# The road to recovery for UK industry clinical trials

December 2024

# Contents

# Executive summary

The past two years have seen a period of positive change within the UK industry clinical trials delivery system. Building on the initial signs of recovery highlighted by the ABPI in 2022, there were further signs of improvement in 2023. Changes have been made in response to the issues identified in the 2023 independent review led by Lord O'Shaughnessy, with actions to improve study set-up and delivery, alongside increased transparency to track progress.

This year's report shows welcome evidence of continued progress, but further work is needed to deliver the full benefits of industry trials to UK patients, the NHS, and the economy.

**Key findings**

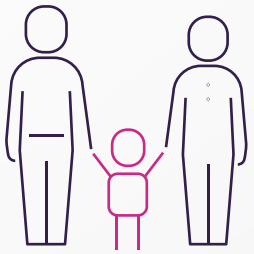
- The number of pharmaceutical industry trials initiated in the UK grew for the second year in a row, from 411 in 2022 to 426 in 2023.
- For the first time since 2017, the UK's global rankings in late-phase pharmaceutical industry clinical trial initiations have improved. Between 2022 and 2023, the UK's global competitiveness rose from 6th to 4th for phase II trials and from 10th to 8th for phase III trials. However, numbers remained 36 per cent below the 667 industry clinical trials initiated in 2017.
- Despite the increase in the number of interventional industry trials initiated in 2023, the number of participants recruited to these trials continued the year-on-year decline observed since 2020/2021.
- While there were some welcome improvements in study approval times, and some progress has been made in study set-up, significant improvements still need to be made, particularly to reduce study set-up times. The UK is also underperforming in the delivery of industry trials to time and target, with between 20 and 30 per cent of industry clinical trials this year not recruiting the agreed participant numbers within specified timeframes.

Maintaining momentum on progress made to date in recovering the UK's position as a reliable destination to deliver industry trials remains critical. The potential size of the prize is considerable. Restoring UK industry clinical trials activity to levels comparable to 2017 would generate an additional £3 billion of gross valued added (GVA) and support 25,000 new jobs, driving forward the government's economic mission through industry and system partnerships.

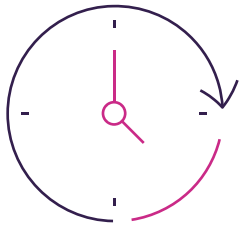
To facilitate achieving this, we encourage government and delivery partners to focus on the following recommendations: seizing the opportunity of the Voluntary Scheme for Branded Medicine Pricing, Access and Growth (VPAG) Investment Programme; demonstrating continued government commitment to delivery of industry clinical trials; embedding research in the NHS; and increasing transparency and tracking progress.

# Recommendations

The VPAG Clinical Trials Investment Programme funds should be invested in line with pharmaceutical industry expectations to boost capacity and infrastructure.



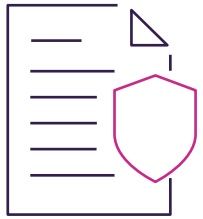
Embed research as business as usual in the NHS, offering every patient the opportunity to participate in studies of novel treatments and cutting-edge interventions.



In implementing improvements in the UK clinical trials environment, government should prioritise reducing set-up times for trial delivery.

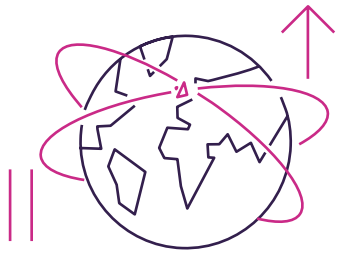
Government and NHS should publish a research workforce plan to improve clinical research delivery within the NHS.

The route for industry engagement with the UK clinical trials delivery system must be streamlined and integrated.

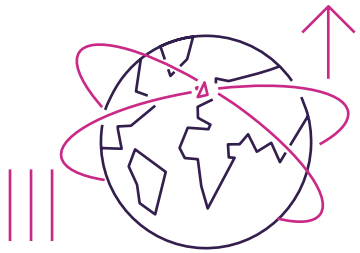


System partners must expedite increased transparency and accountability for UK clinical trial performance through standardisation, timeliness, and consistency of performance reporting.

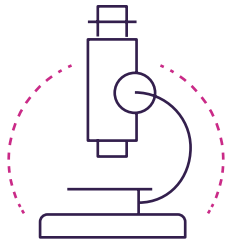
# Key improvements in 2023



The **UK ranks 4th globally for phase II trials,** up from 6th last year



The **UK ranks 8th globally for phase III trials,** up from 10th last year



The number of **UK industry clinical trials** initiated was up **3.7%** between 2022 and 2023

The number of **phase III trial initiations** is **up 16.5%** in 2023 from 2022

# Introduction

The 2022 ABPI report on industry clinical trials highlighted the persistent decline in UK industry clinical trials since 2018, pre-dating the COVID-19 pandemic. Between 2017/2018 and 2021/2022, recruitment to industry clinical trials in England fell by 44 per cent, and the UK's global ranking for phase III industry trials plummeted from 4th to 10th.[1] This report was pivotal in the government commissioning the 2023 independent review of commercial clinical trials led by Lord O'Shaughnessy.

