



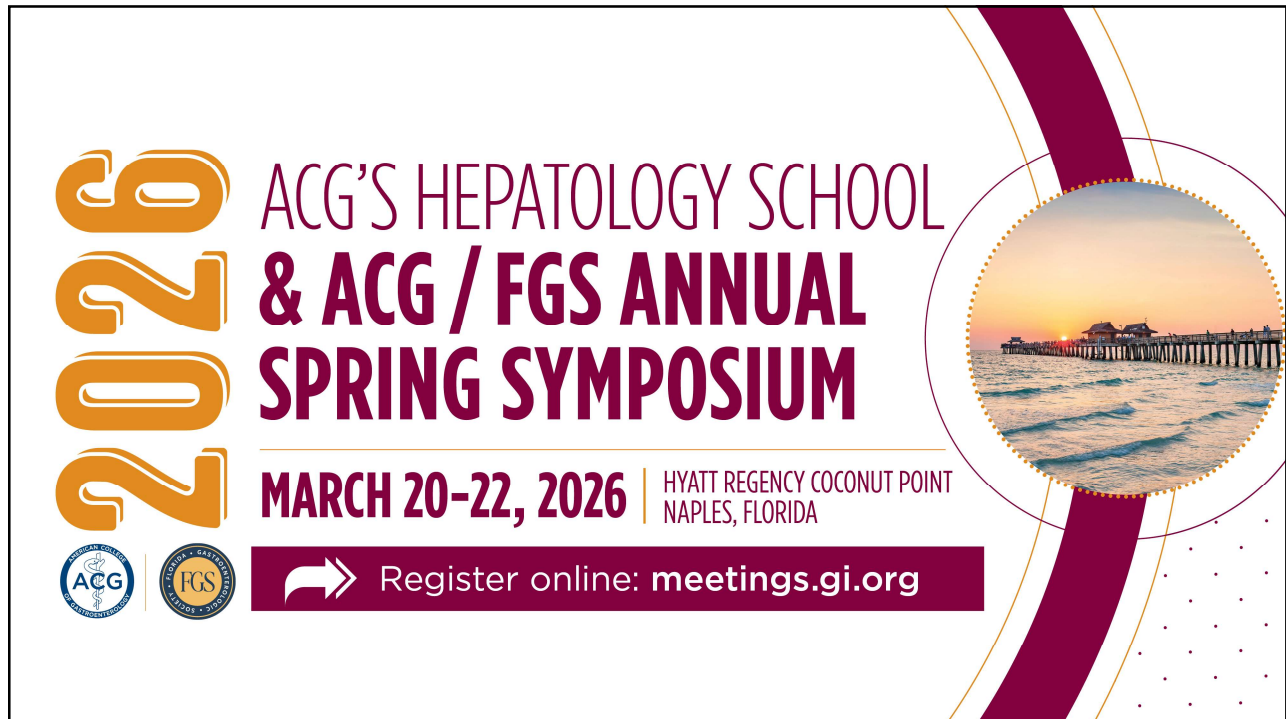
**2026** ACG'S ENDOSCOPY SCHOOL  
& ACG / LGS REGIONAL  
POSTGRADUATE COURSE

**MARCH 6-8, 2026** | HILTON NEW ORLEANS RIVERSIDE  
NEW ORLEANS, LOUISIANA

  Register online: [meetings.gi.org](https://meetings.gi.org)



The banner features a circular inset image of a historic city square with a fountain and a church. The background has a blue and purple curved graphic element on the right side.

1



**2026** ACG'S HEPATOLOGY SCHOOL  
& ACG / FGS ANNUAL  
SPRING SYMPOSIUM

**MARCH 20-22, 2026** | HYATT REGENCY COCONUT POINT  
NAPLES, FLORIDA


  Register online: [meetings.gi.org](https://meetings.gi.org)

The banner features a circular inset image of a pier over the ocean at sunset. The background has a maroon and purple curved graphic element on the right side.

2

Virtual Grand Rounds universe.gi.org

## Participating in the Webinar



Moderators:  
Ronald K. Hsu, MD, FACC

All attendees will be muted and will remain in "Listen Only Mode"

Type your questions here so that the moderator can see them.  
Not all questions will be answered but we will get to as many as possible.

A handout with the slides and room to take notes can be downloaded from your control panel.

G
🔇
👋
?
📄
ⓘ
⌵
⌵
Exit

3

Virtual Grand Rounds universe.gi.org

## ACG Virtual Grand Rounds

### Join us for upcoming Virtual Grand Rounds!





**Week 06 – Thursday, February 5, 2026**  
 The Impact of Violence and Trauma on Patient Care: What the Gastroenterologist Needs to Know  
 Faculty: Christina N. Awad, MD  
 Moderator: Mark D. Hubner, MD  
**At Noon and 8pm Eastern**





**Week 07 – Thursday, February 12, 2026**  
 GI Nutrition Care Series: Nutrition Strategies for Patients with Mucosal Diseases; From Celiac, to IBD and Eosinophilic Disorders  
 Faculty: Laura Manning, RD, and Stephanie L. Gold, MD  
**At Noon and 8pm Eastern**

Visit [gi.org/ACGVGR](https://gi.org/ACGVGR) to Register

4

**ACG VIRTUAL GRAND ROUNDS**  
 Wednesday, February 4, 7:00-8:00 am ET

**The Paradigm Shift from FMT to Live Biotherapeutic Products in the Treatment of Recurrent *Clostridioides difficile* Infection**

Paul Feuerstadt, MD, FACC  
 Moderator: Ronald K. Hsu, MD, FACC

With the Gastroenterological Society of Taiwan & the Taiwan Microbiota Consortium (TMC) [gi.org/ACGVGR](http://gi.org/ACGVGR)

5

International Virtual Grand Rounds [universe.gi.org](http://universe.gi.org)

**The Paradigm Shift from FMT to Live Biotherapeutic Products in the treatment of Recurrent *Clostridioides difficile* Infection**

**UC DAVIS HEALTH | SCHOOL OF MEDICINE**

Ronald Hsu MD, FACC, FRCP (Lond, Edin)  
 Clinical Professor of Medicine  
 University of California Davis School of Medicine

**Yale School of Medicine**

Paul Feuerstadt MD, FACC, FRCP(Edin)  
 Associate Clinical Professor of Medicine  
 Yale School of Medicine

6



## Overview

- *C. difficile* Pathophysiology
- Antimicrobial Treatment of *C. difficile* infection
- Timeline from FMT to FDA approved microbiota restoration
- Shifting landscape of treatment of CDI
- Differences between FMT and FDA approved therapeutics
- Foundational FMT data
- Foundational FDA approved microbiota restoration data
- The future of FDA approved treatments?

7



台灣消化系醫學會

The Gastroenterological Society of Taiwan



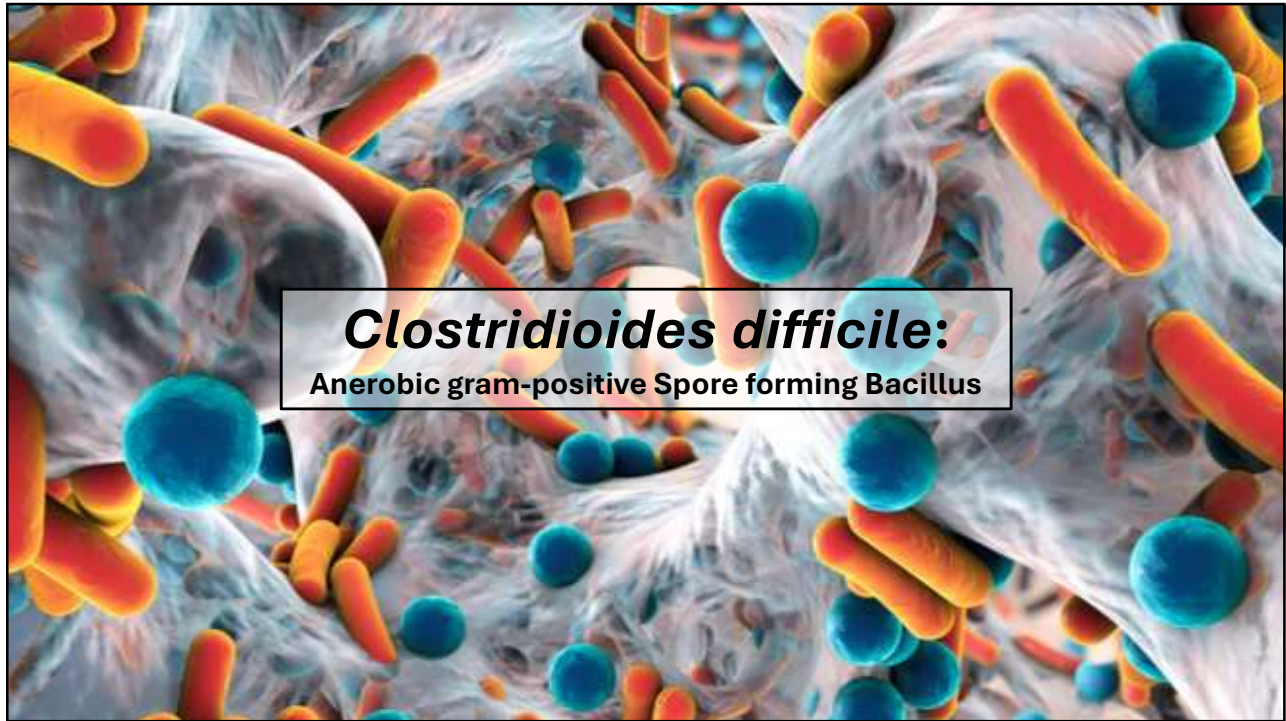
Ronald Hsu MD,  
FACG, FRCP (Lond, Edin)  
Clinical Professor of Medicine  
University of California Davis School of Medicine

UC DAVIS  
HEALTH

SCHOOL OF  
MEDICINE



8

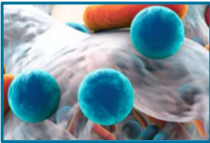


9

ACG International Virtual Grand Rounds universe.gi.org

## *Clostridioides difficile* toxigenic strain

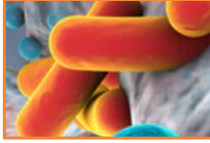
Anerobic gram-positive Spore forming Bacillus



**Spore Form**

- Survives on surfaces for *months*
- Germinates rapidly to vegetative form

**Resistant to**



**Vegetative Form**

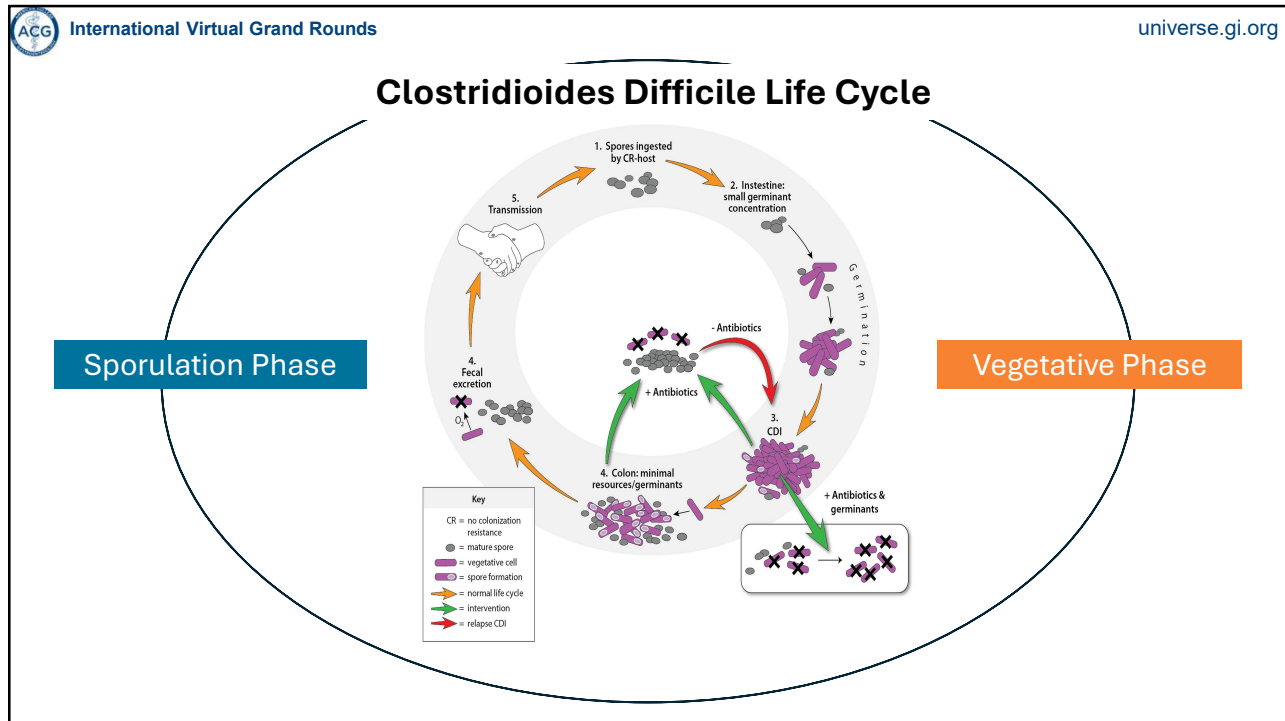
- Survives on moist surfaces up to *6 hours*
- Produces *Toxin A and B*

