How retail pharmacies can transform clinical trials

EY Parthenon
Building a better working world

Retail pharmacies have a strong opportunity to increase their presence in clinical drug trials, expanding the pool of trial participants.

In brief:

- The clinical trial landscape is shifting, with a strong push toward driving more diversity in the pool of trial participants.
- EY-Parthenon research shows retail pharmacies are well positioned to play a major role in this shift, both from a geographic and community-trust standpoint.
- Still, retail pharmacies need to add new capabilities in order to make the most of these opportunities.

Retail pharmacies have an opportunity to play an increasing role in clinical drug trials as pharma sponsors look for ways to attract an increased number and diverse set of trial participants. But are they ready to scale up their participation?

As the clinical trial landscape changes amid an emphasis on subject diversity and ease of access for patients, EY-Parthenon teams interviewed several senior executives of R&D organizations at mid– and large-sized pharmaceutical and biotechnology companies to get their perspectives on partnering with retail pharmacies. The teams also surveyed consumers across various demographics to understand how they viewed their retail pharmacies and their understanding of and interest in the clinical trial process.

The results illustrate that there is a great opportunity for retail pharmacies to expand the current clinical trial system, which could alter the roles of current players such as contract research organizations (CROs) that work with pharma trial sponsors. However, retail pharmacies still have hurdles to overcome, mainly through increased investment and staff training, to have a more significant and sustained impact in the space.

The evolving clinical trial landscape

Clinical research has rapidly evolved due to many factors, including a shift toward narrower patient populations, the COVID-19 pandemic and subsequent supply chain constraints, and the new law enacted in December 2022 (DEPICT Act, Public Law 117-328) that requires more diverse patients in clinical trials. Over the last several years, patients have become more proactive in engaging in their health care and are becoming more comfortable with receiving care in nontraditional settings. This focus on convenient access to care has also had a high impact on how clinical trial recruitment, retention and operations are executed.

This shift has, among other results, led to the entrance of nontraditional players within the clinical trial process. Fresh off their success in the deployment of the COVID-19 vaccines and having stated a desire to expand their role in providing health care services to their patients, retail pharmacies have begun to realize the opportunity to play a more substantial role within the clinical research landscape. But these ambitions have given rise to the need for a new set of capabilities centered around remote patient identification, recruitment, digital monitoring, home treatment, data capture/aggregation and data security platforms (Figure 1).

> “With clinical trials in these locations, you provide access to people in the lower social or economic spheres. So, I think that’s the one benefit of retail pharmacy organizations, they provide increased access to diverse populations because the clinical research sites are right there, local to the patient. But additionally, these individuals trust their pharmacist. So, when you think about it in that way, it’s more than just physical patient access. It really provides that channel for education and trust between clinical research and disadvantaged populations.
>
> Senior Director, Project Management, large pharma

Figure 1: The changing clinical trial landscape

	Shift to narrower patient populations	Accelerated adoption of decentralized clinical trials (DCTs)/ hybrid trials post-COVID-19	Increased focus on diverse patient trial recruitment
Historic clinical trial landscape	▸ Traditionally, conventional methods of patient identification for clinical trials was suitable	▸ Pre-COVID-19, most clinical trials relied upon patients commuting to brick-and-mortar locations for the trial to be conducted. Patients were treated and monitored and data was captured at the physical site	▸ Historically, recruiting diverse patient populations for clinical trials was not a prioritized area of focus for biopharma companies; as a result, clinical trials lacked diversity
Clinical trial disruptors	▸ As biopharma's focus has shifted towards areas with narrower patient populations, the pool of target patient populations has become much narrower and therefore **more difficult to identify**	▸ The COVID-19 pandemic made it unsuitable for many patients to go to physical site locations and therefore forced the industry to o**ffer the necessary capabilities needed to support DCT/ hybrid trials**	▸ FDA guidance and pending US legislation has resulted in an **increased focus on recruiting diverse patient populations in clinical trials**
Future clinical trial landscape	▸ This trend has given rise to the need for disruptive innovation and methods to **identify, attract and retain** suitable patients in order to conduct the clinical trial	▸ Biopharma will continue to seek partners who can offer capabilities surrounding **remote patient recruitment, monitoring, home treatment and data capture/aggregation** in order to continue conducting (DCT/hybrid trials	▸ **Investments and partnerships** into platforms and technologies that can help recruit diverse patient populations will be an area of focus for clinical trial players

Retail pharmacy response to disruptions

- Partnerships with advanced patient identification digital platforms
- Increased investment into DCT supporting capabilities
- Building credibility within communities through acquisition of primary care providers
- Establishing long-term relationships through enhanced continuity of care

Senate Appropriations Committee, "Clinical Trial Diversity and Modernization, Sec. 3601. Diversity Action Plans for Clinical Studies", 19 December 2022, https://aboutblaw.com/6o0.

