

Assessing Infectious Threats in “Healthy” FMT Donors: Results of an Assessment Program to Support a Next-Generation Drug for Recurrent *Clostridium difficile* Infection

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Background: RBX2660 (microbiota suspension), a next-generation fecal microbiota transplant (FMT) drug targeted at recurrent *Clostridium difficile* infection (CDI), is sourced from human stool. A donor program was implemented to provide a reliable source of raw material to supply Phase 2 studies. The results of the screening program are reported here.

Methods: Potential stool donors were recruited word-of-mouth; a one-time recruitment bonus and nominal payments for accepted donations were offered. Screening for an extensive list of blood and stool pathogens was required prior to enrollment as a donor. If accepted into the program, all donors completed a basic health questionnaire just prior to each donation. All donations were made on site and stored under controlled conditions. Every donated stool was tested using the initial pre-enrollment pathogen screen. Donors also underwent blood testing at the end of each approximately 45-day donation cycle. In the case of a positive result on any of the tests, all drug product associated with that donor during a cycle was destroyed.

Results: A total of 47 potential donors were recruited from July 15, 2013 through April 30, 2015. The mean age was: 29 (range 19-59) years; 70% male; 91.4% white; 57.4% full or part-time students. Of these, 8 (17.0%) failed the initial screening protocol: asymptomatic *E. coli* strain #0157, n=1; asymptomatic ova and parasites, n=1; rheumatoid arthritis, n=1; Grave's disease, n=1; antibiotic use within past 90 days, n=4. A total of 39 people (83.0%) passed the screening protocols and made at least one donation. On subsequent retesting, a further 5 donors failed the screens: asymptomatic rotavirus, n=1; asymptomatic norovirus, n=2; asymptomatic ova and parasites, n=1, psoriasis, n=1.

Conclusions: Results of a donor screening program demonstrate that a substantial number of outwardly healthy volunteer stool donors may be unsuitable as stool donors due to underlying conditions including asymptomatic infections. Stool donors and their donations should be thoroughly tested each time their donation is to be used for treatment as their suitability as a donor may change over time.