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BRAIN
OPINION

Mental health research delivery: what can the National Health Service learn from the private sector?

Mental health clinical trial participants and pharmaceutical companies can contribute valuable insights into expanding UK capacity development interventions in mental health research—what can the public sector learn from private research delivery organizations?

In the UK, the National Health Service (NHS) has reported a 44% drop in participants recruited to commercial clinical trials within the past 5 years.[1] Whilst the NHS balances competing demands between care provision and research, some private contract research organizations (CROs) own dedicated research sites, including early phase units, and large patient datasets, which help identify and recruit participants and deliver trials on time and within budget. The decline in NHS involvement and the concomitant rise of CROs is a significant shift in the UK's healthcare and pharmaceutical landscape. This trend is likely to have far-reaching implications for the UK's research capabilities, the global competitiveness of its pharmaceutical sector and future patient care.

Pharmaceutical companies increasingly opt for CROs over NHS Trusts and/or their academic collaborators in higher education institutions (HEIs) to run early-phase clinical trials. For example, in the UK six industry-sponsored interventional depression Phase 1 and 2 clinical trials are currently recruiting or are in set up; all are managed and delivered by CROs.[2]

To understand why CROs provide an attractive option for managing and delivering mental health clinical trials, we consulted leading figures within the pharmaceutical companies and individuals with lived experience of mental illness who had taken part in UK-based mental health clinical trials and/or research studies.

Barriers and incentives for patient involvement in mental health research

We[3] held a focus group with 10 individuals with lived experience of mental illness who had taken part in UK-based mental health trials or studies. The focus group sought to understand barriers and incentives for patient involvement in mental health research and explore participants' perspectives on how delivery settings differed between CROs and NHS/HEIs. The attendees had lived experience of schizophrenia, depression, anxiety, personality disorders, borderline personality disorder, autism, attention deficit hyperactivity disorder and/or post-traumatic stress disorder. They had participated in mental health clinical trials or research studies between 2015–2024, represented different ethnic groups, were from a wide geographical spread across England and Wales, with average age of 46.2 ± 15.6 years.

Attendees said searching for better treatment options was a key motivating factor for participating in interventional clinical trials. Many reported that, compared to standard care, trial participation was associated with closer monitoring of their condition and more support was available between research appointments. For some, post-trial access to investigational medicinal products was a motivator for clinical trial participation. This ensured they continued to get trial medication, which otherwise would not be accessible due to the drug not being licenced in the UK. Another strong motivator for engagement in research was hope and belief that research-driven innovations would drive improvement in mental health services.

Compensating participants financially for their time and commitment was another critical factor that encouraged participation in mental health research. Participants highlighted a difference in financial incentives between the NHS/HEIs and CROs, with the latter providing comparatively more generous compensation for participation. This finding was echoed by leading figures from the pharmaceutical industry, who suggested the public sector should leverage negotiations with commercial study sponsors to revise and increase financial incentives for trial participants, thereby enhancing NHS/HEI competitiveness.

Participants highlighted areas that could be used to build trust and facilitate engagement, regardless of which type of entity was conducting the trial. First, follow-up communication after participation would make participants feel that their contributions were valued. Second, participants would appreciate regular updates on study progress, which was not perceived to be common currently in mental health research. Third, participants highlighted a lack of easily accessible information about research data handling; they cited a limited understanding of participant data ownership and future use, which can lead to mistrust and disengagement. Fourth, participants cited a shift towards participant-centric clinical trials as an area for potential improvement, as where possible, this could allow participants to choose between home visits, research site visits or remote appointments. Finally, logistical convenience played a large role in committing to research, with logistical burden a commonly-cited reason for early drop-out.

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Strengths and weaknesses of private and public sectors in delivering mental health clinical research

We[3] consulted leading pharmaceutical industry figures to identify key factors influencing choice of trial delivery settings in the UK. In particular, we examined specific differences and perceived advantages of CROs over NHS Trusts/HEIs in terms of commercial mental health research study set-up and delivery, and whether these advantages could be leveraged by the NHS to facilitate industry collaboration.

Research trial complexity and its developmental stage play a significant role in determining the appropriate delivery setting in the UK. For delivery of Phase 1 simple single ascending dose and multiple ascending dose studies, pharmaceutical companies typically favour CROs. This preference is driven by the ability of CROs to offer specialized early-phase research facilities with dedicated resources and streamlined operational processes, ensuring that studies are delivered on time, within budget and to target. In contrast, feasibility assessments suggest that NHS Trusts/HEIs often lack the specific expertise, capacity and interest to support early-phase interventional commercial mental health clinical trials.

Notably, HEIs have a strong advantage in delivering Phase 1/2a experimental studies where methodological expertise is required (e.g. specialized imaging techniques). Well-established methodologies in academic research centres contribute to higher quality data, shorter study delivery timelines and reduced costs compared to CROs. Specifically, CROs would first need to develop and validate these methodologies before they could be used for research. In such cases, pharmaceutical companies show a strong preference for academic research centres.