Lord O'Shaughnessy's review set out the key issues affecting the delivery of commercial trials and made a series of recommendations to grow industry clinical trials in the UK. The government accepted the recommendations in full[2] and published implementation plans building on ongoing activities to improve the UK clinical trials environment.

The ABPI 2023 clinical trials report,[3] which included data that preceded and directly followed the O'Shaughnessy review, showed early signs of improvements in the UK commercial clinical trials ecosystem. Participant recruitment into industry clinical trials in 2022/2023 was 15 per cent higher than the previous year and the total number of clinical trials initiated in 2022 in the UK increased, albeit by just 4.3 per cent, for the first time since 2017. The report welcomed these early signs of progress, including the steps taken in 2023 to address the backlog of regulatory approvals and streamline study set-up.

The past 18 months have seen a time of further positive change in the UK clinical trials environment, with the implementation of a variety of measures seeking to improve industry clinical trials delivery. These include increased transparency to track the impact of government actions to implement the O'Shaughnessy review recommendations and mandating the use of a standardised contracting and costing process for NHS research in England. In October 2024, the Research Delivery Network (RDN) comprising 12 regional research delivery networks in England, together with a coordinating centre, replaced the Clinical Research Network (CRN). The main differences between the CRN and the new RDN are that the RDN will work as a single, more integrated network, with improved site identification and account management services. The RDN will also play a more proactive role in delivering the government's priority projects to streamline research delivery.

Last year also saw the agreement of a new VPAG, which included a world-first, industry-funded Investment Programme.[4] Seventy-five per cent of the VPAG Investment Programme funding, up to £300 million, will be invested in expanding the UK's capacity and capability for commercial clinical trials. In addition to funding a UK-wide network of commercial research delivery centres (CRDCs), the programme will fund additional workforce capacity, equipment, and infrastructure to accelerate trial delivery. Aligning this funding to global industry clinical trials pipelines will maximise the potential of this industry investment to attract additional studies to the UK. A goal of the programme will be to foster enhanced working between the UK nations and create more opportunities for participant access to trials across the UK.

Last year also bought a change of government, with a new Labour government manifesto commitment to make research more inclusive and accessible. In line with its health and growth missions, the new government has remained committed to the UK becoming a more desirable destination for delivering industry clinical trials. During its first budget in October 2024, the government increased funding for the National Institute for Health and Care Research (NIHR) and highlighted the importance of clinical research. This increased funding will enable NIHR to continue to deliver its programme of activities designed to improve clinical trial delivery and to better monitor progress.

This is the sixth ABPI annual clinical trials report that charts the UK's performance in delivering industry clinical trials over recent years. In common with previous years, the report includes the status of UK global competitiveness, trial numbers, participant recruitment and set-up metrics. Importantly, to capitalise on the current momentum in the system, the report highlights six priority areas where the government and delivery partners should focus to attract a greater share of industry trials to the UK.

# Methods

### Data sources and timeframes

This report includes a retrospective snapshot of industry research activity in the UK and leading competitor countries, commissioned from Clarivate. Data has also been provided by the NIHR Clinical Research Network (CRN), the NIHR Research Delivery Network (RDN), NHS Research Scotland (NRS), Health and Care Research Wales (HCRW), Northern Ireland Clinical Research Network (NICRN), and Northern Ireland Cancer Trial Network (NICTN). The Medicines and Healthcare products Regulatory Agency (MHRA) clinical trials performance metrics are published monthly on the MHRA website.

Data in this report uses the most recent information available and covers different timeframes ranging from 2022 to October 2024. The timeframes for the data presented are specified in the relevant figure or table.

### Definitions

This report presents an overview of the status of UK industry clinical trials (also known as commercial contract studies), which are sponsored and fully funded by commercial organisations, including both pharmaceutical and device companies. In some figures and tables (where noted), data presented are for pharmaceutical clinical trials only.

For the first time, data are available that distinguish between industry interventional research, including pharmaceuticals and devices clinical trials, and industry observational research studies.

# The state of industry clinical trials in the UK

# Volume

## Number of pharmaceutical industry interventional clinical trials

Positively, the number of pharmaceutical industry interventional clinical trials initiated in the UK grew for the second year in a row, from 411 in 2022 to 426 in 2023 (Figure 1). The number of phase III trials increased by 16.5 per cent, with the number of phase II trials initiated remaining relatively constant over the past two years. There was a 26.6 per cent decrease in the number of phase I trials from 79 in 2022, to 58 in 2023. Although overall there was a 3.7 per cent increase in the number of UK pharmaceutical industry clinical trials initiated between 2022 and 2023, numbers remained 36 per cent below the 667 industry clinical trials initiated in 2017. While there is clear progress in the number of pharmaceutical industry clinical trials initiated in the UK, further action needs to be taken to build on these signs of recovery.

