Globally competitive UK-wide data-enabled clinical trials: the time is now

March 2026

Executive summary

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The case for change

Participating in clinical trials offers patients the potential to access to the latest innovative treatments in development, which can be life changing for patients who have limited options available through standard care. In addition to impacting patient outcomes, industry clinical trials bring significant value to the economy and the NHS. In 2022, industry clinical trials contributed £7.4 billion to the UK economy, including £1.2 billion revenue for the NHS, and supported 65,000 jobs across the UK.[1] There is growing global recognition of the widespread economic and health benefits that commercial trials provide. Consequently, international competition is growing, with countries offering streamlined approaches or fiscal incentives to attract inward trial investment.

In the past decade, the UK was a global powerhouse for commercial clinical trials. However, in part due to the UK's leading role in delivering COVID-19 clinical trials, recovery was slower than other countries, resulting in a major decline in UK competitiveness.[2] To restore the UK's competitiveness in commercial trial delivery, the government has pledged to reduce commercial trial set-up times to 150 days by March 2026[3] and to quadruple commercial trial participant recruitment by 2029.[4] These commitments are supported by a £600 million investment in a Health Data Research Service (HDRS), in partnership with the Wellcome Trust, with a stated aim of enhancing clinical trial delivery.[5]

Following the period of post Covid pandemic decline, there has been a resurgence in the number of industry clinical trials placed in the UK. In 2024, the number of commercial clinical trials initiated in the UK rose by 36 per cent above the previous year, with the UK climbing two places to sixth in global competitiveness ranking for all phase III trials initiated in 2024.[2] Despite an increase in trial initiations, there has been a year-on-year decrease in participation in UK industry trials, with recent numbers reaching their lowest level since 2017/18. This situation contrasts with non-commercial studies, where total participant number in England in 2024/25 were almost double pre-pandemic rates, demonstrating the willingness of patients and the public to participate in research.

A major factor contributing to falling recruitment in industry trials is that trial set-up and recruitment times in the UK are too slow compared to European and global competitors, with more than half of industry trials missing their target

timeframes.[2] ABPI member companies estimate that 10 per cent of all UK sites currently recruit no participants, while 30-50 per cent of sites recruit only one to two individuals, which is costly, inefficient and a deterrent to placing trials in the UK.

The UK has foundational strengths that competitors cannot easily replicate, including longitudinal NHS health records covering the UK's 69 million patient population; proven willingness by the public to take part in research; and clear government commitments to improving delivery of commercial trials in the UK. The recent increase in commercial trial numbers is a positive indication that global companies are still open to choosing the UK as a location for their trials, which presents a real opportunity. However, there is a risk that this improvement in numbers may be short lived without a demonstrable change in the UK trial delivery environment. It is therefore critical for the government to capitalise on the UK's investments and NHS assets without further delay to transform commercial trial delivery at scale across the UK.

Shortfalls in current recruitment processes

Inaccurate feasibility assessments

Feasibility assessments must provide an accurate estimate of eligible populations that will translate into participants who enrol in a trial. Currently it is not possible to obtain accurate feasibility assessments of the number of patients across the UK who may be eligible for a trial, due to the inability to access comprehensive population-wide clinical data. At present feasibility assessments for trials are either generated locally at a selection of sites from current caseload lists and subsequently collated, derived nationally using tools based on proxy indicators of real patient numbers, or extrapolated from access to incomplete patient databases. As a consequence, feasibility assessments do not reliably predict subsequent real-world enrolment at sites, leading to many sites underdelivering on their promised recruitment targets.

