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Assessing Sponsor, Site, and Patient Receptivity to Retail Pharmacy Involvement in Clinical Trials

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Executive Summary

National retail pharmacy chains (e.g., CVS, Walgreens, Walmart, Amazon) have entered the clinical research enterprise with the promise of making clinical trials more accessible to patients and more efficient to research sponsors. To date, however, sponsor, investigative site, and patient receptivity to retail pharmacy involvement in clinical research has not been empirically explored. Tufts CSDD conducted 31 interviews among biopharmaceutical executives, investigative site staff, and patients, to understand the viability and growth potential of potential retail pharmacy services across the various stages of a clinical trial. Interviewees were excited about the ability of pharmacies to assist with site and patient identification and recruitment and highlighted the potential for increased patient and site staff convenience. However, while interviewees saw an opportunity in what retail pharmacies can offer, all three stakeholder groups showed concerns around regulations, quality, and staff competency. Interviewees stated that infrastructure needs to be set up very intentionally and with the support of sponsors, sites, and patients, for retail pharmacies to conduct clinical trials successfully and safely.

Background

Clinical trials have long been criticized for their lack of diversity, with efforts to recruit from underserved communities falling short. Accessibility of clinical trials has been identified as a key barrier to the participation of minority groups[1]. In their entrance into clinical research, retail pharmacies have stated that their accessibility to patients can increase clinical trial participant diversity, in addition to increasing trial efficiency[2–4]. Retail pharmacy success in delivering the COVID-19 vaccine to socially vulnerable communities helped spur this entry, with retail pharmacies relying on their role in the vaccine rollout and the ubiquity of their locations to support their proposed involvement in clinical trials targeting a broad range of diseases[2,3]. CVS Health, which established their clinical trial services arm in 2021, successfully assisted in recruitment for COVID-19 vaccine trials in addition to vaccine delivery, and relied on this experience to extend their entry into the broader clinical research arena. Unexpectedly, CVS' shuttered their clinical trial services offering in May 2023 which seeded doubt across the industry around the viability of retail pharmacy involvement supporting the conduct of clinical trials. [5].

To address these concerns, as well as identify primary barriers and opportunities to retail pharmacy involvement, Tufts CSDD conducted 45-minute virtual interviews with 31 biopharmaceutical executives, investigative site staff, and patients. These in-depth interviews, held between June and July 2023, provide essential stakeholder feedback and perspectives on the viability of retail pharmacy involvement in clinical research.

Considering retail pharmacies' stated ability to recruit diverse participants, it is of particular interest to gather patient perspectives from diverse disease indications and demographic backgrounds. Additionally, biopharmaceutical executives and site personnel can provide important expertise on developing appropriate infrastructure, staffing, and training necessary to provide clinical trial services.

Interviewees shared their overall attitudes on the involvement of retail pharmacies as well as perspectives on potential retail pharmacy-supported trial execution models throughout the clinical trial life cycle, including, but not limited to:

- Site identification and study start-up
    - Pharmacy identifies sites in areas with target patient population.

- Patient Identification
    - Pharmacy identifies potentially eligible patients through database and contacts them via email, phone, in person, or other. Further involvement may include:
        a. Patient is sent to traditional site for screening.
        b. Pharmacy pre-screens, full screening is conducted at traditional site.
        c. Pharmacy fully screens, sends to traditional site for consent and enrollment.
        d. Pharmacy screens and enrolls, but all visits are conducted at traditional site.
- Execution
    - Patient goes to pharmacy for some type of care or procedure. Further involvement may include:
        a. Patient goes to closest pharmacy for basic labs and vitals.
        b. Pharmacy acts as satellite location under oversight of primary site PI.
        c. Pharmacy acts as a site and conducts all activities of a traditional site.
        d. Pharmacy provides some other type of service, such as telehealth.
- Long-term follow-up
    - Patient goes to closest pharmacy for follow-up visits.

Interviewees included 10 biopharmaceutical executives (sponsor interviewees) from six large and four medium pharmaceutical or biotechnology companies, with a range of seven to 34 years of experience in the industry. Half of sponsor interviewees specialized in clinical operations or development, three worked in patient engagement or health equity, with the remaining two interviewees specializing in medical affairs and innovation.

Half of patient interviewees were male and half female, with seven out of 10 identifying as non-white. Seven out of 10 patient interviewees had never participated in a clinical trial prior to the interview. Two out of 10 site personnel interviewees were clinical research coordinators (CRCs), five were administrative personnel, and three were principal investigators (PIs). Six out of 10 site interviewees worked at Academic Medical Centers, with four interviewees working at a Site Network, Research Institute, or Community-based hospital.

