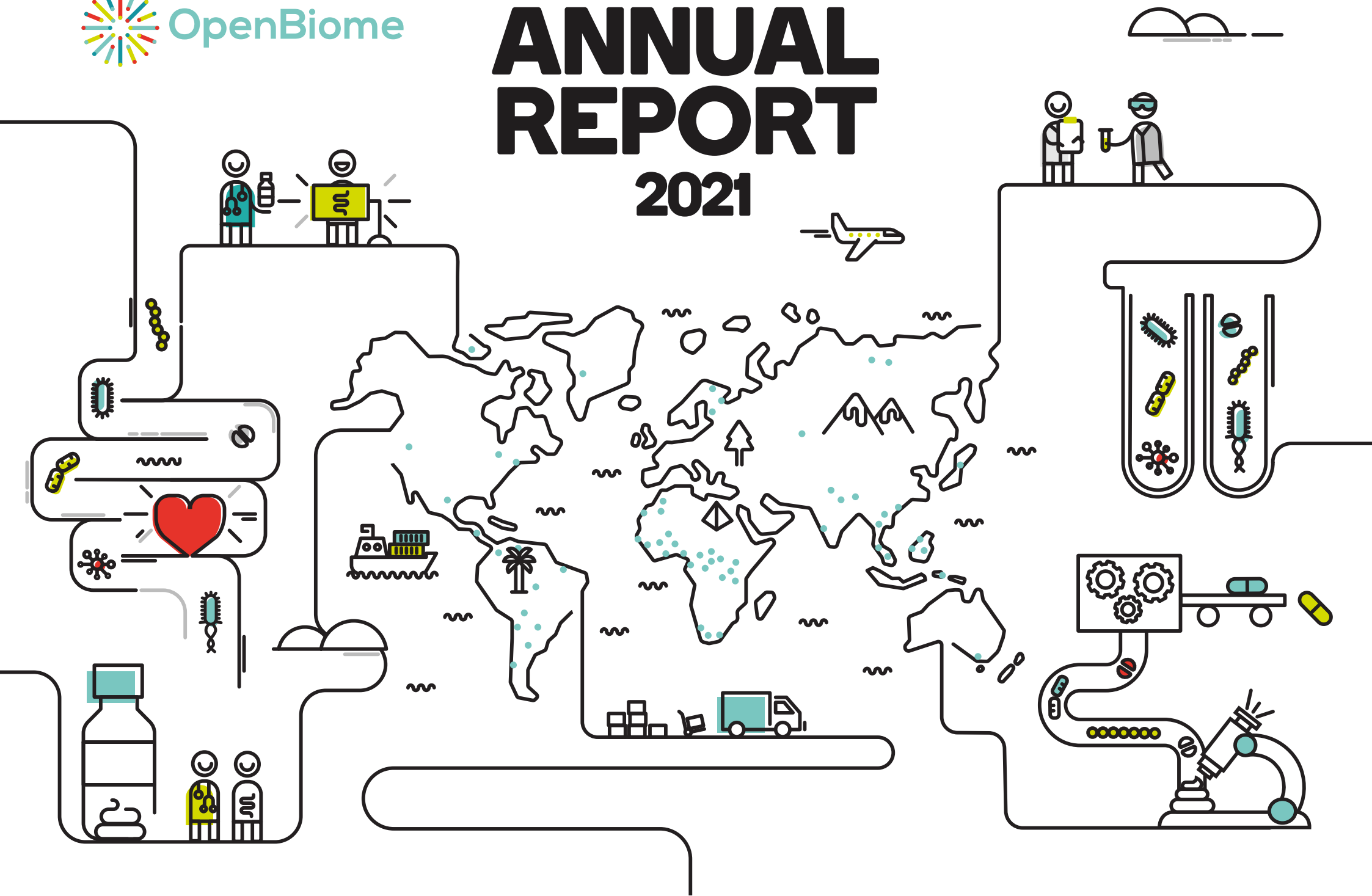


ANNUAL REPORT 2021



As OpenBiome closes out 2021 and looks to the future, we are approaching a rare moment when a nonprofit can proudly say “mission accomplished.” We did it.

The anticipated arrival of FDA-approved microbiome-based therapies for *Clostridioides difficile* infection (CDI) in 2023, means that OpenBiome has effectively bridged an urgent gap in care. By providing fecal microbiota transplantation (FMT) preparations for antibiotic-resistant CDI, we have positively impacted the lives of more than 60,000 patients and their families.

OpenBiome would not be where we are today without the leadership of my predecessor and OpenBiome co-founder, Carolyn Edelstein, from whom I took the reins of this incredible organization in December 2021. In less than ten years, under Carolyn’s leadership, OpenBiome has pushed the boundaries of microbiome-based medicine and set the standard of care for CDI when antibiotics failed.

To prepare for this historic handoff from investigational FMT treatments to FDA-approved microbiome-based therapies, we took major steps in 2021 to evolve into a more nimble and globally focused microbiome research organization. We sold our fecal microbiota manufacturing operation and established a strategic

collaboration with the University of Minnesota, ensuring patients with recurrent CDI will have continued access to FMT until an FDA-approved alternative is readily available.