High screen failure rates

Before an individual can enrol in a trial, they must undergo a screening procedure to assess whether they match the eligibility criteria for the trial. Potentially suitable participants are identified by trial sites and invited to screening. The aim is to achieve high enrolment amongst invited individuals due to the cost and time involved in the screening process, and to avoid screen failures where possible. Current methods for identifying potentially suitable trial participants rely on case load reviews or local searches of incomplete NHS records by each site, frequently in the absence of GP records, where approximately 90 per cent of healthcare contacts occur.[6,7] As a result, many patients are invited to undergo screening assessments, only to be told they are ineligible, when this information was already in their medical records. Meanwhile, other patients who may be eligible to enrol in a trial are not identified or invited for screening. These inefficient practices are the leading cause of costly and time-consuming high screen failure rates, which is frustrating for patients and places an added burden on already stretch NHS staff.

Fragmented approach using NHS data to support trial recruitment

NHS records contain longitudinal medical information on the UK's 69 million patient population. Despite the enormous potential for NHS data to transform commercial trial delivery, to date there has been no UK-wide strategy for utilising NHS data to enhance trial recruitment at scale, directly benefiting the NHS delivery infrastructure where sponsors place their trials.

In the absence of a coordinated strategic approach, a number of public and private data-enabled trial services exist in the UK, locating suitable patients for a trial using information in their medical records. Each organisation operates independently and serves different users or geographical locations based on their access to available datasets. These data services have grown organically, with different governance arrangements, meaning it is not possible or practical to combine them. The result is a fragmented UK offering, with sponsors having to navigate multiple disconnected data services, and trial sites receiving data from multiple sources without sufficient context.

Industry requirements to deliver competitive data-enabled clinical trials

UK teams within global pharmaceutical companies must compete for UK trial allocation against other international markets. Understanding what commercial sponsors need to justify placing and delivering their trials in the UK and where the greatest gains could be made, is fundamental to unlocking the UK's competitive potential. The £600 million investment in the HDRS provides a realistic possibility of creating a compelling UK-wide offer, by utilising NHS assets to significantly accelerate recruitment into phase II-IV commercial trials. To realise this potential, the ABPI and member companies recommend establishing a UK-wide data-enabled clinical trials function within the HDRS, that would seamlessly connect with the existing clinical trials delivery infrastructure to enhance system efficiency and increase UK competitiveness.

Operating principles

The core operating principles of the data-enabled clinical trials function should be:

- **Predictability**. Sponsors return to sites and markets they trust. Reliable delivery of what sites have promised justifies ongoing investment in the UK and will help UK teams to secure larger trial allocations in the future.
- **Accuracy**. Current screen failure rates can approach 90 per cent in some therapeutic areas due to inaccurate feasibility assessments and inability to target the right patients to invite for screening. According to ABPI members, reducing screen failures to 50 per cent by more accurate feasibility assessments and participant identification would nearly halve screening costs and site burden.
- **Speed**. Global teams need feasibility responses within two weeks, or they allocate trials elsewhere. Rapid participant recruitment will increase the likelihood of UK sites successfully delivering their trial quotas within faster timeframes.

Core operating principles of the data-enabled clinical trial function.

Minimum datasets required

GP records capture 90 per cent of patient contacts with the healthcare system,6,7 and contain longitudinal data on chronic diseases and acute conditions, prescribing histories, laboratory test results, diagnoses and referrals. According to ABPI member companies, approximately 60 per cent of eligibility criteria in most industry trial protocols for chronic conditions commonly managed in primary care, such as cardiovascular, metabolic and respiratory conditions can be mapped to diagnoses, prescribing, test results and interventions recorded in GP data, supplemented by national secondary care data. Some protocol criteria within neurology and immunology trials are routinely recorded in GP and national secondary care datasets, and other selection criteria for these conditions depend on access to specialist hospital datasets. Key eligibility selection criteria for oncology trials are, however, entirely dependent on information within datasets held in specialist oncology centres or individual trusts.

At a minimum, comprehensive GP data linked to national secondary care and mortality data is required to provide meaningful feasibility assessments and to locate participants across the UK for most industry trial protocols, excluding oncology and rare diseases. For these datasets to be of value for facilitating recruitment into industry trials, the data need to be updated with sufficient frequency to align with common timebound measures within protocol selection criteria.

