

# Delivering trials in the NHS: more than worth it

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## ABSTRACT

**Randomised trials are the best method to determine the efficacy and safety of health technologies. A recent report by Lord O’Shaughnessy highlighted many of the current challenges to delivering trials in the UK and proposed potential solutions. Among these, making trials the business of all NHS institutions and a valued part of all doctors’ work, while leveraging the potential of the data that the NHS collects routinely, offers an opportunity to improve NHS efficiency, doctors’ job satisfaction and population health simultaneously.**

**KEYWORDS:** randomised trials, clinical research, NHS

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The Coronavirus 2019 (COVID-19) pandemic showed much of what is good about the NHS to the world, such as its ability to treat people equitably while under unprecedented pressure, and to vaccinate its population rapidly and comprehensively. It also delivered research that changed policy and practice globally in a way that many other countries viewed with envy.<sup>1</sup> Within 100 days of the pandemic being declared, the RECOVERY trial silenced misconceptions by demonstrating the futility (at best) of hydroxychloroquine and the life-saving benefits of dexamethasone.<sup>2</sup> All acute hospitals in the UK embraced the uncertainty around these (and many other) treatment decisions and worked together to randomise large numbers of patients as rapidly as possible, which is the best method to resolve such therapeutic uncertainties.<sup>1</sup>

Sadly, one legacy of the pandemic has been an accelerated reduction in the contribution of the NHS to trials, most notably those described as commercial (broadly defined to include those funded or sponsored by organisations other than government and to which industry has provided medical technologies free

of charge, which would include RECOVERY and the Oxford–AstraZeneca vaccine trials). The UK Government commissioned a review led by Lord O’Shaughnessy, published at the end of May 2023, which highlighted the challenge: UK recruitment to such trials fell by over 40% over recent years and is now less than half of that seen in Poland and Germany. The report identified eight broad problems and made 27 recommendations, with the overall aim of doubling recruitment into clinical trials within 2 years, and then doubling it again by 2027.<sup>3</sup>

Even before the pandemic, the positive association between research activity and clinical outcomes was well recognised.<sup>4</sup> In the UK, changes in the law, such as the Health and Care Act 2022, align with guidance from medical royal colleges and professional regulators to embed research into clinical practice.<sup>5,6</sup> As the report recognises, this will require clinicians (doctors in both primary and secondary care, nurses and allied health professionals) to be paid to deliver research. Although additional costs are not welcome in the current economic climate, the report provides plenty of evidence that such changes could pay for themselves. Research must become part of the business of NHS organisations, starting with the executive, with appropriate recognition and reward for those delivering it.

However, providing funding is not enough: it is time that is the scarcest commodity. Burdensome bureaucracy, redundant training, excessive double-checking of documentation and the pressure of internal and external governance and inspection processes are profoundly demotivating. We cannot continue with a system in which it is less effort (and with less scrutiny) to practice medicine in ignorance of the benefits and harms of medicines (those we already have and the new ones that could be in the pipeline) than it is to contribute to the evidence-generation process through participation and support for randomised trials. At many hospitals in the UK, recruitment into RECOVERY became part of the ‘standard’ care pathway and the benefits of doing so were clear, not only to public health, but also to morale in the workforce, who relished the value research added to their clinical care.<sup>2</sup>

O’Shaughnessy recognised that the UK is not making the most of the data it captures routinely during the daily business of the NHS. Such data can save lives. Their use can determine where best to place trial sites in the UK; to identify and invite potential participants (with appropriate trustworthy privacy arrangements); and to inform the analyses of efficacy and safety.<sup>7</sup> This is only one example of innovation in trial conduct that must be fostered and not hampered by duplicative and occasionally contradictory application procedures, a lesson learnt by those responsible for ethics committees many years ago to the benefit of all involved in clinical research. Such

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approaches can radically alter the way in which trials are conducted and simultaneously improve quality. Trials are beginning to leverage the power of these data, but, as raised in another part of the report, trial regulations need to be rewritten to be fit for purpose with modern trial methodology. The recent UK Government consultation of its clinical trials regulation and the current revision of Good Clinical Practice guidance are welcome,<sup>8,9</sup> but good intentions are not enough and regulatory practice must change.

Those responsible for designing trials must also adapt. Anyone can design a trial that no-one can do or would want to participate in; designing trials that align with care pathways and cause minimal disruption to participants is key to success. Carefully designed and executed trials will generate robust evidence on which to base future NHS practice, whether with novel technologies or well-known interventions. These are the trials that O'Shaughnessy's recommended 'clinical trial acceleration networks' should focus on (and the UK Government should commit to funding in full, not in part as suggested by its response).<sup>10</sup> These are the trials that the UK research community, supported, not hindered by the Government, must aim to lead globally with its combination of academia, commercial, charitable and non-profit sectors operating in alignment with, and for the benefit of, the NHS, its staff and population health. ■

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