**Susceptible to**

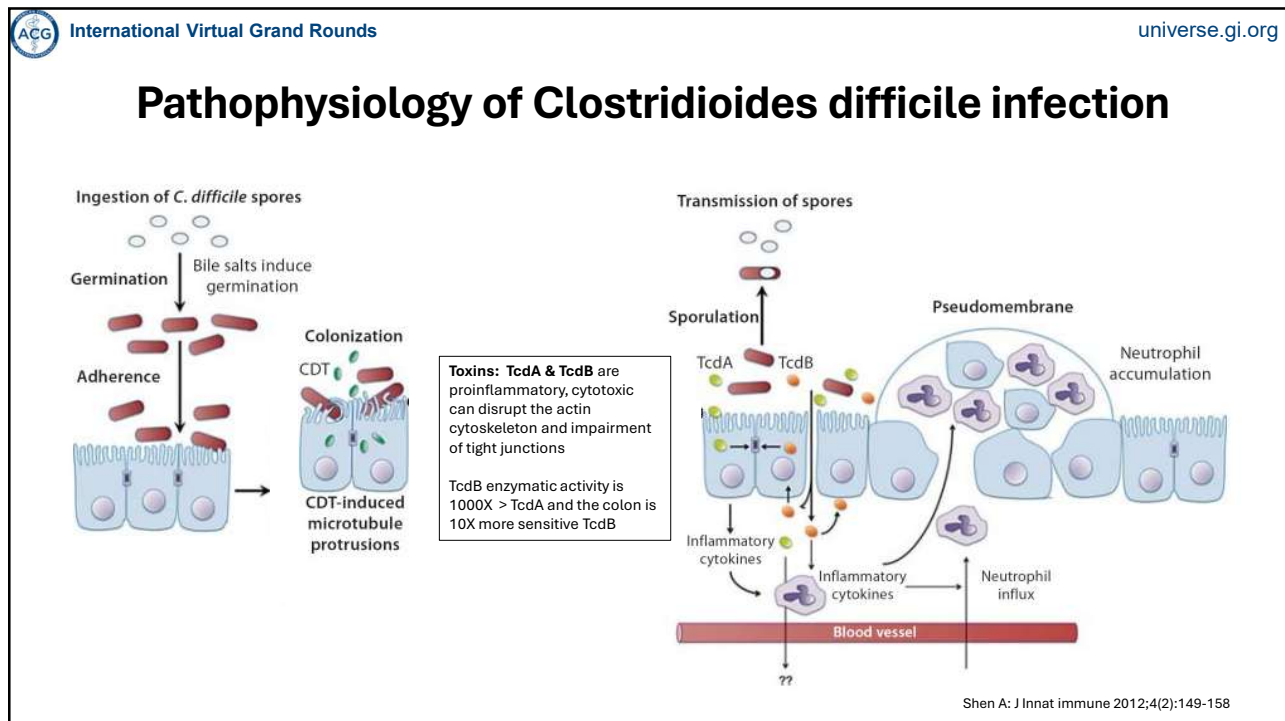
Gastric Acid  
Antibacterial Soaps  
Alcohol based hand sanitizers

1.Jump RL et al. *Antimicrob Agents Chemother.* 2007;51(8):2883–2887.  
 2.Fordtran JS. *Proc (Bayl Univ Med Cent).* 2006;19(1):3–12.  
 3.Cohen SH et al. *Infect Control Hosp Epidemiol.* 2010;31(5):431–455.

10



11



12


ACG International Virtual Grand Rounds universe.gi.org





**Paul Feuerstadt, MD,**  
FACG, FRCP(Edin)  
Associate Clinical Professor of Medicine  
Yale School of Medicine






**台灣消化系醫學會**  
The Gastroenterological Society of Taiwan




13

ACG International Virtual Grand Rounds universe.gi.org


## Important Definitions



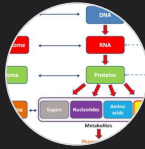
**Microbiota:**  
The microorganisms that live in an established environment




**Microbiome:**  
The combined genetic material of the microorganisms in a particular environment



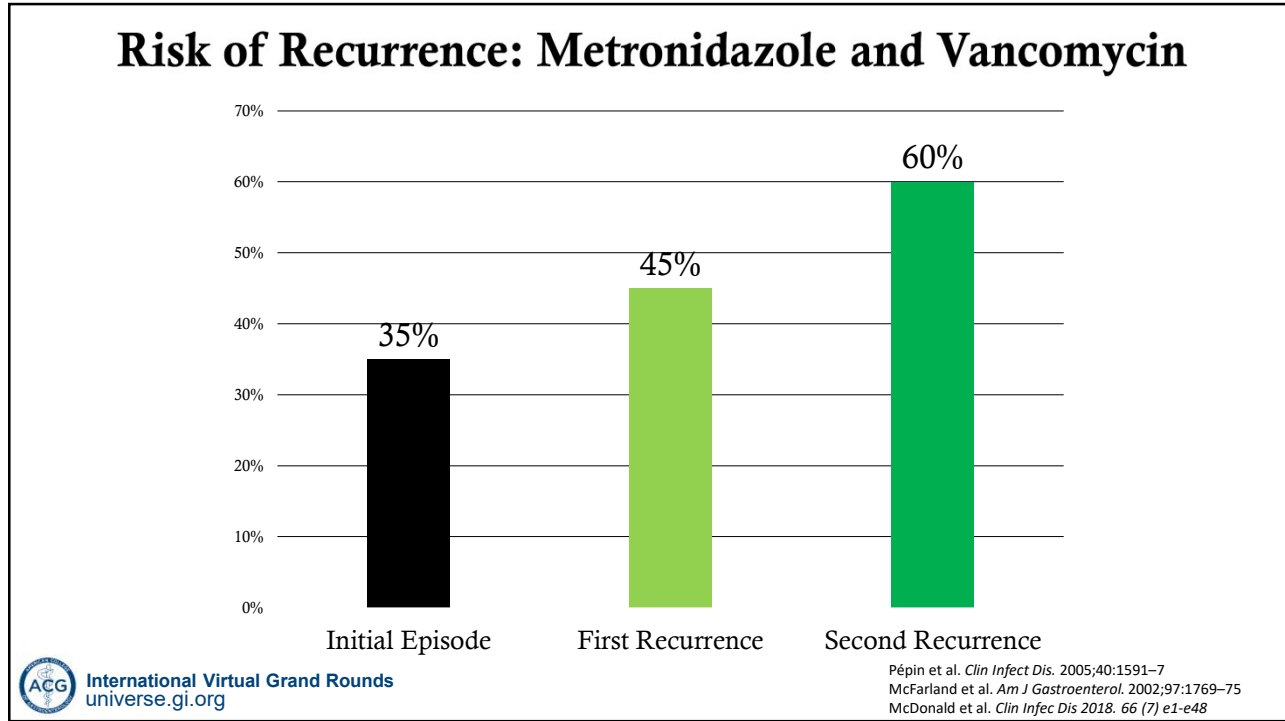
**Dysbiosis:**  
A derangement in the microbiota



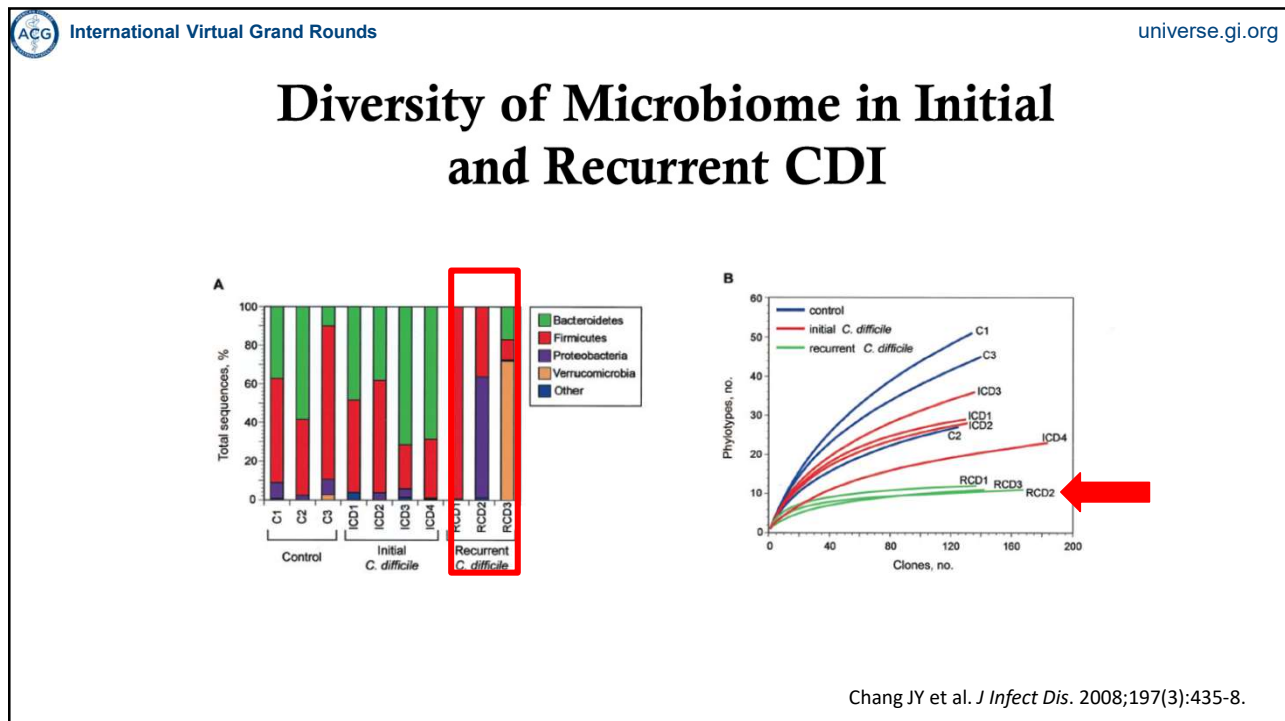
**Metabolome:**  
Functional properties of the gut microbiota



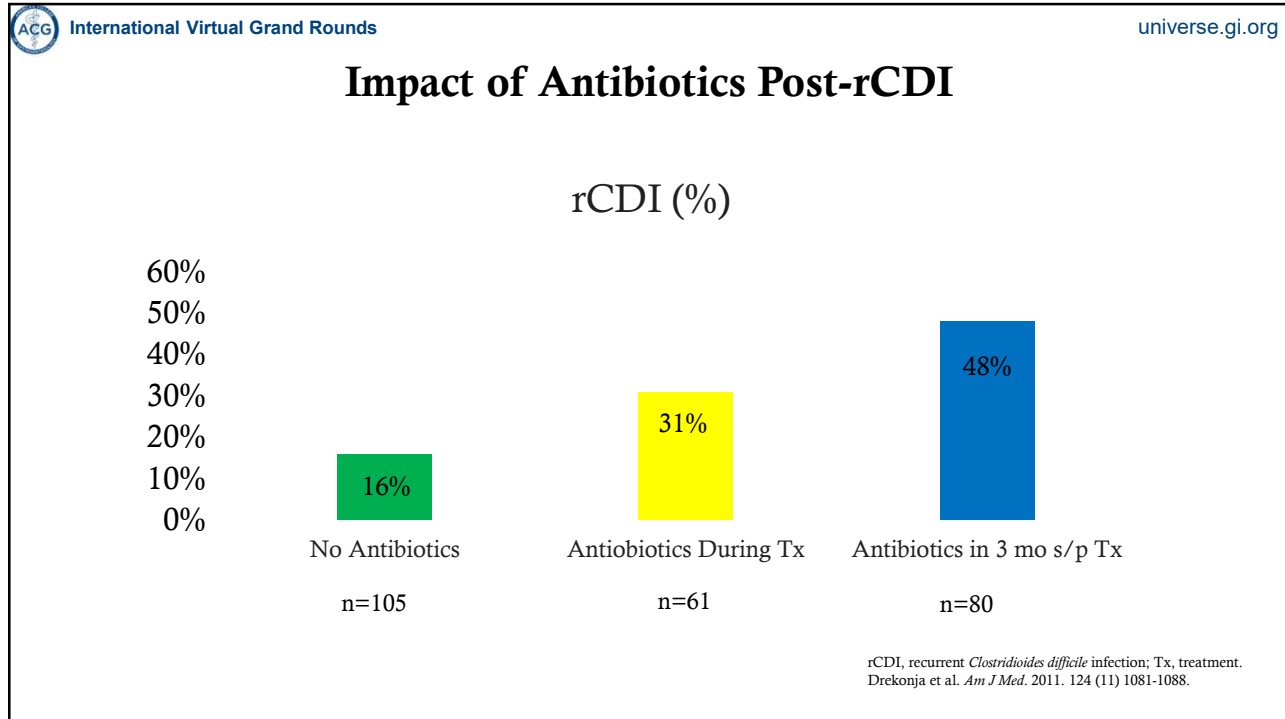
14



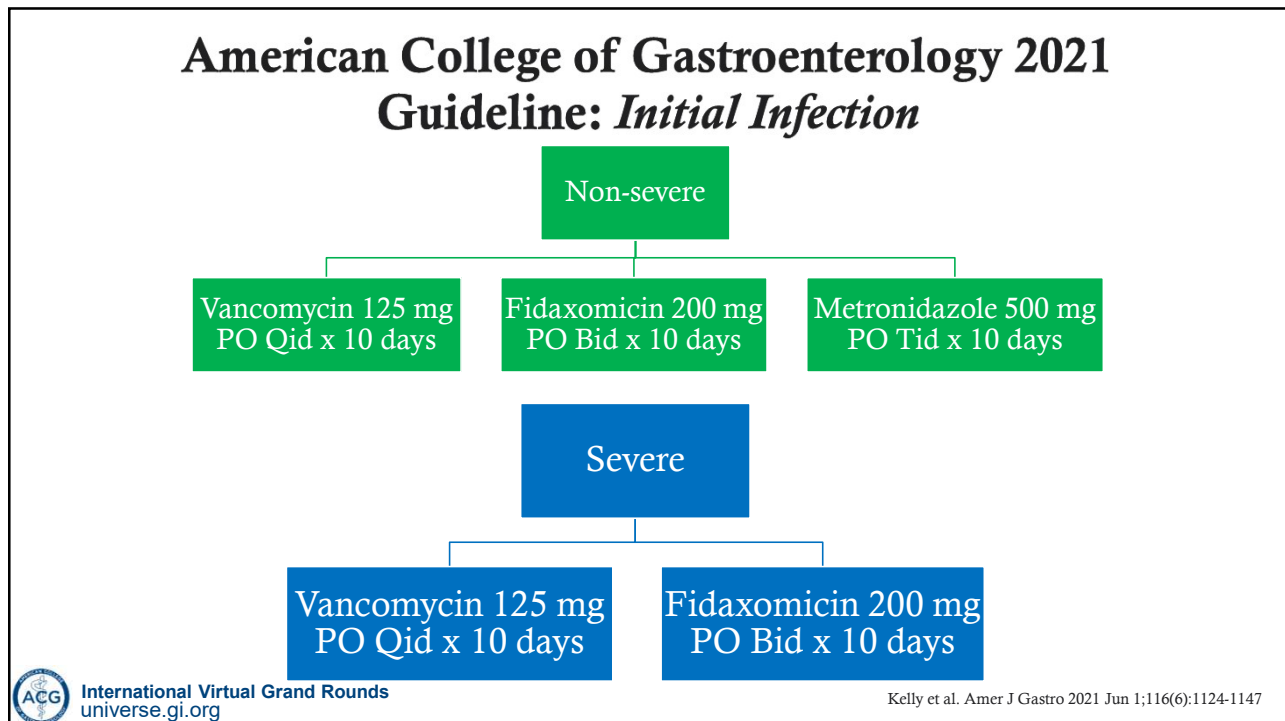
15



16



17



18

ACG International Virtual Grand Rounds universe.gi.org

## Treatment: What are we targeting?

**Attack the Vegetative Phase**

Ingestion of *C. difficile* spores

Germination

Bile salts induce germination

Antimicrobials

**Boost Immune Response**

Transmission of spores

Sporulation

TcdA

TcdB

Glucosylating toxin production

Adapted from: Shen J. *Innate Immun.* 2012;4:149-158.