Site Identification and Study Start-Up

Sponsor interviewees highlighted potential in the possibility of retail pharmacies contributing to site identification by identifying geographic areas with high numbers of the target population for a given trial. This service offering was viewed as targeting an existing need in addition to being low risk.

Patient Identification

Most interviewees viewed retail pharmacy identification of patients positively, with all stakeholder groups further highlighting that a more mainstream push for trial recruitment may also positively impact awareness of clinical trials among the public. Interviewees emphasized how the engagement of retail pharmacies could promote clinical trials more effectively than traditional research sites, given the higher frequency of interactions with the population.

> ***"They bring in patients who don't necessarily have insurance, and are not necessarily even coming to the pharmacy, but may just be there to buy toilet paper and say, 'I can make 50 bucks doing this clinical trial."***
>
> —Site Interviewee

However, there was some skepticism around how much retail pharmacies could improve diversity in clinical trial recruitment, a major value proposition of retail pharmacy involvement. All stakeholders agreed that retail pharmacies have large databases of patients, are located in diverse areas, and have a broader reach than most investigative sites, which may lead to improved diversity in clinical trial participants. However, in cases where the pharmacy only contributes to recruitment and the patient still needs to travel to study visits at a traditional site, interviewees shared that this strategy would not reduce the burdens of travel, time, and cost, that typically represent barriers to recruitment and retention of diverse populations.

> ***"I do think that they're going to get that diverse population. But then that follow through afterwards. I think it's where there's going to have to be some strategic planning."***
>
> —Site Interviewee

Some patient interviewees believe that their pharmacist does not know enough about their medical history to refer them to a clinical trial that is right for them. Patients also shared discomfort with pharmacists being able to access medical information supplementary to what is already available to them, such as lab results, to assess their eligibility.

> ***"I don't know my pharmacist personally. I don't think they know much about my health in general... For them to refer me to a study clinic for a trial is odd to me, because they don't even know what my health history is and why I would be appropriate for one."***
> – Patient Interviewee

Sponsor interviewees identified an additional barrier to patient identification in the "recruitment funnel", described as an outcome of inviting a large number of patients to the study to undergo screening where only a small number will actually be eligible to participate. This was a major concern across sponsor interviewees, particularly due to a perceived lack of experience among pharmacy employees in determining a patient's eligibility. Pre-screening was suggested as a compromise, where pharmacy staff can be trained to conduct basic screening activities, but the site would still fully screen patients—potentially avoiding overwhelming the site with ineligible patients. However, if patients do not consent to pharmacy staff accessing information necessary for pre-screening, as some patient interviewees indicated, then this solution may not be feasible.

Execution

Staff Competency

Each stakeholder group acknowledged feeling distrustful of retail pharmacy staff competency and their involvement in clinical trials. Many interviewees held expectations about the traditional roles of pharmacy staff and expressed doubts over their ability to take on trial-related tasks in addition to their existing responsibilities. Patient interviewees mentioned specifically that they would be comfortable with getting basic lab work done at a pharmacy but would prefer to have any medication or treatment related to the trial administered at the hospital or site.

"If it directly affects my infusion or whatever medication I'm getting, then of course I'd want to be someplace where they know about it. Just your normal blood draw and checking your BP, that's fine…But if it's anything specific…I would rather have that done in the hospital setting…because there's no guarantee that the person at that CVS or Walgreen's knows what they're looking for."
—Patient Interviewee

Site and sponsor interviewees also approved of the administration of lab work and collection of vital signs by retail pharmacy staff but expressed similar concerns as patients around more advanced or technical procedures and patient safety.

"Are these clinics even equipped to handle emergency situations?"
—Site Interviewee

Site and sponsor interviewees highlighted important differences between clinical care and clinical research that pharmacy professionals may not have experience in conducting. These included assessing for adverse events, consenting, and differences in dispensing medication such as blinding, randomization, and placebo creation. Interviewees were also concerned about whether the pharmacy would dedicate staff to the trial, or if the staff would be required to split their time between clinical research and pharmacy duties when receiving time-sensitive samples. For these reasons, site and sponsor interviewees emphasized the need for experienced and dedicated clinical trialists to oversee any retail pharmacy-based trial to ensure patient safety and trial quality.

Loss of oversight

In cases where participants receive most procedures at a traditional site, but undergo some basic procedures at their local pharmacy, PIs were uncomfortable with the loss of oversight over patient care. Some site

interviewees were concerned about losing routine clinic visits, which play a crucial role in ensuring participant safety and monitoring for any possible adverse events.