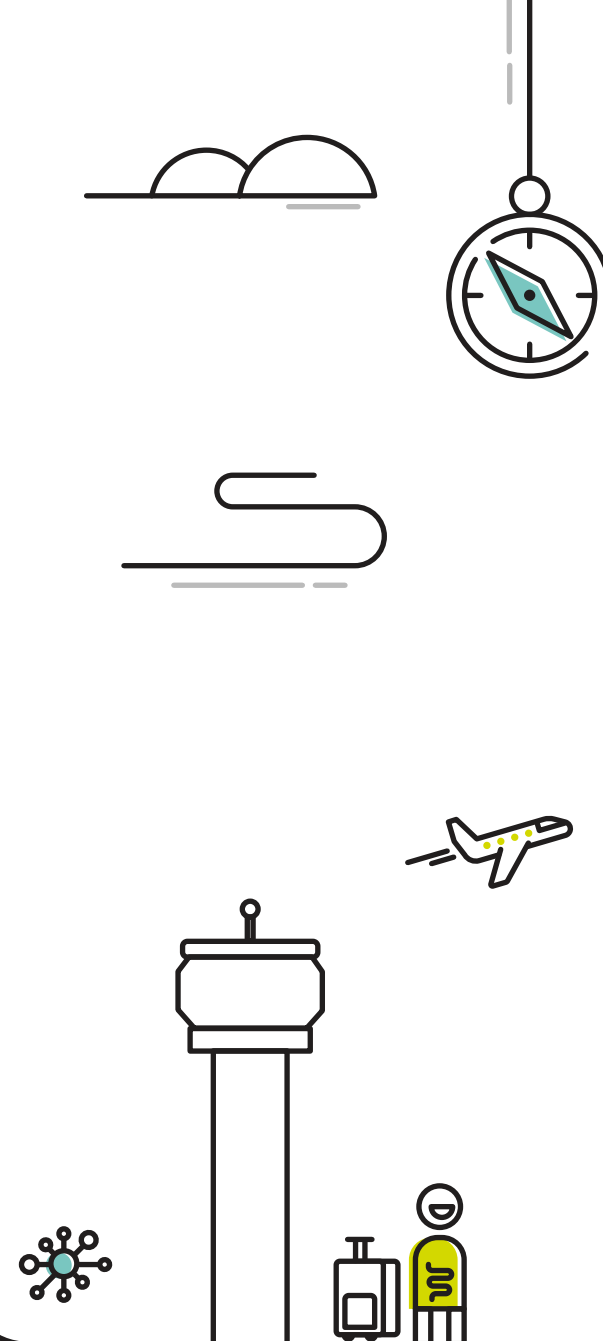
But that’s not all. We’re growing global!

To accelerate bold new discoveries in microbiome science worldwide, we recently acquired the Global Microbiome Conservancy (GMbC) from the Massachusetts Institute of Technology, which represents the largest collection of non-industrialized human microbiome samples and strains in the world. OpenBiome’s unparalleled expertise in microbiome banking, coupled with the GMbC’s growing consortium of 80+ frontline researchers in 37 countries, uniquely positions us to deliver on our global vision where the full potential of the human microbiome radically improves health for all.

Thank you for joining us on this exciting journey – to help patients with *C. difficile* right here, right now – while we build a global ecosystem that accelerates discovery, promotes equitable benefit, and safeguards a vital public health resource for future generations.



-Julie Barrett O'Brien
EXECUTIVE DIRECTOR



“

We envision a world where the full potential of the microbiome radically improves health for all.

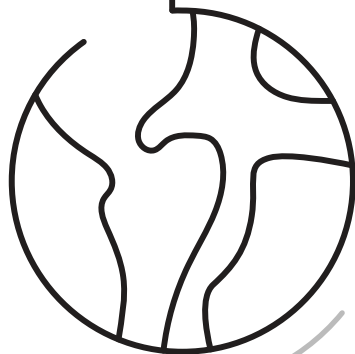


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MEETING AN URGENT MEDICAL NEED

OpenBiome harnesses the bacteria within our bodies to treat patients who have run out of standard medical options. As the world's largest stool bank, we process stool from healthy donors into medical treatments known as Fecal Microbiota Transplantation (FMT). We primarily treat patients with *C. difficile* infections—a debilitating illness that causes chronic diarrhea and dangerous weight loss. Where antibiotics fail, FMT preparations successfully treat 84% of recurrent *C. difficile* infections.