19

ACG International Virtual Grand Rounds universe.gi.org

## Tolevamer vs. Metronidazole vs. Vancomycin *Clinical Success-Overall Cohort*

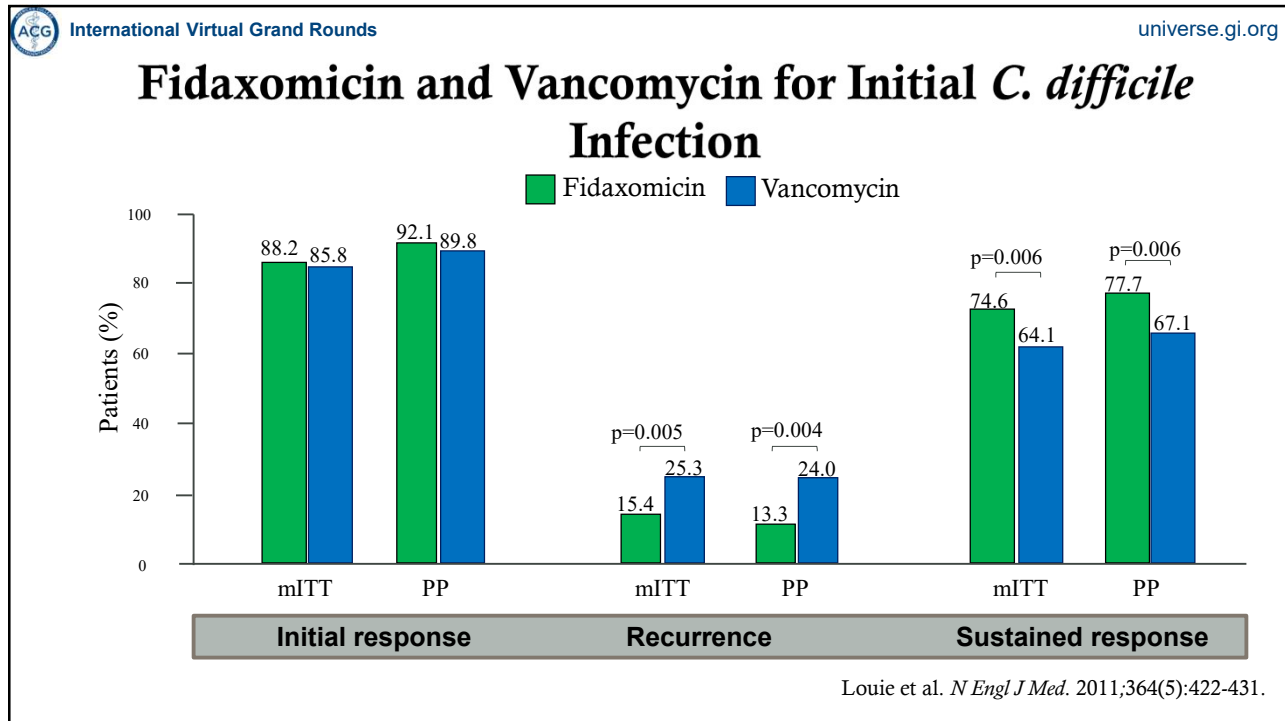
Study	Tolevamer (n)	Metronidazole (%)	Vancomycin (%)
Study 301	266	72.0*	81.3*
Study 302	268	73.3*	80.8*
Combined	534	72.7*	81.1*

Tolevamer  
  Metronidazole  
  Vancomycin

\*p<0.001, tolevamer (T) vs metronidazole (M) and T vs vancomycin (V)  
 \*\*p=0.020, M vs V

Johnson S, et al. *Clin Infect Dis.* 2014;59:345-54.

20



21

ACG International Virtual Grand Rounds universe.gi.org

## American College of Gastroenterology 2021 Guideline: *First recurrent infection*

**Recurrence:**

- Vancomycin
- Fidaxomicin
- Metronidazole

➔

**Vancomycin Taper-Pulse**

- 125 mg 4 times per day for 10–14 days
- 2 times per day for a week
- Once per day for a week
- Every 2 or 3 days for 2–8 weeks

**Recurrence:**

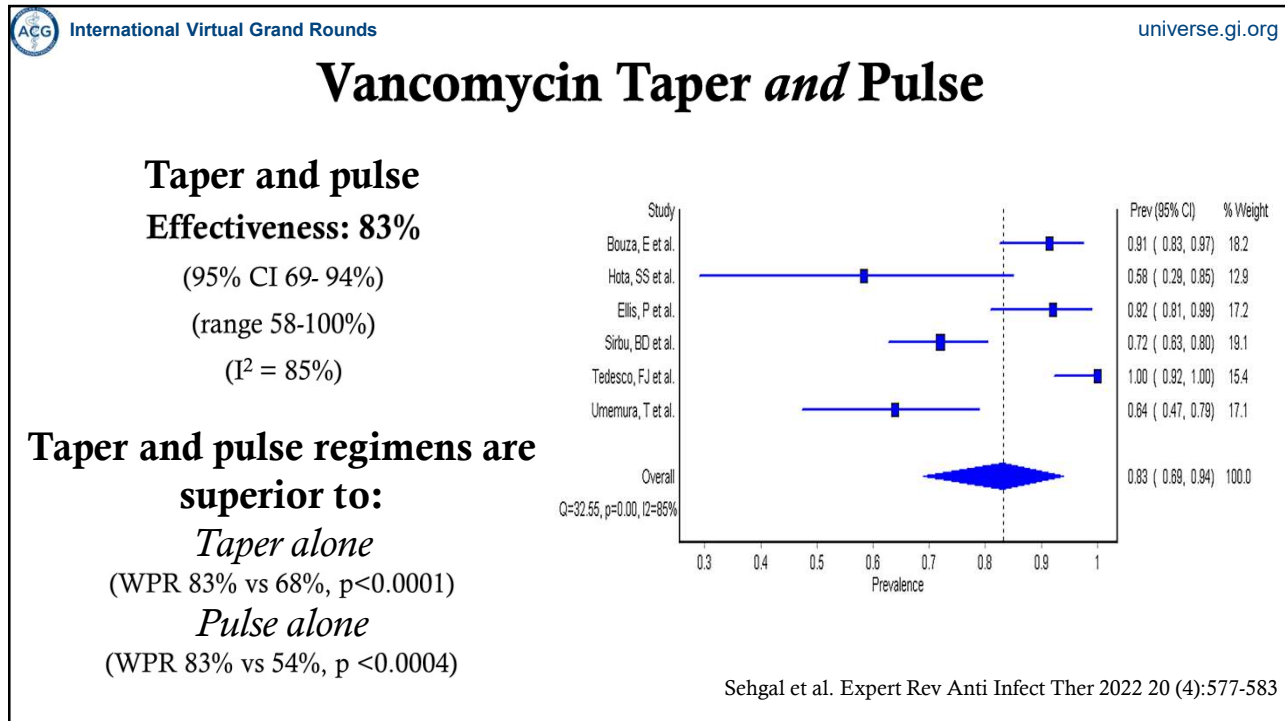
- Vancomycin
- Metronidazole

➔

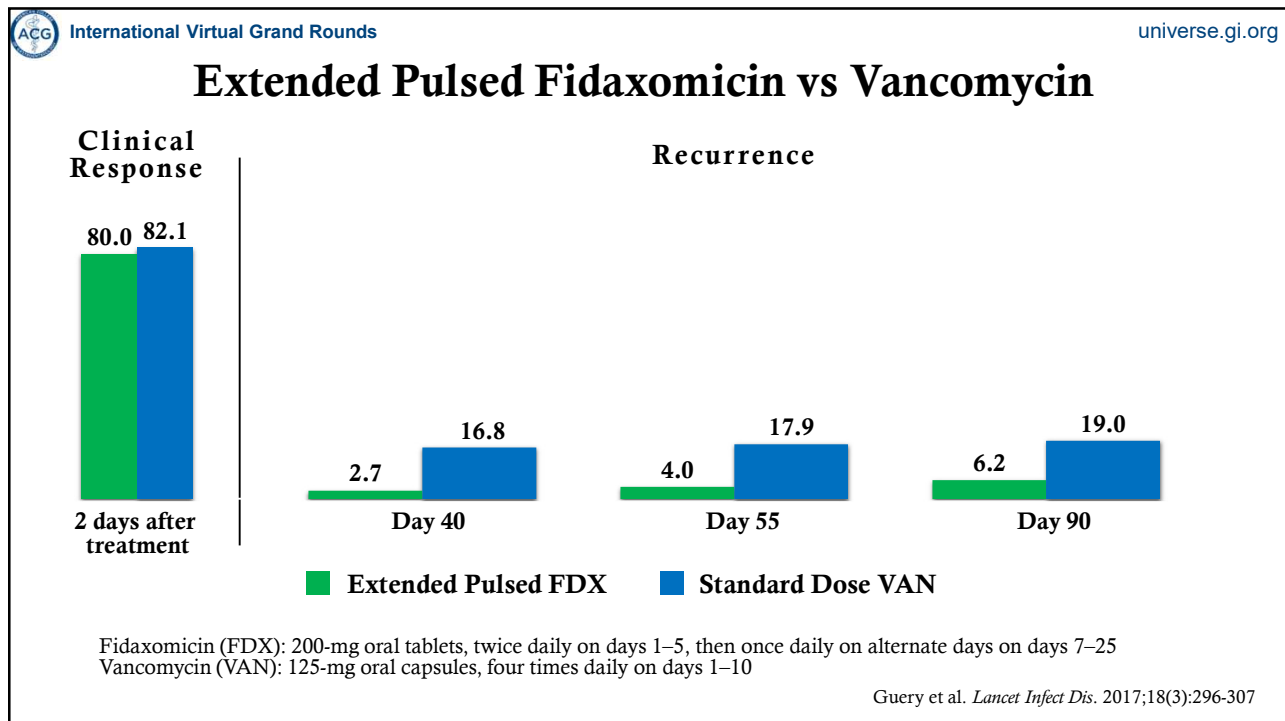
**Fidaxomicin 200 mg PO**  
twice daily for 10-days

Kelly et al. *Amer J Gastro* 2021 Jun 1;116(6):1124-1147

22




23



24

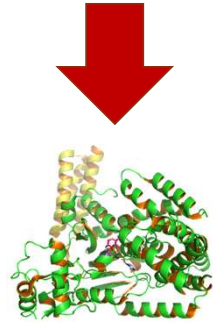
ACG International Virtual Grand Rounds universe.gi.org

## Multimodal Approach to Therapy



**ADD ON**

**Bezlotoxumab**



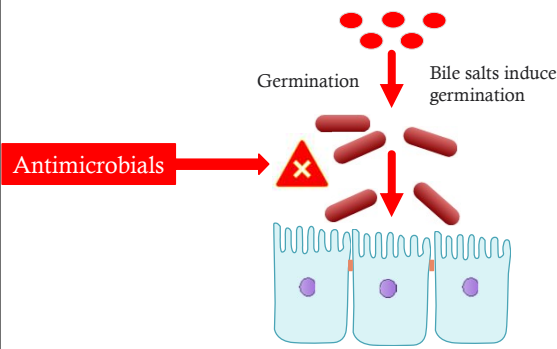
25

ACG International Virtual Grand Rounds universe.gi.org

## Treatment: What are we doing?

### Attack the Vegetative Phase

Ingestion of *C. difficile* spores

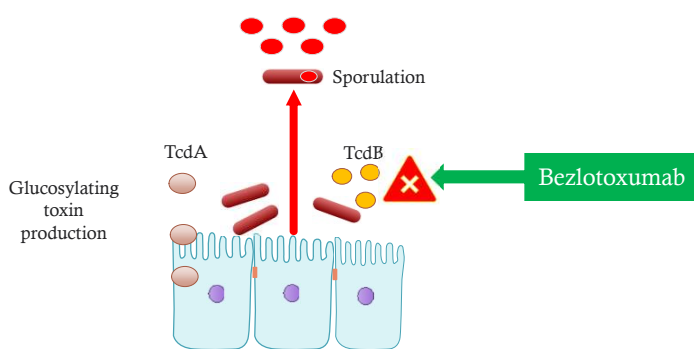


Germination Bile salts induce germination

Antimicrobials

### Boost Immune Response

Transmission of spores



Transmission of spores

Sporulation

TcdA TcdB

Glucosylating toxin production

Bezlotoxumab

Adapted from: Shen J. *Inmate Immun.* 2012;4:149-158.

