Exploring the importance of HCP-based clinical trial recruitment and critical success factors

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Underscore Marketing compares the legacy approach to clinical trial recruitment with considerations for the new paradigm induced by COVID-19

Successfully recruiting patients to clinical trials comes with a host of challenges given their nuances and complexities. Recent data from clinicaltrials.gov counted 409,300 ongoing clinical studies running in 50 states and 220 countries, with 151,155 of them running in the US alone. These studies traverse recruitment, from searching for common healthy patients to sourcing those with highly specific rare diseases. According to BioPharmaDive: 85 per cent of all clinical trials fail to recruit enough patients, 80 per cent are delayed due to recruitment-related problems, and patient dropout rates are poignantly high.

The global race to find an effective and safe vaccine for COVID-19 raised common awareness of clinical trials given daily front page news headlines for the better part of 2020. However, patients willing to participate in clinical trials are outliers rather than population norm. This is particularly applicable for any clinical trial that requires recurring monitoring over an extended period. Patient awareness of clinical trials is low unless it relates to a disease without a cure but that has an engaged patient and/or caregiver population – such as ALS (Amyotrophic Lateral Sclerosis). For example, ALS.org provides its patients with the ability to search for clinical trials that are directly associated with ALS, thus capturing an audience that is already highly engaged. But this is a unique case.

Research by CISCRP highlights the **positive correlation between patients enlisting and the recommendation coming from their physician**: 64 per cent of patients prefer to receive information about a trial from their healthcare provider rather than from a third party.

However, less than 0.2% of patients are referred to clinical trials by their physicians, illustrating the challenge in enrolling HCPs in sharing clinical trial opportunities with their patients at mass scale.

Drilling down, Underscore conducted a survey of 100 neurologists that asked how physicians prefer to learn about trials - from clinical site outreach, clinical trial coordinators and/or conferences.

A clear problem was identified: *many trials only have one site coordinator, making it almost impossible for them to reach every potential physician that could recommend a patient.*

So, what is the most effective way to recruit patients from all backgrounds to participate in clinical trials?

Taking all the above into consideration, Underscore's recommendation for optimal clinical trial recruitment is to focus on the following key themes:

1. Location
2. HCP awareness
3. Automation-based clinical site outreach
4. Decentralization where feasible

1. Location

Patients consider their commute when seeking health care. In research by the National Center for Biotechnology Information, the Washington State Office of Financial Management reported that on average, a patient is willing to travel less than 30 minutes to receive urgent medical care, and 10 per cent less for routine care. When accounting for older patients it is imperative to reduce their required time investment as they are likely to be less patient than younger participants.

Proximity of study centers in relationship to participants is key. Around 70 per cent of prospective participants live more than two hours from trial sites. Strategic site selection can significantly reduce patient travel times. There is significant value in patient recruitment from areas close to study centers, even in urban environments. Choosing a study location close to a larger population increases the probability of satisfying the recruitment number.

Artificial intelligence (AI) can help. AI applications provide scope for decreasing required patient-time investment irrespective of study site location. These algorithms utilize computer simulations of nature's methods of variation and selection to propose solutions to related problems.

Notably:

- Evolutionary algorithms designate the optimal study center for each potential participant
- Flexibility to scale staffing has profound potential to empower site coordinators to reach the largest possible physician pool via strength in their numbers. Scalable site staffing is the AI's ability to allocate staff to support a specific clinical trial given participation by location. It also allows for the pairing of specific staff with specific patients to help personalize the process.

2. Health Care Professional (HCP) Awareness

Clinical trial enrollment and retention levels lack widespread HCP referrals. CISCRP research points to three key causes of this:

1. Suboptimal access to local trials-based data
2. Insufficient time to build awareness of local trials
3. A gap in knowledge of local research centers and staff

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HCPs engage regularly with patients – their safety and longevity as the overarching goal of their care. As a result, most patients trust their HCPs and follow their advice, uncovering an opportunity to build awareness and collaborate with physicians to enlist and keep patients within trials. Building trusted relationships with HCPs is imperative.

The most effective way to open clinical research data to HCPs and build awareness is through nurturing of deeper relationships between physicians and clinical research personnel.

- **Clinical research professionals (CRPs) who contact HCPs in their clinical trial recruitment catchment areas are taking the first step to building a strong HCP-centric network with an expansive subnetwork of potential trial participants.** Efficient two-way communication, robust screening methods and seamless patient clinical-trials-based education makes a drastic difference.
- **CRPs who disseminate clinical-trial-related information can ensure physicians and nurses are fully informed of upcoming new trials.** Such efforts are optimized by offering easy-to-read information comprising:
  - A holistic summary and duration of the trial
  - Eligibility parameters
  - Visit, procedure, and test cadence
- **Providing feedback using the HCP's preferred channel is a key follow-up activity that often increases their comfort recommending their patients for a CRP's trial.** This confidence is then compounded by the positive nature of the prospective treatment's patient outcomes.

