

Financial Barriers to Participation: The Missing Piece of the Patient Centric Jigsaw

The patient centricity revolution has seen the industry pour resources into ensuring clinical trials place the needs of participants front and centre of drug development plans. Collecting insights to inform study design, for example, is a tried and tested method of increasing recruitment and retention rates – but that work is wasted if financial barriers render participation unfeasible. Modern automated payment systems that combine technology and the human touch can ensure people are paid quickly and efficiently and always have a point of contact if things go wrong or they need additional support.

Pharma companies are pouring resources into patient centricity, but complicated or lengthy expense payment processes could be squeezing their return on this investment.

In recent years, the pharmaceutical industry has invested heavily in patient centric programmes and initiatives in a bid to reduce costly patient dropouts and boost recruitment rates.

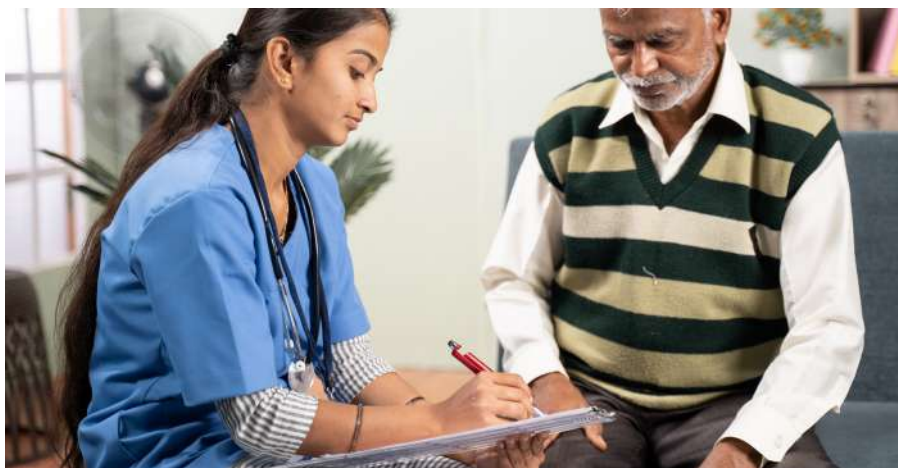
This revolution in thinking has affected every part of the drug development pathway for several reasons – not least that designing a trial to suit the needs of the patient drastically improves clinical outcomes.

Patient centricity in clinical trials can boost recruitment and retention rates in a multitude of ways. Patient-led trial design can, for example, ensure protocols are feasible for those who will take part by steering researchers away from multiple invasive tests or an excessive number of clinic visits.

It can also ensure studies investigate elements of disease that matter to patients, thus increasing the attractiveness of taking part.

More than 75% of people with diabetes, for example, say they want clinical trials to measure the condition's impact on their quality of life, such as the onset of kidney failure and dialysis, or sight loss, rather than surrogate variables, like HbA1c, that tend to be used.¹

The growing recognition that patient insights can help organisations to build and conduct studies people want to be part of, means sponsors and CROs have



put in increasingly more effort to work in partnership with participants.

Patient and public involvement projects are now included at every stage of the clinical journey, including advisory boards and focus groups on everything from candidate selection and protocol design to submissions and marketing materials.

However, many companies are still missing a crucial part of the engagement puzzle. Among the leading barriers to clinical trial participation are financial concerns, an issue that not only blocks access for individuals, but contributes to the enduring legacy of health inequalities.

And by failing to address them, the very same patient engagement teams that spend their days seeking out, collecting, and utilising insights run the risk of wasting all of that hard work.

Recruitment and Retention

The gulf between the number of people who would theoretically be interested in participating in research and those who actually do is staggering.

While more than 70% of the general population believe patients should be given the opportunity to take part, fewer than 5% of people with cancer, for example, enrol on a clinical trial.¹

This has a huge impact on the sector, its progress, and its return on investment.

Globally, more than 80% of studies fail to meet enrolment targets on time,² delaying study initiation – at a cost of between \$600,000 and \$8 million a day³ – and extending already lengthy development timelines. In addition, poor recruitment

is the leading reason for the premature discontinuation of randomised clinical trials (RCTs).⁴

Yet even when trials have recruited adequate numbers to answer the research question, many patients drop out before the study completes. This leaves teams with underpowered studies, insufficient data, and having to choose between re-enrolling or terminating the trial: not an easy decision when replacing lost patients can cost, on average, \$19,533 per participant in direct and indirect costs.⁵

None of this is news to the industry, which has been grappling with recruitment and retention issues for years. Back in 2014, for example, a working group of UK Clinical Research Collaboration-registered Clinical Trials Units decided its top two priorities were “research into methods to boost recruitment in trials” and “methods to minimise attrition”.⁶

Since then, there has been some success, but there is still much work to be done. There has, for example, been an increase in enrolment rates, with one study finding actual enrolment exceeded planned enrolment by 113% in 2019, compared to 96% in 2012.⁷

Yet while this success, which may be credited to improved recruitment strategies and greater awareness of trials among clinicians and patients alike, is promising, it has not been reflected in retention figures. In fact, trial drop-out rates grew from 13.2% in 2012 to 19.1% in 2019.⁷

Patient Centric Thinking

The reasons people drop out of clinical

trials are complex and wide ranging. Individuals may face logistical issues, such as scheduling conflicts, they may forget their appointments, or become too ill to travel to the site. They may feel unappreciated, have some fear and anxiety around the process, or may not have fully understood the expectations placed on them at the start of the process, for instance.

