 13th, and I knew within three days that I was cured. I had prayed for a miracle - and got it!”

- SHIRLEY

PATIENT TESTIMONIAL



84%

clinical cure rate of recurrent *C. difficile* infection across all patient populations and modes of delivery.

Using FMT to cure *C. difficile* infection 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 changing the communities of bacteria that live within us.

The microbiome has been linked to a range of diseases, including other infections, chronic autoimmune conditions such as Crohn's and ulcerative colitis, metabolic disorders such as obesity and Type II diabetes, and even neuropsychiatric disease.

FMT is useful as a point of departure for understanding how the microbiome can affect these diseases. Through the material and services that we provide, OpenBiome serves as a platform connecting scientists across studies and disciplines.

22 clinical trials

In 2016, OpenBiome supported 18 (38%) of the clinical trials studying FMT in the United States. These trials explored the treatment's potential for improving conditions such as ulcerative colitis, Crohn's disease, and irritable bowel syndrome, among others. OpenBiome also supported a study in Spain on HIV-AIDS, and whether FMT could help improve immune system functions.



**CATALYZING
RESEARCH**

Sharing our results

OpenBiome published physician-reported patient outcomes from 2,050 patients — the largest cohort to date — with an 84% clinical cure rate of recurrent *C. difficile* infection across all patient populations and modes of delivery.

The information was shared in one of 17 abstracts that OpenBiome published and presented at conferences held by the national gastroenterological and infectious disease medical societies: Digestive Disease Week, Infectious Disease Week, and the American College of Gastroenterology Annual Scientific Meeting.

Panchal et al.'s poster, "The impact of stool banks on access to fecal microbiota transplantation for recurrent *Clostridium difficile* infection in the United States: A geospatial analysis" was an ACG Poster of Distinction.

Spotlight: CDC support for OpenBiome to study FMT & infectious disease

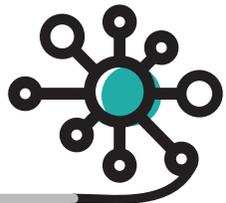
The Centers for Disease Control and Prevention (CDC) awarded OpenBiome two contracts in 2016 totaling \$1,050,000 to study whether FMT might help prevent dangerous antibiotic-resistant infections.

The first study will look at whether FMT can help patients out-compete vancomycin-resistant enterococcus (VRE). The second study will explore the use of autologous fecal transplants, through which patients receive their own banked stool to prevent antibiotic-resistant bacteria from colonizing their intestinal tracts following antibiotic treatments.



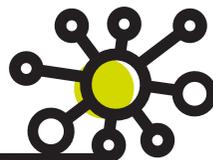
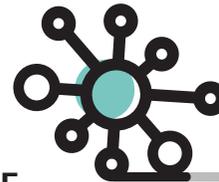
Meet the team: Robert Rosenbaum, Director of Clinical Research Operations

Rob joined OpenBiome in February to oversee the management of our research partnerships and our own, OpenBiome-sponsored clinical trials. Rob joined us from the Center for International Development at the Harvard Kennedy School, where he oversaw a broad range of research projects, including international randomized control trials, and managed funding for exploratory researcher-policymaker engagements. He formerly served as the Regional Director for Children of South Africa (CHOSA, Inc), a US-based nonprofit organization that helps community-based organizations better serve orphans and vulnerable children.



66,000
patients contract VRE
infections resulting in
13,000 deaths

CDC
designates VRE
as serious threat



Currently
no alternative
treatments for VRE once
antibiotics fails

QUALITY & SAFETY

We remain steadfast in our commitment to continually improving the quality and safety of our FMT treatments. Working with our clinical advisory board, we regularly review our processes, introduce upgrades, and endeavor to advance quality and safety in step with developments from our own experience and the field.

In 2016, we added new screens for multi-drug resistant organisms (MDROs) to our regular donor screening program including:

- Extended Spectrum Beta-Lactamases (ESBL)
- Carbapenem-resistant Enterobacteriaceae (CRE)
- Methicillin-resistant Staphylococcus aureus (MRSA)

A new home

OpenBiome moved to a new laboratory and office space at 200 Inner Belt Road, Somerville, in June 2016. The lab reflected significant improvements for our quality and safety program as well as our expanded scale. The office space allowed us to unite our team under a single roof for the first time in our history.



3%

of prospective stool donors pass our screening criteria

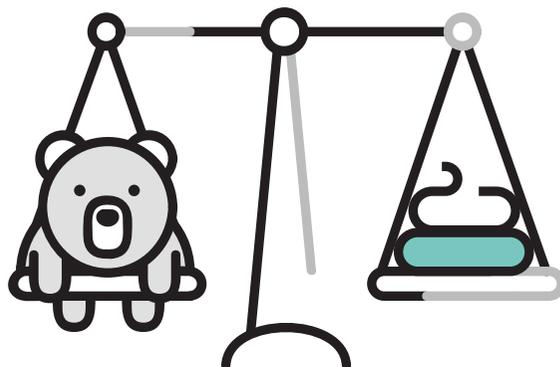


3 in 100 people qualify to donate stool

Three percent of prospective stool donors pass our screening criteria, which include logistical considerations as well as clinical evaluations and stool and blood tests. Our screening criteria may be reviewed [here](#).

