Reporting Adverse Events

As with any medical intervention, FMT carries certain risks. In addition to the possible transmission of infectious pathogens and a theoretical risk of causing microbiome-mediated diseases, the procedure itself poses risks that will vary by delivery modality. The risk of such events should be clearly discussed with your patient during the informed consent process prior to the FMT procedure.

The adverse events contacts for your FMT program should be familiar with these risks, and should communicate the following SUSAR (Suspected Unexpected Serious Adverse Reaction) reporting protocol to all physicians performing FMT at your institution.

**Purpose of reporting adverse events:** We ask that clinicians notify us of SUSARs as soon as possible so that we can effectively respond in a timely manner for the protection of all patients being treated in the OpenBiome network. In the case of an adverse event related to FMT material, timely reporting could be critical in protecting other would-be recipients.

As well, because the FDA regulates the stool used in FMT as an investigational new drug, our clinical partners are required to report any related adverse events to OpenBiome, and in some circumstances, to the FDA. We will assist you with this process.

**Reporting suspected adverse events:** If the treating physician or a member of the FMT program staff become aware of a SUSAR that could be related to an OpenBiome FMT treatment, please follow these steps:

1. **Report to OpenBiome within 24 hours:** An adverse event contact or the treating physician must inform OpenBiome using our online reporting tool at [www.openbiome.org/adverse-events](http://www.openbiome.org/adverse-events). Consult the checklist below for the information needed to submit this report. This report will be passed on to Finch Therapeutics, OpenBiome’s contract manufacturer.

2. **Triage call:** Upon receipt of an adverse event report, a Finch medical professional will reach out to the report’s author to triage the case according to FDA guidelines* and determine next steps in the investigation. Finch and OpenBiome medical staff and the members of the Finch and OpenBiome Clinical Advisory Boards will work together with the reporting site to carry out this investigation.

3. **FDA reporting:** A Finch medical professional will use the details of your report and any ensuing investigation to advise you and your program of any additional reporting requirements, which may include submission of Form FDA 3500. Please consult with us before filing Form FDA 3500, as over-reporting can create inefficient delays.

If you have any questions regarding an adverse event please contact our Clinical Safety team at safety@openbiome.org or call (617) 575-2201, option 9.
Clinician Checklist for Reporting Adverse Events to OpenBiome

To report an adverse event to OpenBiome, please collect the following information, and submit your report through the online form at www.openbiome.org/adverse-events. This report will be passed on to Finch Therapeutics, OpenBiome’s contract manufacturer. A member of the safety team from Finch will contact you.

**Case Information**

- Patient demographics: age, sex, weight, race, and ethnicity
- Preexisting medical condition(s)
- Medication(s) taken prior to FMT and any known allergies
- Comprehensive Clostridium difficile infection (CDI) history
  - Initial diagnosis technique (e.g. toxin EIA, qPCR, anaerobic culture)
  - Modified Horn Index
  - Recurrent or refractory disease
  - Number of recurrences
  - Anti-CDI therapy
  - Previous FMT history
- Information about the FMT procedure including the following key pieces of information:
  - The Unit ID(s) of the OpenBiome treatment(s) used
  - Route of administration
  - Pre-procedural preparation by the patient
  - Site of material delivery and how verified, if applicable (e.g., fluoroscopic verification of nasogastric tube placement)
  - Any documented difficulty during the procedure
  - Any significant findings documented during the procedure
  - Current patient disposition and discharge date, if applicable
- Detailed description of adverse event, including tests performed (with both dates and results), new medical conditions, new medications, etc.

*A Finch clinician will assist you in determining if the adverse event meets the criteria for reporting to the FDA. Adverse events should only be reported to the FDA if it meets ALL three of the following criteria as outlined in [21 CFR 312.32(c)(1)(ii)]:

1. Suspected: Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the FMT material caused the adverse event. For the purposes of FDA safety reporting, ‘reasonable possibility’ means there is evidence to suggest a causal relationship between FMT and the adverse event.

2. Unexpected: An adverse event or suspected adverse reaction is considered “unexpected” if it is not consistent with the risk information described in the FMT inserts.

3. Serious: An adverse event or suspected adverse reaction is considered “serious” if it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.