The delivery of Phase 2b and later-stage studies introduces additional complexities, with CROs and NHS/HEIs each bringing different strengths and expertise. CROs offer specific research sites and a workforce fully committed to clinical studies. This focus on research delivery is often preferred over the NHS setting, where the competing demands of clinical service provision can create challenges. CROs with fully owned and operated clinical research sites can typically recruit more participants across fewer sites than studies conducted in research-active NHS Trusts. The limited research capacity within any single NHS organization usually requires a greater number of research sites be set up in order to meet the recruitment target, which can be costly and time consuming.

Another advantage of CROs is standardization of trial management and operations. Later-phase clinical trials are often multi-site and global, but it is essential to minimize ‘site-specific effects’ and to maintain constant operational and quality standards across sites. Most CROs used by pharmaceutical companies have a global footprint that enables standardization across research sites. Major CROs also have proprietary trial/study management software that allows more efficient monitoring and conduct of studies. This commercially built and maintained technology stack is difficult to replicate in the NHS/HEI setting. CROs also benefit from working with a large and diverse set of clients, conducting trials for various indications and in a variety of patient populations. As a result, CROs rapidly gain significant experience and use specific mechanisms to capture this learning and create an ‘institutional memory’ that can be used to anticipate problems and improve processes. Further, CROs take advantage of large trial portfolios to shift resources as needed. For example, by maintaining bio-sample collections or management capabilities that can be allocated on demand to various clients. This ability to smooth out demand across a large portfolio of work allows them to maintain multiple capabilities at scale.

In comparison, a significant strength of the NHS/HEIs is its ability to access a reliable source of research participants. Mental health conditions such as depression have no defined biomarkers, which can make identifying research participants challenging. Leading industry figures report that 20%–30% of research participants in depression clinical trials in the USA are professional patients, also known as duplicate subjects, who frequently participate in clinical trials for unscrupulous reasons, such as financial gain. The NHS and healthcare system contain patients’ medical histories and can provide reliable protection from professional patients, something that is more challenging for CROs.

The public sector has large patient datasets, access to underserved populations, giving better representation of mental health conditions. Another advantage for recruitment and retention is that some patients are more likely to commit to a clinical trial if it is delivered by their healthcare team, with whom they have an established relationship. This facilitates enrolment to clinical trials but also reduces the likelihood of early drop-out. In addition, some patients perceive the NHS as a more suitable setting for providing investigational interventions post-trial, particularly those who have previously benefited from them.

Considerations for public clinical research delivery centres

Whilst NHS/HEIs in the UK are well positioned to recruit and retain participants in mental health clinical trials, competing with resourceful CROs presents challenges. In consultation with clinical trial participants and leading figures from the pharmaceutical industry, we provide several recommendations on how NHS/HEIs could build research capacity and become more competitive in securing collaborations with industry.

For Phase 2b and later-stage clinical trials, industry values working with established network(s) of specialized clinical research centres. To significantly facilitate collaboration with industry, we suggest implementing a coordinated patient recruitment approach, creating a network of principal investigators interested in commercial research and clearly communicating the capacity and capabilities of such networks. Strategic investments into dedicated clinical trial delivery resources, such as trial coordinator type roles, would increase research delivery capacity. Securing protected research time for consultant psychiatrists would also provide a significant boost to research capacity. We also encourage opportunities for mental health researchers to spend time working in pharmaceutical or medical technology companies, which would provide valuable insights into commercial project management and operational processes and facilitate bridging the gap between public research institutions and industry partners.

Opening new study sites is costly and time consuming, which is why pharmaceutical companies prefer to reach their recruitment targets across fewer research sites. To support collaboration with industry and deliver multisite commercial interventional clinical trials, there would be significant value in expanding research capacity within mental health research centres of excellence. Large mental health NHS Trusts with dedicated facilities, state-of-the-art equipment and dedicated resources, including healthcare staff, would provide the opportunity to successfully secure new partnerships with industry. Collected expertise and best practices garnered within these Trusts could then be shared with developing research delivery centres.

In the current mental health research landscape, CROs often provide more generous and competitive reimbursements to clinical trial participants, and patients have indicated that financial incentives are a key factor in committing to clinical trials. We recommend that the Health Research Authority/NHS revise patient reimbursement guidelines to make these more competitive and to align with the private sector. The NHS should adopt similar communication and advertising strategies to those of CROs, which clearly highlight financial incentives.[4] The NHS/HEIs have an opportunity to accelerate recruitment for research studies and simultaneously reach out to more potential participants by using various media channels, raising awareness of clinical trials and providing clarity and reassurance by using testimonials from previous trial participants. Self-referral options would provide patients with a direct link to clinical trials and potentially prevent interference from 'gatekeeping' clinicians.

Lack of unified approval systems[5] and the risk-averse culture of NHS/HEIs result in lengthy contracting and governance processes. The government's recent risk-proportionate framework significantly reduces approval timelines for low-risk clinical trials.[6] Further progress should be made towards unified administration across NHS/HEIs and streamlined approvals across research sites.[5] In the future, we expect the UK public sector to become more competitive at securing collaborations with pharmaceutical and medical technology companies, with building mental health research delivery capacity key to this. We advise: establishing and promoting mental health research centre networks; streamlining legal and regulatory approvals; investing in mental health centres of excellence and trial-focused research roles; and supporting industry fellowships/internships for researchers. To facilitate improved participant recruitment, we suggest revising patient reimbursement guidelines and using a variety of communication channels and self-referral options.

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