Another important barrier is financial constraints. People taking part in a clinical trial will often need to take time off work for site visits, and pay out of pocket expenses such as lodgings, meals, childcare, and transport. In some countries, these additional outgoings will be set to the backdrop of routine care costs, including co-payments and deductibles.⁸

Under the patient centricity banner, sponsors and CROs have been attempting to eradicate many of the well-known barriers to participation. Decentralised clinical trials, for example, can help remove travel issues, and improved eConsent procedures help sites ensure patients are fully cognizant of the protocol.

However, the financial obstacles tend to be overlooked. Often, participant expenses are still subject to complex claim procedures, and many people face lengthy delays to receiving the promised reimbursements.

This can effectively price people from lower socioeconomic backgrounds out of taking part in clinical trials and, aside from the obvious human cost, the potential impact on study diversity and representation is huge.

Patient populations with historically lower financial resources, including uninsured and those from minority backgrounds, are often underrepresented in cancer clinical trials, for example, whereas those patients with higher socioeconomic status tend to enrol more often. Downstream, these disparities in research cohorts contribute to a lack of data on certain therapies in certain patients, and perpetuate health inequalities.⁸

What's more, this is a problem that is only set to get worse as the global cost of living crisis deepens, disproportionately affecting the poorest people in society.

Automation Augments Human Interaction

Modern automated payment systems streamline the payment and reimbursement process, helping to plug the affordability gap, thus increasing trial engagement, and boosting retention.

Configured on pre-set, study-specific expense limits and policies, industry-leading payment technologies can integrate with all major banks across a range of countries, currencies, and payment thresholds, to deliver speedy payments to all participants,

no matter where they live or how they bank.

Such systems also enable sponsors and CROs to ensure they are fully compliant with the different international regulations on clinical trial payments, by viewing near real-time information about spend, transaction type, thresholds, reconciliation, and invoicing via a reporting dashboard.



Of course, technology alone is never the answer, and this is particularly true of the multifaceted issue of retention.

Clinical trials take place over a period of months or even years, and participants' circumstances are bound to change. If they want to keep people on trial, and the trial on track, sponsors and CROs must make sure people have everything they need to stay engaged, no matter what happens.

This can only be achieved with human interaction and support. Tech-led chatbots or tick boxes are simply not up to the task of maintaining a relationship. That is why it is so important that any platform augments, rather than replaces, site staff. By enabling two-way communication, for example, automated payment systems provide the best of both worlds.

Full-circle Centricity

There is no denying that patient centricity is the future of drug development. But when companies are drawing up their plans and investing their hard-earned resources, they need to make sure they have all their bases covered. And that includes removing as many financial barriers to participation as possible.

Enabling quick and easy payments during clinical trials, without removing any crucial in-person support, is a simple yet effective way to maximise trial efficacy, boost ROI on patient centricity activities, and, ultimately, tackle the health inequalities of the future.

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REFERENCES

1. Sacristán, J. A., Aguarón, A., Avendaño-Solá, C., Garrido, P., Carrión, J., Gutiérrez, A., ... & Flores, A.

(2016). Patient involvement in clinical research: why, when, and how. *Patient preference and adherence*, 10, 631.

2. Desai, M. (2020). Recruitment and retention of participants in clinical studies: Critical issues and challenges. *Perspectives in Clinical Research*, 11(2), 51.
3. Pharmafile. Clinical trials and their patients: The rising costs and how to stem the loss. (2016). Available at: <http://www.pharmafile.com/news/511225/clinical-trials-and-their-patients-rising-costs-and-how-stem-loss> Last accessed: 25th May 2022.
4. Briel, M., Elger, B. S., McLennan, S., Schandelmaier, S., von Elm, E., & Satalkar, P. (2021). Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada. *Trials*, 22(1), 1-13.
5. mdgroup. The true cost of patient drop-outs in clinical trials. (2020). Available at: <https://mdgroup.com/blog/the-true-cost-of-patient-drop-outs-in-clinical-trials/> Last accessed: 25th May 2022.
6. Crocker, J. C., Ricci-Cabello, I., Parker, A., Hirst, J. A., Chant, A., Petit-Zeman, S., ... & Rees, S. (2018). Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. *BMJ*, 363.
7. WCG CenterWatch. Recruitment rates rising, but retention rates fall, according to new study. (2020). Available at: <https://www.centerwatch.com/articles/24543-recruitment-rates-rising-but-retention-rates-fall-according-to-new-study> Last accessed: 25th May 2022.
8. Nipp, R. D., Hong, K., & Paskett, E. D. (2019). Overcoming barriers to clinical trial enrollment. *American Society of Clinical Oncology Educational Book*, 39, 105-114.



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With more than 27 years of experience in the industry, Caroline brings a wealth of knowledge and understanding of the clinical development process to **mdgroup's** Patient Service Department. In her role as Executive Vice President of Patient Services, Caroline helps our clients embrace new technologies and decentralised solutions to facilitate better patient care, increase clinical trial diversity and reduce drop-out rates by empowering patients. After graduating from the University of Southampton with a BSc in Pharmacology, Caroline then went on to work for companies including Bayer, PRA Health Sciences and Synteract where she was Vice President of Vendor Management. Caroline is passionate about truly putting patients first and increasing clinical trial accessibility by giving patients more choice in how they participate.