

Category

Best Incubator, Accelerator, Equity

Program/Fund Name

Walgreens Clinical Trials

Corporate Name

Walgreens

Date Of Creation

2022-06-16

Indications (if applicable)

N/A

Therapeutic Categories (if applicable)

N/A

History of the development of the fund / Incubators

Walgreens clinical trials business is focused on transforming the future of clinical trials as we redefine the patient experience and access through a proactive, equitable patient-centered enterprise to provide all patients across the U.S an opportunity to participate and promote clinical research as a promising care option. Since launching in June 2022, Walgreens has directly addressed industrywide access, experience, and diversity challenges. Built on a fully compliant regulatory framework that ensures patient privacy and security, Walgreens's flexible operating model is supported by cutting-edge technology and is designed to offer patients a choice in how they want to participate in trials - whether in store, hybrid, or at home - across a range of therapeutic areas.

We aim to engage and empower the communities we serve and deliver trials to more patients than ever before. Introducing more diverse patients to suitable clinical trials provides access to cutting-edge therapies as a care option that can improve their health, while also establishing stronger relationships with their healthcare providers and delivering a more connected healthcare experience. Walgreens believes the more we can enable, engage, and empower, the more likely patients will routinely ask their healthcare providers, whether a pharmacist or doctor, if a clinical trial may be a suitable care option for them.

Walgreens clinical trials model combines the company's established pharmacy presence and nationwide footprint with enterprise-wide health solutions and a legacy of delivering meaningful real-world evidence to break through barriers and engage broader and more diverse communities. This offering coincides with recent steps taken by the U.S. Food and Drug Administration to increase racial and ethnic diversity.

The three service lines launched focuses on patient identification and recruitment, bringing trials

closer to patients in their local communities, and real-world evidence generation and analytics.

Focus

N/A

How do you address your portfolio needs

Big problems remain to be solved for clinical trial participation and the diversity of participants, nearly 80 percent of clinical trials fail to meet their enrollment goals in the stated timeframes. To address these challenges, Walgreens is taking meaningful action by working across healthcare and life sciences industries to deliver a flexible patient experience by administering clinical trials to local communities focused on accelerating cycle times for patient acquisition, engagement, and retention in trials. Clinical trials are not only a research path, but also a way to get patients in underserved communities into the overall healthcare system, helping to advance treatment options for diverse communities.

Our focus is on localization and the individual, and Walgreens has created a more personalized, flexible, and seamless clinical trial engine to provide patients who have traditionally been left out of the clinical trial domain with an opportunity to participate or learn more. In fact, 20 percent of drugs have a variation in responses across ethnic groups, yet 75 percent of clinical trial participants are white, while only 11 percent are Hispanic and fewer than 10 percent are Black and Asian. To this end, Walgreens is proactively matching diverse populations to trials across a range of therapeutic areas and geographies with our patient reach and access to an extensive foundation of pharmacy and patient-authorized clinical data.

When analyzing large cohorts of patients, we see that the sample size in many cases is representative in terms of ethnic groups as compared to the overall diversity mix of the U.S. population. However, we also see that there are systemic barriers to more inclusive clinical research based on how and where traditional research sites are located. At Walgreens, we utilize alternative approaches to recruit diverse patients and collect the appropriate data based on the prevalence of the condition within specific ethnic groups. By addressing the SDoH barriers the targeted cohort of patients are likely to be experiencing, the proposition of participation in research becomes more attainable for more challenged patients. Walgreens has started to leverage SDoH to shape the recruitment and retention efforts for our trials.

Impact / metrics to measure success

After launching Walgreens clinical trials business in June 2022, we have had discussions with 16 of the top 20 pharmaceutical companies and large healthcare systems with strong resonance for our ongoing and planned service offerings. To date, we've signed ten partner contracts including recent announcements with Prothena and Freenome to support Alzheimer's Disease and early cancer detection research, respectively.

Over the past year, we've launched several clinical trials in the areas of COVID-19 studies (e.g., adolescent vaccines, vaccine safety and, antiviral therapies), cardiovascular outcomes, diabetes, Alzheimer's disease, and cancer screenings. Over 2 million potential diverse study participants have been contacted as part of these efforts, including at our Clinical Trial Hubs whereby pharmacists are alerting prospective patients if they are candidates for clinical trials.

As we continue growing the business, we are at various sales stages with several other biopharma, medical device partners, and healthcare systems about their needs and how Walgreens can meet the objectives for patient identification recruitment, bringing trials to patient communities, diversity initiatives, and real-world prospective evidence generation.

Success within these partnerships and programs is benchmarked on:

- Increasing recruitment of underrepresented patient populations: The increased recruitment of underrepresented populations not only tackles health disparities, but also helps diversify clinical trial participation as recently required by the FDA.
- Improving patient retention throughout the length of the clinical trial: Leveraging Walgreens reputation of trust in the local communities as well as the pharmacist's ability to educate patients on a personal level, we are helping patients feel confident in completing their trial.
- Delivering high-quality, real-world evidence to unlock value in therapeutics: We are striving for clinical research to be grounded in the community to validate medicines through a more diverse and representative population, ultimately helping to develop therapeutics that provide better patient outcomes for patients of all races, genders, and ages.