Retail pharmacies expand capabilities with M&A and partnerships

Over the last couple of years, retail pharmacies have acted on this need for new capabilities through acquisitions, investments and partnerships.

Patient identification: CVS proposed an acquisition of Oak Street Health in a $10.6b deal in February 2023, an acquisition aimed at strengthening its health care delivery capabilities as its patient base is primarily Medicare-eligible patients in underserved communities.

Primary care providers: CVS acquired Signify Health, a home health care company that offers patient care through virtual and in-person visits, in March 2023 for $8b and has partnered with Medable to strengthen its patient engagement capabilities.

Decentralized clinical trials: Walgreens has established a partnership with VillageMD to bolster its credibility through provider networks and with CareCentrix to boost its capabilities within real-world evidence (RWE) generation and continued patient care in a decentralized format.

Continued patient care: Rite Aid and Homeword, a rural health startup, announced a joint venture to better provide comprehensive care for patients in rural areas in the United States. The joint venture began in Q3 2022, with Rite Aid pharmacies introducing Medicare-eligible customers to Homeword's clinical services and with Rite Aid hosting Homeword's mobile care units at store locations in rural Michigan.

Sponsors see value in broad footprint and patient reach

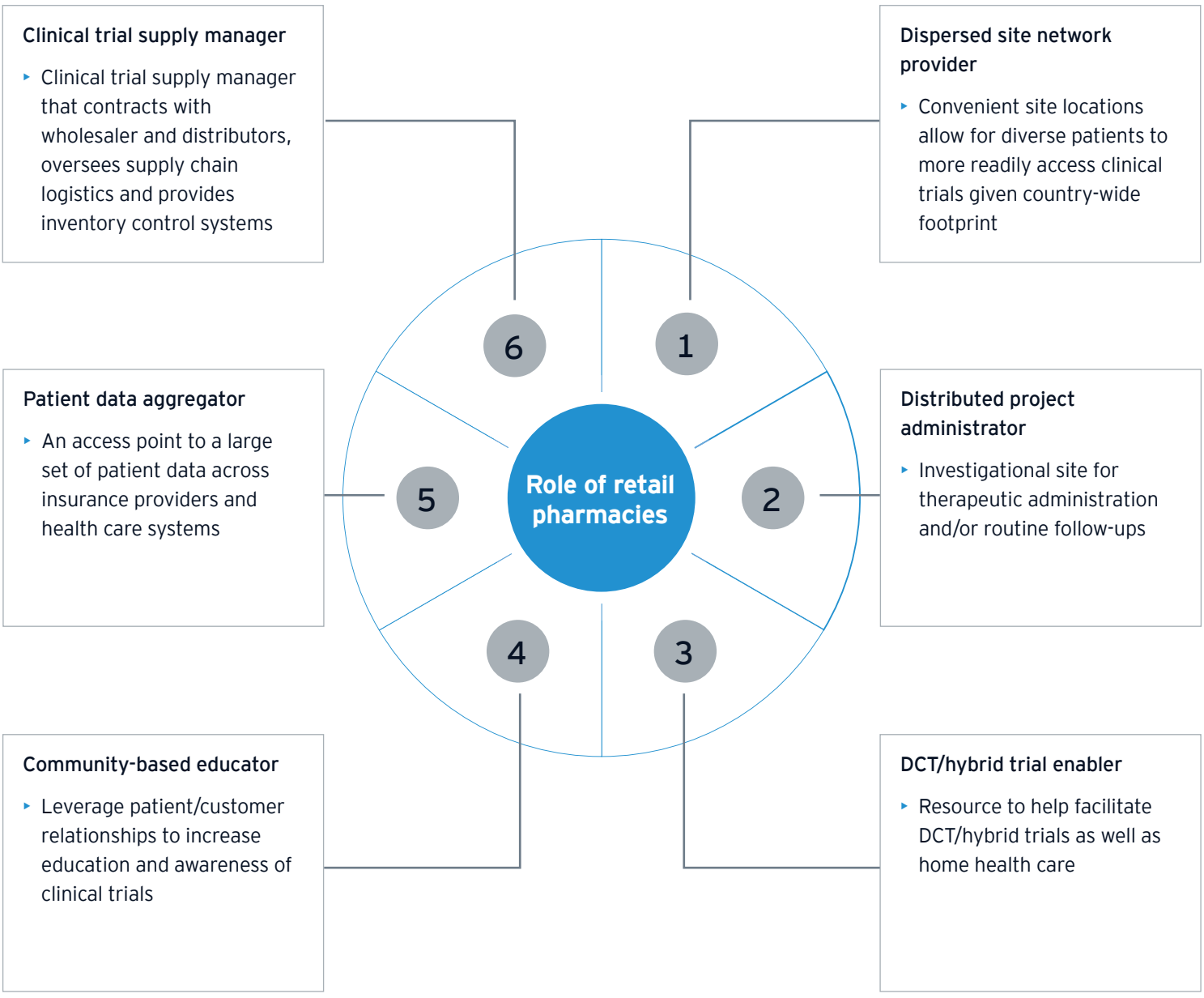
The push for diversity has regulatory weight behind it. The US Food and Drug Administration (FDA) now requires diversity action plans for clinical trials, for therapies seeking FDA approval, to ascertain a drug's efficacy and safety. The purpose is to encourage principal investigators to develop a comprehensive diversity protocol designed to reach a more representative set of the intended treatment population instead of either failing to do so altogether or acting later and increasing an already lengthy and costly clinical trial process.