A stool ton

This year, OpenBiome processed 593,800g of stool — and passed the metric ton milestone in mid-November.



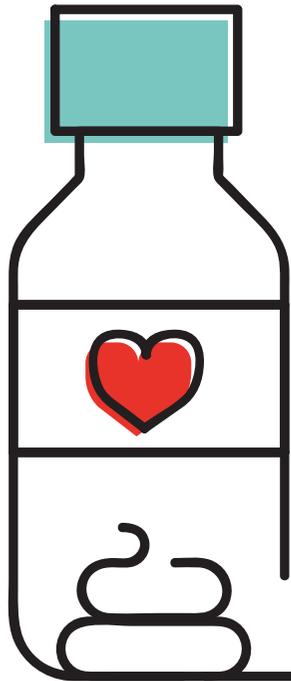
593,000g

About half a ton of stool was processed in 2016 - twice the weight of a full grown grizzly bear!



Team Spotlight: Dr. Colleen Kelly, Clinical Advisory Board

Dr. Colleen Kelly, MD, FACG, has been serving on OpenBiome's Clinical Advisory Board since its establishment in 2013. One of the world's leading experts on FMT, Dr. Kelly has authored some of the seminal research on the treatment's use in *C. difficile* and inflammatory bowel disease and is one of the principal investigators overseeing the American Gastroenterological Association's Fecal Microbiota Transplantation National Registry. Dr. Kelly is an assistant professor of medicine at The Warren Alpert Medical School of Brown University, a gastroenterologist in the Center for Women's Gastrointestinal Medicine at the Women's Medicine Collaborative, and a fellow of the American College of Gastroenterology.



“Within
24 hours
of receiving the
donor sample via
colonoscopy, my
body felt normal
for the first
time since I first
developed the
infection. ”

“I struggled with a recurrent *C. diff* infection for six months before finding a doctor that provides stool transplants. Once I finally had my FMT, it was truly miraculous for me - and I use that term sparingly!

Within 24 hours of receiving the donor sample via colonoscopy, my body felt normal for the first time since I first developed the infection. It was as if someone had pressed a reset button within me, and my body was finally at rest.”

- CLAUDIA



PATIENT TESTIMONIAL

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.

Board of Directors

Jim Burnham – Chairman of the Board

Mark Smith, PhD – President

Eric Alm, PhD – Member

James Burgess – Member

Elliot Mattingly - Member

Neil Rasmussen – Member

Jane Williams, MD – Member

News & Honors from 2016

Boston

[You stool could be the next breakthrough in Medicine](#)

[Stool bank OpenBiome is expanding to Somerville](#)

WIRED

[Are you ready to swallow a pill full of poop?](#)

HBO
VICE

[Fecal medicine](#)

TALIT
DISRUPT 100

[Disrupt 100](#)

MD
MAGAZINE

[OpenBiome helps lead the way in fecal microbiota transplant](#)

TEDMED

[“What if we could fight antibiotic resistance with bacteria?”](#)

