
# Perspectives on the PUNCH™ CD Trial of a Microbiota-based Drug Targeted at Recurrent *Clostridium difficile* Infection

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Mary Kay Sobcinski is an employee of Rebiotix® Inc.

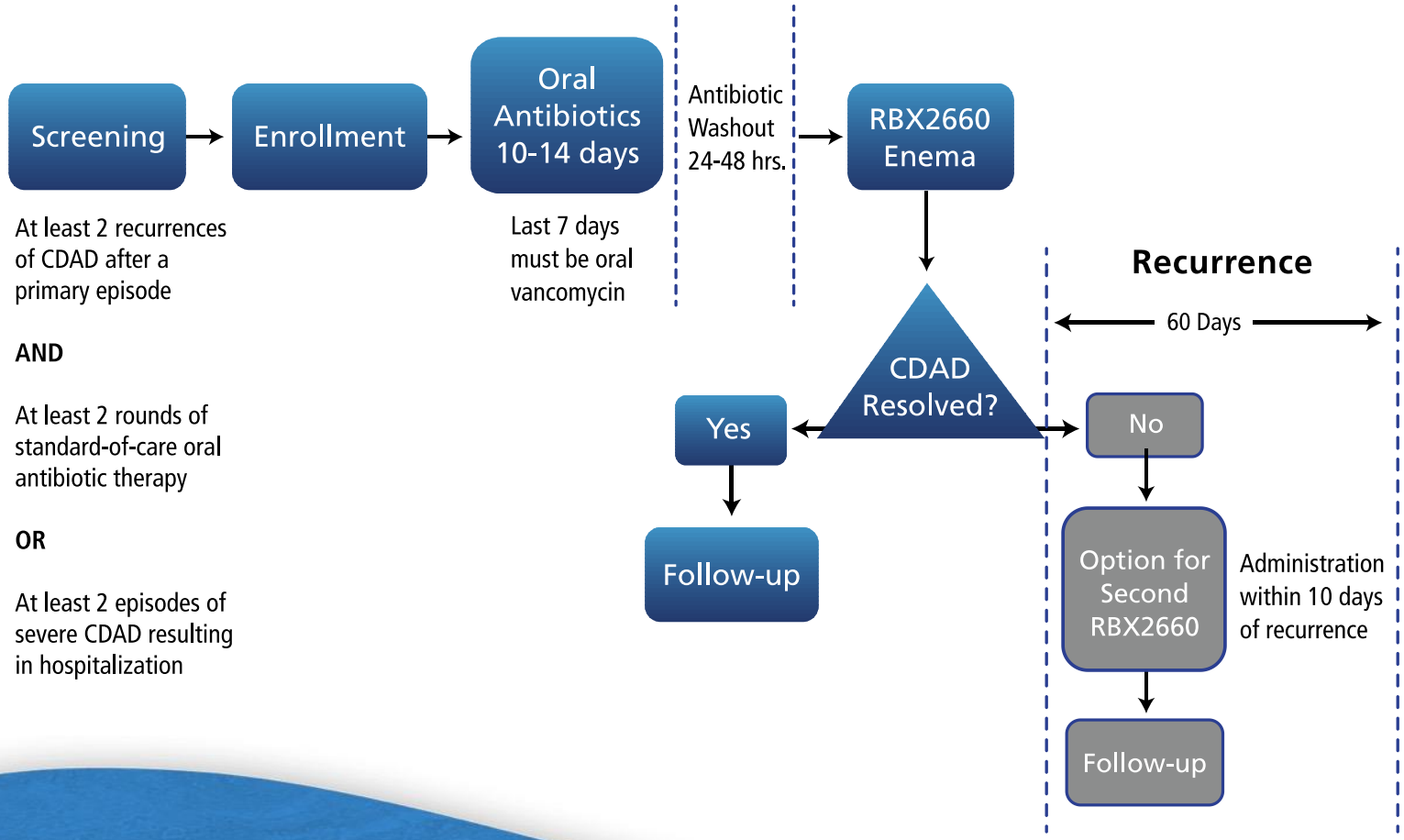
# PUNCH™ CD Study

- First multi-center study of a next-generation fecal microbiota transplant (FMT) product
- Phase 2 open-label study of RBX2660 (microbiota suspension) for recurrent *C. diff*. infection
- Multicenter, prospective, study using a single protocol under an FDA Investigational New Drug application
- Objective: Evaluate the safety and effectiveness of RBX2660

# RBX2660 Compared with FMT

- Designed to mimic FMT but provides a consistent, quality-controlled product
- Manufactured using standardized, quality-controlled processes
- Donors are rigorously screened (blood and stool)
- RBX2660 contains a minimum guaranteed quantity of live intestinal microbes
- Supplied in a ready-to-use enema format
- Saves patients the considerable time, trouble, testing and cost of finding their own donor