As biopharmaceutical sponsors continue to develop their own initiatives to address clinical trial diversity in their respective portfolios of studies, they are continually assessing whether to leverage various resources and potential partners. In interviews, executives expressed interest in collaborating with retail pharmacies for their active and pipeline portfolio of studies given pharmacies' broad footprint and potential utility in executional activities for late-stage large clinical programs (Figure 2).

Among their comments:

- R&D leaders believe that once retail pharmacies have proven their ability to support complex, late-stage clinical trials (i.e., Phase III/IV), they will gain traction.
- The depth and breadth of these partnerships are likely to grow 2x-3x over the next 3-5 years.
- Retail pharmacies are uniquely positioned to support their organizations' efforts related to increasing patient access, supporting the decentralization of trials, and driving patient identification and trial-matching activities.
- Retail pharmacies have favorable delivery potential in safety monitoring and serving as a potential trial site.
- As it relates to specific therapeutic areas (TAs), sponsors anticipate utilizing retail pharmacies in TAs where trial design requires large study sizes (e.g., allergy, infectious disease, dermatology, gastroenterology).
- There is notable hesitancy to use retail pharmacies for clinical trial protocols that require infusions and close post-treatment monitoring.
- R&D leaders expressed concern that retail pharmacies currently lack the necessary clinical expertise (e.g., nurse practitioners (NPs), medical doctors (MDs), doctors of osteopathic medicine (DOs)) on-site to be able to conduct patient enrollment evaluations.

Figure 2: How retail pharmacies can support clinical trials



Conducting more representative clinical trials

With the recent FDA guidelines and additional potential legislation aimed at increasing diversity in clinical research, pressure is being exerted on sponsors to enroll a more representative set of trial participants. This sentiment is further amplified as more-nuanced disease states are identified (e.g., rare diseases, biomarker segmentation) that provide additional challenges for sponsors in trying to increase diverse study enrollment.

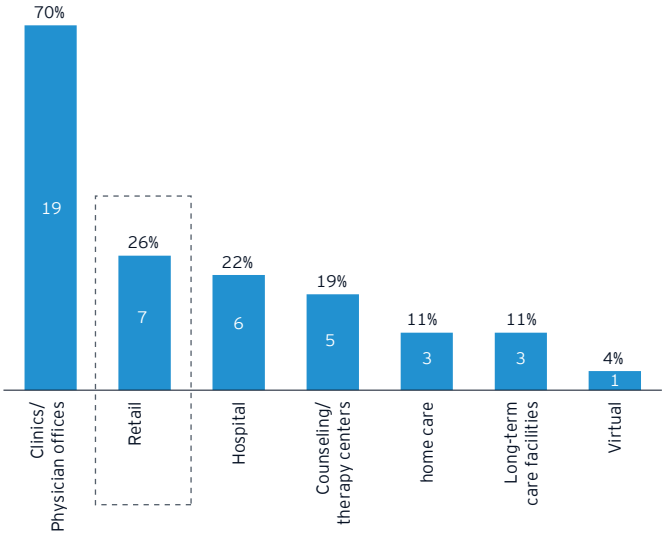
Retail pharmacies are seen as well positioned to help bridge the patient gap based on their proximity and relationship to a broad base of patient populations in the community.