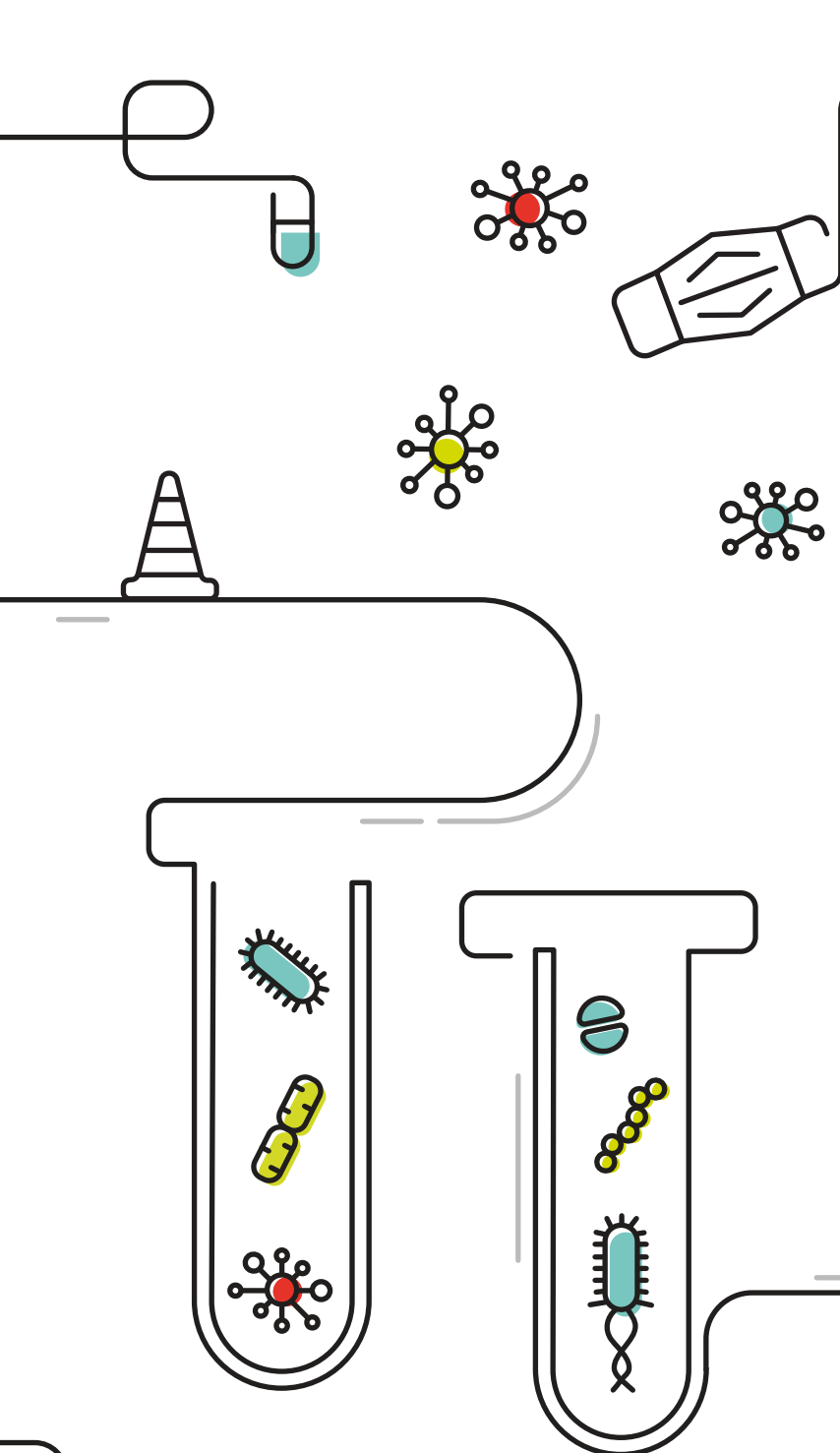
Spotlight on 60K Treatments

This September, OpenBiome reached a major milestone—shipping out our 60,000th FMT treatment. 60,000 is an apt number to reflect on because it is roughly the number of steps in a marathon. For OpenBiome, serving patients has been a long and rewarding journey—one that has seen FMT grow from a fringe medical treatment to the standard of care for recurrent *C. difficile*. We are grateful for all the physicians, medical workers, advocates, and patients who have joined us along the way and look forward to advancing this emerging field of medicine and treating as many patients as possible.

In their Own Words

“I had a fecal transplant done when I had *C. difficile* for 5 months. It worked for me and I felt better within 48 hours. I would tell anyone who has *C. difficile* to have this done. It was a life saver for me.

-Jeannette



Our Commitment to Patients

OpenBiome is committed to providing investigational FMT preparations for recurrent *C. difficile* infections until an FDA-approved alternative becomes available.

To make sure patients have safe access to the treatments they need, we have screened our entire inventory for SARS-CoV-2 using a newly developed direct stool test. We implemented this test, along with increased measures for monitoring donor health, in 2021 after review by the FDA.

OpenBiome is also expanding access to FMT through a collaboration with the [University of Minnesota's Microbiota Therapeutics Program](#). This collaboration will allow us to treat more patients by distributing FMT preparations manufactured by the University, a world leader in microbiome-based therapeutics. This new source of FMT material will be available in 2022.

Every Treatment Counts

In **2021** we:

4,017

Cleared 4,017 FMT preparations for clinical use by implementing a newly developed SARS-CoV-2 test for donor stool.

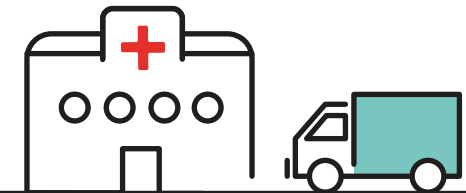
3,666

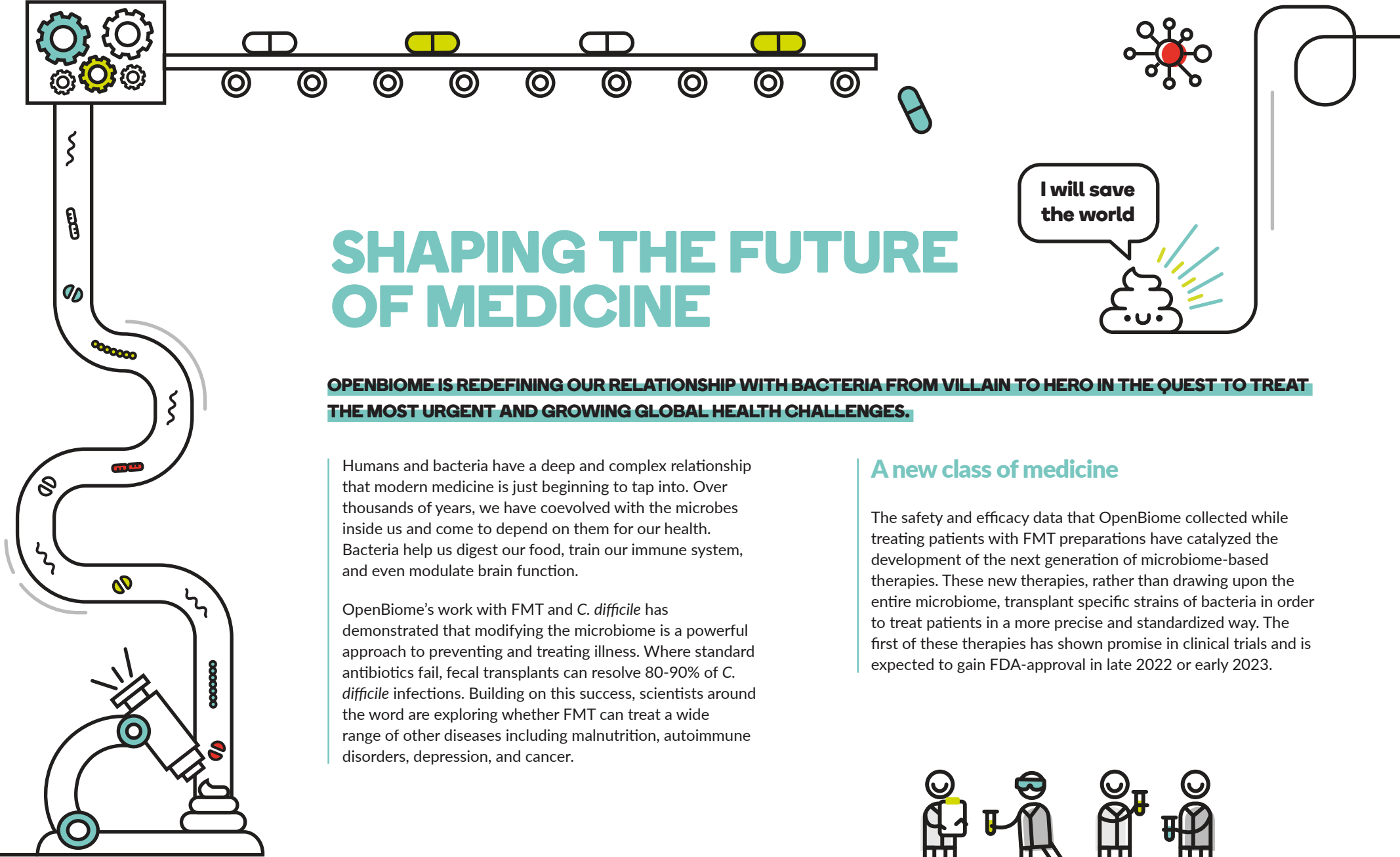
Shipped 3,666 FMT preparations and partnered with 36 new hospitals.

