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OpenBiome Announces New Collaboration with the University of Minnesota to Treat Patients with Recurrent *C. difficile* Infections

CAMBRIDGE, MA— OpenBiome is announcing a collaboration with the University of Minnesota's [Microbiota Therapeutics Program](#) to ensure that patients with recurrent *C. difficile* infections have access to fecal microbiota transplantation (FMT) until an FDA-approved alternative is available.

Through this collaboration, OpenBiome will distribute preparations of intestinal microbiota manufactured under Good Manufacturing Practice by the University of Minnesota under the guidance of gastroenterologist [Alexander Khoruts](#), MD and microbiologist [Michael Sadowsky](#), PhD. This influx of inventory will supplement OpenBiome's ongoing service to patients and physicians. Since August, the nonprofit microbiota bank has been providing FMT preparations for non-emergency *C. difficile* infections to its [FMT referral network](#), while also providing material to all partner sites for emergency treatment of fulminant cases.

"Our team cares deeply about patients and specializes in the clinical and operational aspects of running a bank of fecal microbiota-based products," said Khoruts, describing a program that has been a pioneer and world leader in the development of microbiota-based therapeutics. In collaboration with the non-profit Achieving Cures Together, the [Microbiota Therapeutics Program](#) has provided FMT treatments to physicians and researchers since 2008, and published protocols that have been used to treat nearly 100,000 patients worldwide. "We're excited to team up with OpenBiome and its extensive network of clinical partners to bridge the gap in patient care and collect systematic outcome data in the real world."

OpenBiome expects to begin shipping FMT preparations manufactured by the University of Minnesota to its [FMT referral network](#) in the second half of 2022 and to continue using its own inventory for emergency treatments. Microbiota preparations from the University of Minnesota will be available in capsules for oral delivery of freeze-dried microbiota or in liquid formulations for lower intestinal delivery via colonoscopy, sigmoidoscopy, or enema. To advance the practice of FMT, physicians will collect short-term safety and patient outcomes and enter those data into the [American Gastroenterological Association's FMT National Registry](#). The registry, funded by the National Institutes of Health (NIH), aims to systematically track the health of 4,000 FMT recipients to better understand the risks and benefits of microbiota therapeutics.

The collaboration with the University of Minnesota will help OpenBiome fulfill its mission of providing safe access to FMT. Its nonprofit microbiota bank was founded in 2013 to

provide an immediate solution to an urgent healthcare need—treating patients with recurrent *C. difficile* who had failed standard antibiotic regimens. Since its inception, OpenBiome has provided more than 60,000 FMT preparations to a clinical network of over 1,300 healthcare centers across the country. These investigational treatments, made available to patients outside of clinical trials through an [FDA policy enacted in 2013](#), have served as a bridge to FDA-approved alternatives to FMT, which are expected to become available to patients in 2023.

“An FDA-approved microbiota-based therapy will be a huge step forward for patient care and the microbiome field,” said Julie O’Brien, OpenBiome’s Executive Director. “It’s a day that patients and OpenBiome have been anticipating for years. Until then, we could not be more pleased to collaborate with the University of Minnesota to provide *C. difficile* patients with much needed treatments.”

About OpenBiome

OpenBiome is a 501(c)3 nonprofit organization founded to catalyze research on the microbiome’s role in human health and expand safe access to fecal transplantation for patients with recurrent *C. difficile* infections. As the first public stool bank, OpenBiome provides clinicians with rigorously screened, ready-to-use preparations and supports researchers with a suite of tools to discover how gut bacteria might treat diseases beyond *C. difficile*. Since 2013, OpenBiome has partnered with over 1,300 healthcare institutions across all 50 states to deliver more than 60,000 treatments for recurrent *C. difficile*. For more information, visit www.openbiome.org.