

FMT Follow-Up Form



OPENBIOME

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Your participation in our Quality & Safety Program is invaluable and allows us to monitor the outcomes of FMTs on a per-donor basis across our network. We appreciate your contribution to patient safety and the field of FMT. Only submit this form once the patient has been assessed for clinical cure and all sections are complete.

FMT Unit ID: _____

Partner ID: _____

Patient Information

Patient Initials: _____

Patient Age: _____

Case Information

Delivery method: Lower Delivery (250mL)

Sigmoidoscopy

Colonoscopy

Enema

Upper Delivery (30mL)

Upper endoscopy

Nasogastric delivery

Nasoduodenal delivery

Oral

Capsule

Other: _____

Recurrent CDI: Yes No

If recurrent, number of confirmed episodes pre-FMT: _____

Refractory CDI: Yes

No

CDI Severity:

Mild-to-moderate

Severe

Severe-complicated

8 Week Clinical Follow-Up

Clinical Cure: Yes

No

Adverse Event: Yes

No

If **adverse event** is **Yes**, select one of the following:

A Non-Serious Adverse Event (AE)

A Serious Adverse Event (SAE)

An Adverse Event of Special Interest (AESI)

If **adverse event** is **Yes**, complete form at <http://www.openbiome.org/adverse-events>. This information will be passed on to Finch Therapeutics, OpenBiome's licensed manufacturer. A member of the Finch safety team will contact you to follow up on this report.

Please return this form to safety@openbiome.org or fax to 617-575-2201.

Glossary

Recurrent CDI: Recurrence of CDI symptoms for 48 hours or longer within 8 weeks after the completion of at least 10 days of CDI treatment.

Refractory CDI: Persistent or worsening of diarrhea characteristic of CDI and 1 of the following:

- Ongoing abdominal pain, fever (temperature $\geq 38.0^{\circ}\text{C}$)
- Peripheral white blood cell (WBC) counts greater than $15.0 \times 10^9/\text{L}$ despite treatment with oral vancomycin at a dose of 500mg 4 times daily for at least 5 days

Mild-to-moderate CDI: Diarrhea plus any additional signs or symptoms not meeting severe or complicated criteria

Severe CDI: Hypoalbuminemia (albumin $< 3 \text{ g/dl}$) and WBC count $\geq 15,000 \text{ cells/mm}^3$ or abdominal tenderness

Severe-complicated CDI: Any of the following attributable to CDI:

- Admission to ICU for CDI
- Hypotension with or without required use of vasopressors
- Serum lactate levels $> 2.2 \text{ mmol/l}$
- End organ failure (mechanical ventilation, renal failure, etc.)
- Mental status changes
- WBC $\geq 35,000 \text{ cells/mm}^3$ or $< 2,000 \text{ cells/mm}^3$
- Fever $\geq 38.5^{\circ}\text{C}$
- Ileus or significant abdominal distention

Clinical Cure: The absence of treatment failure.

Treatment Failure: Any of the following from 0- to 8-weeks of FMT:

- Persistence of diarrhea (> 3 unformed stool for 48 hours) with either a positive C. difficile toxin assay (EIA) or toxin B polymerase chain reaction (PCR) assay
- The need for additional therapy for CDI
- The need for colectomy for CDI
- Death directly attributable to CDI

Non-Serious Adverse Event (AE): (An event that does not meet the criteria of a Serious adverse event as described below.)

An adverse event is defined as any untoward medical occurrence in a patient or a clinical trial subject who is administered a drug/product which does not necessarily have a causal relationship with the product. An AE can be an unfavorable sign or unintended sign, a symptom, or a disease temporally associated with the use of a product, whether or not considered related to the product. An AE can arise from the use of the drug (or in combination with another product) and from any route of administration, formulation, dose including an overdose. An AE also includes, but is not limited to, any clinically significant worsening of a pre-existing condition

Serious Adverse Event (SAE): Any of the following outcomes:

- Death,
- Life-threatening health events,
- Hospitalization (initial or prolonged),
- Disability or permanent damage,
- Congenital anomaly/birth defect,
- or other serious important medical event(s)

Adverse event of special interest (AESI):

- Suspected Transmission of an Infectious Agent: Any adverse event where transmission of an infectious organism via the FMT may have occurred
- Suspected Transmission of a Multi-Drug Resistant Organism: Any adverse event where transmission of a multi-drug resistant organism via the FMT may have occurred.