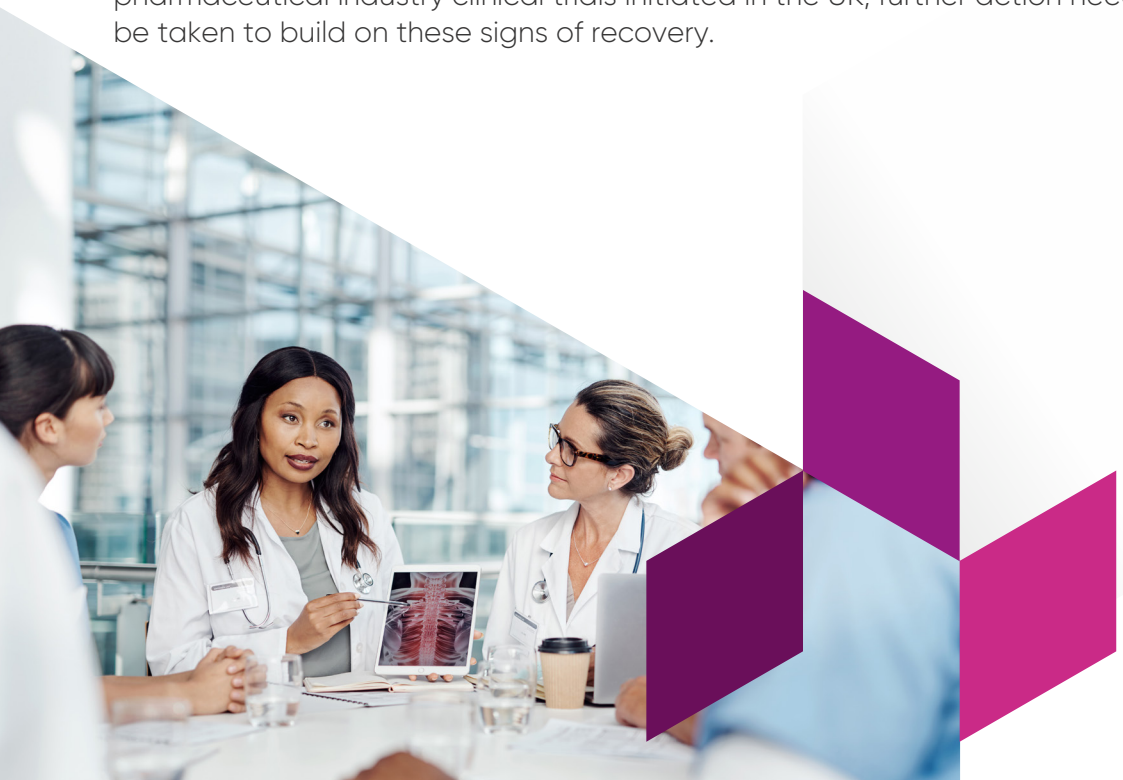
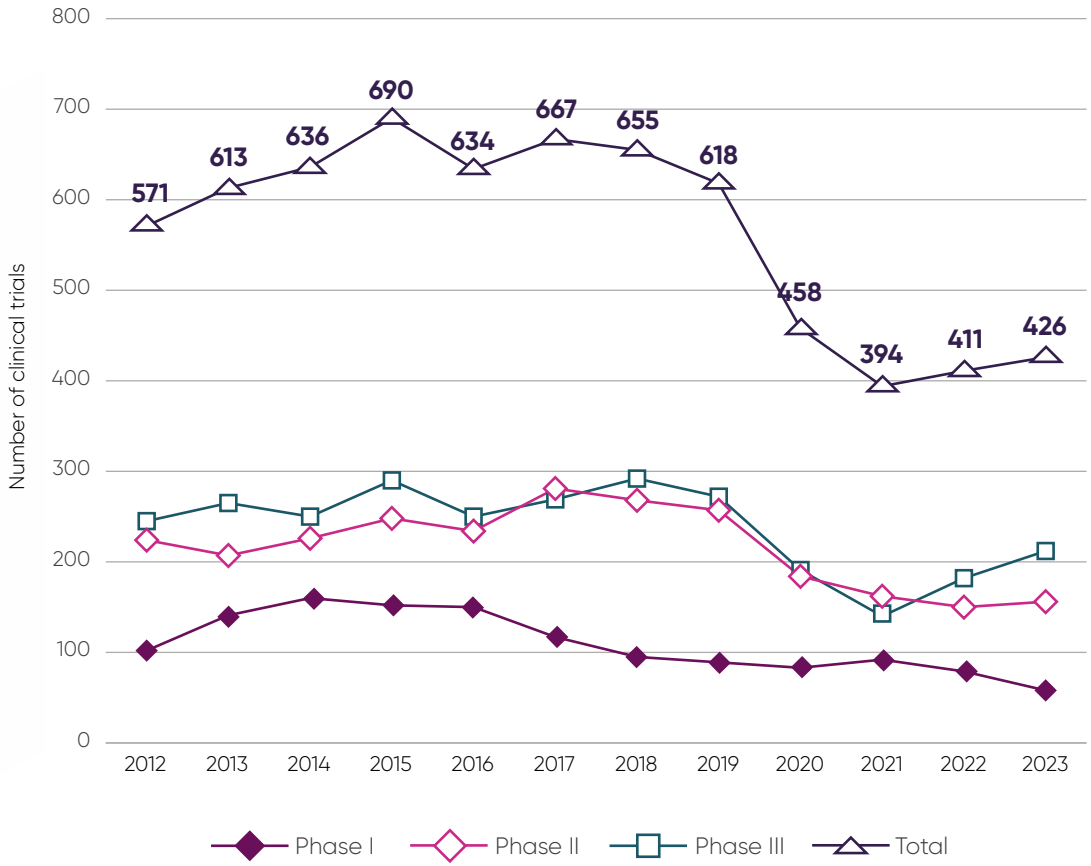


