



Press Release: OpenBiome receives grant to support FMT patient safety study

Funds will support data collection of long-term patient outcomes following fecal microbiota transplantation (FMT) treatment for recurrent C. difficile infection

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Medford, MA – OpenBiome has received a foundation grant to support a study of the long-term safety profile of FMT as a treatment for patients with recurrent *C. difficile* infections. The study is a component of a U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application and will include patient follow-up assessments for at least one year following FMT. While data from previous small-scale trials for FMT show outstanding efficacy and short-term safety, long-term safety remains a priority area of investigation.

Given the breadth and diversity of OpenBiome’s clinical and research networks, with over 800 treatments provided to over 80 hospitals in 30 states, this research represents the largest formal data collection effort investigating FMT therapy for *C. difficile* infection to date.

“We launched OpenBiome to enable safe, accountable, and high-quality treatments for patients,” said Dr. Mark Smith, OpenBiome Co-Founder and President. “This grant allows us to look into one of the key remaining questions on the role of FMT in the fight against the leading cause of hospital-acquired infections in the U.S.”

“While the regulatory classification of FMT remains a topic for ongoing discussion, the FDA has requested that safety and efficacy data be collected and reported following the process for investigating new drugs,” said co-founder and Executive Director James Burgess. “We strongly agree that this reporting process is important to ensure patient safety, and a key step in moving FMT from an experimental to a mainstream therapy, standardizing treatment methodologies, and making this low-cost therapy available to individuals suffering from recurrent *C. difficile* everywhere.”

About OpenBiome

OpenBiome is a nonprofit stool bank dedicated to expanding safe access to fecal microbiota transplantation (FMT) therapies. Founded by a team of microbiologists, public health advocates, and concerned citizens, OpenBiome aims to significantly reduce the practical barriers for clinicians providing FMTs, while connecting scientists across studies and disciplines.

Contact: info@openbiome.org | 617 575 2201 | www.openbiome.org

Twitter: @OpenBiome