Global Feasibility
Study and Country Feasibility

Dear Doctor,

In partnership with Vedanta Biosciences, Inc., we will be conducting a randomized, double-blind, placebo-controlled, Phase 3 clinical study that will enroll study participants with **recurrent Clostridioides difficile infection (rCDI) and those with primary CDI who are at high risk for recurrence (pCDI-hr)**. The study will assess the safety and efficacy of **VE303**, an investigational, orally administered, rationally-defined bacterial consortium consisting of 8 well characterized, clonally-derived nonpathogenic, nontoxigenic, commensal strains of Clostridia.

The study populations will be enrolled in a staggered manner, with two distinct study stages: Stage 1 will enroll participants with rCDI; Stage 2 will enroll participants with pCDI-hr. Participants who experience an on-study CDI recurrence in either study stage will have the option to receive a course of open-label VE303 treatment.

VE303 has been investigated in a Phase 1 study in healthy volunteers and a Phase 2 study in individuals at high risk of CDI recurrence. The Phase 1 study found that following pretreatment with vancomycin, a 14-day course of VE303 was well tolerated and promoted rapid, durable VE303 strain colonization. The Phase 2 study also showed favorable safety and strain colonization profiles; moreover, compared with placebo, VE303 was effective in preventing rCDI.

Given your area of expertise, we would like to invite you to be a potential investigator for the upcoming study. You may review the following for more information about the Sponsor and previous VE303 studies:

- Overview of Vedanta Biosciences, Inc.
- Phase 1 study Ct.gov & Publication
- Phase 2 study Ct.gov

The Phase 3 study is anticipated to **begin enrollment of Stage 1 involving enrollment of participants with rCDI in 2Q 2023; enrollment in Stage 2 involving participants with pCDI-hr is expected to be completed by 1Q 2027.**

To start the pre-qualification survey, please click here.

We kindly ask you to complete this survey within 5 business days. If you are not interested and/or are unable to serve as an Investigator for this study, please access the link provided above and indicate your reason for choosing not to participate. This step will deactivate any automated system reminders.

Once we receive your survey responses, we will carefully review and evaluate them against study requirements. We will inform you about next steps within 2 to 4 weeks of survey completion.

Thank you very much for your time and consideration. We look forward to working with you.

Sincerely,
Niklas Roetz
Global Feasibility – Site Strategy
Parexel International

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