Figure 1: Number of UK pharmaceutical industry interventional clinical trials initiated per year, by phase (2012-2023)



These changes in UK pharmaceutical industry clinical trials initiations are mirrored by changes in the UK's comparative global ranking for pharmaceutical industry clinical trials. Encouragingly, for the first time since 2017, the UK's global rankings in late-phase pharmaceutical industry clinical trials have improved. Between 2022 and 2023, the UK rose from 6th to 4th place for phase II trials and increased from 10th to 8th position for phase III trials (Table 1). While the UK remains the top European country for phase I pharmaceutical industry trials, its global ranking slipped from 4th to 5th, with Japan moving into 4th place. This decrease in phase I clinical trials, historically a UK strength, is notable, given the increased likelihood of later phase trials subsequently being placed in the UK. The decrease in the global share of phase I trials has also been observed in Europe.[5]

Table 1: Global rankings – number of pharmaceutical industry interventional clinical trials initiated in 2023, by country, by phase (compared with global rankings in 2022)

| Rank | Country | Phase I | Country | Phase II | Country | Phase III |
|---|---|---|---|---|---|---|
| 1 | USA | 384 | USA | 702 | USA | 415 |
| 2 | China | 349 | China | 361 | China (↑1) | 315 |
| 3 | Australia | 82 | Spain | 185 | Spain (↓1) | 241 |
| 4 | Japan (↑1) | 72 | **UK** (↑2) | 156 | Japan (↑2) | 226 |
| 5 | **UK** (↓1) | 58 | Germany | 149 | Canada (↑4) | 225 |
| 6 | Canada (↑2) | 45 | France (↓2) | 144 | Germany (↑2) | 221 |
| 7 | Spain (↓1) | 43 | Japan (↑2) | 141 | Italy | 217 |
| 8 | Germany (↓1) | 37 | Canada | 139 | **UK** (↑2) | 212 |
| 9 | France | 31 | Australia (↓2) | 131 | France (↓4) | 200 |
| 10 | Belgium (↑1) | 21 | Italy (↓1) | 122 | Poland (↓2) | 195 |

The UK continued to punch above its weight in innovative clinical trials in 2023. The UK retained its 9 per cent global share of clinical trials involving advanced therapy medicinal products (ATMPs), while globally there was a 10 per cent decrease in these trials.[6] Eighty per cent of all UK ATMP trials were sponsored by industry, with industry investment driving more than a twofold increase in the size of the UK's ATMP trial portfolio since 2018.[7] While globally there has been a shift in vaccine trials away from the US and Europe towards China, Japan and Australia, the UK has seen an increase in vaccine trials.[8]

In contrast to the increase in the number of pharmaceutical clinical trials initiated in the UK over the past two years, Europe has seen a declining share of clinical trials from 11 per cent of global clinical trial starts in 2021 to 9 per cent in 2023. The full impact of the new EU clinical trial regulation that came into force in January 2023 is currently unclear, but there are reports that approval timelines have increased in some countries.[9] Additionally, the EU in vitro diagnostic regulation introduced in 2022 brought more stringent requirements around the use of in vitro diagnostics in clinical trials, which may have played a part in the recent decline in oncology clinical trial initiations in the EU.[10]

The number of **phase III trial initiations** is **up 16.5%** in 2023 from 2022

# Recruitment

**Recruitment to interventional industry clinical trials**

Between 2022/2023 and 2023/2024, recruitment to UK industry research studies increased from 44,564 to 150,092 (Table 2). The sharp increase in participant numbers was due to a small number of commercial observational research studies, which together recruited upwards of 100,000 individuals.

Table 2: Number of participants recruited to interventional and observational industry research studies in the UK per year, as reported by the NIHR CRN, NRS, HCRW, NICRN, and NICTN (2017/18-2023/24)

| Study type | 2017/18 | 2018/19 | 2019/20 | 2020/21 | 2021/22 | 2022/23 | 2023/24 |
|---|---|---|---|---|---|---|---|
| Interventional | 30,971 | 33,802 | 24,466 | 33,507 | 26,822 | 25,730 | 22,191 |
| Observational | 27,309 | 18,444 | 15,956 | 10,050 | 11,708 | 18,834 | 128,000 |
| **Total** | **58,280** | **52,246** | **40,422** | **43,557** | **38,530** | **44,564** | **150,191** |

Despite the overall increase, the number of participants recruited into UK industry interventional clinical trials fell by 13.8 per cent from 25,730 in 2022/2023 to 22,191 in 2023/24. This continues a year-on-year decrease in the number of participants since 2020/2021 and is the lowest number of individuals participating in industry trials over the past seven-year period.