26

ACG International Virtual Grand Rounds **Reuters** World Business Markets Sustainability Legal Breakingviews Technology Investiga universe.gi.org

## Merck to discontinue drug for bacterial infection

By Reuters  
December 23, 2024 6:42 PM EST · Updated 2 months ago




Signage is seen at the Merck & Co. headquarters in Kenilworth, New Jersey, U.S., November 13, 2021. REUTERS/Andrew Kelly/File Photo Purchase Licensing Rights


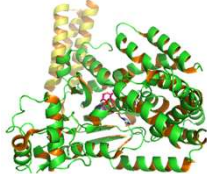


27

ACG International Virtual Grand Rounds universe.gi.org

## Multimodal Approach to Therapy



**Bezlotoxumab** **Fecal Microbiota Transplantation**



28



# The FMT Story in the United States

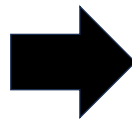


<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-82048e0ae45>

29



# The FMT Story in the United States





<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-82048e0ae45>  
<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-182048e0ae45>

30

ACG International Virtual Grand Rounds universe.gi.org

## 2013 Option's

31

ACG International Virtual Grand Rounds universe.gi.org

## FDA Saga Begins...

July 2013	September 2013	March 2016
<ul style="list-style-type: none"> <li>○ Stool is a drug</li> <li>○ Investigational New Drug (IND) application required</li> </ul>	<ul style="list-style-type: none"> <li>○ Enforcement discretion</li> <li>○ FMT available for CDI without an IND</li> </ul>	<ul style="list-style-type: none"> <li>○ Enforcement discretion rescinded for stool banks</li> <li>○ Safety concerns related to the use of FMT from a small number of donors</li> </ul>

32

ACG International Virtual Grand Rounds universe.gi.org



Diagram illustrating the relationship between OpenBiome and Finch, and the logos for Rebiotix and Seres Therapeutics.

OPENBIOME  
↓  
FINCH 

  
**Rebiotix**<sup>®</sup>  
Microbiota Restoration Therapy

 **SERES**  
THERAPEUTICS™

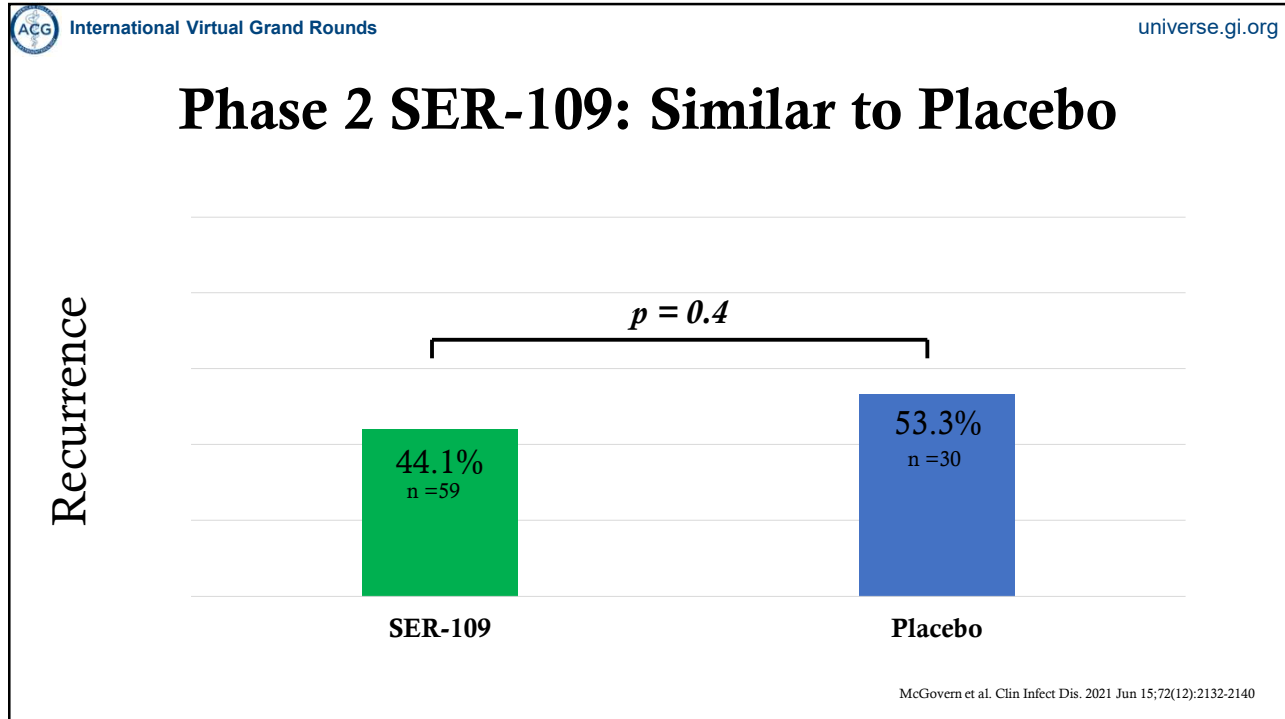
<https://chatgpt.com/c/67616c08-48a8-8012-8ae1-182048e0ae45>

33

ACG International Virtual Grand Rounds universe.gi.org

# SER-109

34

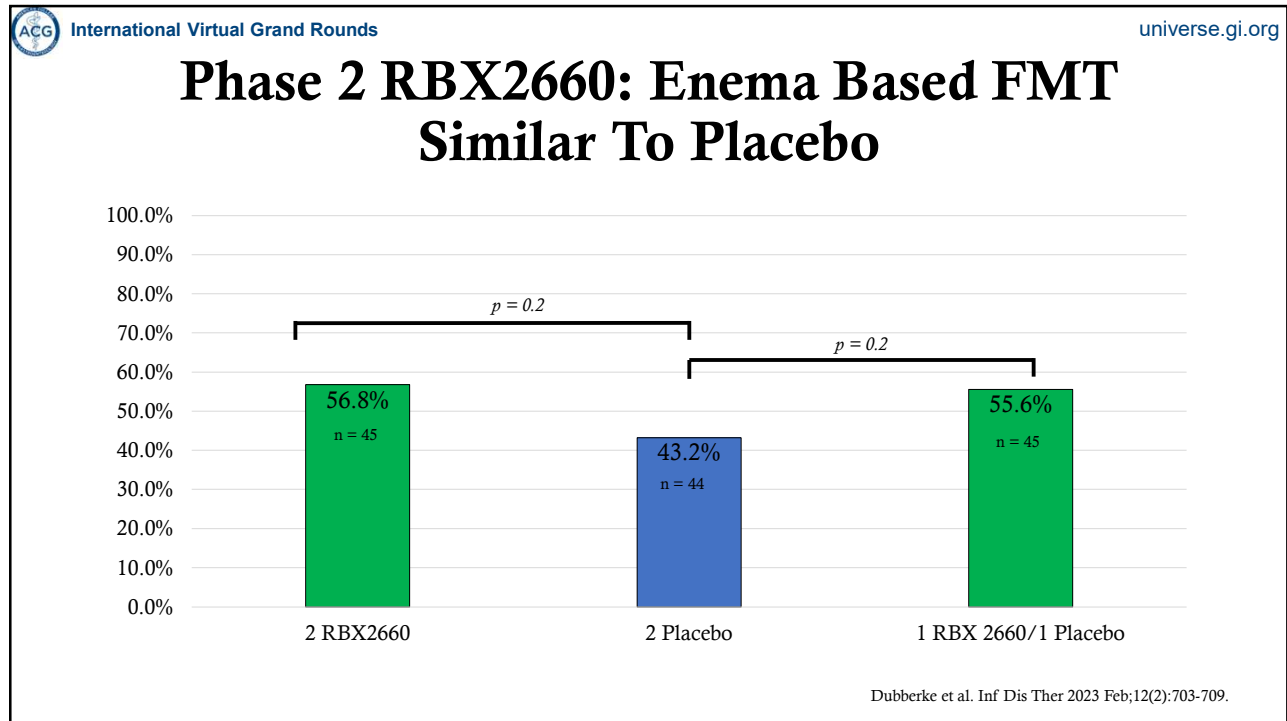


35

ACG International Virtual Grand Rounds universe.gi.org

# RBX-2660

36



37

ACG International Virtual Grand Rounds universe.gi.org

## FDA Saga Continues...

June 2019	October 2019
<ul style="list-style-type: none"> <li>○ 2 FMT immunocompromised recipients enrolled in research trial acquired ESBL following FMT, resulting in 1 death; donor not screened for MDRO<sup>1</sup></li> <li>○ High risk history (healthcare exposures, travel); testing for ESBL, VRE, CRE and MRSA</li> </ul>	<ul style="list-style-type: none"> <li>○ Public hearing on the use of FMT</li> <li>○ Pharma and academia discuss enforcement discretion and its impact on the development of an FDA approved product</li> </ul>

38

ACG International Virtual Grand Rounds universe.gi.org

## Resolution of rCDI with FMT/MRT

### All Clinical Trials (n=19 trials, 18 studies)

Study	Rate (95% CI)	% Weight
Van Nood 2013	0.81 ( 0.58, 0.97)	4.4
Cammarota 2015	0.85 ( 0.43, 0.95)	4.8
Kelly 2016	0.91 ( 0.74, 1.00)	4.9
Hata 2017	0.44 ( 0.20, 0.69)	4.4
Hvas 2019	0.71 ( 0.51, 0.88)	5.0
McGovern 2021	0.44 ( 0.32, 0.57)	0.0
Feuerstadt 2022	0.88 ( 0.80, 0.94)	0.2
Louie 2022	0.85 ( 0.75, 0.94)	5.9
RBX 2000 (P2 & P3)	0.83 ( 0.62, 0.74)	0.0
Youngster 2014 (a)	0.70 ( 0.48, 0.88)	4.8
Youngster 2014 (b)	0.70 ( 0.48, 0.88)	4.8
Orenstein 2016	0.87 ( 0.73, 0.97)	5.3
Khanna 2016	0.97 ( 0.86, 1.00)	5.3
Lee 2019	0.62 ( 0.55, 0.69)	0.5
Kao 2017	0.98 ( 0.92, 0.99)	0.3
Jiang 2017	0.88 ( 0.79, 0.94)	0.1
Jiang 2018	0.85 ( 0.77, 0.94)	0.0
Alkgret 2022	0.83 ( 0.76, 0.89)	0.4
<b>Overall</b>	<b>0.78 ( 0.71, 0.85)</b>	<b>100.0</b>

**1,176 patients**  
*Efficacy: 78% (95% CI: 71-85%)*

### Trials with a Control Arm (n=10 trials, 9 studies)

Study	Rate (95% CI)	% Weight
Van Nood 2013	0.81 ( 0.58, 0.97)	9.1
Cammarota 2015	0.85 ( 0.43, 0.95)	9.8
Kelly 2016	0.91 ( 0.74, 1.00)	10.1
Hata 2017	0.44 ( 0.20, 0.69)	9.1
Hvas 2019	0.71 ( 0.51, 0.88)	10.4
McGovern 2021	0.44 ( 0.32, 0.57)	12.4
Feuerstadt 2022	0.88 ( 0.80, 0.94)	13.0
Louie 2022	0.85 ( 0.75, 0.94)	12.3
RBX 2000 (P2 & P3)	0.83 ( 0.62, 0.74)	13.7
<b>Overall</b>	<b>0.72 ( 0.60, 0.82)</b>	<b>100.0</b>

**523 patients**  
*Efficacy: 72% (95% CI: 60-82%)*

Tariq et al. Ther Adv Gastro 2023 Vol 16:1-9

39

ACG International Virtual Grand Rounds universe.gi.org

OPENBIOME

↓

FINCH

Rebiotix<sup>®</sup>

Microbiota Restoration Therapy

SERES

THERAPEUTICS™

<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-182048e0ae45>

40

ACG International Virtual Grand Rounds universe.gi.org

## March 2020: Serious Adverse Events



FDA

IN THIS SECTION: Safety & Availability (Biologics)

Safety & Availability (Biologics)

### Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Risk of Serious Adverse Events Likely Due to Transmission of Pathogenic Organisms

[f Share](#)
[Twitter](#)
[LinkedIn](#)
[Email](#)
[Print](#)

**March 12, 2020**

The Food and Drug Administration (FDA) is informing health care providers and patients of the potential risk of serious or life-threatening infections with the use of fecal microbiota for transplantation (FMT). The agency is now aware of infections caused by enteropathogenic *Escherichia coli* (EPEC) and Shiga toxin-producing *Escherichia coli* (STEC) that have occurred following investigational use of FMT that it suspects are due to transmission of these pathogenic organisms from FMT product supplied by a stool bank company based in the United States. The stool bank provides FMT product manufactured from pre-screened donors to healthcare providers and researchers.

In accordance with FDA's disclosure regulations and general practices, FDA is not disclosing the name of the company at this time.

**Summary of the Issue**


- FDA has been notified of six patients who received the company's FMT product for *Clostridium difficile* (also called *Clostridioides difficile* or *C. difficile*) infection not responsive to standard therapies and who developed infections caused by EPEC (two patients) or STEC (four patients). Four of the six patients required hospitalization.
- The two patients who developed EPEC infection received FMT product that was prepared from stool from two different donors.