MEDPAGE
TODAY

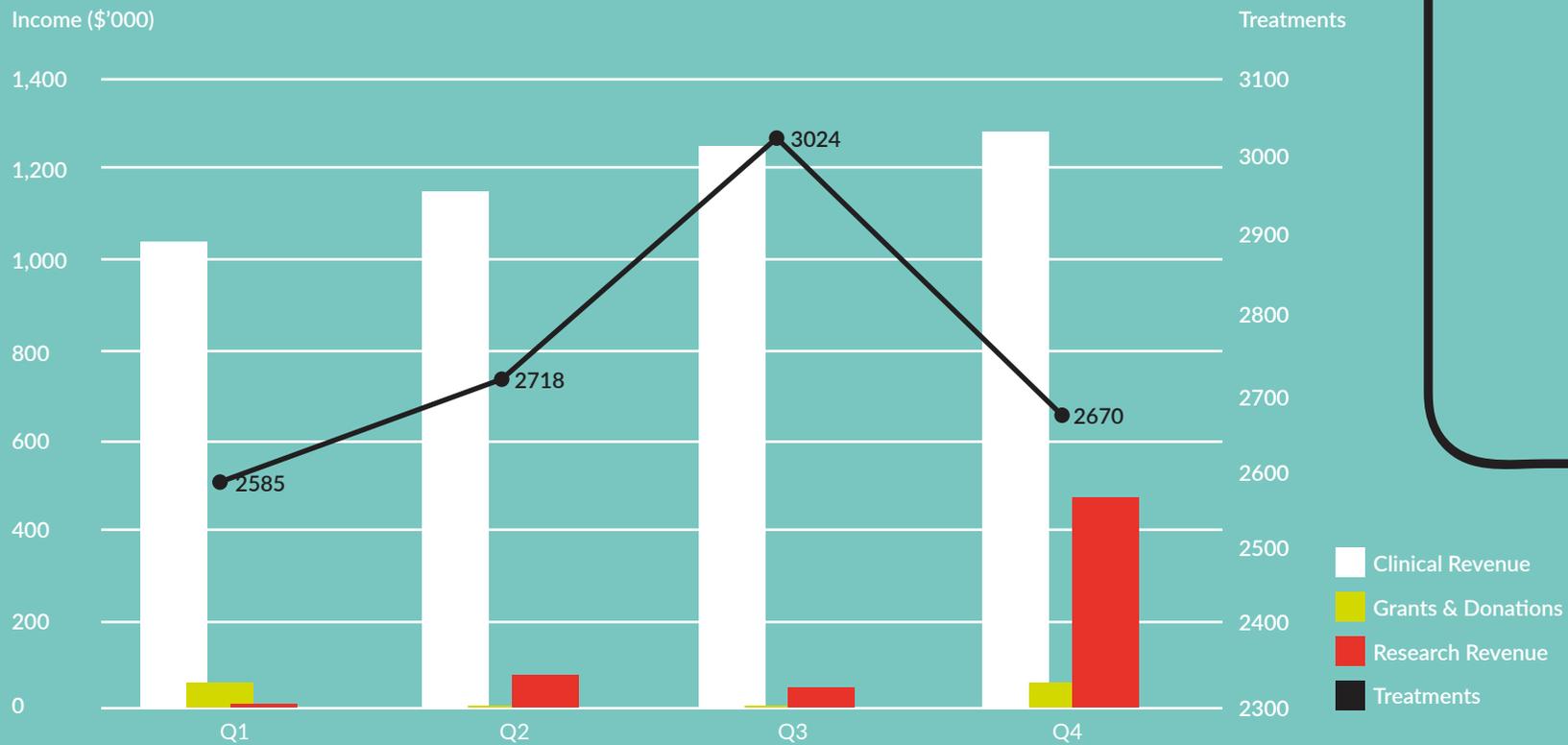
[Fecal transplants area of focus](#)



ABOUT
OPENBIOME

FINANCIAL

Quarterly growth: income & treatments provided



Balance Sheet

Assets

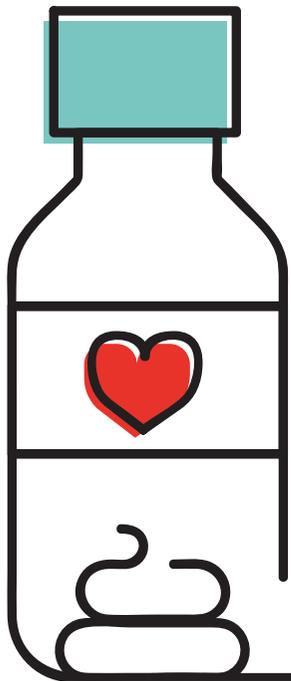
Current Assets	
Cash	\$228,169
Accounts Receivable	\$945,520
Inventory	\$551,182
Prepaid expenses	\$30,062
Total current assets	\$1,754,933
Property and equipment, net	\$360,822
Security deposits	\$235,782
Total assets	\$2,351,537

Liabilities and Net Assets

Current liabilities	
Accounts payable	\$161,807
Net accounts payable - related party	\$246,885
Accrued expenses	\$330,146
Current portion of note payable	\$58,938
Current portion of capital lease payable	\$5,019
Total current liabilities	\$802,795
Capital lease payable	\$19,315
Total liabilities	\$822,110
Net assets	
Unrestricted	\$1,516,396
Temporarily restricted	\$13,031
Total net assets	\$1,529,427
Total liabilities and net assets	\$2,351,537

Income Statement

	Unrestricted	Temporarily R	Total
Unrestricted operating revenues and support			
Sales of product (net of discounts)	\$4,276,016	-	\$4,276,016
Research Sales:			
General research	\$119,987	-	\$119,987
Government contracts	\$443,636	-	\$443,636
Private Grants	\$10,990	\$24,021	\$35,011
Shipping and handling fees	\$446,165	-	\$446,165
Less cost of clinical program sales	(\$2,578,082)	(\$10,990)	(\$2,589,072)
Gross profit on sales	\$2,718,712	\$13,031	\$2,731,743
Other income	\$11,213	-	\$11,213
Major donations	\$100,000	-	\$100,000
Other donations	\$5,006	-	\$5,006
Total unrestricted operating revenues and support	\$2,834,931	\$13,031	\$2,847,962
Operating expenses			
Program:			
Clinical	\$399,255	-	\$399,255
Research	\$1,248,394	-	\$1,248,394
Total program expenses	\$1,647,649	-	\$1,647,649
General and administrative	\$1,206,418	-	\$1,206,418
Fundraising	\$34,015	-	\$34,015
Total operating expenses	\$2,888,082	-	\$2,888,082
Change in net assets	(\$53,151)	\$13,031	(\$40,120)
Net assets, beginning of year	\$1,569,547	-	\$1,569,547
Net assets, end of year	\$1,516,396	\$13,031	\$1,529,427



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