**RBX Abstract for** [**ACG2021** – due June 21st, 11:59p ET](https://acgmeetings.gi.org/call-for-abstracts/)

**RBX2660, an Investigational Live Microbiota-based Biotherapeutic, Improves Outcomes of *Clostridioides difficile* Infection in a Real-World Population: A Retrospective Study of Use Under Enforcement Discretion**

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**Background**
Recurrent *Clostridioides difficile* infection (rCDI) is an urgent public health threat. RBX2660 is a standardized, stabilized, investigational microbiota-based live biotherapeutic that has been evaluated in 5 prospective clinical trials. Eligibility criteria in clinical trials are often narrowly defined, excluding broader patient populations. Herein, we report a retrospective analysis of safety and efficacy of RBX2660 given under FDA enforcement discretion (ED) in a cohort with broad eligibility criteria.

**Methods**

Participants were ≥18 years old with rCDI and received RBX2660 rectally. The investigator determined the number of doses administered. Participant data were collected from electronic health records. The primary safety set (PSS) population included participants who had not been previously treated with RBX2660 and who had continuously comprehensive medical records for 6 months after therapy. Safety, treatment success (absence of CDI recurrence within 8 weeks post-RBX2660), and clinical response duration were evaluated.

**Results**
94 participants were enrolled from 5 sites between Nov-15 and Sep-19. Comorbid conditions included gastroesophageal reflux disease (47.9%), irritable bowel syndrome (17%), gastritis (11.7%), constipation (8.5%), microscopic colitis (7.4%), diverticulitis (6.4%), Crohn’s disease (5.3%), and ulcerative colitis (4.3%). 16% of patients were using concomitant immunosuppressant’s such as glucocorticoids (7%) and monoclonal antibodies (6%) at the time of RBX2660 administration. 64 of the 94 participants were in the PSS, with a treatment success rate of 82.8% (53/64), with no difference observed between participants who received 1 dose (83.3%; 20/24) versus 2 doses (82.5%; 33/40) after the qualifying CDI diagnosis. Of those that responded initially, sustained clinical response to 6 months was 88.7% (47/53). Safety outcomes were comparable to prospective studies for RBX2660, with most (92.2%) adverse events being mild to moderate in severity, including participants with immune-mediated/autoimmune disorders and non-specific inflammation conditions.

**Conclusion**

In this retrospective analysis, RBX2660 administered to participants under ED demonstrated high clinical efficacy to reduce rCDI with a sustained clinical response to 6 months. Safety results were consistent with prospective trials. The results substantiate the potential safety and efficacy of RBX2660 in “real world” populations with common rCDI comorbidities.

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