41

ACG International Virtual Grand Rounds universe.gi.org

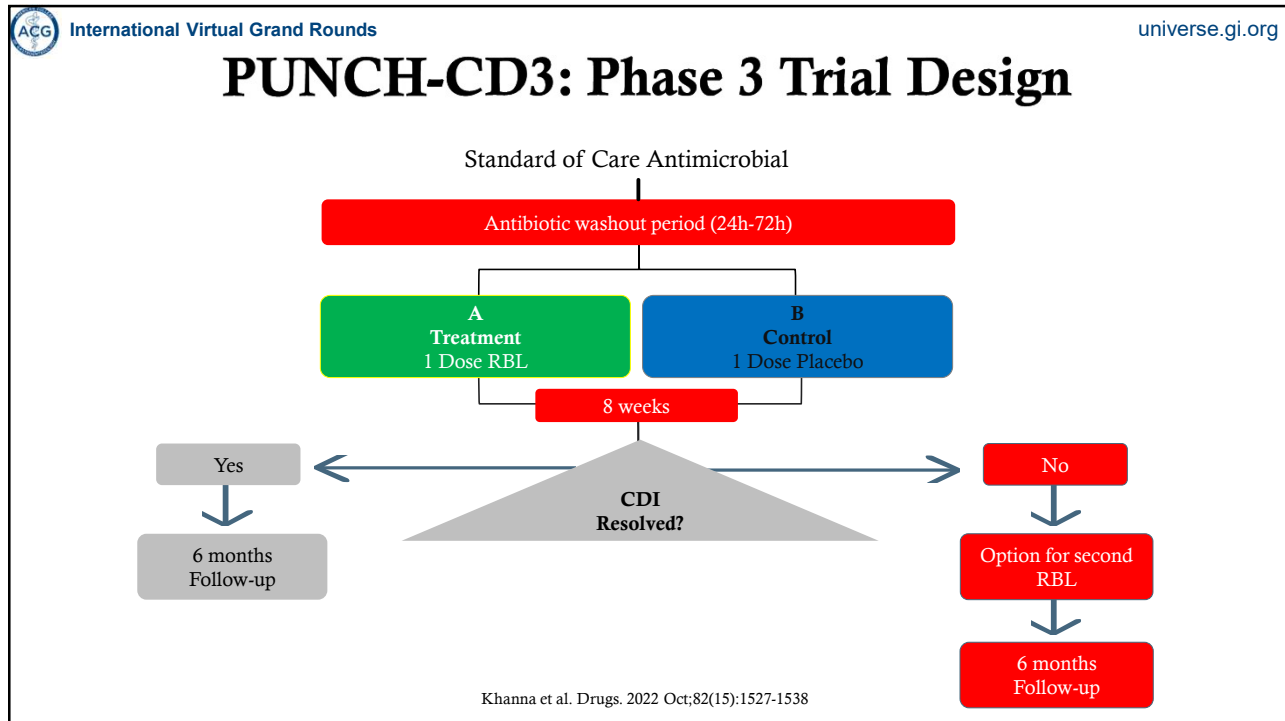
## Fecal Microbiota Live-JSLM (Rebyota™, RBL)

- Single-dose, microbiota-based live biotherapeutic agent
- Rectally administered
- 150 mL of therapeutic material
- $10^7$  microbes per mL or  $15 \times 10^8$  microbes per treatment
- Broad consortium
- A proprietary manufacturing process preserves diverse spore-forming and non-spore-forming bacteria, including *Bacteroides*

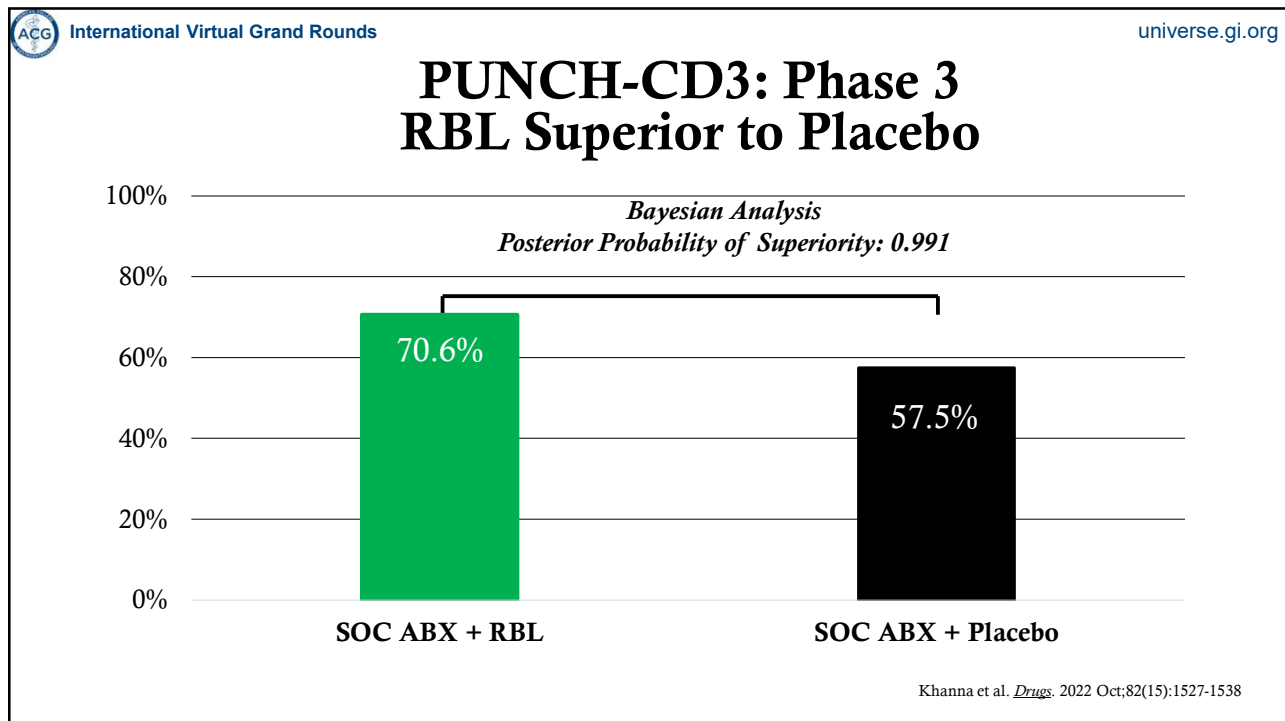


Orenstein R et al. *Clin Infect Dis*. 2016;62:596-602.  
Blount KF et al. *Open Forum Infect Dis*. 2019;6:ofz095  
Ray A, Jones C. *Future Microbiol*. 2016;11:611-616.

