



## HEALTH EQUITY IN CLINICAL TRIALS

# MBA Business Plan Competition

## OVERVIEW AND INSTRUCTIONS

BioNJ is hosting the inaugural Health Equity in Clinical Trials Business Plan Competition on December 3, 2022 at Rutgers University.

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### 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:

October 25, 2022

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 indications?
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.*

## Diversity and Inclusion Statement

The BioNJ Health Equity in Clinical Trials Business Plan Competition has adopted a definition of diversity and inclusion aligned with the U.S. Food and Drug Administration, which recognizes the urgent need to “enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color, in clinical trials... FDA advises sponsors to seek diversity in clinical trial enrollment beyond populations defined by race and ethnicity, including other underrepresented populations defined by demographics such as sex, gender identity, age, socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity.”

SOURCE: “Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials,” Draft Guidance for Industry, U.S. Food and Drug Administration, April 2022, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations>

## Eligibility and Team Composition

The competition is open to graduate schools offering a credentialed full-time MBA program (or equivalent if designated by Competition Steering Committee). Participating students must be enrolled in at least one course as of Fall 2022.

Teams should be made up of 4-5 students. Each must include at least one MBA student and are encouraged to include individuals from other graduate degree-seeking programs within the same university or formally affiliated universities. Teams should be inclusive and reflect diversity, as defined above.

Students should self-organize, drawing on guidance from peers, other graduate programs, faculty, and staff. In the case of multiple teams registered from the same university, the Competition Steering Committee will review team credentials and make a final selection for participation in the Competition.

All participating teams must [register their team](#) and members with BioNJ and sign a release form prior to participation. The deadline for registering a team is November 6, 2022.

## Business Proposal and Presentation Preparation

At least one team member must attend the virtual Bootcamp event on Saturday, October 29 to better understand the case statement/prompt and business proposal requirements. This Bootcamp will also introduce teams (and students considering forming a team) to medical product development, key pain points in medical product development and representativeness in clinical trials, and biopharmaceutical leaders.

In developing their business proposals, teams are encouraged to consult community-level organizations for input and feedback. Teams are allowed to consult peers, faculty, and staff in preparing their business proposals. Proposals should be based on students' original work.

## Business Proposal and Presentation Requirements and Submission

**Proposal requirements and restrictions:** Business proposals should be submitted by 5:00 PM ET on November 28, 2022 as a PDF or Word document via email to [sam@kithcollective.com](mailto:sam@kithcollective.com). All data must be cited. Proposals should address the questions in the case statement/prompt and should include:

- Up to 8 pages (target 4-6 pages)
- Single-spaced, 12 pt. font, 1-inch margins
- Up to 5 additional pages (reference list, appendices, background material)
- Cover page with student names, school, degree-seeking programs, proposal name/title, and case statement question summary responses ([see cover sheet template link on website](#)). (Cover page does not count towards the page number requirements.)

**Presentation requirements:** Presentations should be submitted by 5:00 PM ET on Thursday, December 1, 2022, as a PowerPoint document via email to [sam@kithcollective.com](mailto:sam@kithcollective.com). You may not make any changes to your slides once they are submitted. Please also bring a back-up copy of your slides on a flash drive to the December 3, 2022, Pitch Event. Presentations will be pre-loaded, and you will be able to advance slides. Teams may determine how best to present their proposals and what to include in their presentations. Some guidance:

- Teams will have a total of 15 minutes of presentation time. Pitches should be delivered in no more than 7 minutes. Judges will have the remaining time to ask questions.
- Teams may determine who will give the presentation (one designated team member, trading off speaking, etc.)
- Teams will present in a random order which will be assigned on the day of the Competition.
- We unfortunately cannot accommodate audio or video embedded within a slide.

- Teams will not be permitted to observe other teams' pitches, except for during the final round of pitching. Teams that do not advance to the final round or who have already presented will be permitted to watch the finals.

## Competition Event: December 3, 2022

Preliminary agenda (subject to change)

Time	Event
<b>10:00 AM-10:15 AM</b>	WELCOME
<b>10:15 AM-10:30 AM</b>	Teams and judges settle into breakout rooms and practice/waiting areas
<b>10:30 AM-12:00 PM</b>	PITCHES: Group A
<b>10:30 AM-12:00 PM</b>	PITCHES: Group B
<b>12:00 PM-12:30 PM</b>	Judging deliberation Networking break
<b>12:30 PM-1:15 PM</b>	LUNCH
<b>1:15 PM-1:30 PM</b>	ANNOUNCEMENT: Top 4 teams
<b>1:30 PM-2:15 PM</b>	Final team prep Networking break
<b>2:15 PM-3:30 PM</b>	PITCHES: Finalist teams
<b>3:30 PM-4:00 PM</b>	Judging deliberation Networking break
<b>4:00 PM-4:30 PM</b>	ANNOUNCEMENT: Winning teams and awards

All team members are expected to attend the pitch event in person. Faculty advisors and other team supporters may not attend.

Teams will be divided into two groups for the initial round of competition. The top two teams from each group will compete in a final round. Teams will not be permitted to adjust their presentations between presentations.

## Travel

Students will be responsible for booking their travel. Student teams should consult with their university for travel authorization and/or reimbursements. If a school or team requires additional travel assistance funds, please reach out to [sam@kithcollective.com](mailto:sam@kithcollective.com) to inquire about available funds.

Hotel information and travel policies (including any COVID-19 guidelines) TBA. See website (<https://bionj.org/health-equity-in-clinical-trials-mba-business-plan-competition>) for latest information.

If a team member is unable to travel and/or may require any travel accommodations, please contact [sam@kithcollective.com](mailto:sam@kithcollective.com) as soon as possible for arrangements.

## Judging

Judges will be given the proposals before the competition for review. A minimum of three judges will be present during each presentation.

Judges will be biopharmaceutical industry leaders with a diverse set of backgrounds and interest in addressing diversity in clinical trials.

Judges will score each team's proposal and presentation separately.

Written proposal scoring criteria will be based on relevance to the community, thoroughness of prompt questions responses, clarity of the problem and proposed solution, considerations of potential risks and uncertainties, quality of writing, and feasibility of potential solution.

Presentation pitches will be scored on the basis of clarity of delivery, ability to respond to judges' questions, and overall quality of responsiveness to the case statement/prompt.

The written proposal submitted in advance will constitute 60% of the score and the presentation pitch will be 40% of the overall score.

In the event of a tie, the team with the highest score on the written presentation will win.

## Cash Awards & Recognition

First Prize – \$10,000

Second Prize – \$7,000

Third Prize - \$3,500

Once winners are announced, winning teams will be required to complete a prize remittance form to route prize money.

All teams and participants will have the opportunity to:

- Present their ideas to industry leaders from global biopharmaceutical companies.
- Network with competition sponsors, judges, and attendees from leading biopharmaceutical industry companies.
- Share their resumes with biopharmaceutical industry stakeholders.
- Have their teams' proposals, presentations, and team member information highlighted in a widely distributed white paper in early 2023.