Overall, since **2013**, we have:

60,651

Shipped 60,651 FMT treatments to a network of 1,372 hospitals.





SHAPING THE FUTURE OF MEDICINE

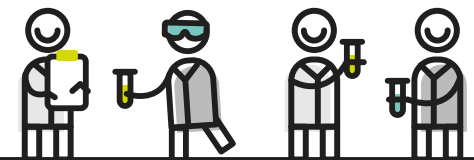
OPENBIOME IS REDEFINING OUR RELATIONSHIP WITH BACTERIA FROM VILLAIN TO HERO IN THE QUEST TO TREAT THE MOST URGENT AND GROWING GLOBAL HEALTH CHALLENGES.

Humans and bacteria have a deep and complex relationship that modern medicine is just beginning to tap into. Over thousands of years, we have coevolved with the microbes inside us and come to depend on them for our health. Bacteria help us digest our food, train our immune system, and even modulate brain function.

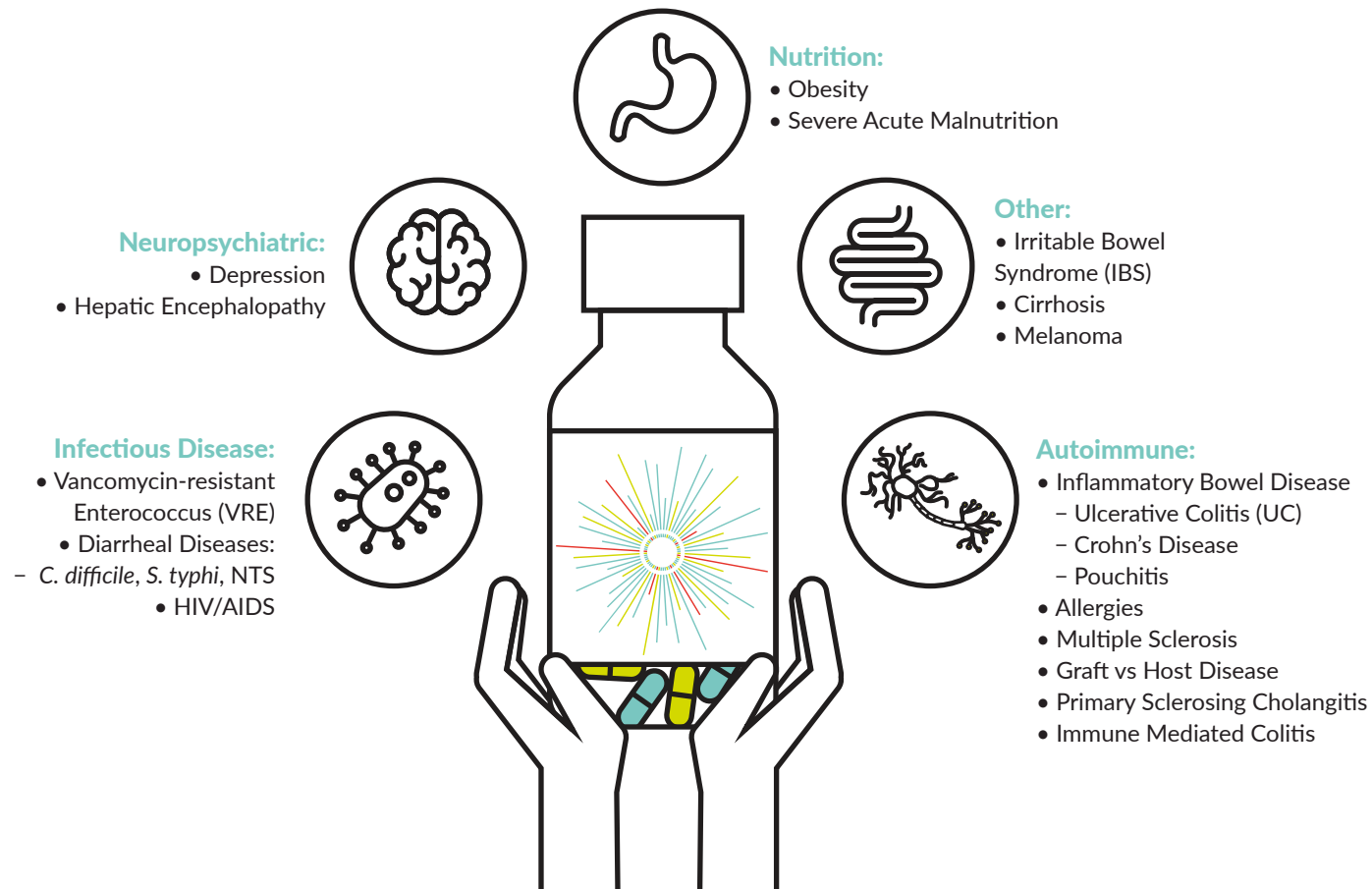
OpenBiome's work with FMT and *C. difficile* has demonstrated that modifying the microbiome is a powerful approach to preventing and treating illness. Where standard antibiotics fail, fecal transplants can resolve 80-90% of *C. difficile* infections. Building on this success, scientists around the world are exploring whether FMT can treat a wide range of other diseases including malnutrition, autoimmune disorders, depression, and cancer.