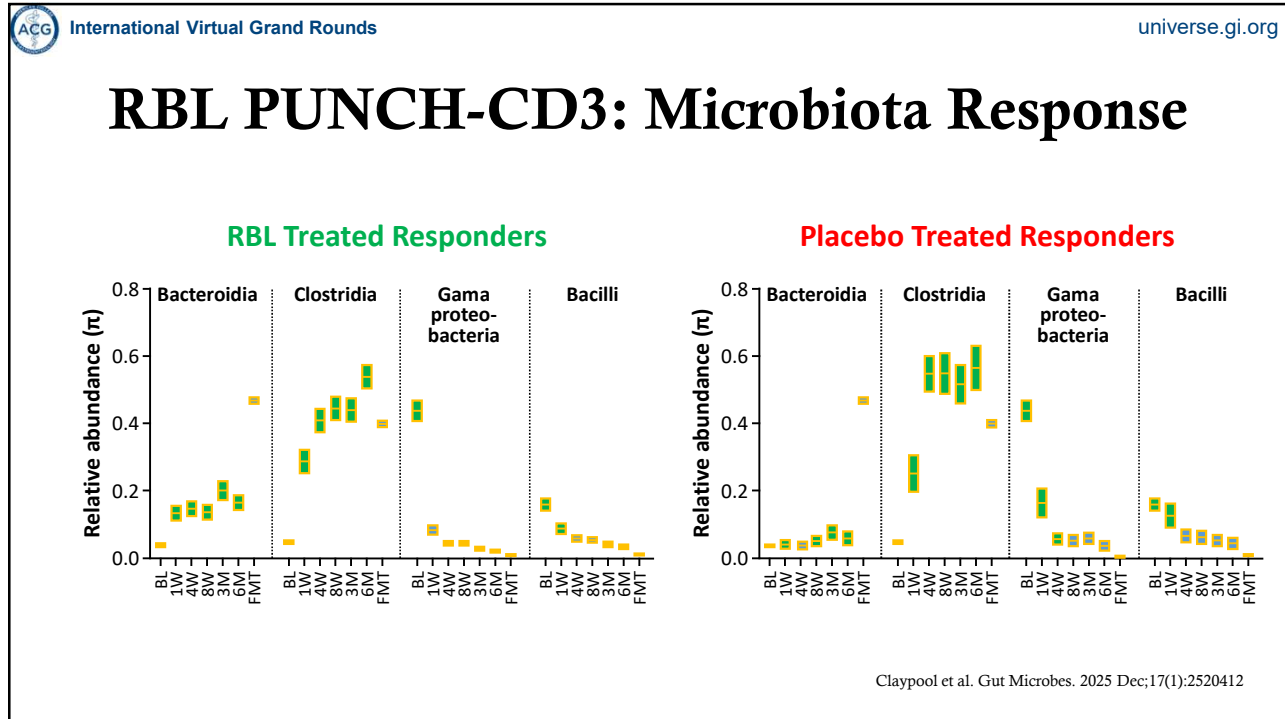
42



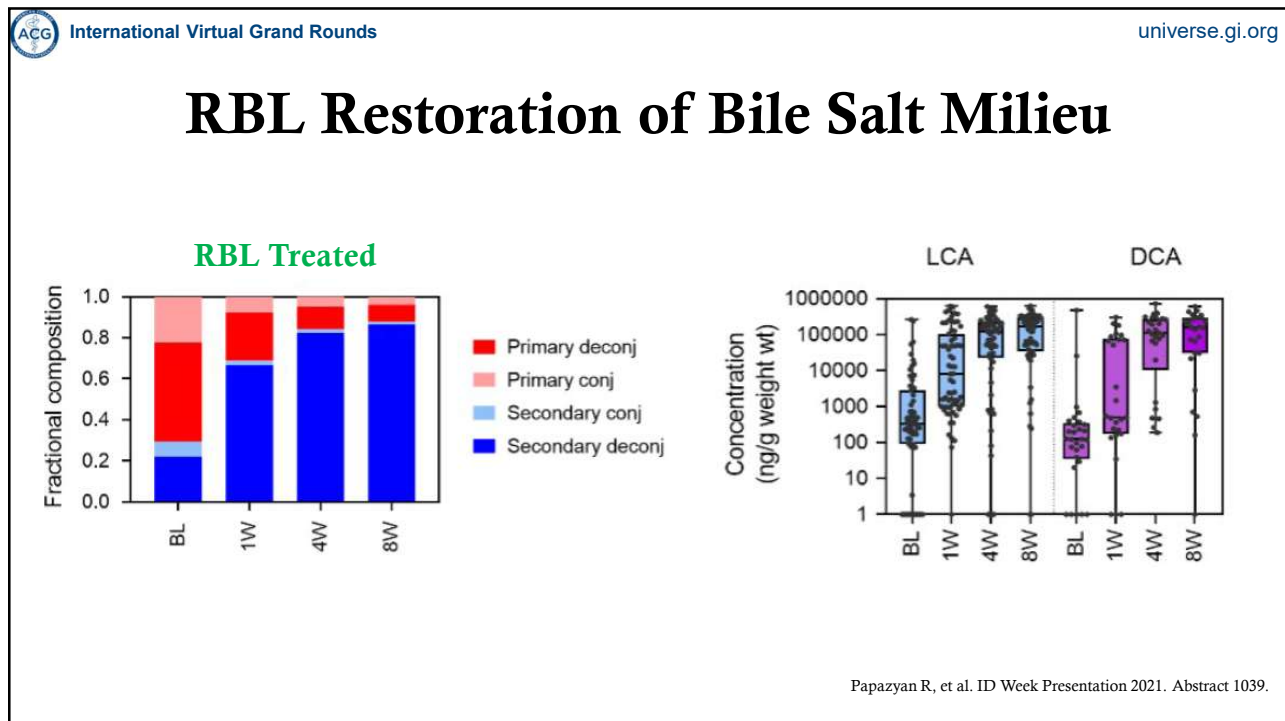
43



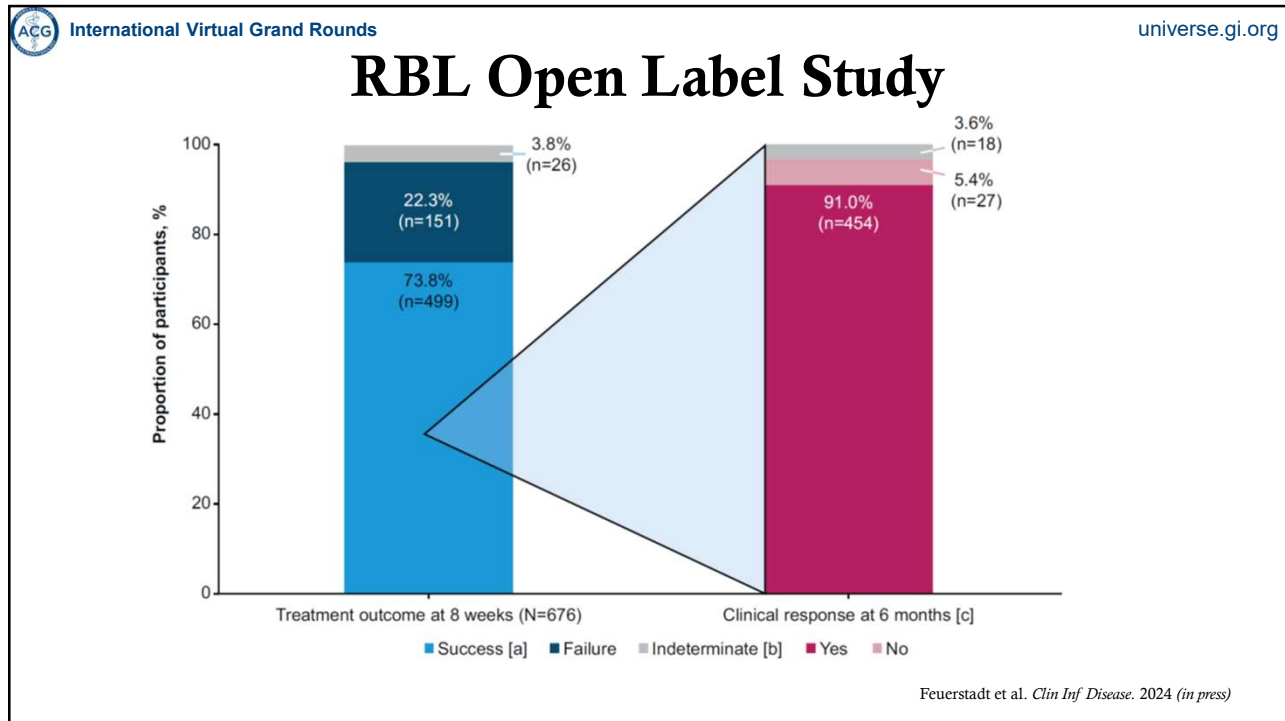
44



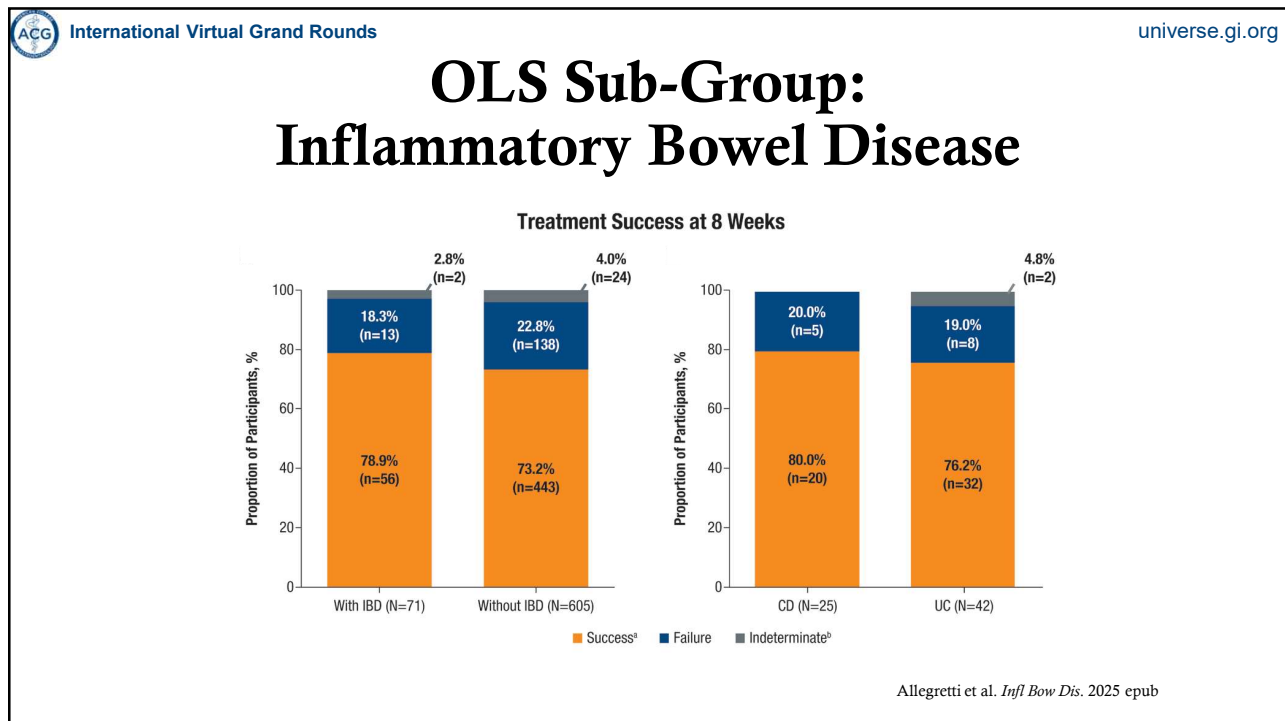
45



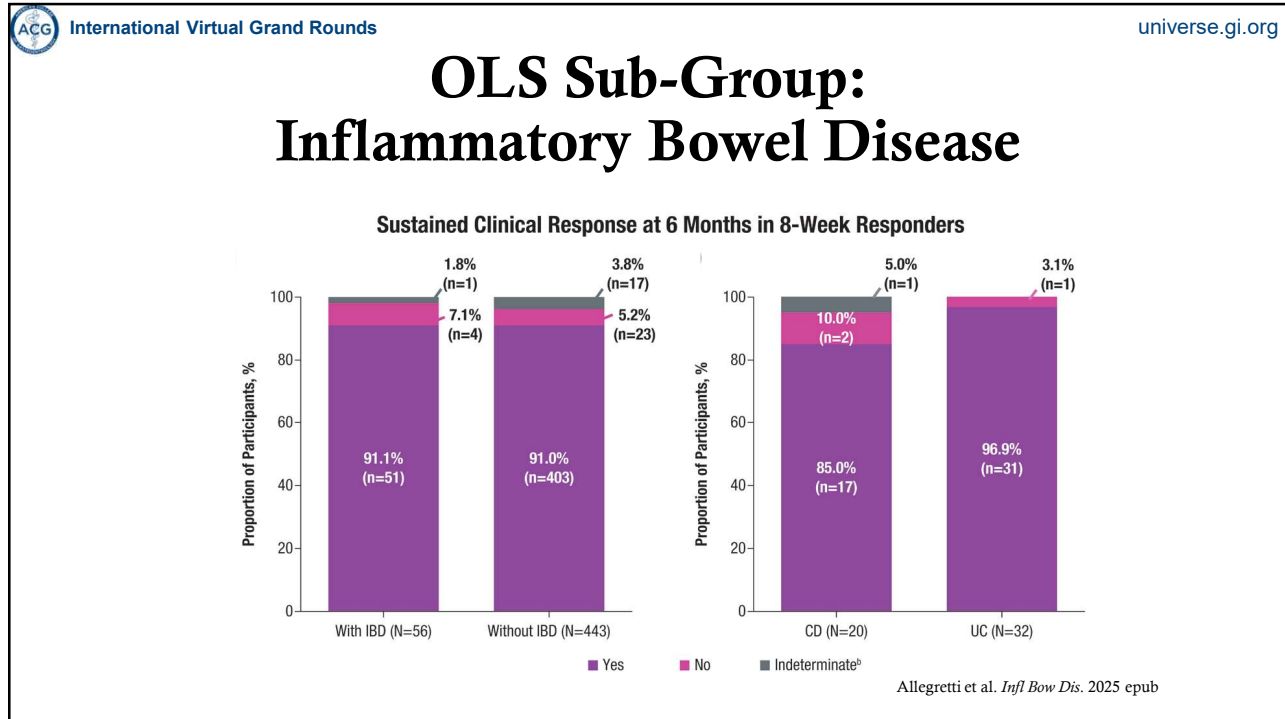
46



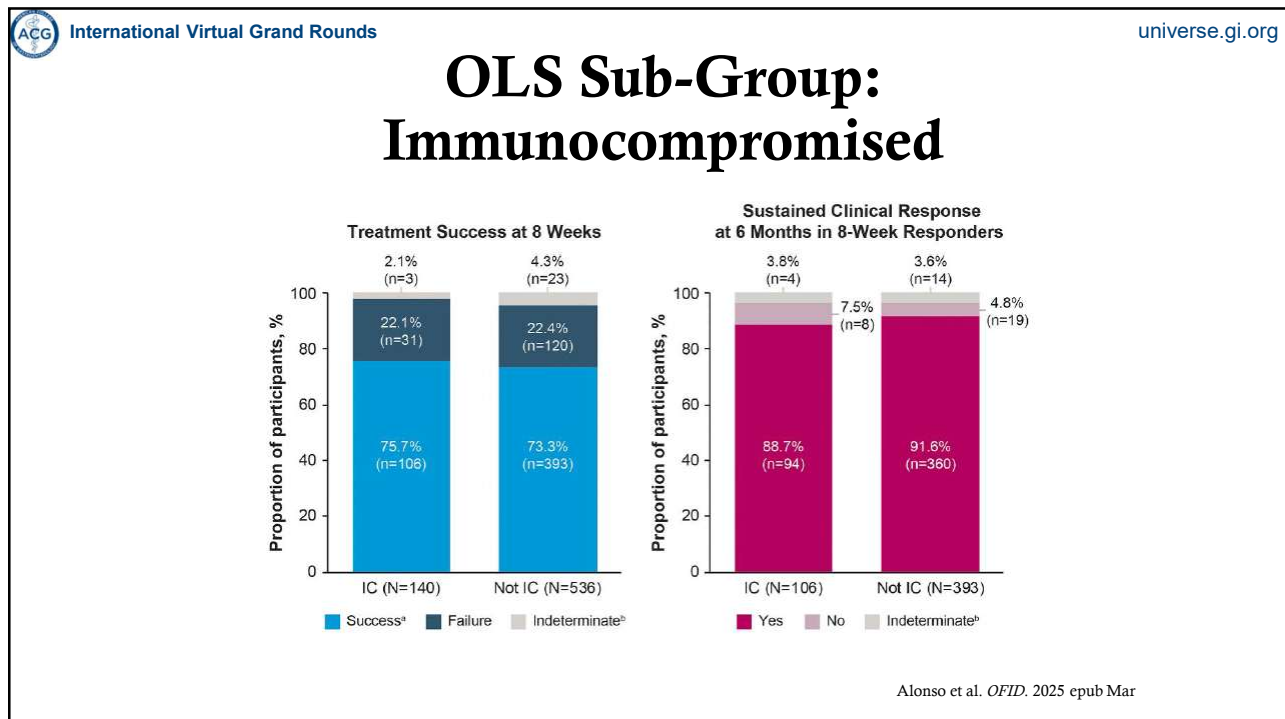
47



48




49



50


ACG International Virtual Grand Rounds universe.gi.org



**D**

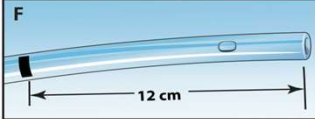
**Left-side position:** Lie on left side with knee bent and arms resting comfortably.

OR




**E**

**Knee-chest position:** Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.




**F**

Insert approximately 12 cm (5 inches) into rectum



**G**

OR



**H**

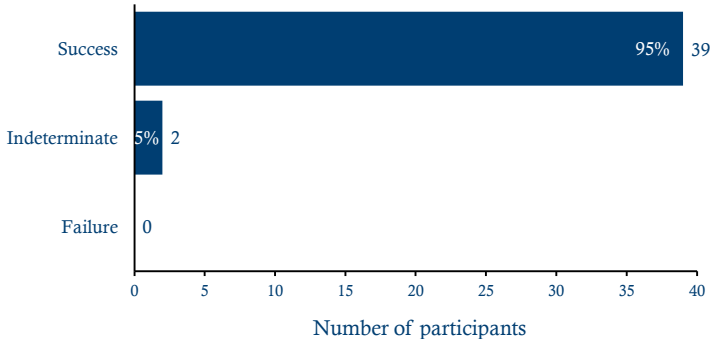
Adapted from FDA package insert: <https://www.fda.gov/media/163587/download>

51

ACG International Virtual Grand Rounds universe.gi.org

## CDI-Scope Study (Prospective)

**Treatment Success at 8 Weeks (N=41)**



Outcome	Percentage	Number of Participants
Success	95%	39
Indeterminate	5%	2
Failure	0%	0

Number of participants

- Treatment success<sup>a</sup> at 8 weeks occurred in 39/41 participants (95%)**
- Two participants had indeterminate outcomes due to withdrawing consent prior to the 8-week follow-up assessment:
  - One due to an unrelated SAE (brain neoplasm)
  - One due to scheduling conflicts
  - Neither reported any CDI symptoms up to the time of withdrawal

CDI, *Clostridioides difficile* infection; SAE, serious adverse event.  
<sup>a</sup>Defined as the absence of CDI recurrence through 8 weeks  
 Data on file. REB064. Ferring Pharmaceuticals Inc.


Khanna et al. 2025 Apr 22:18:17562848251339697

52

ACG International Virtual Grand Rounds universe.gi.org

## Fecal Microbiota Spores, Live-BRPK (Vowst™, VOS)

- Microbiota-based live biotherapeutic agent administered with 4 capsules daily over 3 days
- Orally administered
- 3 x 10<sup>7</sup> CFU per full treatment
- Narrow consortium
- A proprietary manufacturing process removes most fungi, parasites, viruses and non-spore forming bacteria resulting in predominantly Firmicutes spores

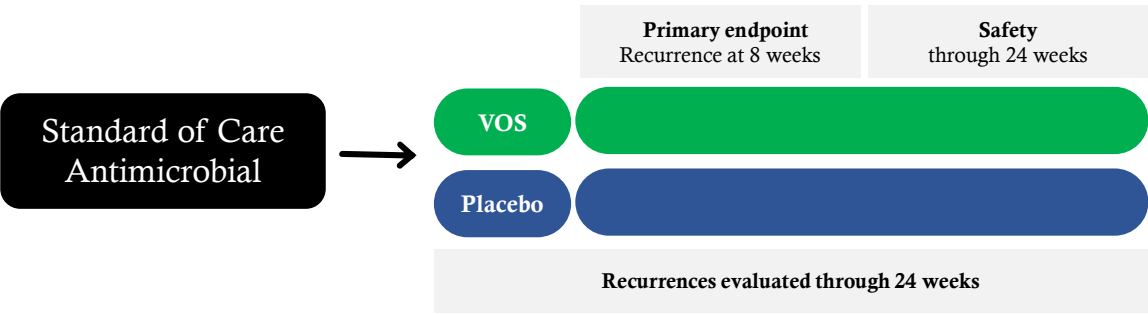


Korman L et al. *Gastroenterology* 2021;6:S-368.  
Feuerstadt et al. *N Engl J Med.* 2022 Jan 20;386(3):220-229c

53

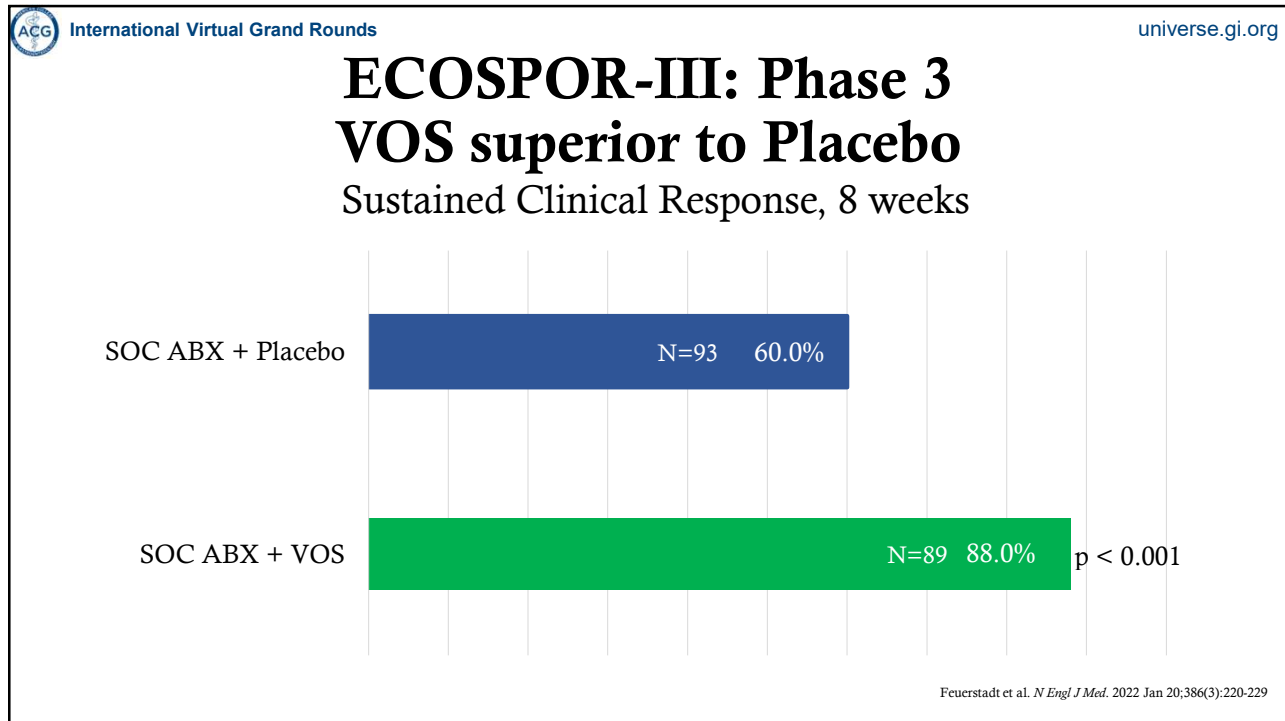
ACG International Virtual Grand Rounds universe.gi.org