There are variations in this trend across the UK. Between 2022/2023 and 2023/2024 recruitment to interventional industry clinical trials remained stable in Wales (Appendix 1), and increased in Northern Ireland, but declined in England (by 13 per cent) and Scotland (by 20 per cent), which together account for the overall decrease, as 98 per cent of all participants in interventional industry trials conducted in the UK are in England and Scotland. This decline in Scotland is due to a single high throughput study with over a thousand recruits, which completed towards the end of 2022. There may be several explanations for this continuing decline in numbers, including increasingly complex clinical trials coming to the UK or more rare disease trials taking place, both of which require fewer overall participant numbers. Regardless, every effort must be made to ensure that all eligible patients across the UK are offered the opportunity to participate in clinical trials testing the latest therapies.

Participant numbers in industry interventional clinical trials in England over the seven years to 2023/2024 are illustrated in Figure 2. A total of 4.8 per cent of individuals participating in all interventional trials in the UK (industry and non-commercial) in 2023/2024 were recruited into industry interventional clinical trials, which is down from 5.4 per cent in 2022/2023, but still higher than during the pandemic years.

Figure 2: Number of participants recruited to industry interventional clinical trials (pharmaceutical and devices) in England per year, as reported by the NIHR CRN/RDN


# Speed

Streamlined and reliable study set up and delivery is vital to maximising UK patients' access to research. Delays in regulatory approval, costing and contracting, and overall study set-up reduce the time available for clinical trials with sites in multiple countries to recruit UK participants, as well as impacting the UK's reputation for speed and reliability of delivery.

## Regulatory approval

In 2023 there were significant delays in the regulatory approval of clinical trials by the MHRA. Action taken by the MHRA, including triaging applications, redeploying staff, and contracting and training additional assessors, resolved this backlog during 2023.[11] Since then, the timelines for MHRA regulatory approvals have remained stable and within statutory target times. Between September 2023 and October 2024, the average time taken to assess an initial clinical trial authorisation application was 28 days, within the MHRA's 30-day statutory target,[12] while the average time taken to assess an amendment to a trial's protocol was 29 days, well below the target of 35 days.[13] Ensuring that MHRA clinical trials assessments remain within statutory and agreed timelines will be crucial if the UK is to restore its reputation as a reliable destination to carry out multi-national industry clinical trials.

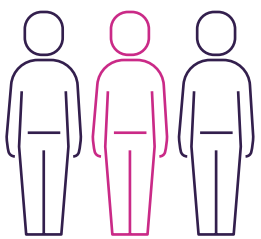
## Costing and contracting

The National Contract Value Review (NCVR) initiative is a standardised, national approach to costing industry research in the NHS. Introduced in 2023 to streamline costing and contracting, the NCVR became mandatory for most late-phase trials in October 2023. The NCVR is having a positive overall impact on accelerating study set-up. The average time taken to complete an initial study resource review is now 40.5 days, and the average time taken to set up commercial studies in the NHS is now 291 days faster than before the COVID-19 pandemic.[14]

However, as with the implementation of any new system, initial issues have been experienced for some studies, with delays to costings reviews at lead study sites, negative feedback on the quality of costings produced through NCVR, and unpredictable study set-up timelines. Members also report study sites requesting additional funding on top of the standardised costings produced through this new process. Positively, NIHR and NHS England have worked closely with the ABPI and our members to understand and unblock these issues, and we look forward to continuing this partnership approach. We also welcome the expansion of the NCVR to early-phase and ATMP trials from October 2024, following a successful six-month pilot.

## Study set-up

In response to the recommendations of the Lord O'Shaughnessy 2023 independent review of industry clinical trials, the Department of Health and Social Care (DHSC) introduced two new performance indicators for industry clinical trials: the proportion of commercial contract studies that open to recruitment within 60 days of regulatory approval; and the proportion of commercial contract studies that recruit their first participant within 30 days of opening to recruitment. In a welcome move to increase transparency, UK performance against these metrics is published monthly.[15]

