

# DIVERSIFYING CLINICAL TRIALS THROUGH OPEN INNOVATION



## INTRODUCTION

Clinical trials provide evidence to validate the safety and efficacy of new pharmaceuticals and treatment protocols. To be effective, clinical trials must have a broad sampling of users the intervention is intended to serve. In the case of a medication, factors such as age, race, gender, and genetic profile can impact the way the medication reacts with individuals, potentially leading to poor outcomes. Most clinical trials are homogenous, only accessible to a small fraction of the population, and fail to reflect the diversity of the addressable market of the tested intervention.

Recruitment and retention of underrepresented communities in clinical trials is difficult, expensive, and time consuming. Recent estimates indicate that the average cost to recruit one patient to a clinical study is \$6,533. Participants that drop out or are removed due to non-compliance are estimated to cost \$19,533 to replace. Currently, it costs approximately \$2.6B to bring a drug/therapeutics to market which is highly affected by high dropout rates. **Since clinical trial participant recruitment and retention remain a significant problem and a persistent barrier to effective clinical trials, it is incumbent on the industry at large to examine the problem, explore innovative approaches to addressing underlying issues, collaborate and implement effective solutions to improve diversity in clinical trials.**

IndyGeneUS Health Group and Ibility want to change the status quo by sourcing and testing innovative approaches to improving clinical trial diversity. IndyGeneUS Health Group, a veteran-led healthcare technology company, is on a mission to build the most genetically diverse data bank to improve health, prevent disease, and discover novel therapeutics for conditions primarily affecting underserved communities. Ibility, a Service-Disabled Veteran Owned Small Business and Woman Owned Small Business, employs a creative program leveraging user centered design principles to solve today's complex challenges. **Together, these two companies have designed a compelling market solution and are looking for a sponsoring organization passionate about improving clinical trial diversity and participant recruitment and retention for their targeted clinical trial.**



## PROPOSED SOLUTION

**Challenge Competitions** are a proven way to ignite the creative process by building interdisciplinary teams around an end user in a fun and engaging way. **The goal of our proposed challenge competition is to identify branding, messaging, communication channels, tools, applications, solutions, etc that will resonate with the minority and underrepresented community to improve recruitment and retention of underrepresented communities in clinical trials.**

To have a successful Throwdown, we need to consider the various key stakeholders in clinical trial research – the FDA as the regulatory body, pharmaceutical and medical device companies, academic institutions, healthcare systems, payers, and even the federal government (HHS, DHS, VA, etc.), all incentivized in their own unique way to improve the diversity of clinical trial participants. Moreover, we also need to consider the end user for which the Throwdown campaign is targeted to. As such, we have established partnerships with some Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs) to participate in Challenge Competitions and be part of developing the solution.

Our challenge competitions will bring these stakeholders together to discuss, collaborate, ideate, and create meaningful solutions. Our team will first work with the sponsoring organization to understand their upcoming clinical trials (i.e. drug, device, diet, etc) and the unique trial needs. Outreach will be performed to form 8-10 interdisciplinary teams with a member from an underrepresented community that is pre-contemplative, objects to participating, or has agreed to participate to inform the solution development process.

Each team will rapidly ideate and develop proof-of-concept solutions over an intense week-long sprint. Following the one-week innovation sprint, teams will present their solutions to an esteemed panel of judges during the closing ceremony, which will be a highly publicized virtual event. Discussions are underway with WJLA / ABC7, the Washington Post, and respected online media companies to widely share the solutions. The most promising solutions will be awarded cash prizes.



## EXPECTED RESULTS

Stakeholders that partner with us can benefit from the Challenge Competition in the following ways:

**1. More solutions:** The Challenge Competition will expose more problem solvers to the persistent issues surrounding clinical trial participant recruitment. Our combined market solution will identify and implement effective solutions to clinical trials participant recruiting and diversification.

**2. Better insights:** Gain insight into persistent and addressable barriers to clinical trials participation and diversification by working side-by-side with people from underrepresented groups focused on designing and developing innovative solutions.

**3. Social impact:** Increased brand awareness and recognition for demonstrated support for diversity, equity, and inclusion by sponsoring and collaborating corporations and institutions.

**4. Business development:** Strengthened relationships between participating public and private sector stakeholders and demonstrated support for diversity, equity, and inclusion.



## PROPOSED APPROACH / SCOPE