Why your model is innovative, and/or how it will improve the human condition?

Today, we are witnessing a fundamental shift in the U.S. healthcare ecosystem whereby we are more focused on the consumer and reimagining the way we can deliver healthcare services to improve patients' health outcomes. We currently have a network of 9,000 retail locations in America, Puerto Rico and the U.S. Virgin Islands with more than 110 million trusted pharmacist/patient relationships where the healthcare and life sciences companies can expand their trial access and increase patient retention due to our convenient and accessible stores.

Our Clinical Trials business model is leveraging our community pharmacies as clinical trials hubs to serve as critical welcome and trusted entry points, to educate and empower our communities to make informed decisions to participate in clinical research. As we continue to scale and improve access, we are slowly breaking down system-level barriers that have historically prevented patients in marginalized communities to join.

During the COVID 19 pandemic, we learned it is not a one size fits all strategy for our communities. As a result, Walgreens made investments to create a Real-World Evidence engine that leverages our extensive foundation of pharmacy and retail patient insights coupled with patient-authorized clinical data to understand the patient's treatment journey as we proactively match diverse patient populations with speed and precision to trials across a range of disease areas based on race, gender, socioeconomic status, and location. This helps companies not only comply with new FDA diversity guidelines in clinical trials, but also gives them a diverse patient population that increases accuracy and reliability of treatments for all demographics.

Walgreens also uses these real-world insights to provide a good standardized starting point to develop assumptions around specific SDoH challenges at the local level. However, with mistrust and lack of understanding being a large part of clinical trial participation hesitance, there is a need to appeal to patients on more of an individual basis. Leveraging the trusted reputation of Walgreens and our local

pharmacies we can refine our approach to be more targeted, helping biopharma companies conduct a more inclusive and representative research study.

There is a need to 'talk less ... and do more' by showing and setting industry standards on addressing access and health equity. We know these problems have existed for decades. By simply making small tweaks, we will not be able to move the needle in a significant manner. While we are focused on getting the science right, we also need to think about the totality of health. We need to think about how we can make clinical research an inherent care option across this nation if the standard of therapy is not a viable option. We must partner in new ways across the ecosystem to build stronger trust and relationships with our local communities, so the patient is always at the center of care.

Please provide appropriate references (Examples / Case Study)

Walgreens aims to engage and empower the communities we serve and deliver trials to more patients than ever before.

We are being intentional and purposeful as we create an ecosystem of community-based partnerships. This ensures we not only drive a more equitable research enterprise, but also allows us to put our "Triple E" framework of Engage, Empower and Enable in action to allow for activated clinical trial patients.

We believe active community engagement and education are the doorway to improve access for patients who have traditionally been left out of the clinical trial domain. We can then match those patients to trials quickly and efficiently to ensure they are part of the drug development process moving forward.

Walgreens established a track record of engagement during the COVID-19 pandemic, not only educating and administering vaccinations to millions of Americans, including those with distrust in American health systems and/or a lack of access to care, but also delivering insights through the Walgreens COVID-19 Index to help inform national and local health decisions and plans. These lessons have been applied to our overall clinical trials approach, we've challenged ourselves to identify what more can be done to improve care in the communities that need it most.

Building on lessons learned from the COVID-19 Vaccine Equity Initiative, Walgreens new clinical trials operating model provides patients who have traditionally been left out of the clinical trial domain with an opportunity to learn more and participate, with the goal of redefining the patient experience and increasing access and retention in sponsor-led drug development research.

A current, and vital way in which Walgreens is helping to bridge the gap in diversity and clinical trial participation is through targeted and strategic recruitment efforts. In one recent example, Walgreens was able to leverage pharmacy data (including patient proximity and opt-in status for emails and texts) to allow a greater focusing and personalization of engagement materials for specific patient populations. This resulted in almost double the randomized participants compared to all other recruitment partners in the study combined. In another trial, their engagement and recruitment efforts resulted in participant referrals that exceeded the average trial participation among Black (from 8% to 17%) and Hispanic (from 11% to 19%) populations.

Retail pharmacies have already begun to play a key role in advancing decentralized clinical trials –

which are designed and executed using a combination of delivery channels – and will continue to be recognized as a way to reduce operational complexities, cycle times, costs, and patient burden. Pharmacies open access to more diverse patient populations, bolstering enrollment and offering increased flexibility that reduces patient burden and improves retention. By running hybrid trials supported by cutting-edge technology and industry partners, Walgreens is introducing trials to patients across a range of therapeutic areas and geographies, virtually and in-person, with the support of principal investigators and clinical research staff. This model offers patients a choice of how they want to participate in trials and promotes clinical research as a promising care option to manage or potentially cure their condition.