A new class of medicine

The safety and efficacy data that OpenBiome collected while treating patients with FMT preparations have catalyzed the development of the next generation of microbiome-based therapies. These new therapies, rather than drawing upon the entire microbiome, transplant specific strains of bacteria in order to treat patients in a more precise and standardized way. The first of these therapies has shown promise in clinical trials and is expected to gain FDA-approval in late 2022 or early 2023.



OPENBIOME WORKS WITH RESEARCHERS AT LEADING ACADEMIC INSTITUTIONS TO RUN GROUNDBREAKING STUDIES EXPANDING THE THERAPEUTIC POTENTIAL OF MICROBIOME-BASED TREATMENTS.



Since 2013, we have supported more than 40 clinical trials and single patient case studies. Our clinical trial portfolio spans autoimmune, infectious, metabolic, and neuropsychiatric disease and accounts for 30% of all active or completed FMT trials in the United States.

Catalyzing Microbiome Research

In **2021** we supported:

3

3 clinical trials,

9

and 9 single patient investigation new drug applications (IND).

38

Along with our research partners, published 38 articles in peer-reviewed journals

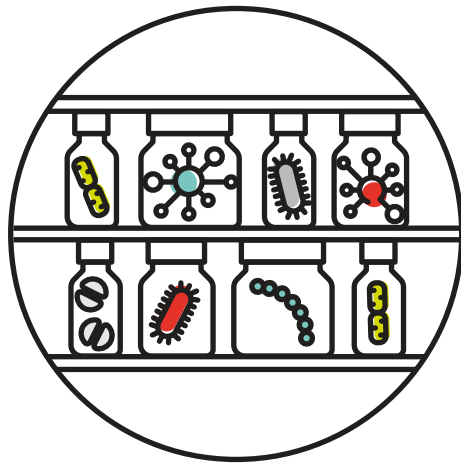


OVER THE PAST DECADE, OPENBIOME HAS REALIZED THE TRANSFORMATIVE POWER OF THE MICROBIOME TO REDUCE SUFFERING FROM C. DIFFICILE INFECTION AND UNLOCK NEW TREATMENTS FOR INTRACTABLE DISEASES WITH RESEARCHERS IN THE U.S. NOW, WE ARE TAKING THIS EXPERIENCE GLOBAL TO ENSURE CLINICIANS AND SCIENTISTS AROUND THE WORLD CAN HARNESS THE MICROBIOME TO IMPROVE HUMAN HEALTH.

“ACCELERATING BOLD
DISCOVERIES IN MICROBIOME
SCIENCE TO IMPROVE
HEALTH FOR ALL”



A GLOBAL NONPROFIT, OPENBIOME WILL CATALYZE CUTTING EDGE RESEARCH, ADVANCE TREATMENT, AND EXPAND SCIENTIFIC CAPACITY TO UNLOCK THE FULL POTENTIAL OF THE HUMAN MICROBIOME.



Catalyzing Research

Build and openly share the world's most globally representative collection of samples and strains to fill critical gaps in microbiome science.



Advancing Treatment

Harness the healing power of gut microbes by providing clinicians and researchers with protocols and treatments to help people with recurrent *C. difficile* infections and other microbiome-mediated diseases.

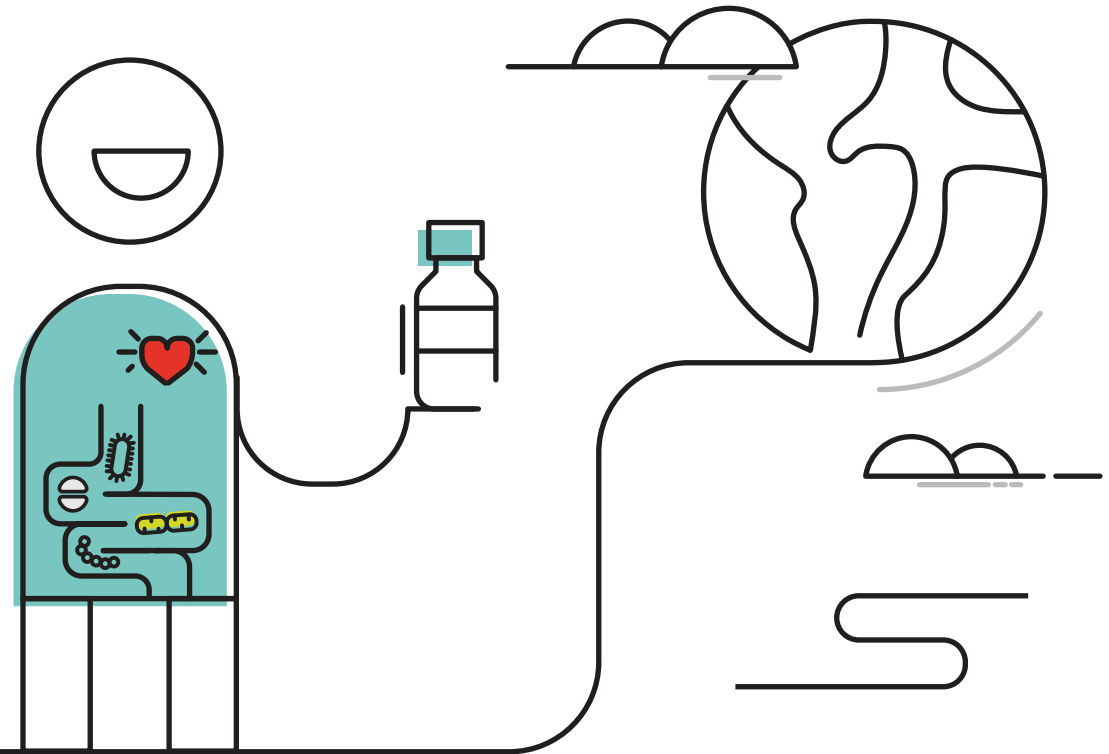


Expanding Scientific Capacity

Build global scientific capacity and share microbiome therapy know-how with all researchers, including those on the frontline of infectious diseases and in communities with weak health systems.