Patients look for trust and convenience in clinical trials

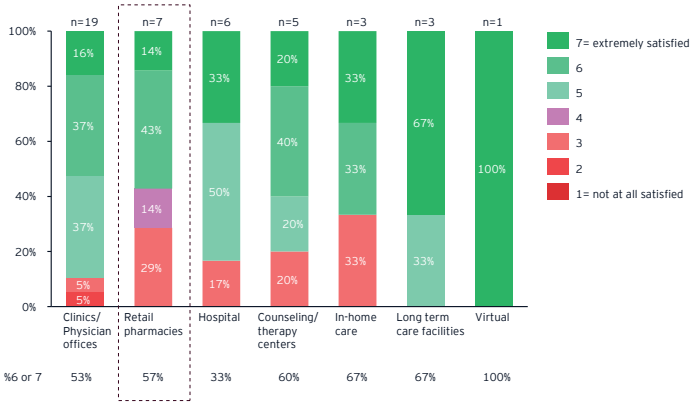
In order to more clearly understand the potential trial participant's perspective, EY-Parthenon teams surveyed a diverse and representative set of about 250 US health consumers across various demographics including gender, race/ethnicity, age and geography. Nearly 90% of respondents had a strong familiarity with clinical trials, with 26% of those indicating a high willingness to participate in clinical research, regardless of race and geographic setting (Figure 3).

Figure 3: Trial participants and setting of care

Clinical trial participants' interaction with settings of care[1]



Clinical trial participants' satisfaction by setting of care[2]



1. Q: When participating in the clinical trial(s), in what setting was the trail conducted? Please select all that apply

2. Q: On a scale of 1 to 7 (1 = not at all satisfied, 7 = extremely satisfied), how satisfied were you with your experience in each setting of the clinical trial?

Source: EY-Parthenon patient survey and analysis

Retail pharmacy organizations are viewed as trusted members of the communities, with about 95% of respondents interacting on a regular basis with their local pharmacy for regular health care product needs, such as over-the-counter (OTC) medication or refilling prescriptions. Of the sampled population, about 40% received low-touch health care services from retail pharmacy organizations, including primary care or vaccine administration, while about 15% received high-touch services, such as chronic disease management or mental health counselling. These interactions have fostered strong patient-provider relationships within the local community and a degree of patient trust that has been created by staff professionalism, communication, compassion and respect. This point was further emphasized when 56% of respondents indicated that their primary reason for enrolling in a clinical trial supported by a retail pharmacy is that they offer local providers that they know and trust. Also, with 40%-50% of consumers using retail pharmacies at least monthly, the frequency of these interactions potentially indicates that consumers perceive retail pharmacies as dependable health care establishments.

Because of these factors, many consumers view retail pharmacy organizations as viable partners in the larger clinical trial ecosystem. In fact, clinical trial participants are already familiar with the use of retail pharmacies as a component of the research program and indicate high levels of satisfaction (57%), similar to those seen in clinics and physicians' offices (53%) (Figure 3).

More importantly, about 70% of trial participants live more than two hours away from a clinical research site. With 11-14 clinic visits required for pivotal trials, about 51% of respondents indicated that the logistical convenience of their retail pharmacy locations would be a driver in their willingness and ability to participate in trials.

Previous research also indicates that to drive increased diverse patient enrollment in clinical trials, the development of meaningful, ongoing and mutually beneficial relationships between patients and providers is critical. This continues to hold true, with 41% of respondents citing physician and staff trust as a major motive to participate in retail pharmacy-supported clinical trials. In addition, our results indicate a willingness to participate in clinical trials regardless of race (24% White; 29% Hispanic or Latinx; 31% Black or African American; 63% American Indian, Alaska Native or Pacific Islander) and geographic setting (24% suburban, 30% rural, 34% urban).

However, barriers to uptake within the retail pharmacy setting remain. Specifically, clinical trial education and communication remain the largest hurdles, with 25%–35% of consumer respondents indicating limited top-down initiation coming from retail pharmacy physicians and staff.

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I think since they have that outreach, they may even have a little bit more of a trust factor. The number of times that a patient goes into their pharmacist vs. the time that they go into their doctor, you may have that level of immediate trust and familiarity that could be leveraged by those retail pharmacies. I think that that’s a factor that could come into play.