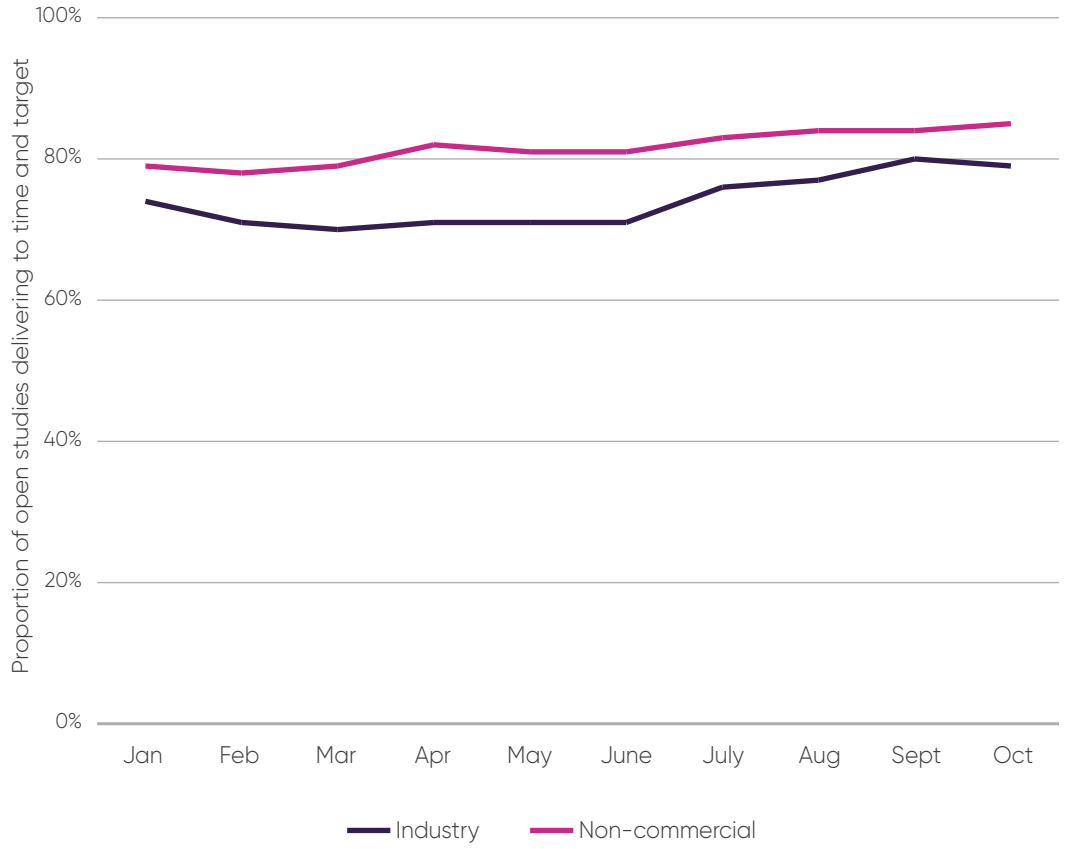


**20-30%** of industry trials **fail to hit recruitment targets** on time

The ABPI and our members are concerned that the proportion of commercial research studies opening to recruitment and recruiting their first patient within these timeframes has remained well below the government target of 90 per cent during 2024. According to the government's published performance data, the proportion of commercial research studies open to recruitment within 60 days of being approved declined from 29 per cent in January to 9 per cent in August.[16] The proportion of commercial research studies recruiting their first participant within 30 days of opening to recruitment remained more stable, varying between 44 per cent and 31 per cent during the period January to September 2024.[17]

Slow start-up times are likely to be the major contributor to many industry clinical trials not delivering to time and target. Between January and October 2024, between 20 per cent and 30 per cent of industry clinical trials were not recruiting the agreed number of participants within the agreed timeframe (Figure 3). Interestingly, time-to-target metrics for industry trials have remained consistently below those for non-commercial trials. There is a strong emphasis in industry trials to not only rapidly recruit the first patient into a trial, but also to recruit the last patient within the agreed timeframes. It is therefore important to understand where the delays are occurring across the whole process. This is particularly important as ABPI members report that the costs of conducting a study in the UK are high compared with competitor countries.

Figure 3: Proportion of industry and non-commercial studies delivering to time and target, by month, by study type (2024)[18]



While the causes will vary from trial to trial, feedback from ABPI members indicates that widespread NHS capacity constraints are the most common cause of delays, with the most frequently cited relating to personnel shortages, review of pharmacy manuals and radiation exposure. The sudden influx of studies following clearing of the MHRA's regulatory backlog in 2023, alongside the increasing numbers of clinical trials initiated (Figure 1), has increased demand on limited NHS research capacity.

In 2023, 74 per cent of the UK clinical research workforce reported it had been more difficult to deliver research over the previous 18 months due to pressures on health services, staff vacancies, and a lack of dedicated time for research.[19] Shortages within the research workforce and other critical professions are causing capacity constraints for the delivery of NHS research. The number of clinical research vacancies reached an all-time high of 295 full-time equivalents in 2023,[20] while the UK had 1,952 fewer radiologists than needed to provide an adequate radiology service, with this shortfall forecast to rise to 3,670 by 2028.[21]

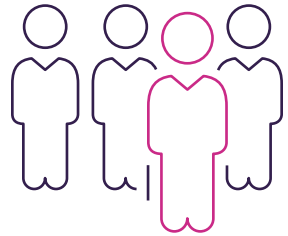
Delays in opening clinical trials and recruiting patients are a significant risk to the UK clinical trials recovery plans. Expanding NHS capacity for research should remain a key focus over the coming year.

# Benefits of clinical trials

Industry clinical trials generate significant benefits to patients, the NHS, the UK economy and the R&D base. According to a Frontier Economics report commissioned by the ABPI,[22] industry (pharmaceutical and devices) clinical trials in 2022:

- Generated significant economic benefit leading to £7.4 billion of GVA and supporting a total of 65,000 jobs across the UK. Of this GVA, £0.9 billion is from the contribution of industry clinical trials to improved patient outcomes in research-active hospitals, compared with research-inactive hospitals. These health improvements are estimated to prevent 3 million sick days per year.
- Generated benefits to the NHS bringing £1.2 billion of NHS revenue and supporting 13,000 jobs in the NHS.
- Strengthened UK R&D by resulting in almost 5,000 academic publications between 2019 and 2023, 11 per cent of which were in the top 1 per cent of most cited papers (compared to an EU benchmark of 5.7 per cent). These publications supported 283 patent applications, contributing to R&D spillover effects estimated to be worth £1.1 billion of GVA.

