Strategies for 21st Century Patient Recruitment

Each new year brings with it new challenges and approaches to clinical research. As we approach the quarter-way mark of the 21st Century, what are some of the emerging trends in patient recruitment that can be expected to take hold and how can they be optimised?

Lisa Dyment and Michael Stratton at PPD, part of Thermo Fisher Scientific

In a recent survey conducted by Industry Standard Research (ISR), of 150 decision-making leaders at international pharmaceutical and biotech companies, more than half of respondents (55%) said their organisations face challenges with patient recruitment in clinical trials, including patient retention and population diversity (1). Some of the ways that the clinical research industry is responding to these challenges include:

- Increasing decentralised capabilities to allow for virtual patient visits and remote patient monitoring, database modelling, and more targeted direct-to-patient recruitment marketing, all of which enable a study sponsor to make course corrections, if necessary, during a trial
- Tapping into patient communities and patient advocacy groups to offer education and easy access to clinical trial information, as a way of overcoming the challenges presented by small pools of patients available for multiple competing trials

A strategic combination of marketing, technology, and patient engagement will always be required to meet patient recruitment goals.

e-Recruitment and Virtual Screening

According to another recent market report, "The majority of people now learn about clinical trials through online sources compared to traditional print or TV/radio outreach" (2).

e-recruitment leverages the power of the internet to enroll qualified trial candidates in a more timely and efficient manner than traditional advertising methods. Numerous e-recruitment tactics have emerged in recent years, including internet searches, social media, web listening, and online screeners.

By utilising pre-screening of patients in real time, initial analysis of patient suitability can be explored without the patient having to visit a study site in person, and without study staff having to take time out of their day for screening activities. The most sophisticated systems include a virtual visit platform and a First Office Visit (FOV) checklist to ensure the application of best practices, and a performance management dashboard to monitor and measure every patient interaction. Technology has also afforded the opportunity to fully customise the patient pathway on a study-by-study basis. From a recruitment perspective, this can range from trials for vaccines, which are relatively straightforward and involve healthy volunteers, to highly complex, chronic conditions like Crohn's disease, which requires patient identification of flares and self-reporting of symptoms.

Opt-In Databases and Database Modelling

For the most effective and efficient outreach, a recruitment database should contain patients who:

- Opt in and agree to be contacted – making it easier for sponsors and clinical research organisations (CROs) to find, evaluate, and recruit participants from a wide geographical area
- Express interest in clinical trial opportunities
- Have the specified condition and/or required medications
- Provide location information and other demographics

For example, in the US, patients may opt in to a database through the trial pre-screening process. Outside of the US, the process may vary by country (e.g., in EMEA, the requirements are more stringent and require opt-in and explicit permission to be contacted in the future using specific tactics).

Digital media targeting is a precise tool that uses a patient database (including clinical, lifestyle, and interest data) to narrow recruitment parameters while expanding search scope. In database modelling, a profile of the target patient is created based on successful recruitment in past studies of the same indication, so that the current recruitment efforts can be tailored to find more patients who have similar attributes.

These techniques can be especially helpful in following recent guidance from the FDA, which recommends that sponsors develop and submit a 'Race and Ethnicity Diversity Plan' early in clinical development.

Social Listening

Through monitoring digital conversations such as on Facebook, group chatrooms, or Twitter, social listening gleans insights from patients about how their condition affects their daily lives, their experience with existing treatments, and their openness to participating in a study for a new drug. Social listening can influence strategies for patient recruitment/awareness and patient retention. For example, CROs may maintain organic Facebook pages on various conditions and monitor the incoming comments to generate ideas for building trust in the patient community.

Using indication-related conversations and keywords to engage with potential patients in their existing online communities via social listening, clinical research providers can identify patient concerns and apply those learnings to their day-to-day interactions, actively connecting with the patient over their preferred communication channels to overcome hurdles, and possibly even using the patient's unique insights to shape clinical trial design and protocol development.

Patient Communities and Advocacy Groups

Recruitment strategies that leverage enhanced engagement with patient communities and patient advocacy groups, both online and locally, can also be very useful. The informed patient or care provider looks to these sources to understand their own or their loved one's condition, gain support by sharing their experience, and learn about opportunities for better and potentially more cost-effective care. This patient will often actively discuss their condition with others across various forums, seek out research studies, and assess whether the latter are appropriate for their condition. Making a clinical trial's information available in the places where these patients are learning more about their health issues can provide a direct way to gauge their interest in trial participation.

Mike Strauss, writing in *Applied Clinical Trials*, suggests that "beyond technology solutions, [pharmaceutical] companies [and CROs] are increasingly going directly to the patients with a more humanised appeal" (3). Many are starting to build patient advocacy groups or approach existing ones (e.g., the National Kidney Foundation, or Cystic Fibrosis Foundation) to reach patients in their communities via appearances at health fairs, churches, food pantries, etc.