TEACHING THE WORLD TO STOOL BANK

Since 2013, OpenBiome has scaled the power of the microbiome to change the lives of thousands of patients with treatment-resistant *C. difficile*. Each FMT preparation that leaves our doors is a ripple effect for good that impacts patients who are getting their health back, clinicians who are learning more about the microbiome, scientists working towards the next breakthrough, and public health at large as we redefine our relationship with bacteria. OpenBiome aims to put this power in the hands of physicians and researchers around the world by sharing our knowledge of stool banking.



What We Provide

OpenBiome provides guidance on important aspects of stool banking including:

- Recruiting and screening donors
- Manufacturing and storing FMT preparations
- Navigating FMT regulatory landscapes
- Communicating with a clinical network
- Treatment monitoring and traceability

The Benefits of Local Banks

- Improves therapeutic potential of FMT by matching patients with local donors who have similar diets and lifestyles.
- Expands safe access to FMT for patients with recurrent *C. difficile*—an urgent antibiotic-resistant threat in the United States and around the world.
- Diversifies research by empowering scientists to run clinical trials using FMT to treat health conditions that are relevant to their community.

Sharing Our Expertise

In 2021, we published 3 articles in peer-reviewed journals sharing data and protocols from our stool banking operations.

- [Stool Banking for Fecal Microbiota Transplantation: Methods and Operations at a Large Stool Bank](#) (Frontiers in Cellular and Infection Microbiology)
- [Carriage Rates of Multidrug-Resistant Organisms Among Prospective Stool Donors](#) (Lancet Infectious Diseases)
- [16S rRNA Sequencing of Samples from Universal Stool Bank Donors](#) (BMC Res Notes)



MAJDI OSMAN

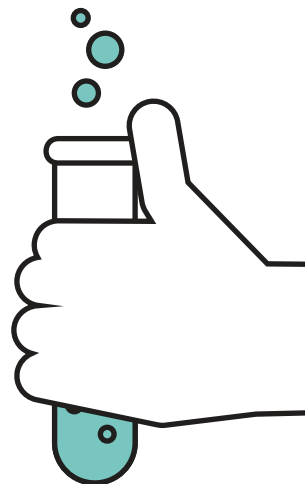
MD MPH
Chief Medical Officer



My interest in the microbiome began in medical school when I saw doctors administer an FMT treatment to a patient with recurrent *C. difficile*. After scaling access to FMT in the U.S., we're at an incredibly exciting juncture where harnessing the microbiome could have a profound impact on improving human health globally. We want to lead that collective effort.

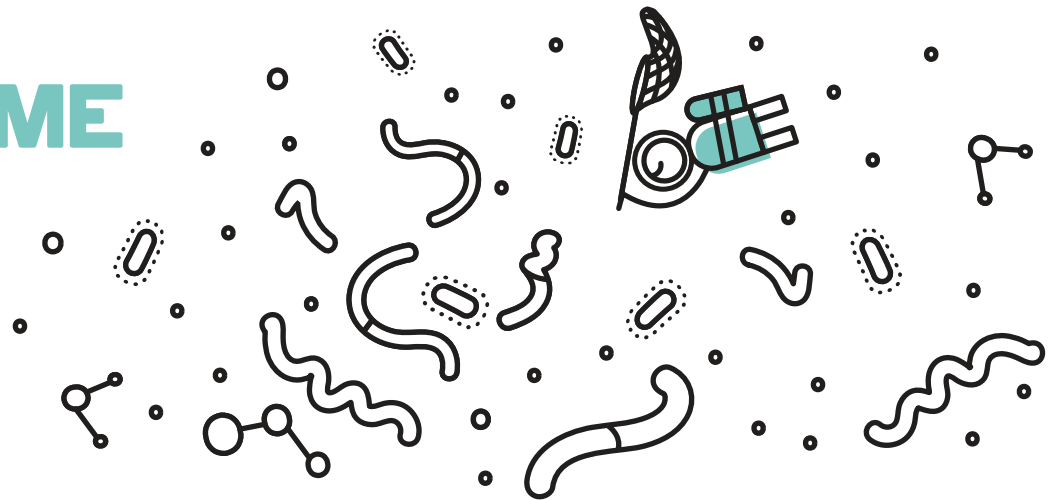


Dr. Majdi Osman, OpenBiome's Chief Medical Officer, is leading our efforts to teach the world to stool bank. Majdi is an internal medicine physician who trained at University College London and completed his Master's in public health at the Harvard T.H. Chan School of Public Health. He has previously worked at the World Health Organization and is passionate about the potential for microbiome research to impact global health. As an extracurricular project, Majdi is working on a children's book about the microbiome.



OPENING MICROBIOME RESEARCH TO THE WORLD

OpenBiome is expanding our global mission by welcoming the Global Microbiome Conservancy (GMbC) as a new flagship program. The GMbC is a nonprofit initiative dedicated to conserving and providing access to the global diversity of the human microbiome.



Building a Global Microbiome Library for All

Understanding the human microbiome is critical for public health but our current knowledge, largely focused on U.S. and European populations, is biased and vastly incomplete (1). The GMbC is building the globally representative microbiome library that the world urgently needs. Working in close partnership with scientists around the world, we collect, analyze, and culture human microbiome diversity from underrepresented communities. Over the next year, we will begin providing access to the GMbC library as a research tool to radically expand scientists' understanding of the microbiome and human health.