## ECOSPOR-III: Phase 3 Trial Design

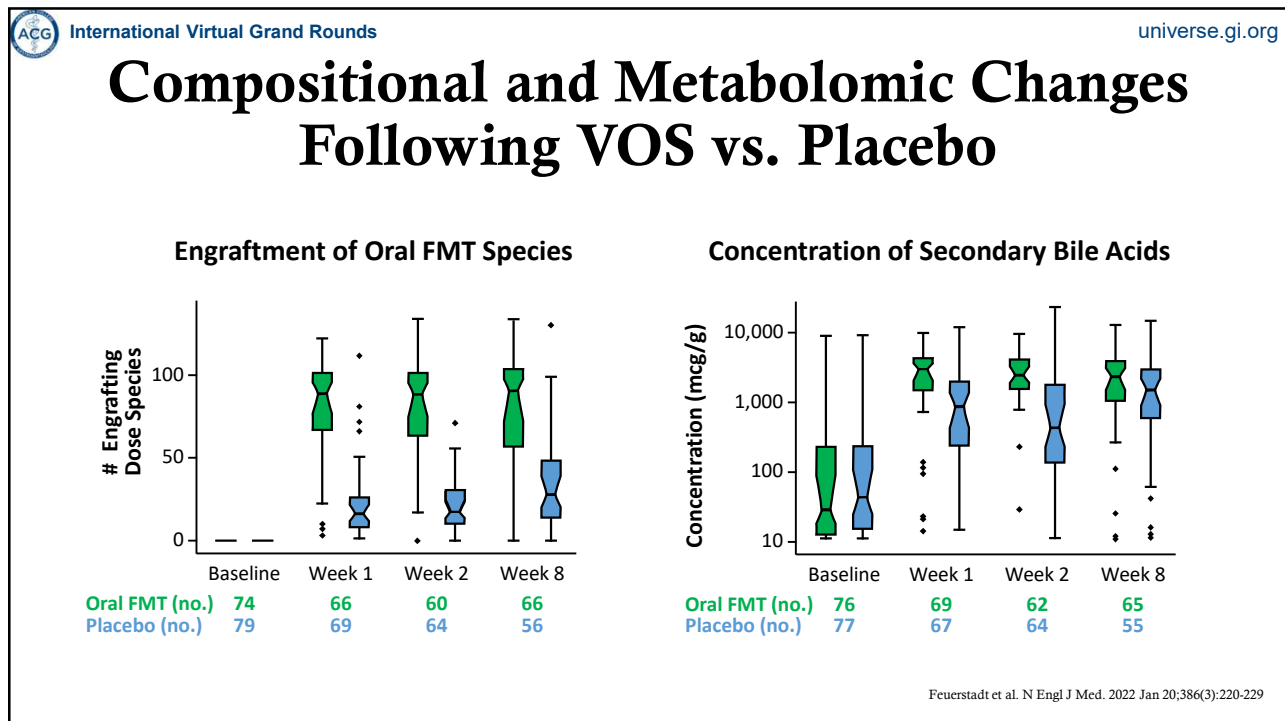


Feuerstadt et al. *N Engl J Med.* 2022 Jan 20;386(3):220-229

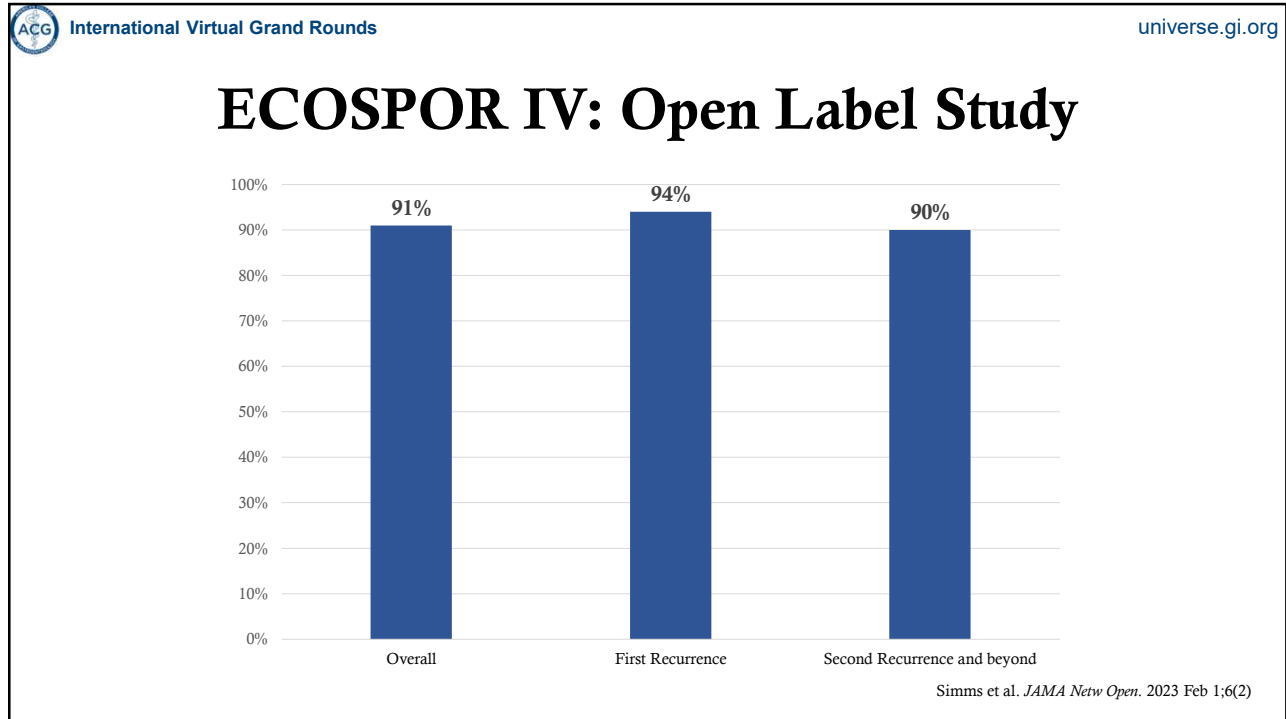
54



55



56



57

ACG International Virtual Grand Rounds universe.gi.org


## How I do it...VOS

- **Before Dosing**
  - Finish Antimicrobials for CDI 2-4 days prior to starting VOS
  - The day prior, or at least 8 hours prior to administering the first dose, patient should drink 10 oz of magnesium citrate.
    - For those with renal impairment consider 250 mL of polyethylene glycol
- **Dosing**
  - Taken on an empty stomach prior to the first meal of the day
  - 4 capsules administered daily for 3 days
  - When not being taken, capsules are heat stable and can be left out until administered

Fecal Microbiota Spores, Live-BRPK Package Insert


58

ACG International Virtual Grand Rounds universe.gi.org




OPENBIOME

↓




FINCH

↓



**BANKRUPT**

# 2023




Rebiotix<sup>®</sup>  
Microbiota Restoration Therapy

↓


**FERRING**

PHARMACEUTICALS



SERES  
THERAPEUTICS™

↓




Nestlé  
HealthScience®

59

ACG International Virtual Grand Rounds universe.gi.org

## OpenBiome...in 2023



- ◆ Distributed FMT material for rCDI under an investigational new drug application with FDA
- ◆ To receive an investigational FMT manufactured by the University of Minnesota and distributed by OpenBiome, your patients must meet all of the following requirements:
  - ◆ Have a confirmed diagnosis of recurrent *C. difficile*
  - ◆ Failed standard therapies
  - ◆ Provided informed consent including acknowledgment that investigational FMT is not an FDA-approved therapy.
- ◆ <https://openbiome.org/fmt-access/placing-an-order/>

60

ACG International Virtual Grand Rounds universe.gi.org

## Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening		
Good Manufacturing Procedure		
Clinical Trial Data		
Safety Data		
Ease of access		

61



62

ACG International Virtual Grand Rounds universe.gi.org

### Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening	?	💩 💩 💩
Good Manufacturing Procedure		
Clinical Trial Data		
Safety Data		
Ease of access		

63

ACG International Virtual Grand Rounds universe.gi.org

### Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening	?	💩 💩 💩
Good Manufacturing Procedure	?	💩 💩 💩
Clinical Trial Data		
Safety Data		
Ease of access		

64



# Fecal Microbiota Transplantation



65



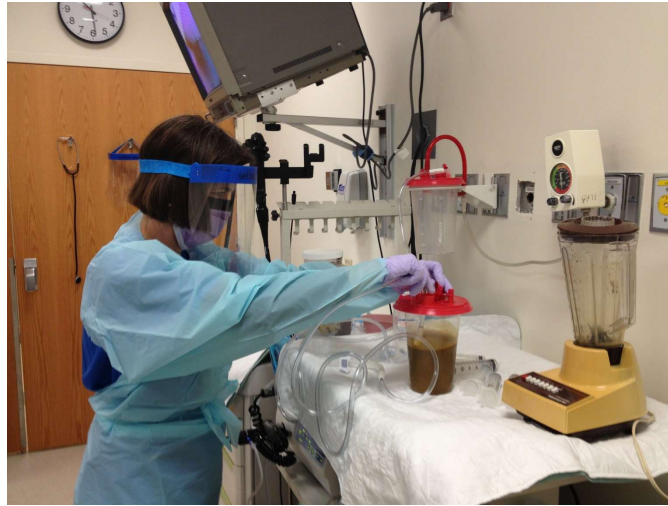
# Fecal Microbiota Transplantation



66



# Fecal Microbiota Transplantation



67



# Fecal Microbiota Transplantation



68



# Fecal Microbiota Transplantation



69



## Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening	?	💩 💩 💩
Good Manufacturing Procedure	?	💩 💩 💩
Clinical Trial Data	💩	💩 💩 💩
Safety Data		
Ease of access		

70

ACG International Virtual Grand Rounds universe.gi.org

## Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening	?	💩 💩 💩
Good Manufacturing Procedure	?	💩 💩 💩
Clinical Trial Data	💩	💩 💩 💩
Safety Data	💩 / 💩	💩 💩 💩
Ease of access		

71

ACG International Virtual Grand Rounds universe.gi.org

## Fecal Microbiota Transplant vs. Live Biotherapeutic Product

	FMT	FDA+MRT
Donor Screening	💩 💩	💩 💩 💩
Sample Screening	?	💩 💩 💩
Good Manufacturing Procedure	?	💩 💩 💩
Clinical Trial Data	💩	💩 💩 💩
Safety Data	💩 / 💩	💩 💩 💩
Ease of access	?	💩

72

ACG International Virtual Grand Rounds universe.gi.org

## The End of “Conventional FMT” in the US?



<https://chatgpt.com/c/67616c08-48a8-8012-8ae1-182048e0ae45>

73

ACG International Virtual Grand Rounds universe.gi.org

## FDA Saga Continues...

June 2019	October 2019	November 2022
<ul style="list-style-type: none"> <li>○ 2 FMT immunocompromised recipients enrolled in research trial acquired ESBL following FMT, resulting in 1 death; donor not screened for MDRO<sup>1</sup></li> <li>○ High risk history (healthcare exposures, travel); testing for ESBL, VRE, CRE and MRSA</li> </ul>	<ul style="list-style-type: none"> <li>○ Public hearing on the use of FMT</li> <li>○ Pharma and academia discuss enforcement discretion and its impact on the development of an FDA approved product</li> </ul>	<ul style="list-style-type: none"> <li>○ “Centralized manufacturing in stool banks presents safety concerns related to the number of patients that may be exposed to a particular donor and particular manufacturing practices.”</li> <li>○ IND requirements were needed to ensure safety</li> </ul>

74

ACG International Virtual Grand Rounds universe.gi.org

The screenshot shows the Fierce Biotech website interface. At the top, there are navigation links for Fierce Pharma, Fierce Biotech, Fierce Healthcare, and Fierce Life Sciences Events. The main header includes the Fierce Biotech logo and a menu with categories like Biotech, Research, Medtech, CRO, Special Reports, and Trending Topics. A search bar and social media icons (LinkedIn, Facebook, X) are also present. The article featured is titled "With first microbiome drug approved, Seres slims R&D efforts and workforce" by Annalee Armstrong, dated Nov 2, 2023. Below the title are tags for Seres Therapeutics, microbiome, restructuring, and Nestle Health Science.

<https://www.fiercebiotech.com/biotech/1st-microbiome-product-approved-seres-slims-rd-efforts-and-cut-staff-focus>

75

ACG International Virtual Grand Rounds universe.gi.org


The screenshot shows the Fierce Pharma website interface. At the top, there are navigation links for Fierce Pharma, Fierce Biotech, Fierce Healthcare, and Fierce Life Sciences Events. The main header includes the Fierce Pharma logo and a menu with categories like Pharma, Manufacturing, Marketing, and Special Reports. A search bar and social media icons (LinkedIn, Facebook, X) are also present. The article featured is titled "Ferring trims US workforce by 134 with layoffs in New Jersey, Minnesota" by Zoey Becker, dated Dec 12, 2023. Below the title are tags for Ferring Pharmaceuticals, layoffs, and Rebiotix.