**UK Industry clinical trials** delivered **£7.4 billion of GVA** in 2022



**UK Industry clinical trials** supported **65,000 jobs** in 2022

**UK Industry clinical trials** bought the NHS **£1.2 billion of revenue** in 2022

**13,000 NHS jobs** were supported by **UK Industry clinical trials** in 2022

# Realising the potential of industry clinical trials in the UK

Increasing industry clinical trial activity in the UK would play a significant role towards realising the government's missions for health and economic growth, benefitting individuals and society. A recent ABPI-commissioned report estimated that a 40 per cent increase in industry clinical trial activity (comparable to 2017 levels) could generate an additional £3 billion of GVA and support 25,000 new jobs, including £485 million of NHS revenue and 5,000 clinical research jobs in the NHS.[23]

Globally, the UK has one of the highest potentials for growth in industry clinical trials in the world, particularly for large-scale, late-phase clinical trials.[24] It will be important for the UK to capitalise on this potential, at a time when trials are pivoting away from Europe.[25] Public enthusiasm for clinical research is high, with 76 per cent saying they would support their MP campaigning for their local hospital to deliver more trials.[26]

While this report demonstrates that there are encouraging signs of improvement in the UK clinical trials ecosystem, there are still ongoing challenges, especially with lengthy set-up times leading to trials not delivering to time and target. Addressing these systemic challenges[27] faced by companies delivering UK trials will be essential to increasing the UK's competitiveness. Expanding patient access to trials by boosting NHS research workforce capacity and implementing system efficiencies to expedite trial delivery must remain a government priority.

Within the context of the current barriers and emerging opportunities in the UK clinical trials ecosystem, the ABPI recommends that the government focus on addressing the following six priorities:

# Seizing the opportunity of the VPAG Investment Programme

**Recommendation 1:**
**The VPAG Clinical Trials Investment Programme funds should be invested in line with pharmaceutical industry expectations to boost capacity and infrastructure.**

Announced in August 2024, the VPAG will bring significant investment to UK health and life sciences over the next five years. Three-quarters of the VPAG Investment Programme funding, up to £300 million, will be invested in expanding the UK's capacity and capability for commercial clinical trials.

CRDCs, comprising NHS trusts working in partnership with primary and community care, will be established across the four nations to enhance and build on the UK's commercial clinical trials infrastructure. Additional funding will also be available to boost workforce capacity, infrastructure, and resources, supporting industry trials and patient recruitment across a range of care delivery settings. The ABPI has commissioned an exercise to map global industry clinical trial pipelines and the resulting capacity and infrastructure needs for the UK to deliver these trials. Decisions about targeting this additional VPAG Investment Programme funding should be informed by the findings of this exercise, to ensure that the UK can rapidly respond to industry's current and future trial demands.

The VPAG Investment Programme funding contributed by the pharmaceutical industry is a world first and a unique opportunity for the UK to address some of the key barriers preventing the timely delivery of industry trials. It provides an impetus for the four UK nations to work together in a more coordinated way, enabling more patients to reap the benefits of participating in trials, through the UK-wide reach of the clinical trials Investment Programme funding. To realise this promise, the government must invest the Investment Programme funds as intended by industry as part of the VPAG deal, to facilitate the accelerated delivery of pharmaceutical industry clinical trial pipelines.

# Demonstrating continued government commitment

## Recommendation 2:

**In implementing improvements in the UK clinical trials environment, government should prioritise reducing set-up times for trial delivery.**

Industry's confidence in the UK as a reliable delivery partner was severely damaged in the immediate years after the pandemic. These perceptions still need to be reversed to encourage the global pharmaceutical industry to place more clinical trials in the UK. Demonstration of continued government commitment and focus on improving the UK ecosystem to support the timely delivery of industry clinical trials will play an important role in rebuilding the UK's reputation.

During 2023 and 2024, significant progress was made in implementing the recommendations of the 2023 O'Shaughnessy review of commercial clinical trials. It is vital that implementation of these activities continues and is prioritised by the new government. The uplift in NIHR funding, promised in the Autumn Budget, should earmark funds to accelerate the delivery of the review recommendations, in particular supporting additional capacity within the NHS research workforce and allied professions. The upcoming Life Sciences Sector Plan offers a further opportunity to clearly demonstrate government commitment and ambition to continued improvement of UK clinical trial delivery.

Although there have been some reductions in trial set-up times in 2024, significant improvements still need to be made. Additional streamlining and standardisation of site set-up processes would further reduce timelines. Options for sustainably achieving this should be taken forward by government as a priority.

## Recommendation 3:

**The route for industry engagement with the UK clinical trials delivery system must be streamlined and integrated.**

The UK clinical trials delivery infrastructure can be complex to navigate, with many different organisations and touchpoints involved across the UK. The route for industry engagement should be simplified wherever possible, offering commercial sponsors a more integrated, personalised, and responsive service. This would facilitate a better two-way flow of information between sponsors and delivery partners, enabling the system to plan and respond to future capacity needs in advance of trials arriving in the UK. Any proposed solutions to integrate and streamline entry points and engagement with industry, such as the RDN account management service, should be designed in partnership with sponsors. The ongoing NIHR industry engagement review should play an important part in informing how the NIHR and the RDN work with industry. This should be augmented by NIHR and DHSC engagement with senior global R&D leads to build a shared understanding of the UK's attractiveness as a clinical trials destination and trends in future clinical trials pipelines.