These efforts can further support recruitment of diverse populations. For example, in a major COVID-19 vaccine trial, tactics deployed to recruit more diverse participants included holding 'town halls' and other events with trusted community leaders, establishing a diversity advisory board and running ads with culturally-tailored messages.

Ultimately, 45% of the participants added by the CRO were from underrepresented groups – compared to the industry average of 25%.

By maintaining a focus on direct patient engagement, and viewing study recruitment as an exchange of information for the patient to consider prior to committing to a trial, patients are put 'in the driver's seat' in making informed decisions about their participation. In addition, when sponsors remove physical barriers to participation, such as offering transportation to study visits, providing pre-paid expense cards for meals and travel costs, and organising certain study visits to be conducted via home health care, patients no longer have to worry about cost or logistics when deciding whether to take part in a clinical trial.

Remote Monitoring

Once patients are enrolled in a trial, retention becomes paramount. Through remote monitoring solutions, clinical trial administrators are able to extend studies more effectively into the lives of trial participants and derive insights in-between site visits that can provide a better understanding of the patient experience and support patient engagement and retention.

Digital tools and systems that support remote monitoring include electronic consent (eConsent), telemedicine, electronic clinical outcome assessments (eCOAs) – generated both during home healthcare visits and by patients as patient-reported outcomes (PROs) – and long-term follow-ups where needed. Tracking site performance and study progress in real time is possible without the need to be on site, and repeatable processes are standardised using document templates and centralised data storage.

Virtual and mobile sites, wearables (such as smart watches), custom smartphone apps, telehealth visits, home care visits, and related tools enable decentralised trials (DCTs) to ease patient participation.

These tools can broaden access and outreach to all interested participants, 'taking the therapy to the patient' wherever they reside. They can also reduce trial complexity. With the right systems in place, remote monitoring can enable sponsors to employ more innovative and efficient protocol designs in DCTs, reducing both the number of patients studied and the time to complete studies.

According to *European Pharmaceutical Review*'s Hannah Balfour, "By opening up the patient pool and reducing the need to travel to attend in-person assessments, decentralised and hybrid designs are expected to improve patient recruitment, particularly in low-income and minority populations [addressing the demographic recommendations of the FDA]…and potentially even reduce trial attrition rates" (4).

Other advantages of remote monitoring technologies include:

- Improved communication and compliance
- Greater flexibility and resilience in the face of challenges
- Better accommodation of adaptive and other new trial designs
- Alignment with growing expectations around real-world data
- Management of data generated by wearables

She goes on to state, "The true impact of technology on clinical trials may not be its implementation by industry, but instead its adoption by patients. The real disruption will come from how patients choose to adopt technology to create the healthcare pathways they desire" (4).

Conclusion

According to a recent Tufts Center for the Study of Drug Development report, "Less than 5% of the US population participates in clinical research (5). This has resulted in approximately 50% of trials not completing due to insufficient enrolment. Retention complicates the problem, as 30% of those who agree to participate in a trial will drop out of studies. The research found screen failure rates in Phase III trials with wearable devices and mobile apps decreased by approximately 10%, while dropout rates decreased from 28.6% to 26.1%." The solutions noted above can further reduce these numbers.

References

1. *Visit: www.ppd.com/pharmaceuticals-research-and-development/*
2. *Visit: https://bit.ly/3N2FUCl*
3. *Visit www.appliedclinicaltrialsonline.com/view/patient-recruitment-goes-high-tech*
4. *Visit: www.europeanpharmaceuticalreview.com/article/168179/clinical-trial-trends-what-will-2022-bring/*
5. *Visit: https://bit.ly/3MD0XeG*

In her role as Executive Director, Patient Enrollment Optimization, **Lisa Dyment** currently leads the patient enrolment optimisation group within **PPD**, part of Thermo Fisher Scientific. The focuses of this group include patient recruitment and retention, patient advocacy, patient travel and reimbursement, and home health care services.

She has over 20 years' experience in the CRO industry in roles involving increasing responsibility for patient-focused services, project management, strategic feasibility, proposal strategy, and strategic partnership oversight. Lisa earned a Bachelor of Arts from the University of North Carolina at Chapel Hill, US.

Lisa.Dyment@ppd.com

Michael Stratton, Executive Director, Patient Recruitment Operations at PPD, part of Thermo Fisher Scientific.

He has over 10 years of experience in the life science space, primarily focused on patient recruitment. He previously served as Senior Director of Global Marketing Operations; Senior Director, Global Contact Center; Senior Director of Marketing Finance and Business Partnerships; and Director of Operations Finance at Accelerated Enrollment Solutions (AES), part of Thermo Fisher Scientific. He earned an MBA from Holy Family University and a Bachelor of Business Administration (BBA) from Peirce College, both in Philadelphia, Pennsylvania, US.

Michael.Stratton@ppd.com