



HEALTH EQUITY IN CLINICAL TRIALS

BioNJ Health Equity in Clinical Trials - MBA Business Plan Competition

Case Statement/Prompt

You are a Program Leadership Team* for a mid-size biopharmaceutical company with revenue-generating commercial products and a robust research and development pipeline of novel therapies with the potential to treat a suite of rare and common diseases. Although the company has successfully secured regulatory approval for a number of therapies, it has often struggled to recruit and retain participants in its clinical trials that truly reflect the demographics of the populations affected by the disease being studied. This is especially true of the challenge it has met recruiting and retaining people from historically marginalized groups that are generally underrepresented in clinical research.

In your role as Program Team Leaders, you are charged with presenting a business plan to the Executive Leadership Team for how your program's next US-based clinical trial will address this challenge. In keeping with the company's commitment to patient-focused therapy development, your plan must reflect perspectives drawn from individuals or communities that you are attempting to engage in the clinical trial.

Competition teams should prepare a business plan that addresses each of the following topics:

1. What disease/therapeutic area are you choosing to focus on and why?
2. Which group(s) of individuals from historically marginalized communities are you choosing to focus on and why?
3. Which community-based partner(s) have you engaged to provide input and feedback on your strategy?
4. What specific barriers to clinical trial participation among this target group have you identified and attempted to address with your proposed plan?
5. What innovative technologies, business models, and approaches do you propose using to reach, recruit, and retain individuals from this community in your clinical trial?
6. What budget is required to implement your proposed strategy? What return on investment can you forecast, in both quantitative and qualitative measures? Is this approach scalable to other diseases/conditions?
7. What change(s) did you make to your business plan that reflect(s) input and/or feedback from your community-based partner?

The virtual Bootcamp event on October 29, 2022 will provide foundational information to help competition teams understand clinical trials and drug development, as well as some of the common pain points in conducting fully representative clinical trials. Additional Resources and Suggested Reading provide background related to the Economic Impact of Medical Research, Medical Product Development and Clinical Trials, and Health Equity (available at [BioNJ.org/HECT/MBACompetition](https://www.bionj.org/HECT/MBACompetition)).

**For purpose of this case, the "Program Leadership Team" is responsible for coordinating the various functional teams (such as clinical development, clinical operations, medical affairs, patient advocacy, regulatory, etc.) that must work together to develop a particular therapy for a specific disease indication, from pre-clinical stage research through to commercial launch.*