The GMbC by the Numbers:

- **1,200+** participants from underrepresented communities
- **1,000** metagenomic surveys
- **10,000** whole genome-sequenced bacterial cultures
- **80+** research collaborators in 37 countries worldwide

Growing a Global Microbiome Research Community

We believe that global science must build, and be built through, local science. We engage in long-term partnerships with our global collaborators, and provide them training, tools, and access to our community knowledge sharing platform to grow microbiome research capacity worldwide.

About the Global Microbiome Conservancy (GMbC)

The GMbC was founded in 2016 by scientists Mathieu Groussin, PhD and Mathilde Poyet, PhD in the laboratory of Professor Eric Alm at MIT, with seed funding from the Center for Microbiome Informatics and Therapeutics and key support from Dr. Ramnik Xavier of the Broad Institute and Massachusetts General Hospital.



(1) Abdill RJ, Adamowicz EM, Blekhman R. Public human microbiome data are dominated by highly developed countries. PLoS Biol. 2022 Feb 15;20(2):e3001536

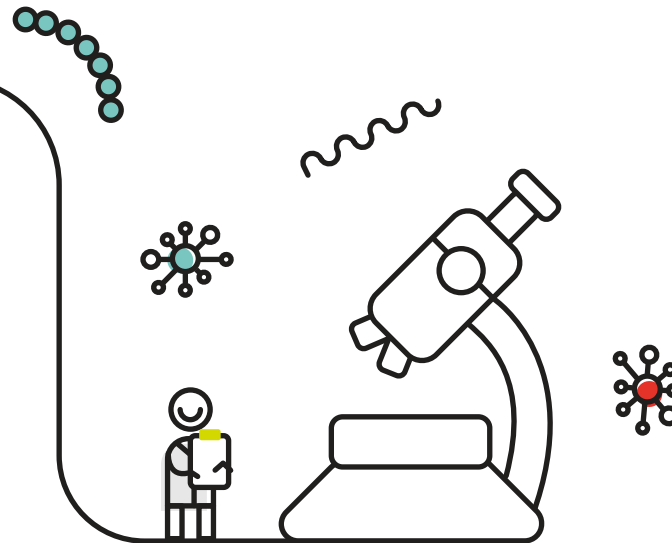


KATYA MONIZ

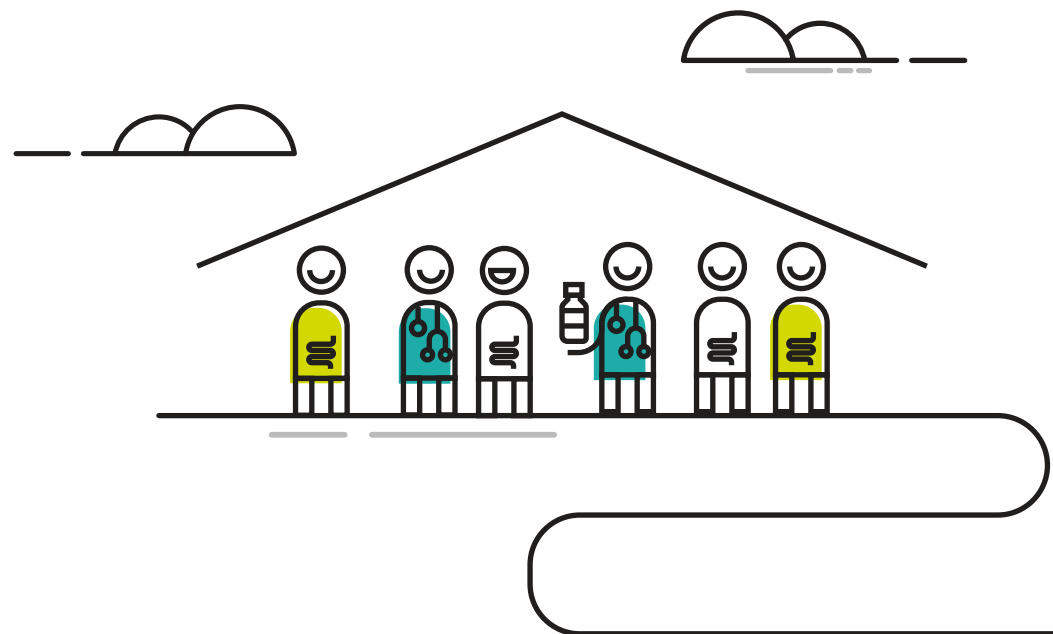
PhD
Director of the Global Microbiome
Conservancy Program



The Global Microbiome Conservancy program builds on OpenBiome's unparalleled expertise in microbiome biobanking and its deep commitment to solving public health challenges through catalyzing microbiome-based treatments and research. Together, the GMbC and OpenBiome collections comprise the most globally representative biobank of microbiome samples and bacterial cultures. We are excited to continue growing this invaluable resource in partnership with our global research collaborators, and make it available to scientists and clinicians around the world.



Katya Moniz joined OpenBiome in September 2021 to oversee the transfer and management of the GMbC program. Katya joined us from the Alm Lab at the Massachusetts Institute of Technology, where she oversaw a broad range of research projects, including the GMbC and wastewater-based surveillance of pathogens such as typhoid and SARS-CoV-2. She is excited to advance representation in both the content and practice of microbiome science to benefit public health and grow scientific capacity worldwide.



ABOUT US

OpenBiome accelerates bold discoveries in microbiome science to improve health for all. An independent nonprofit, we catalyze cutting edge research, advance treatment, and expand scientific capacity to unlock the full potential of the human microbiome.

Since our founding at MIT in 2012, we have provided FMT treatments to more than 60,000 patients with recurrent *C. difficile* infections and supported over 40 studies investigating how the microbiome affects human health. Through OpenBiome's new flagship program, the Global Microbiome Conservancy (GMbC), we are building and sharing the world's most globally representative collection of microbiome samples and strains to fill critical gaps in microbiome science.

