UK clinical trials in decline

Standfirst: Reducing administrative and regulatory hurdles could restore momentum

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The number of clinical trials conducted in the UK has declined markedly in recent years. Recent reports from the Association of the British Pharmaceutical Industry (ABPI),[1,2] showed UK industry trials falling both absolutely and in relative terms to other countries. Setting aside the exceptional COVID-19 pandemic period, the trend in UK industry clinical trials has clearly been downwards in terms of scale (both trials and participants recruited). Annual recruitment fell from 58,280 in 2018 to 44,564 by 2023 (24% decline)[2]. Phase 1 studies seem to be particularly affected with only 58 in 2023 versus around 100 annually in the preceding decade.[2] Direct industry input is valued at around £30K per participant to the NHS

notwithstanding wider economic benefit – in 2022 the UK commercial trials supported 65,000 roles, with an estimated turnover of £7.4 billion.[3-5]

The UK should be exceptionally well placed to deliver clinical trials given a unified healthcare system, prominent research universities, and active biotech and pharmaceutical industries. The scale, quality, and global impact of UK-led COVID-19 clinical trials were widely recognised and admired by the international research community. However, the UK (212 trials in 2023) is now behind Canada, Germany, Italy and Spain (between 217-241) in new Phase III industry trials.[2] Multiple factors appear to have contributed - the move of the European Medicines Agency away from the UK post Brexit, along with the loss of automatic access to the EU market when a drug or medical device is approved in the UK. Competing European countries like Spain and Poland have made strides to improve processes and develop competencies (e.g. reducing costing and contracting time).[6,7] UK regulatory approval and set-up times had become increasingly slow and unpredictable.[4] Decline in clinical researchers, driven by institutional financial pressures, and the increasing demands of pursuing clinical and research careers, will have also contributed.[8]

Concerns over the decline of the UK industry clinical trials led to the government initiated review by Lord O'Shaughnessy.[11] This stimulated new targets particularly for commercial studies for speeding up regulatory approval (90% of studies opening recruitment within 60 days of the approval decision) and also having first recruit within 30 days opening).[12,13] Other initiatives include the Clinical Trials Delivery Accelerator (e.g. UK Vaccine Innovation Pathway) and the creation of NHS commercial delivery centres to increase capacity and infrastructure.[14] Subsequent APBI reports[2,4] highlighted priorities to address industry trial challenges. The UK Clinical Research Delivery programme replaced an earlier UK wide programme,[15] which brought together representatives of the home nations to make pan UK studies simpler, and the devolved nations more attractive hosts for commercial research. Performance indicators have been clarified, targets set, and data are being released more quickly, with some progress in approval.[16]

Earlier this year a target of 150 days by March 2026 was announced for the entire set-up period of clinical trials (regulatory submission to first recruit), modestly building on the existing targets.[17] The Research Delivery Network replaced the Clinical Research Network in October 2024 to support clinical research in the NHS in England, to ensure consistency and greater access and capability, with a particular focus on industry research. Efforts to ensure standardised contracting is underway. Furthermore, a new Health Data Research Service is being established to provide single UK wide access point, motivated by the Sudlow review of the UK health data landscape, which was peppered with references to clinical trials.[18,19] Early indication are the funders and other bodies are responding to need to enhance support for clinical researchers.[20]

Persisting challenges

Despite some progress, there are several areas that still require attention to improve the state of clinical trials in the years ahead. Aligning of processes and terminology across the whole of the UK can and should go further. Differences in legislation and governance make recruiting participants in Scotland (and to an extent Wales and Northern Ireland) more difficult for some trials than in England. Legislative adjustments should be made to standardise processes (such as consent[21]) across the UK. Second, a programme to remove

barriers to patients (and related data) in the NHS is needed to aid the conduct and delivery of commercial and non-commercial clinical trials. New UK clinical trials legislation for drugs needs careful implementation to avoid burdening with additional expectations about conduct and monitoring trials which are not conducted for drug marketing authorisation.[22] More generally, HEI and NHS infrastructure[23] and related pressures should not be allowed to prevent important trials from being conducted e.g. surgical trials impacted by waiting times.[24] Increasing clinical research and clinical trials capacity requires the infrastructure, especially clinical trial units, to support, mentor and partner with clinicians and industry partners; existing trials groups need increased investment to grow, and in turn support more investigators.[25,26]

There are early signs of progress in speeding up the set-up and recruitment to clinical trials though it too early to say if the welcome aspirations are achieved and sustained.[8] Further decline in the US clinical trials infrastructure seems likely over the next few years, which both presents opportunities for the UK but also a stark warning that the current position cannot be taken for granted. This will take investment in people as well as process; specifically NHS and Higher Educational Institution investment in the training and support of both clinical and non-clinical academics with expertise in clinical trials. It would be regrettable if the warning signs were not headed, and the potential not embraced.

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