- **CRPs operating in de facto study liaison positions can effectively support HCPs with pre-identifying trial participants**. Part of the CRP's role is to also act as a qualified point of contact for interested potential participants who are referred to by the HCP themselves. And of equally critical importance, conversely, is that CRPs keep HCPs informed of their patients' progress post clinical-trial enrollment. They may also work to inform physicians of novel clinical trials, handle inquiries and keep them cognizant of the necessity to communicate with patients regarding clinical trial opportunities.

- **Providing patient-centric educational resources for HCPs to disseminate and leave in waiting rooms will build awareness tenfold.** CRPs should strive to ensure their site contact and website information is easily found throughout the content, while it is equally important that there is a well specified call-to-action prescribed for the patient curious to discover more about such trials.

- **Maintaining HCP engagement for the duration of the trial itself is just as crucial as recruitment steps.** CRPs should provide frequent status updates pertaining to patient progress in the trial and send trial results to the HCP when logical to do so. Furthermore, trust – a critical pillar of HCP awareness and subsequent patient-to-trial referral – is built by informing patients that they intend to maintain clear lines of communication with their HCP throughout the trial, while relaying to the HCP that their role as the primary care doctor or nurse is esteemed, has the same effect.

3. Technology & Automation-based Clinical Site Outreach

Technology has brought a new clinical-trial paradigm to the forefront spanning several areas. The migration of clinical-trial operations in closer proximity to patients has been facilitated by a nexus of emerging technological and service-based forces.

Tools including electronic consent, tele-healthcare, remote patient monitoring, and electronic clinical-outcome assessments (eCOAs) **empower investigators to keep communication with trialists while mitigating the need for in-person visits.** Mobile and home healthcare, in addition to alternative-care sites, make it possible for more procedures to take place externally of research centers.

Returning to BioPharmaDive's report, Nick Darwall-Smith explains that, when done properly, leveraging technology to decrease the number of site visits needed to participate in a trial would be "transformational," but such advances must be executed in a truly patient-centric manner. Wearables, tele-health visits, online patient diaries, eConsent, video dosing confirmation, patient apps and numerous other technologies already available all provide immense potential for making step-changes in the feasibility and availability of decentralized clinical trials.

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In terms of automation, surrounding the patient with reminders and messages helps the patient access information how they want, whether it is through email, a patient portal, or text messages. Text messages have emerged as a critical tool for patient outreach. Unlike the patient portal, text message reminders reach the patient directly via their SMS inbox and remove obstacles patients face with logging into and accessing their patient portal, thus greatly decreasing the logistical friction related to healthcare visits – including for clinical trials.

4. Decentralization

The COVID-19 pandemic turbocharged the adoption of decentralized clinical trials while displaying the key benefits of virtual trials and enhancing the patient and physician experience. As health-system resources became fully occupied with COVID-19-based care and travel was severely hindered by social distancing, according to a McKinsey report, patient access to trial sites declined by 80 per cent.

Trial sponsors responded by leveraging tools including remote consent and patient monitoring, videoconference assessment and at-home procedures like phlebotomy. The notion of meeting patients where they are when running clinical trials existed long before the COVID-19 pandemic and strived to enhance both patient convenience and experience. Bringing trial activities to the patient remotely and in their homes helped boost participant convenience and experience, with 72 per cent of physicians reporting a comparable or enhanced experience with remote engagement.

- **Decentralization extends trial access to reach a greater number and, potentially, a more diverse patient cohort.** This means that age, gender, race, and cultural disparities that have plagued clinical trials to date, can be alleviated.
- **Decentralization helps to streamline the work of trial investigators** by enabling conventional site activities – drug administration, evaluations, and data validation – to be conducted remotely by others or even by trialists themselves.

5. Diversity Bias

The global race for an effective Covid-19 vaccine propelled clinical trial awareness. This also drove higher visibility of the systemic inequalities and bias of legacy approaches to trial recruitment.

In the FDA (Food and Drug Administration) 2020 data snapshot of trial diversity and inclusion:

- 75% of participants were white
- 11% Hispanic
- 8% Black or African American
- 6% Asian
- No inclusion for Native Americans

In the 2021 snapshot the FDA noted minority enrollment had risen in categories of Black, Asian, and Hispanic/Latino ethnicity, yet **there were still many programs with low representation of certain racial and ethnic groups.**

"Nearly half of black patients with metastatic breast cancer are never informed about clinical trial participation, despite the fact that most are open to the idea",

reported Stephanie Walker, RN (Registered Nurse) of the Metastatic Breast Cancer Alliance of New York reported during ASCO (American Society of Clinical Oncology) 2022.

A Bloomberg Businessweek + Equality article, *Alzheimer's Trials Exclude Black Patients at 'Astonishing' Rate* stated, "black people are more prone than white people to develop Alzheimer's yet represent only 2 per cent of those in clinical trials, but for years the pharmaceutical industry has left them out of trials intended to prove new drugs are safe and effective."

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Legacy approaches in recruitment and factors to drive adoption, equality, and diversity have historically not been a significant component or requirement in the recruitment equation.