Essential services

The following three services, which are based on access to timely UK-wide GP and secondary care data, would increase the efficiency of UK commercial trial delivery and offer the UK a competitive advantage.

Feasibility assessments with self-service option

By centrally matching comprehensive GP data linked to national secondary care data to key

selection criteria in the trial protocol, it will be possible to rapidly obtain more accurate UK-wide feasibility assessments. This will enable UK affiliates to bid for a UK trial allocation and be more confident that these estimates will subsequently translate into patients enrolled. It is not uncommon for companies to need to submit feasibility assessments within a two-week timeframe, so accuracy combined with speed is vital. Both a managed feasibility service and self-service option should be provided.

Geomapping and site selection

The UK could gain further competitive advantage by understanding where relevant potential participants are physically located across the UK and therefore which trial delivery sites may hold the greatest recruitment potential. Using evidence-based geomapping, in conjunction with site capacity and performance information for site selection, would drive efficiencies by placing trials in areas with greater certainty of delivery. This approach should also reduce costly set up of sites that fail to recruit or deliver well below their recruitment target.

Recruitment pre-screening

Significant time and cost savings can be made in pre-screening of potentially suitable participants, by carrying out centralised detailed modelling of linked GP and national secondary care datasets against protocol eligibility criteria. Carrying out this process once, on pseudonymised patient data encompassing all delivery sites, alleviates the need for each site to carry out individual searches from scratch, often in the absence of essential longitudinal GP data. Supplying individual sites with a pre-screened list should also expedite trial startup if the centralised lists were generated during the regulatory approval process. NHS staff could focus their time on selecting the most appropriate participants from the list and inviting them for screening immediately after the site receives regulatory approval for the study to commence.

Service design

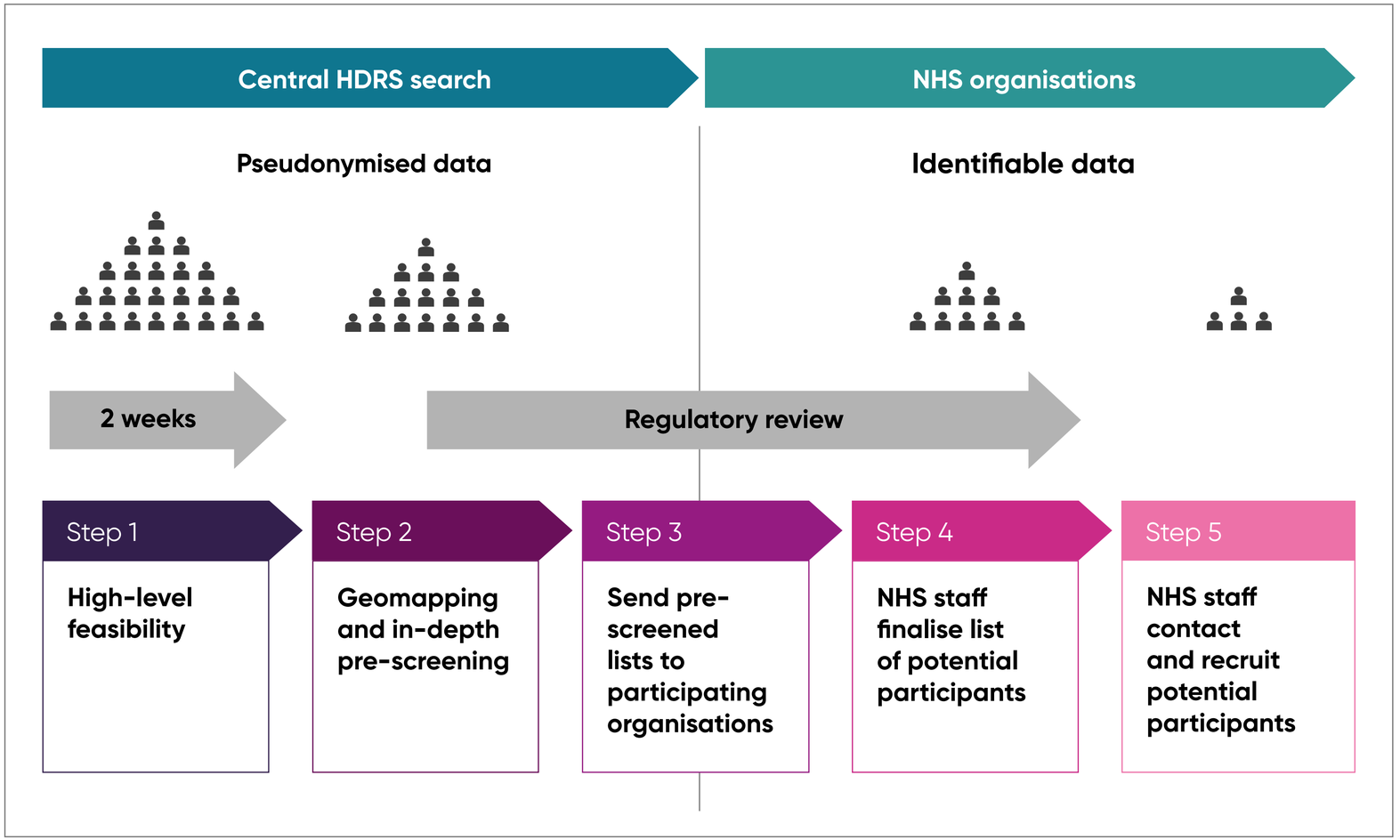
A new data-enabled clinical trial function should be based within the HDRS and provide a coordinated UK-wide offering, carrying out pseudonymised NHS data searches modelled against industry protocol criteria. These centralised data services should seamlessly interface with the trial coordinating infrastructure and directly support subsequent clinical validation, patient identification and recruitment at secondary and primary care trial delivery sites across the UK.

