Thesis Portfolio

Simulating Nutrient Preferences to Inform Co-culture Design for Probiotic Manufacturing

(Technical Report)

The Effect of Racial Discrimination on the Underrepresentation of Minority Groups in Clinical Trials

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

The drug development process from the initial discovery to the eventual administration of the drug to a patient takes an average of 10 years to complete. The clinical trials phase alone can take up to 6 to 7 years. The extensive process is necessary to make sure that all drugs are safe and effective. Clinical trials are an important step for determining the performance of a drug in humans using an initial sample of patients. If the drug yields positive responses in the patients and it is approved by the FDA, pharmaceutical companies will develop a plan to manufacture the drug for widespread use. Even though results from clinical trials provide important information about a drug's efficacy and safety, it is still extremely difficult to completely understand if that drug will be safe when used by patients. In addition, once a drug has passed the approval phase there are still issues when it comes to scaling up the production of the drug so that it can be commercialized and used by patients. Both the STS and Capstone projects in this portfolio focus on different portions of the drug development process and improving the quality of drugs that are administered to patients. The STS project focuses on clinical trials and how racial discrimination plays a role in the underrepresentation of minorities. The Capstone project focuses on improving the manufacturing process of probiotics.

After a drug is approved by the FDA, there are still many more obstacles to overcome before it can be administered to patients, which includes the development of a process that allows drugs to be manufactured at a larger scale. Next generation probiotics, also sometimes referred to as live biotherapeutics, are probiotics that act in a pharmaceutical capacity by shifting the gut microbiome to address specific needs. To bring these probiotics to market, a method for improving the growth of gut microbes in co-culture is needed to increase scalability and decrease costs during the manufacturing process. The Capstone project aims to use optimization

techniques to simulate nutrient preferences using genome scale metabolic network models (GENRES) from gut microbes. Simulating nutrient preferences for any gut microbe will help determine if there will be competition among various gut microbial strains for nutrients or if there will be a cooperative process of producing and consuming different nutrients. These results will help find combinations of species that are best suited for co-culturing. This will serve to lower costs in manufacturing by reducing nutrients required per batch and improve scalability by utilizing a more robust combination of strains to help make live biotherapeutic strategies more accessible.

In order to make sure that results from clinical trials accurately reflect the effectiveness of a drug in patients, it is important that the patient sample is representative of the actual patient population. Currently, clinical trials have little to no representation from minority groups despite the fact that those groups may comprise a significant population of patients who could potentially benefit from the drug. The following STS project focuses on the issue of underrepresentation of African Americans in clinical trials and the effect of racial discrimination on this issue. The social construction of technology framework is used to analyze how racial discrimination in various historical case studies led to the mistrust of the medical research institution and how it has shaped current perceptions on clinical trial participation among African Americans. In addition, current barriers that have been shown to decrease the enrollment and participation of African Americans in clinical trials are identified and organized into different systematic levels. Actor network theory is used to explain how these barriers and actors influence each other across these different systematic levels.

After working on projects that focus on different steps of the drug development process, I have truly valued the importance of the understanding how societal factors such as racial

discrimination can influence the development of drugs and probiotics. Since clinical trials only include a sample of the population that will eventually receive the drug or treatment being tested, there is still a degree of uncertainty as to how a drug will perform once it is actually administered to the public. The results from clinical trial process can affect the drugs that are manufactured further down in the development process. Therefore, a better understanding of the population that will receive the drug will improve clinical trial results and also the development of new drugs. Evaluating how African Americans perceive the medical research institution is an important step for creating better ways to include underrepresented communities when developing future innovations in the field of biomedical engineering. As a biomedical engineer, it is necessary to understand the importance of how new and current technologies in the field can affect different communities so that current technologies can be improved and better technologies can be developed in the future.