Global Trial Leader, large pharma

Retail pharmacy footprint across community types

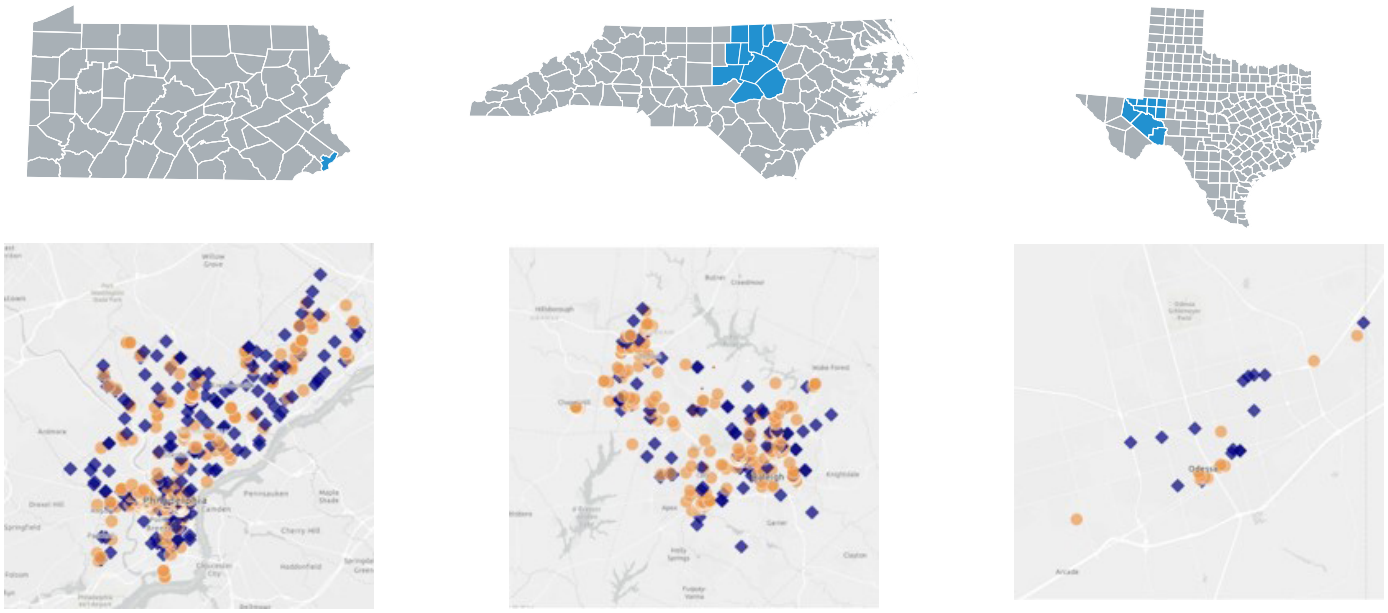
Given how critical convenience of site location is to attracting trial participants, EY-Parthenon teams conducted a geospatial analysis of urban (Philadelphia, Pennsylvania), suburban (Research Triangle, North Carolina) and rural (Odessa, Texas) communities to better understand how much time would be saved for an average enrollee if they were traveling to a trial site vs. a retail pharmacy (Figure 4).

Figure 4: Proximity to retail pharmacies and clinical trial sites

Urban community (Philadelphia, PA)

Suburban community (Research Triangle, NC)

Rural community (Odessa, TX)



