Monitoring and Traceability
Material Tracking | Efficacy Monitoring | Adverse Event Reporting

The OpenBiome Quality & Safety Program governs our operations from donor assessment through stool processing, monitoring controls, and continuous improvement. In this section, we introduce the roles and responsibilities of clinical sites using OpenBiome material to record and report safety and efficacy data. Your participation helps to ensure that this lifesaving therapy continues to be available for patients nationwide.

Regulatory Context
The U.S. Food & Drug Administration (FDA) regulates fecal microbiota transplantation (FMT) as an investigational drug. Typically, a clinician needs to file an investigational new drug application (IND) to provide an investigational therapy to a patient. However, given published data suggesting that FMT may be an effective therapy for management of recurrent Clostridioides difficile infections (rCDI) not responsive to standard therapy, the FDA allows clinicians to provide the therapy to rCDI patients without an IND. We aggregate and share your submissions to our safety data collection program with FDA and across our clinical network.

Your Contribution
We depend on the participation of our clinical partners in the continuous assessment of our material, which is central to our mission of enabling safe, accountable, high-quality access to FMT.

This program requires your participation in three parts:

1. Material Tracking Logs – to be submitted with every order, or as completed, whichever is first
2. FMT Follow-Up Forms – to be submitted 8 weeks after FMT procedure for every patient treated
3. Adverse Event Reporting – to be submitted within 24 hours of an adverse event

These three touchpoints with our clinical network are instrumental to patient safety, and to compliance with FDA reporting requirements. They are also a mandatory component of your partnership with OpenBiome. For clinical programs that are noncompliant with our reporting requirements, we will not ship to the noncompliant program until outstanding data are submitted.
Points of Contact
At registration, OpenBiome asks for important points of contact from the registering site, including:
- One person who will manage the submission of Material Tracking Logs and the distribution of Follow-Up Forms
- One person who will manage the reporting of any suspected adverse events following administration of FMT
- Any physician planning to administer OpenBiome FMT at your facility

This guide explains how these forms should be maintained and submitted, and the rationale behind each requirement. Please review it before selecting the points of contact for your program.

Questions or Comments: You may contact our Clinical Outreach Team at info@openbiome.org, or call 617-575-2201, option 3.

Material Tracking Logs

A Material Tracking Log will be included in every shipment you receive from OpenBiome. We use this log to facilitate inventory tracking across our network. The person in charge of Material Tracking Logs at your facility will also receive a digital copy attached to an email when we ship your order.

The Material Tracking Log will list the Unit ID for every treatment included in your shipment, and any treatments not marked used or destroyed that are still in your inventory. As you receive, store, and use the units in your order, we ask that you record the information shown in Table 1.

Table 1: Sample row from an OpenBiome Material Tracking Log, with columns labeled A through H.

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>FMP250</td>
<td>0001-0001-01</td>
<td>2/16/20</td>
<td>8/16/19</td>
<td>❑ Yes ❑ No</td>
<td>❑ Used ❑ Destroyed</td>
<td>❑ Yes ❑ No</td>
<td></td>
</tr>
</tbody>
</table>
Automatically-generated columns (A-D):

**Column A: Item**
This column will be automatically generated. This represents the type of product.

**Column B: Unit ID**
This column will be automatically generated. This represents the unique unit ID of the product.

**Column C: Expiration Date**
This column will be automatically generated. This represents the last date you can use the material if you store it in a -20 degrees Celsius freezer. The expiration date is 6 months after the ship date.

If you are storing your unit at -80 degrees Celsius, the expiration date is 1 year after the date shipped. This date will not be reflected on the material tracking log.

**Column D: Date Shipped**
This column will be automatically generated. This is the date OpenBiome shipped the material.

Columns to be completed by the facility (E-H):
Completion of the following columns is mandatory. The MTL contact is responsible for completing these columns as treatments are received, stored, and used.

**Column E: Frozen on Receipt**
Confirm that the units in your order are frozen at arrival. You may use the temperature indicator affixed to the lid of the shipping cooler or visually inspect that each treatment is frozen solid. We ask you to validate that the cold chain was maintained from our facility to yours to help ensure the treatments’ viability.

**Column F: Unit Status**
Mark the unit “used” once it is administered to a patient. Mark the unit “destroyed” if it is discarded (e.g. upon expiration or after being thawed without use). Do not mark this column if the unit is still in your freezer.

**Column G: Physician Initials**
For every treatment unit marked “used” on the Material Tracking Log, OpenBiome requires a record of the authorized physician who used that unit. **All physicians**
authorized to provide OpenBiome FMT at your facility must be registered with
OpenBiome with current contact information prior to administering OpenBiome FMT,
and will appear in a legend on your Material Tracking Log. To add a new authorized
physician, please visit www.openbiome.org/add-physician. This record supports the
traceability of treatment units throughout our network and allows us to conduct
appropriate follow-up regarding adverse events and safety data reporting.

Column H: Follow-Up Form Sent to Physician
Provide an FMT Follow-Up Form (see below) to the administering physician or his or her
staff at the time of the procedure. Make sure the proper Unit ID is legibly recorded on
the form. Mark “Yes” in this column once the appropriate staff member has received
this form.

Which sections need to be complete to avoid a hold on my order?

Orders will be put on hold for the following reasons:
- Frozen upon receipt column not completed
- Usage status is not provided for previously received material
- Physician initials are not complete or are from an unregistered physician
FMT Follow-Up Form

An FMT Follow-Up Form must be completed for each patient that receives an OpenBiome FMT. It asks for de-identified case specifics, including delivery modality, disease phenotype, treatment outcome, and incidence of any adverse events. The form should be provided to the administering physician or his or her staff and returned to OpenBiome after an 8-week post FMT follow-up with the patient.

When we ship an order, the Material Tracking Log contact at your facility will receive an email with the Material Tracking Log and FMT Follow-Up Forms, each pre-populated with a Unit ID that corresponds to a treatment in your shipment. Your shipment will also include a blank paper copy of the FMT Follow-Up Form that you may duplicate and use as needed.

When a treatment is used in a procedure, the Material Tracking Log contact should provide the FMT Follow-Up Form with the matching Unit ID to the administering physician or their staff. Be sure to record this transaction on the Material Tracking Log. Either the digital or paper version of the form may be used, but it is crucial that the Unit ID on the form matches the Unit ID of the treatment being used.

The administering physician should schedule a phone call or office visit with the patient to assess for clinical cure 8 weeks after the FMT procedure, following standard of care. Clinical guidelines define clinical cure of CDI as the absence of diarrhea. Although there is no test of cure, patients with active diarrhea should be evaluated for *C. difficile* recurrence as well as alternative diagnoses (e.g. post-infectious irritable bowel syndrome).

This form allows us to proactively monitor the efficacy of our treatments network-wide and on a per-donor basis. We are committed to tracking outcomes in case a discrepancy should arise.

Additionally, because our partners are treating patients with a novel intervention that is considered investigational, we feel it is our collective duty to the medical community and the patients we serve to collect, evaluate, and share safety and efficacy data on this therapy.