- **It is critical to accelerate minority recruitment and retention of investigators and trial administrators.** This requires a grass roots approach verses grass tops, to engage and educate community-based HCPs, clinics, pharmacists and leaders of disease-state prevalence and trial awareness.
- **In addition to advocacy, CROs should engage non-traditional groups working to level the playing field and establish novel approaches to current or less familiar ecosystems.** Organizations including MedTech Color Collaborative and the Metastatic Breast Cancer Alliances, Black Experience of Clinical Trials, and Opportunities for Meaningful Engagement (BECOME) are setting a new standard. Meanwhile, retailers like CVS Health and Walgreens Boots Alliance are identifying issues, opportunities, and technology solutions to guide diverse engagement, education, and access to trial participation.
- **Next-generation decentralized trial recruitment and delivery is needed.** In a PWC overview of disruption on the horizon, large retail pharmacies with a wealth of patient data and sophisticated infrastructures are creating interconnected health systems, with the ability to transform and disrupt clinical trial delivery models, reduce patient barriers to participation, and assist pharma and biotech organizations in connecting with patient populations. The report noted, "large national retail pharmacies, health clinics and community practices have a broader geographic reach and exponentially more opportunities to engage with patients compared to academic medical centers and research hospitals, allowing for trial activities to be delivered locally and virtually, leading to stronger research findings."

At the forefront of the disruption, with a focus on community engagement are Walgreens Health and CVS Health, with both hiring chief clinical trial officers with the goal of ensuring community awareness, easier participation, enhanced experience, retention, and effectiveness of research.

In Conclusion

While there are considerable key behaviors and processes that can be adopted by different industry players such as CRPs, patients, and ever-advancing technology, the potential for HCPs to enable well-attended and successful clinical trials is significant.

To uncover the opportunities for referring their patients to clinical trials, physicians and nurses should:

1. **Connect with local researchers and centers** to understand how they can contribute as referrers, request engagement with research liaisons to garner real-world, trial-based data, or join professional organizations like ISPOR, DIA and ACRP.
2. **Stay updated on local research**, be it searching for applicable clinical trials on a per-patient basis at routine exams through relevant applications and websites, staying close to the most recent clinical-trials industry updates through appropriate subscriptions, or training staff on the clinical research process and participation protocols to enable clearly answering patient queries.
3. **Make educational clinical trial resources available** in waiting areas and exam rooms, encouraging frank conversations when patients challenge with alternative treatment paths, or identify patients that are a strong match for clinical trials and are highly probable to fulfill all necessary exams and procedures.

Underscore's clinical trial recruitment reaches both patients and physicians with *omnichannel messaging*. Each clinical trial campaign is different depending on the disease state, size of the trial, and budget.

- **The key to enlisting more physicians is through targeting and personalization from the clinical research professional.** HCPs may learn about clinical trials from the CRP; however, that outreach is limited. Using a CRM email campaign with a target list and personalizing the messaging from the CRP is a tactic to generate more awareness, in tandem with other channels such as:

  - SEM (Search Engine Marketing)
  - Programmatic
  - Social media
  - Conferences
  - Journals

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It is important to note the nuances of each unique campaign, but this paper posits that **personalization and targeting will offer the best path to generating results**. Using physician-level data to identify doctors showing interest in the trial and generating outreach from the CRP will help move the physician from awareness to the consideration phase.

- **Patients are more willing to join a clinical trial if recommended by their physician.** In addition to targeting their physicians, generating awareness through SEM and disease-state associations will help foster the conversation between doctor and patient.
    - Once a patient is enrolled, communication throughout the trial is critical to prevent drop-off. The more communication, the more patient progress can be tracked. And if there is a drop-off, identify areas in need of improvement. Furthermore, when utilizing omnichannel and adherence campaigns, campaign measurement and optimizations are vital to gauging success.
    - Identify the optimal way to communicate with the patient – be it via text message, email, patient portal or phone – and if they have a caregiver, make sure to factor them into the communication.

The inherent nuances of each clinical trial must be carefully considered and calibrated – rather than cookie-cutter approaches – to attain optimal results. The combined research in this paper highlights the **need for a custom approach to successful clinical trial recruitment by engaging HCPs and patients directly**. Numerous factors including location, HCP awareness, technology, decentralization, and diversity bias must be considered to empower both potential participants and HCPs to take part and remain engaged for the duration of the specific clinical trial.

About the Contributors

Sonja (Sparkle) Fisher

Sonja is a marketing leader with 15+ years leading integrated omichannel and digital marketing communication strategies for fortune 500 Pharmaceutical, Biotechnology and global technology companies.

Her passion is in building bridges through the interconnectivity of evidence and data, and translating insights into patient, caregiver, and HCP care-pathways and integrated health equity ecosystems; initiating customer activation and delivering focused next generation education, experiences, and sustainable solutions to improve patient and caregiver lives.

John Marino

John Marino is Underscore's VP, Strategy and brings 15 years' experience and a breadth of marketing technology and automation expertise to the table. John's skillset comprises omnichannel program development encompassing targeting media tactics tailored to strategic imperatives.

He is passionate about leveraging data to effectively map user journeys, segmentation strategy, and tailoring content and messaging for target audiences based on their online (digital engagement) and offline (engagement with reps, script data) behaviors.

John has worked in multiple categories in pharma including both HCP and patient campaigns in both the rare disease and medical device space.

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