# PUNCH™ CD Study Design



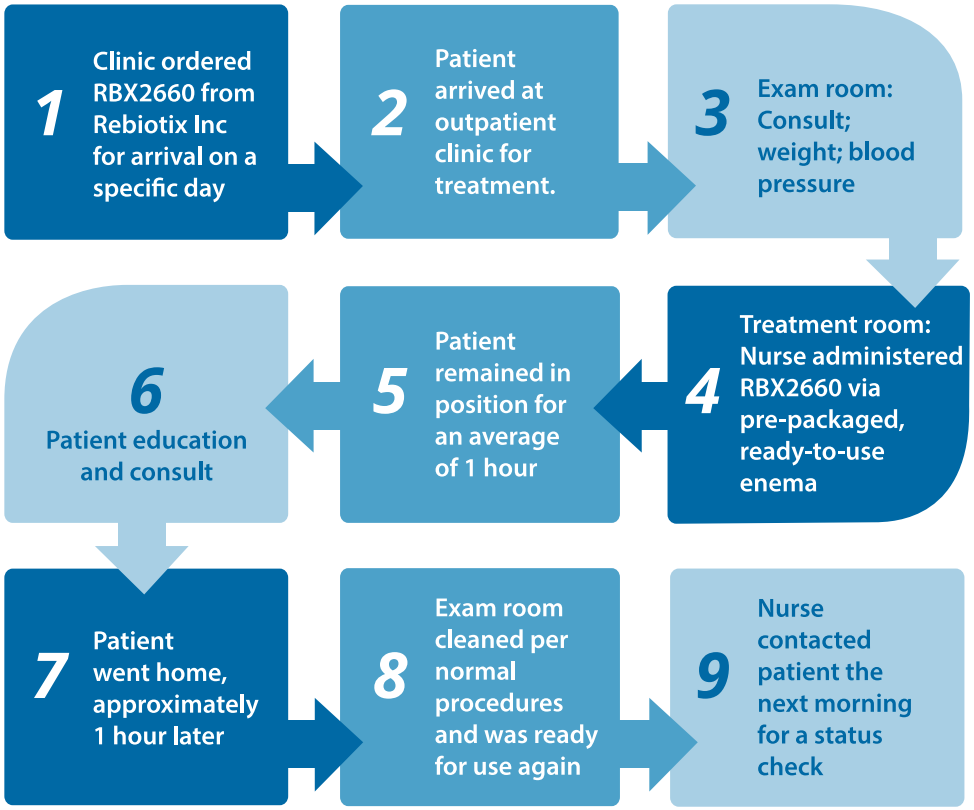
# About the PUNCH™ CD Protocol

- First dose: Administered within 24-48 hours of completion of a 7-day course of standardized oral vancomycin
- Second dose: Permitted if CDI reoccurred ≤ 8 weeks; administered to patients with active CDI symptoms
- Bowel prep not needed
- No sedation, special room or equipment needed for enema delivery
- Administered by a healthcare professional (doesn't need to be a physician)

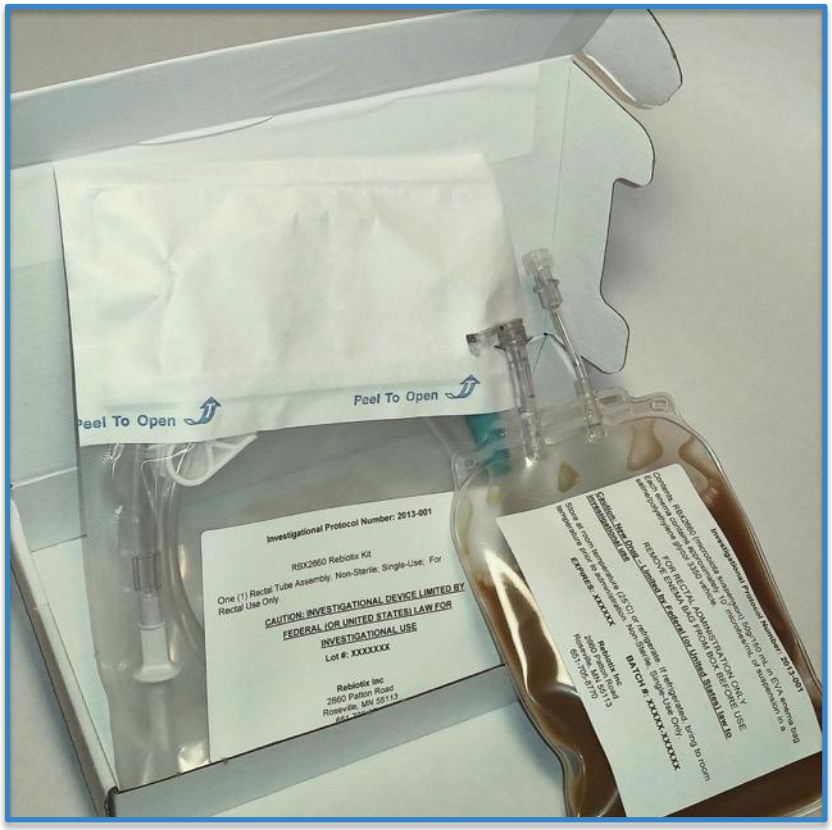
# Chevy Chase Clinical Research Experience

