Recurrent Clostridium difficile infections (rCDI) are strongly associated with dysbiosis—the disruption of a healthy intestinal microbiome. We have developed two forms of Microbiota Restoration Therapy™ (MRT): RBX7455 is a first-of-its-kind room temperature stable, orally administered MRT; and RBX2660, a ready-to-use liquid suspension MRT.

In a recent investigator-sponsored Phase 1 trial, RBX7455 was effective at preventing rCDI and restored a healthier microbiome among responding participants.

Since quantitative markers have not been definitively confirmed a prototype Microbiome Health Index™ (MHI) to enable unidimensional quantitation of microbiome health and restoration.

Here we report MHI data from an interim analysis of the Phase 1 trial of RBX7455 in recurrent CDI patients. Baseline participant MHI values are similar among the trials and post-treatment MHI data are consistent among three clinical trials of both RBX2660 and RBX7455, regardless of sequencing methods.

MHI as a potential diagnostic
Successful response to microbiota-based therapies RBX7455 and RBX2660 is associated with increased MHI:

- RBX7455 and RBX2660 product MHI values are similar
- Baseline participant MHI values are similar among the trials
- Responder MHI values (30 days) are similar among the trials.

Microbiome Health Index (MHI) analysis

ROC Analysis: Baseline vs RBX2660

Receiver Operating Characteristic (ROC) analysis of baseline from RBX2660 trials vs RBX2660 product profile yielded an area under the curve (AUC) of 0.996 and an optimal cut-off point of MHI=8.2 (violet dotted line: sensitivity=0.96, specificity=0.99, likelihood ratio=0.8).

Microbiome Health Index (MHI) is defined as a unidimensional mathematical expression in the relative abundance of taxonomic classes known to have relevance to microbiome health and colonization resistance.

**Microbiome Health Index (MHI)**

- **Responders** (30 days) are similar among the trials
- **Baseline participant MHI values** are similar among the trials
- **Responder MHI values** (30 days) are similar among the trials

**Microbiome Health Index (MHI) Analysis**

- **MHI as a potential diagnostic**
- Successful response to microbiota-based therapies RBX7455 and RBX2660 is associated with increased MHI.
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**Conclusions**

- **Among rCDI trial participants,** MHI increased sharply after RBX7455 and RBX2660 treatment, with a majority of responders above a defined diagnostic threshold.
- **Pre- and post-treatment MHI data** are consistent among three clinical trials of both RBX2660 and RBX7455, regardless of sequencing methods.
- **Future efforts** will focus on prospective evaluation of MHI as a clinical trial endpoint to confirm the robustness of the metric.

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