<https://www.fiercepharma.com/pharma/ferring-trims-us-workforce-134-new-jersey-minnesota-layoffs>

76


ACG International Virtual Grand Rounds universe.gi.org

2024




OPENBIOME

↓




FINCH

↓



**BANKRUPT**




Rebiotix<sup>®</sup>  
Microbiota Restoration Therapy

↓


FERRING

PHARMACEUTICALS



SERES  
THERAPEUTICS™


↓



Nestlé  
HealthScience®

77

ACG International Virtual Grand Rounds universe.gi.org



- World
- Business
- Markets
- Sustainability
- Legal
- Breakingviews
- Technology
- Investigations
- More

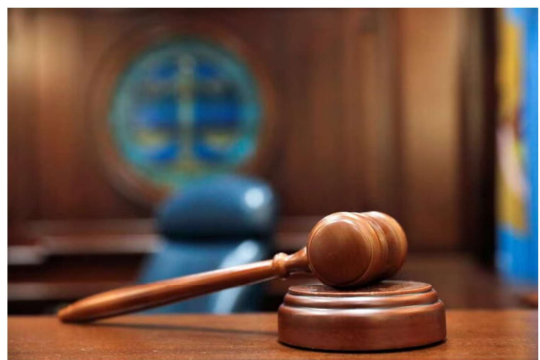
My News

Sign In Subscribe

## Finch wins US jury trial against Ferring over fecal-transplant patents

By Blake Brittain  
August 9, 2024 6:25 PM EDT - Updated 4 months ago

📄
Aa
↻



REUTERS/Andrew Kelly Purchase Licensing Rights

Get 30 US blue chip stocks in a single trade with DIA.

STATE STREET GLOBAL ADVISORS

Report this ad

<https://www.fiercepharma.com/pharma/ferring-trims-us-workforce-134-new-jersey-minnesota-layoffs>

78

ACG International Virtual Grand Rounds universe.gi.org

# AGA Microbiota Transplant Guideline

## Recurrent *C. difficile* Infection

### Is the patient at high risk for recurrence?

Immunocompetent adults	Immunocompromised adults	
<div style="background-color: #00B050; color: white; padding: 10px; text-align: center;">           Recommend use of fecal microbiota-based therapies upon completion of SOC ABX         </div> <div style="text-align: center; margin-top: 5px;"> </div>	<div style="background-color: #00B050; color: white; padding: 10px; text-align: center; margin-bottom: 5px;"> <i>Mild-Moderate Immunocompromise</i> </div> <div style="background-color: #00B050; color: white; padding: 10px; text-align: center;">           Recommend use of conventional FMT upon completion of SOC ABX         </div> <div style="text-align: center; margin-top: 5px;"> </div>	<div style="background-color: #C00000; color: white; padding: 10px; text-align: center; margin-bottom: 5px;"> <i>Severe Immunocompromise</i> </div> <div style="background-color: #C00000; color: white; padding: 10px; text-align: center;">           Recommend against use of fecal microbiota-based therapies upon completion of SOC ABX         </div> <div style="text-align: center; margin-top: 5px;"> </div>

Peery et al. *Gastroenterology* 2024;166:409–434

79

ACG International Virtual Grand Rounds universe.gi.org

[Access FMT](#) | [Our Work](#) | [Resources](#)

OPENBIOME

[Contact Us](#) | [Search](#)

---

[About Us](#) | [Join Us](#) | [Media](#)

Give

## OpenBiome Voluntarily Suspends FMT Shipments

Share

On September 29, 2024, OpenBiome will voluntarily suspend the distribution of investigational Fecal Microbiota Transplants (FMT) for patients with recurrent *Clostridioides difficile* infection (C. diff). Until then, we will be limiting orders to **confirmed cases only**. We understand the impact of this decision and want to ensure that clinicians have ample time to explore alternative therapies for your patients, such as the use of FMT prepared by hospital laboratories, if available.

<https://openbiome.org/feature/openbiome-voluntarily-suspends-fmt-shipments/>

80

American College of Gastroenterology

40

ACG International Virtual Grand Rounds universe.gi.org

## The FMT Story in the United States

<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-82048e0ae45>  
<https://chatgpt.com/c/67616e08-48a8-8012-8ae1-182048e0ae45>

81

ACG International Virtual Grand Rounds universe.gi.org

## 2025: Last Products Standing

**FERRING**  
PHARMACEUTICALS

**Nestlé**  
HealthScience®

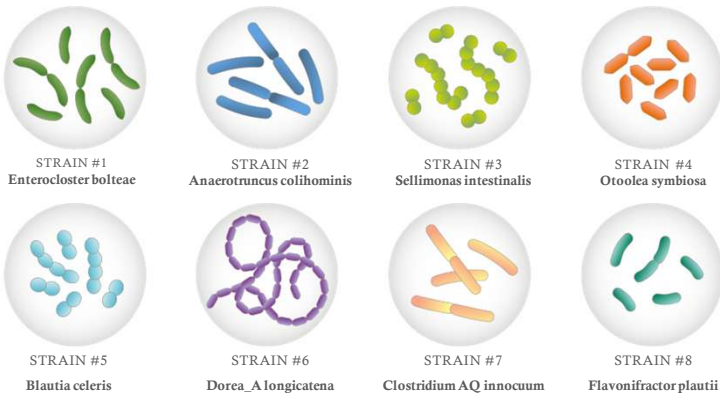
**Fecal Microbiota, Live-jslm**

**Fecal Microbiota spores, Live-brpk**

82

ACG International Virtual Grand Rounds universe.gi.org

## VE303 (Vedanta Biosciences)

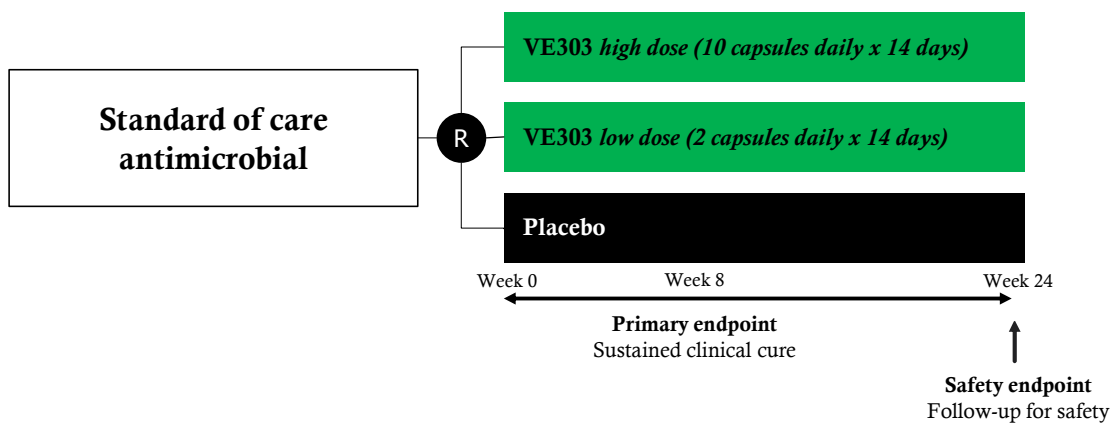


STRAIN #1 *Enterocloster bolteae*    STRAIN #2 *Anaerotruncus colihominis*    STRAIN #3 *Sellimonas intestinalis*    STRAIN #4 *Otoolea symbiosa*  
STRAIN #5 *Blautia celeris*    STRAIN #6 *Dorea\_A longicatena*    STRAIN #7 *Clostridium AQ innocuum*    STRAIN #8 *Flavonifractor plautii*

83

ACG International Virtual Grand Rounds universe.gi.org

## CONSORTIUM TRIAL: Phase 2 Trial Design VE303



Standard of care antimicrobial

R

VE303 high dose (10 capsules daily x 14 days)

VE303 low dose (2 capsules daily x 14 days)

Placebo

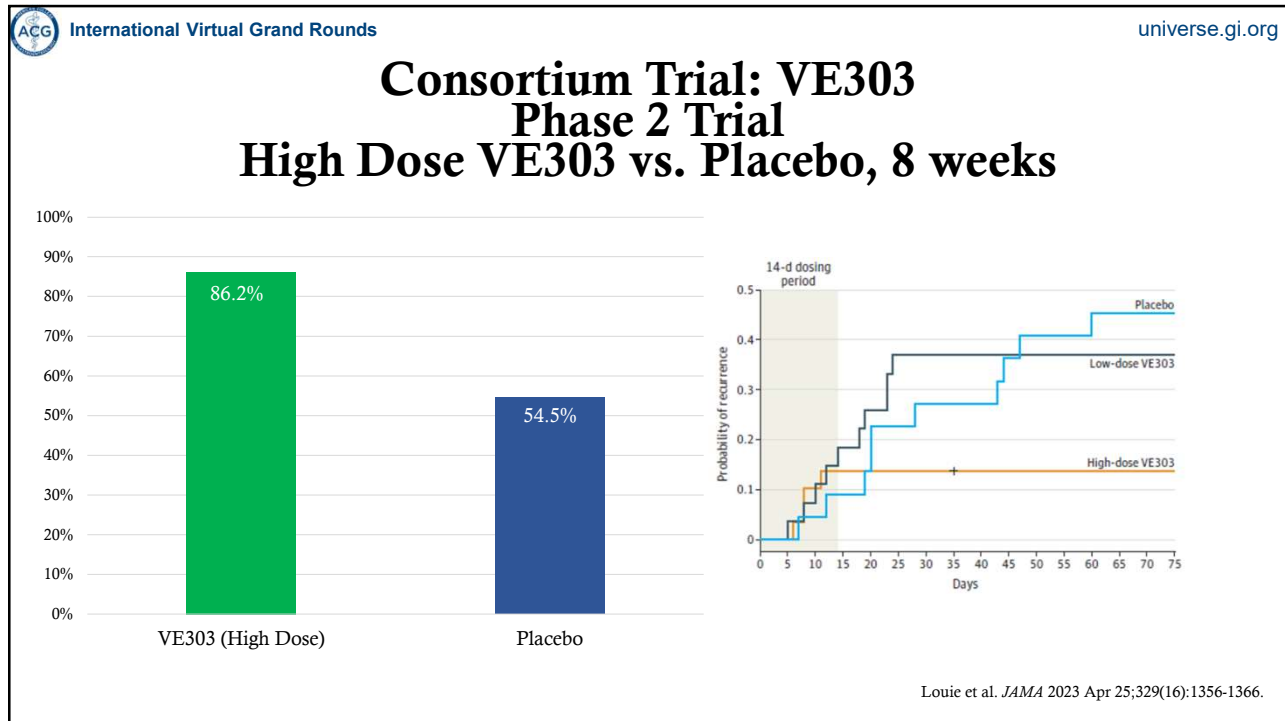
Week 0      Week 8      Week 24

Primary endpoint  
Sustained clinical cure

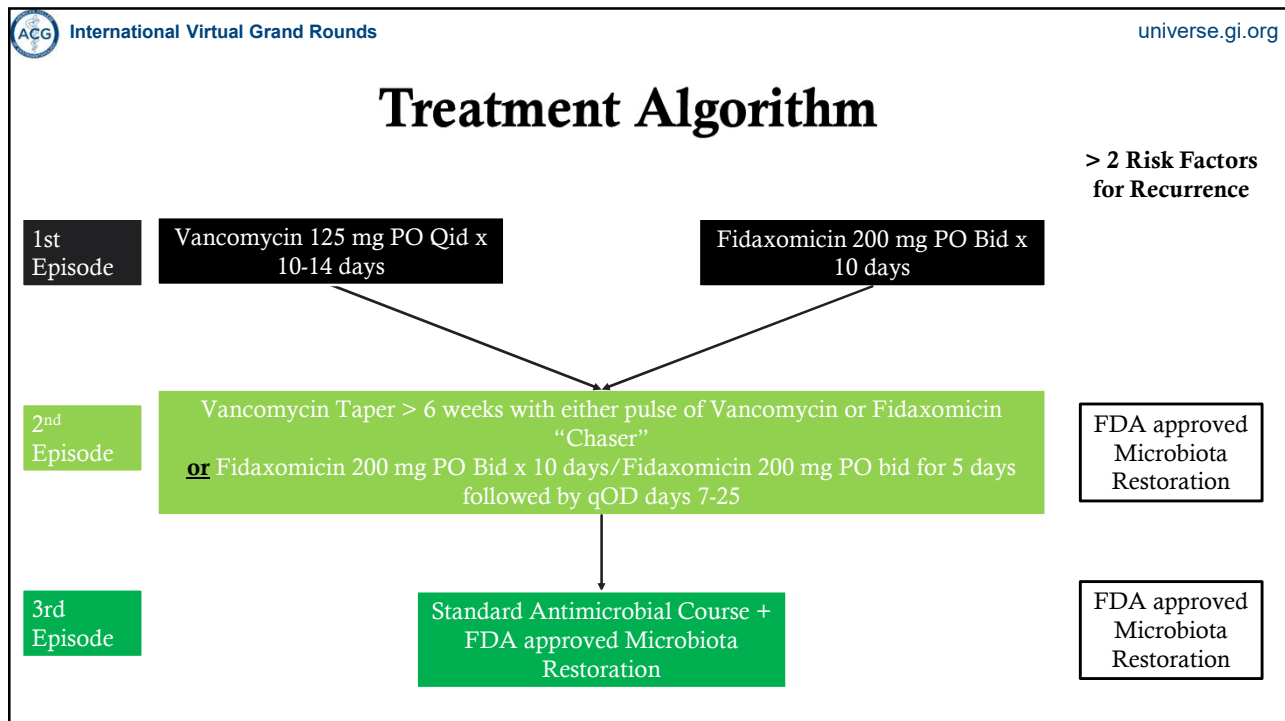
Safety endpoint  
Follow-up for safety

Louie et al. *JAMA* 2023 Apr 25;329(16):1356-1366.

84



85



86

ACG International Virtual Grand Rounds universe.gi.org

## Current Thoughts

- We have come a long way
- Currently, FDA approve therapies seem to be the current and future for MRT in the United States
- There remains an unmet need for Fulminant disease as there are no FDA approved products
  - Unclear how the FDA will respond to this with Openbiome sunsetting its distribution plan for rCDI and fulminant disease


87

Virtual Grand Rounds universe.gi.org



## Questions



Paul Feuerstadt, MD, FACP



Ronald K. Hsu, MD, FACP

88

On behalf of the American College of Gastroenterology (ACG), the Gastroenterological Society of Taiwan (GEST), and the Taiwan Microbiota Consortium (TMC),

Thank you for joining us.