The proposed architecture for an end-to-end service design maintains appropriate information governance boundaries between centralised pseudonymised feasibility assessments, site selection and pre-screening in the HDRS and subsequent patient identification following clinical review at NHS sites. Pseudonymised datasets would be centrally matched against industry protocol inclusion and exclusion criteria within the HDRS to determine trial feasibility, and to geomap where the highest number of potential participants may be located to help inform site selection.

Following more in-depth data modelling and clinical interpretation against complex protocol eligibility criteria, a pre-screened potential participant list would be generated and passed on to selected delivery sites within the NHS.

Trial sites would receive pre-screened, pseudonymised participant lists from the HDRS, accompanied by information indicating which eligibility criteria have been modelled in data searches and which require further clinical review by local NHS site teams. The provision of pre-screened lists would negate the need for each delivery site to search available information from scratch, saving NHS resource and time. Local clinical teams at sites with a legitimate basis to access identifiable health data, would then validate pre-screened lists and identify suitable individuals for a trial. The clinical validation and participant identification would take place during the regulatory approvals process. As soon as regulatory approvals have been granted, participants can immediately be invited for screening, which would drive system efficiencies by reducing recruitment timeframes.

UK-wide data-enabled clinical trials: from feasibility to recruitment.



Targeting the right participants for screening

The process of matching patient eligibility criteria to their medical history would increase efficiency by more effectively targeting suitable patients with a higher likelihood of being eligible to participate in a trial, prior to inviting them for screening. The result would reduce costly and time-consuming screen failures and reduce the number of patients who are contacted only to subsequently find out they are not eligible based on existing information in their health records.

Delivering trials that include participants representative of the patient population that will ultimately benefit from the medicine is key to developing robust evidence on the safety and efficacy of new medicines. Identifying representative populations through current recruitment methods creates substantial challenges. Using the proposed privacy-preserving eligibility searches of NHS records would not only accelerate the recruitment process but would support recruitment of a more representative cohort.

To further improve recruitment efficiency and inclusivity, protocol archetypes characterising applicability of NHS data to common phase II-IV selection criteria in the trial protocol could be developed. This would reduce the workload involved in data modelling, by removing the need to generate novel algorithms requiring clinical interpretation for every new trial protocol.