Both sponsor and site interviewees shared their reservations regarding remote PIs and remote oversight, highlighting notable instances where absence of in-person oversight resulted in lapses in regulatory compliance. Interviewees further noted that a remote PI would need to travel significant distances before being able to assess a participant in the event of safety concerns or adverse events. Furthermore, sponsor interviewees expressed their concerns about the capability of pharmacies to adequately train research-naïve staff to comply with regulations. Interviewees emphasized that pharmacies must be prepared to demonstrate robust security practices and regulatory training; any failure in regulatory compliance can jeopardize trust within the population and hinder future participation in clinical trials.

Site personnel interviewees were particularly apprehensive about accountability. They raised questions about whether pharmacy staff would be held accountable for deviations, whether the accountable party would be identifiable, and whether pharmacies would be held to the same standards as traditional sites.

Data privacy

Although most interviewees were unconcerned about data privacy within the pharmacy systems due to existing regulations such as HIPPA, site and sponsor interviewees shared apprehensions regarding the transfer of data between the pharmacy and clinic site. Patient interviewees, while less concerned about data privacy, recommended that pharmacies implement a private area for clinical research both for procedures and to discuss any sensitive topics. Many stakeholders believed that adjusting the pharmacy infrastructure would be a simple solution to maintain patient privacy. Recommendations for infrastructure adjustment included creating a space for private conversations between the site staff and participants, as well as a dedicated area for storing study documents and drugs.

Convenience

Convenience was highlighted as a primary benefit to pharmacy involvement in the execution stage, particularly the ability of patients to conduct study visits at a location closer to their home. Interviewees suggested that this could improve patient recruitment and retention by removing commonly cited barriers such as travel time and costs. Patients and site interviewees also highlighted the importance of free and accessible parking at pharmacies compared to the typical site, particularly for low-income, elderly, and disabled patients.

"Parking is a good 20-minute walk…and we have studies specifically focusing on elderly patients."
—Site Interviewee

Long-Term Follow-Up

Sponsor interviewees viewed retail pharmacy involvement in long-term follow-up (LTFU) positively due to lower risk for adverse events, decreased need for major procedures, and the fact that most data collection has already been completed. Additionally, LTFU is often done remotely, making this stage more adaptable for further innovation. Allowing patients to conduct LTFU at their closest retail pharmacy would also increase patient convenience, removing the need to travel to the research center after the trial has ended.

Conclusions

The results of this research provide insight into the viability and growth potential of retail pharmacy chain involvement in clinical trials. The identified benefits and barriers associated with pharmacy involvement across the various stages of a clinical trial carry significant implications for the integration of pharmacies into the clinical research enterprise.

The convenience offered to patients was seen as a key advantage, potentially streamlining participation and contributing to improvements in recruitment and retention effectiveness. Moreover, the ability of pharmacies to raise awareness about clinical trials introduces a novel channel for enhancing recruitment efforts, tapping into their widespread presence within communities. The expansive databases maintained by pharmacies underscore their potential as valuable resources for site and patient identification.

However, the barriers identified in this study highlight crucial challenges that need to be addressed to fully realize the potential benefits of retail pharmacy chain involvement. Building trust among sponsors, sites, and patients was seen as a pivotal factor, requiring concerted efforts to establish credibility and transparency in pharmacy-led clinical research initiatives. Stringent regulations present a formidable challenge, demanding a thorough understanding and compliance framework to ensure the seamless integration of pharmacies into the clinical trial process. The ability to hire experienced clinical trialists to oversee research-naïve pharmacy employees emerged as a deciding factor in achieving these goals.

Concerns raised regarding the lack of sufficient physical space and adequate privacy underscore the importance of building appropriate infrastructure to facilitate effective and ethical clinical trial conduct within the retail pharmacy setting. The identified issue of the “recruitment funnel” emphasizes the need for strategic interventions, such as pre-screening, to address bottlenecks and enhance the efficiency of retail pharmacy-supported participant recruitment.

Interviewees across stakeholder groups shared that their willingness to work on—or participate in—a retail pharmacy-supported clinical trial is dependent on additional details provided regarding the quality and training of retail pharmacy staff and the quality and appropriateness of dedicated physical space and infrastructure. This lack of detailed information on the strategies and execution models that retail pharmacies plan to employ also limited the scope of this study. Future research may benefit from investigating case studies of pharmacy-supported trials to better determine the potential of these models.

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