- Enrolled 8 of the 40 patients in the study
- Six patients were treated with RBX2660
  - Mean age 71.5 years; range: 26-89 years
  - Female: 83.3%
  - White: 100%
  - Multiple comorbidities
- Efficacy at 8 weeks: 80.0% (4/5)

# PUNCH™ CD Study Logistics

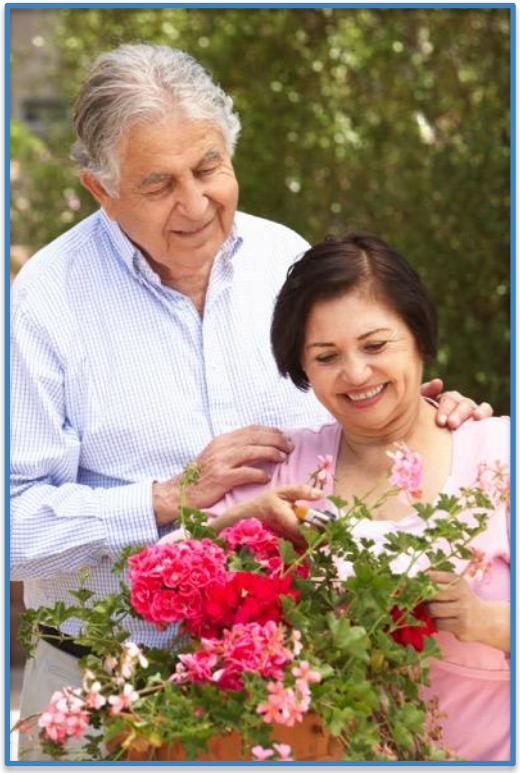


# RBX2660 Kit: Ready and Easy to Use



# Patient Recruitment

- FMT was an unfamiliar therapy when we first started recruiting in August 2013
- Surprisingly, almost all of the patients who contacted us had some basic knowledge about FMT
- Highly educated patient population
- Social media was an effective recruitment tool
- Great support from our referral network
- No one refused screening after learning about the therapy and study



# Patient Education

- Advance diet slowly
- Disinfect home with a 10% bleach solution; allow to air dry
- Vigorously wash hands with soap and water (not sanitizers)
- Two doses may be needed

# Administration

- RBX2660 (microbiota suspension) supplied as a ready-to-use enema
- Easy to administer and comfortable for the patient
  - Administered by a nurse
  - No bowel prep or sedation required
- Patients remained in position for approximately 1 hour
- Minimal leakage; none in most patients
- Did not cause a bowel movement
- Patients could have family present

# Follow-up

- In-office follow-up visits at 7, 30, and 60 days
- Phone call follow-up at 2, 3, 5, 6, and 7 weeks and at 3 and 6 months
- We did much more; encouraged patients to call, e-mail or text at any time if they had a question or concern
- There is no such thing as too much communication for this condition
- No patients lost-to-follow-up
- Patients anecdotally reported feeling much better, “calmer,” immediately or very shortly after administration

# Safety

- Very aggressive adverse event (AE) collection through a detailed subject diary and phone calls
- 7 AEs
  - Mostly mild; GI or orthopedic
  - Lasted only 1-2 days
  - 1 case of food poisoning
- 4 serious AEs
  - 1 for recurrent *C. diff.* hospitalization after dose 2
  - 3 in one patient: UTI → pelvic fracture → respiratory distress

# Results

- Chevy Chase Clinical Research enrolled 8 of the 40 patients in the study
- Six of 8 patients were treated with RBX2660; 5 patients had efficacy data at 8 weeks
- Overall efficacy was 80%
- We were very excited to participate in this study and to provide a new therapy to our patients
- Some of our patients are still in contact with us even though the study has been completed

# Case Study

- 84-year-old white male; BMI 21 kg/m$^2$
- Medical history
  - Anemia (Hb 8.2 g/dL)
  - Pacemaker
  - Segmental colon resection
  - Kidney failure
  - Depression
- Living in a long-term care facility
  - Mild-to-moderately active when free of recurrent *C. diff.*

*For illustrative purposes only. Not designed to represent overall study results*.

# Case Study

- Received 2 doses of RBX2660 7 days apart
  - Symptoms returned 4 days after 1st dose
  - Complete resolution of *C. diff.* symptoms within 7 days after 2nd dose
- Quality of life scores (SF-36) improved over time
- Adverse events
  - Dose 1: Vomiting with dehydration when symptoms reoccurred
  - Dose 2: Constipation for 1 day at 30 days
- At 30-day visit, reported that he had gone on a 2-mile walk
- Continues contact with study coordinator; remains free of *C. diff.* 18 months after 2nd dose

*For illustrative purposes only. Not designed to represent overall study results*.

# Conclusion

- The PUNCH™ CD study to assess RBX2660 for recurrent *C. diff.* infection provided patient access to a new therapy with minimal disruption to clinic operation
- Overall, our patients had very good success (4/5 had resolution of recurrent *C. diff.)*
- Study was interesting and well-supported by the sponsor
- We're participating in the next study, PUNCH CD 2


# Thank you!

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