Oncology trial screen failure rates often reach 90 per cent because matching patients to the complex trial eligibility criteria requires access to multiple NHS data sources held within hospitals and specialist oncology centres. Due to the challenges of collating these specialist data sources, a different approach is needed for an oncology data-enabled clinical trials offering. A network of major tertiary oncology centres across the UK could be formed to develop a standardised data framework, defining which datasets are of most value and what standards should be used, and to practically test data-sharing approaches across sites before roll-out.

Recommendations

The following seven recommendations, which set out industry requirements and expectations for UK-wide data-enabled clinical trials, provide a pathway for translating the UK's structural advantages into predictable and timely trial delivery.

Recommendation 1

Establish a UK-wide data-enabled clinical trials function built to meet industry needs

The function should accelerate phase II-IV trial feasibility and recruitment to commercial interventional studies, operating at scale across all four nations. Investment in the HDRS provides the foundation for creating this capability.

Recommendation 2

Core operating principles must be predictability, accuracy and speed

Services must consistently deliver what is promised, provide accurate timely feasibility assessments based on clinical information that translates into participants enrolled, and speed up recruitment by providing sites with pre-screened lists of potential participants during the regulatory approvals process.

Recommendation 3

The minimum dataset should include UK-wide GP data linked to Secondary Uses Service data in England, or equivalent secondary care data in devolved nations, and mortality data

Comprehensive UK GP data coverage, linked to national secondary care and mortality data, which is updated on a frequency that aligns with pharmaceutical trial protocol selection criteria, should form the minimum viable dataset. Together these datasets can encompass 60 per cent of protocol criteria (excluding oncology and rare diseases), which enables more reliable targeting of participants, reducing costly and time-consuming screen failures.

Recommendation 4

Essential services should include centralised feasibility assessments, geomapping and site selection, and recruitment pre-screening services

Providing centralised services based on comprehensive pseudonymised population coverage enables more reliable feasibility predictions of trial participants and site selection, informed by where relevant patients are geolocated. Centralised pre-screening of potential participants for subsequent clinical review at sites reduces the burden on each site and increases efficiencies in trial startup processes and times.

Recommendation 5

Data-enabled services should be based within the HDRS and integrate with the existing UK clinical trial infrastructure to enhance system efficiencies and UK competitiveness

Data-enabled services should be embedded within the HDRS and use a centralised data-driven approach that protects patient confidentiality and facilitates targeted and more rapid efficient recruitment trial delivery sites, to enable NHS staff to focus resources on screening the most suitable participants for a trial.

Recommendation 6

Create a reusable resource of protocol archetypes by therapeutic area

To understand which eligibility criteria commonly used in industry phase II-IV trial protocols can be reliably mapped to NHS data, a mapping exercise across different NHS data sources

should be carried out to generate protocol archetypes by therapeutic area. Creation of a central repository characterising the utility of NHS datasets for interpreting trial protocols would significantly reduce time taken to model each new protocol.

Recommendation 7

Establish a dedicated oncology network across the four nations to explore the potential for a replicable, data-enabled approach for improving recruitment into oncology trials

Recruitment to oncology trials depends on accessing essential information in specialist hospital datasets. To understand whether oncology trials could benefit from a data-enabled approach, major tertiary oncology centres across the UK should work together to develop and test a data-sharing framework aimed at improving identification of cancer patients eligible for trials.

Measuring success

The primary driver for establishing a dedicated function to support data-enabled clinical trials at scale, is to increase UK competitiveness by improving efficiency of recruitment into commercial trials. Evaluating the impact of data-enabled services should therefore be based on measures of timely and accurate feasibility assessments and subsequent rapid, targeted participant recruitment by the trials delivery system. The following performance indicators, using comparisons to current baseline measures, are proposed:

- **Feasibility assessments** within two weeks, based on an overview of whole population national datasets
- **Reduced proportion of non-recruiting sites** by geomapping sites with the highest recruitment potential
- **More efficient and targeted recruitment** through centralised evidence-based pre-screening

Other benefits that a data-enabled clinical trials function should bring include time saved by NHS staff at each site carrying out pre-screening from scratch, and increased inclusivity and representativeness in clinical trials due to the ability to review all potential suitable trial participants. These benefits may be more difficult to quantify, as currently relevant metrics are not routinely collected.