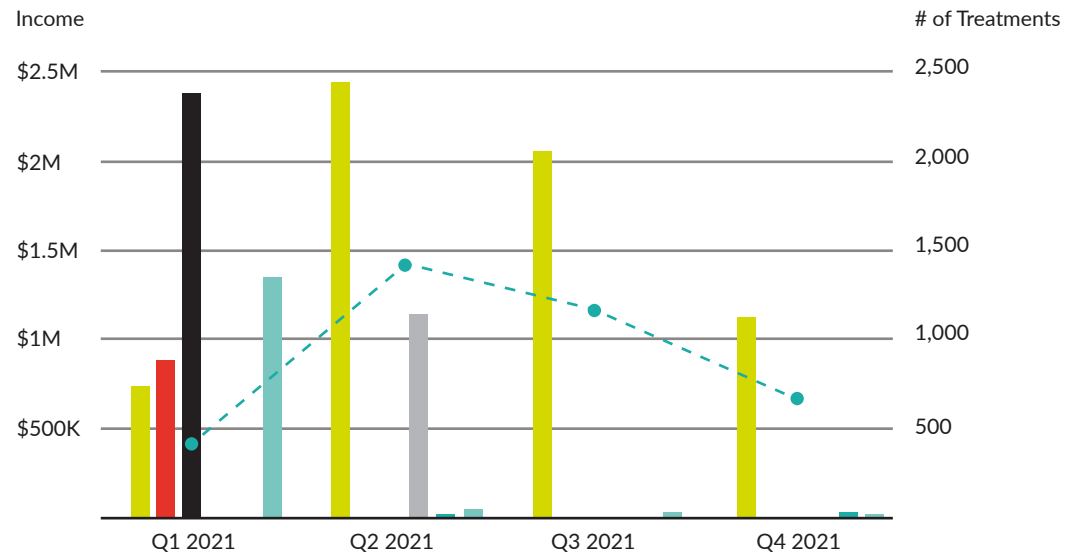


Board of Directors

Lisa Serwin — Chair of the Board
Eric Alm, PhD
Jim Bildner, JD
Neil Rasmussen
Jane Williams, MD MPH

FINANCIALS

2021 Quarterly Revenue



- Clinical Revenue
- CP101 Revenue
- Gain on Sale of Manufacturing Assets
- Gain on PPP Loan Forgiveness
- Donations
- Data and Research Revenue
- Shipments

Balance Sheet

Assets

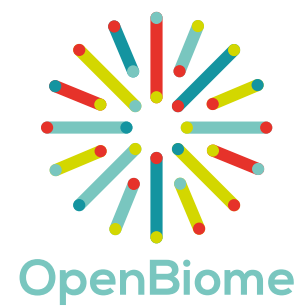
Current Assets	2021	2020
Cash and equivalents	\$7,553,224	\$2,514,362
Accounts receivable, net	\$650,400	\$291,501
Inventory, net	\$2,183,545	\$4,625,678
Net accounts receivable - related party	\$10,268	\$180,937
Prepaid expenses	\$157,105	\$171,964
Total current assets	\$10,554,542	\$7,784,442
Property and equipment, net	\$62,545	\$410,995
Security deposits	\$270,455	\$62,055
Total assets	\$10,887,542	\$8,257,492

Liabilities and Net Assets

Current liabilities		
Accounts payable	\$71,739	\$220,734
Net accounts payable - related party	-	-
Accrued expenses	\$259,427	\$500,354
Current portion of Paycheck Protection Program Loan	\$106,623	\$385,078
Deferred revenue	\$22,100	\$22,100
Total current liabilities	\$459,889	\$1,128,266
Paycheck Protection Program Loan	\$983,972	\$770,239
Total liabilities	\$1,443,861	\$1,898,505
Net assets		
Without donor restrictions	\$9,443,681	\$6,358,987
With donor restrictions	-	-
Total net assets	\$9,443,681	\$6,358,987
Total liabilities and net assets	\$10,887,542	\$8,257,492

Income Statement

	2021	2020	
	Total Without Donor Restrictions	Without Donor Restrictions	With Donor Restrictions Total
Operating revenues and support			
Sales of product (net of discounts)	\$5,967,680	\$5,256,585	- \$5,256,585
CP101 revenue	\$898,803	\$4,022,826	- \$4,022,826
Research activities:			
Contact revenue	\$127,368	\$88,544	- \$88,544
General research revenue	-	-	- -
Grant revenue	\$2,347	\$76,000	- \$76,000
Shipping and handling fees	\$429,400	\$278,520	- \$278,520
Less cost of clinical program sales	(\$6,032,990)	(\$7,043,384)	- (\$7,043,384)
Gross profit on sales	\$1,392,608	\$2,679,091	- \$2,679,091
Data licenses and royalties	\$1,325,000	\$220,000	- \$220,000
Other income	\$23,357	\$39,796	- \$39,796
Other donations	\$55,120	\$287,967	- \$287,967
Release from restrictions	-	\$105,323	(\$105,323) -
Total operating revenues & support	\$2,796,085	\$3,332,177	(\$105,323) \$3,226,854
Operating expenses:			
Program:			
Clinical	\$2,154,509	\$2,955,269	- \$2,955,269
Research	\$515,428	\$1,694,361	- \$1,694,361
Total program expenses	\$2,669,937	\$4,649,630	- \$4,649,630
General and administrative	\$575,830	\$489,122	- \$489,122
Fundraising	\$69	\$50,251	- \$50,251
Total operating expenses	\$3,245,836	\$5,189,003	- \$5,189,003
Change in net assets from operations	(\$449,751)	(\$1,856,826)	(\$105,323) (\$1,962,149)
Non-operating activities:			
Gain on PPP loan forgiveness	\$1,155,317		
Gain on sale of assets (Note XX)	\$2,379,128	\$1,000,000	- \$1,000,000
Change in net assets	\$3,084,694	(\$856,826)	(\$105,323) (\$962,149)
Net assets, beginning of year	\$6,358,987	\$7,215,813	\$105,323 \$7,321,136
Net assets, end of year	\$9,443,681	\$6,358,987	- \$6,358,987



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