Source: EY-Parthenon analysis

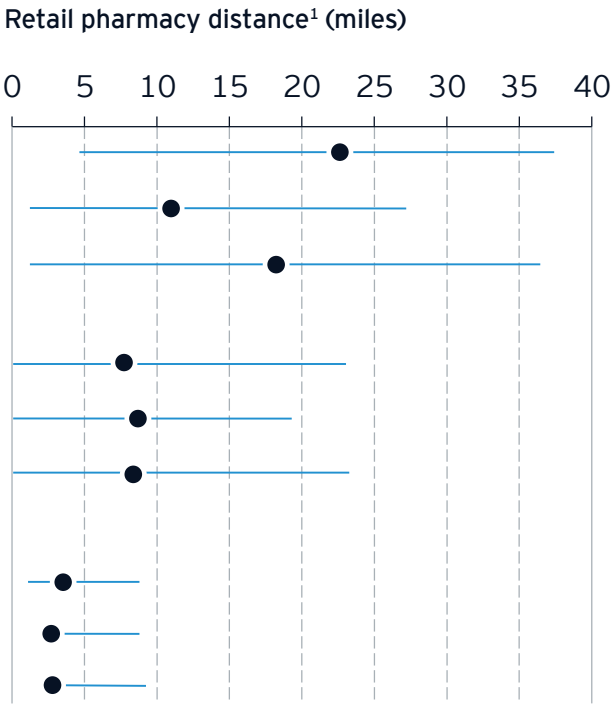
Trial Site

Retail Pharmacy

Our analysis indicates that more than 85% of the US population lives within 10 miles of a retail pharmacy. However, in suburban settings such as North Carolina's Research Triangle, adding retail pharmacy clinical research locations could be the most beneficial, reducing patient travel about 40 miles per visit. In urban settings, such as Philadelphia, retail pharmacy clinical sites have the potential to reduce patient travel 10-20 miles per visit and eliminate parking logistics. Due to city planning, more rural geographies tend to have a concentration of trial sites and retail pharmacies. While narrow deployment of clinical research to surrounding retail pharmacies has the potential to reduce local patient transportation by 20%-30%, expansion of clinical trial services into broader geographies could reduce patient travel logistics >90% (Figure 5).

Figure 5: Distance of retail pharmacies from trial sites

	Matched trials	% trials in region
Research Triangle		
▸ UNC – School of Medicine	1,474	25%
▸ Wake Research Associates – Raleigh	473	8%
▸ Duke Clinical Research Institute (DCRI)	458	8%
Philadelphia		
▸ University of Pennsylvania	5,212	34%
▸ Temple Health – Fox Chase Cancer Center	1,584	10%
▸ Children's Hospital of Philadelphia (CHOP)	1,354	9%
Odessa		
▸ TX Oncology – Odessa West TX Cancer Center	63	46%
▸ Naidu Clinic	24	18%
▸ Permian Research Foundation (PRF)	19	14%



- ~70% of clinical trial participants live >2 hours from clinical site
- On average, each participant visits the clinic 11x-14x for pivotal trials
- Many clinical trial patients are physically impaired requiring support from caretakers, 2x the travel burden

~35% reduced patient transportation burden with narrow site expansion

>90% reduced patient transportation burden with broad site expansion

1. Relative to the top three trial provider locations per geography

Source: EY-Parthenon geospatial analysis; ScrapeHero; Informa SiteTrove; Moore et. al. BMJ OPEN (2020)

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The mentality is, there’s a CVS or Walgreens on every corner, and in some places, it’s pretty much true. I think it’s an attractive way to avoid needing patients to make a two-hour drive to a central site. Further, I think the CVS, the Walgreens of the world, have recognized this.

Former Senior Scientific Director and Senior Fellow, large pharma

What retail pharmacies need to do next

As previously illustrated, the footprint of retail pharmacies positions them well to serve as convenient locations for patients to access clinical trials more easily. This would likely lead to an increase in the participation of more diverse patients while also potentially reducing the local patient transportation distance by 20%-30% and by more than 90% for non-local patients.

EY-Parthenon research and experience working with both retail pharmacies and pharma companies show retail pharmacies are well positioned strategically to support the efforts of various R&D organizations by:

- Providing increased physical and psychological patient access — indicated by high levels of trust (32%) and higher health service engagement driving greater likelihood of clinical trial participation (48% when receiving additional care services)
- Propelling decentralized clinical trial hybrid trial adoption by serving as community-based access points for potentially life-saving clinical trials, supporting RWE generation and leveraging large digital assets for data consolidation
- Leveraging their position as a member of local communities to address the two largest factors inhibiting clinical trial participation — patient communication and education
- Using their role as data aggregators for insurance providers and health care systems to collect patient information to support patient recruitment and trial site selection

However, there are still additional capabilities that sponsors believe retail pharmacies should invest in to enter the clinical trial market. These include developing additional product storage, ensuring good clinical practice compliance for their specific policies and procedures, upskilling their current staff to provide quality training and qualifications, and developing or purchasing the appropriate technology to capture and safely store sensitive patient data. Leveraging all these capabilities needs to be considered early in the design of trials for both sponsors and CROs.

EY-Parthenon teams believe that market, regulatory and community pressures create a critical opportunity for increasing access to clinical trials, specifically in underserved communities. It is of utmost importance that sponsors and CROs identify how to integrate and partner with retail pharmacies early in the trial design as well as throughout the execution. We are able to help all stakeholders consider how to leverage this new resource.

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