Public trust in responsible use of health data in research is paramount. The proposed architecture is designed to protect patient confidentiality, with only staff at participating NHS organisations being able to access identifiable patient data. The central data feasibility assessments and recruitment pre-screening would be carried out on pseudonymised data within the HDRS, where researchers do not have access to identifiable patient information. Use of pseudonymised data to support clinical trials should be part of HDRS planned discussions with patients, the public and healthcare professionals, which are aimed at building trust in transparent use of patient data for research.

The path forward

Government has recognised the immense value that industry clinical trials bring to patients, the NHS and the economy. To make the UK a more attractive destination for global industry, government has set ambitious targets, backed by a series of measures are designed to improve commercial trial delivery. However, for the UK to seriously compete with preferred European and global markets, a transformational change is required.

Fortunately, the UK now has an opportunity to enact this transformational change by strategically aligning two major government commitments: to establish a HDRS; and to improve the environment for delivering commercial clinical trials. If successfully implemented, creation of a data-enabled clinical trials capability that harnesses this globally unique NHS asset, offers the UK a competitive advantage in accelerating recruitment into commercial trials via the UK's established trial delivery infrastructure. A service designed to meet the rigorous requirements of commercial trials would, by its nature, meet the needs of non-commercial research, ensuring benefits across the entire UK clinical research ecosystem.

The seven recommendations outlined in this report to drive UK-wide data-enabled clinical trials capability, would unlock the potential of NHS data to significantly increase efficiency of recruitment into commercial clinical trials. Critical to success is centrally collected GP data, as is the need to seamlessly integrate the data service with the existing trial infrastructure. Implementing the full suite of proposed UK-wide data-enabled services is a major endeavour and will take time to be fully operational. In the meanwhile, a modular stepwise approach, building on existing data-services, in particular those that have access to GP data given its criticality for matching patients to industry protocols, should be adopted to inform end-to-end service design and workflows.

The next step should be to convene a UK-wide service design group (SDG) bringing together government representatives from the four nations, the HDRS team, key parts of the clinical trials delivery system and the pharmaceutical industry to define how the delivery of data-enabled commercial trials at scale could be achieved.

The SDG would have five core objectives:

- **Validate the proposed design with clinical research delivery systems** to confirm that it meets real-world needs for facilitating rapid feasibility assessment, site selection and recruitment across the UK.
- **Set out the operational approach** and workflows needed to connect HDRS data searches with trial coordination and delivery systems and recommend governance structures with clear responsibility for implementation.
- **Recommend a phased roadmap** to guide prioritisation of set-up and implementation of the key data-enabled services, including access to comprehensive UK-wide GP data linked to national secondary care and mortality data to form the minimum service dataset.

- **Expand the Clinical Practice Research Datalink (CPRD) as a minimum viable product to demonstrate proof of principle**, building on its existing industry-facing trial services and linking secondary care data with CPRD's UK-wide GP data to provide quick wins and inform UK service design.
- **Define success metrics** translating the key performance indicators into measurable targets.

Convening the SDG in the first half of 2026 would signal a strong commitment to translating the UK's structural advantages into coordinated strategic actions aimed at significantly improving predictability and efficiency of commercial trial delivery. Successful delivery of data-enabled clinical trials would reverse declining recruitment, secure international investment and deliver on government commitments. Importantly, creating services that aligned with industry requirements will finally realise the potential of NHS data to increase the UK's competitive advantage and reinstate its position as a global leader in clinical trials delivery.

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We represent companies of all sizes which invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world.

In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

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