# Embedding research in the NHS

## Recommendation 4:

**Embed research as business as usual in the NHS, offering every patient the opportunity to participate in studies of novel treatments and cutting-edge interventions.**

NHS trusts that engage in research have better patient outcomes with lower mortality, shorter hospital stays and improved patient-care experiences. Research also offers patients the opportunity to be involved in testing cutting-edge treatments and innovations. This is particularly important for patients where there are no standard-of-care treatment options. Commercial research also generates significant income for the NHS – £1.2 billion in 2022/2023 – in addition to NHS savings on provision of care, which is funded by industry.

Industry-sponsored research supports jobs in the NHS and improves staff satisfaction. Leadership of NHS organisations should drive a step-change in the way research is viewed and valued within the NHS, by promoting and embedding research as part of routine care. This cultural change will ensure all patients who are eligible to take part in research are offered the choice to participate. The upcoming NHS 10-Year Plan is an opportunity to set out how this change will be led by NHS leadership. The Life Sector Plan should include a commitment for integrated care systems research activities to be measured and the findings made available, allowing government, the NHS, patients, and their families to understand whether patients have been offered the opportunity to participate in studies of the latest cutting-edge treatments.

## Recommendation 5:

**Government and NHS should publish a research workforce plan to improve clinical research delivery within the NHS.**

Research is being embedded within integrated care systems, as mandated by the 2022 Health and Care Act, and should be supported by work to embed research into staff roles.[28] This includes staff upskilling and protected research time, and allowing for staff such as pharmacists to become more involved in research.[29] Industry clinical trials generate significant revenue for the NHS. Reinvesting this additional income into creating a research-enabled workforce, alongside an implementation plan for expanding the NHS research workforce, would directly contribute to delivering this vision, and should be a commitment in the NHS 10-Year Plan.

# Increasing transparency and tracking progress

## Recommendation 6:

**System partners must expedite increased transparency and accountability for UK clinical trial performance through standardisation, timeliness, and consistency of performance reporting.**

The monthly Clinical Research Delivery Performance Indicator reports[30] are a welcome move towards tracking closer to real-time status of UK clinical trials delivery. However, further transparency is needed to enable real-time identification of blockers and issues within the UK trial delivery system so they can be tackled in a more agile way. For example, metrics should be introduced measuring the time taken from first site opening to last site opening.

Standardisation of metrics, with increased timeliness and consistency should be facilitated using improved data collection systems. This further transparency and metrics will demonstrate how equitable and widespread access to industry clinical trials is throughout the NHS. In addition, there should be clear accountability for addressing delays and blockers when they arise, alongside flexible resources that can be deployed to unblock delivery issues when needed, for example when a particular trial or site encounters delays. This approach should be set out within the upcoming Life Sciences Sector Plan and the NHS 10-Year Plan.

# Conclusion

During 2023, there was a welcome increase in the number of industry clinical trials initiated in the UK, suggesting the initial progress observed in 2022 towards restoring UK competitiveness[31] is continuing. However, serious delays persist in the set-up and delivery of clinical trials in the UK, and these need to be resolved if the UK is to return to one of the top destinations in Europe for the delivery of clinical trials. There is increasing competitiveness within European countries to attract industry clinical trials. Spain has shown a particularly strong performance over the past decade with investment in clinical trials rising at an average annual rate of 5.7 per cent.[32] Germany is also taking steps to attract more inward investment in clinical trials by providing incentives for commercial terms for new medicines if at least 5 per cent of all global clinical trial participants are enrolled at German sites.[33]

There is an opportunity for the UK to significantly course-correct, with a new government committed to improving UK clinical trial delivery, a new RDN across England and a major injection of funds to improve clinical trial delivery from the VPAG Investment Programme. The pending NHS 10-Year Plan and Life Sciences Sector Plan can provide the blueprint to deliver on these promises.

The forthcoming clinical trials legislation, which, after a long delay, is set to be passed in early 2025, will encourage sponsors to provide diversity and inclusion plans alongside their trial applications. Other jurisdictions require similar trial diversity plans. Although the UK is only a medium-sized country, it has a diverse population, which can be attractive to the global pharmaceutical industry seeking greater diversity in trial participants.

Restoring UK industry clinical trials activity to levels comparable to 2017 would generate an additional £3 billion of GVA and support 25,000 new jobs.[34] These potential benefits directly align with the government's economic mission, delivered through industry and system partnerships. In addition to bringing significant patient benefits and developing cutting-edge medicines and vaccines, the Darzi review[35] recognised that innovation can form an important cornerstone for NHS sustainability. "Partnerships with the life science sector for research or treatment too often fall into the category of 'important but not urgent'… But in the medium term, it is innovation that can make the NHS more sustainable."

We believe the six recommendations made by the ABPI and our members should be addressed if we are to build on the signs of recovery demonstrated in this report. We urge the government and delivery partners to focus on these priorities and work in partnership with the pharmaceutical industry to co-design a more efficient system to deliver industry trials across the UK. The potential size of the prize to the economy, the NHS, R&D base and patients is considerable. Now is the time to seize this opportunity and demonstrate that the UK is genuinely back in business.

# Appendix 1: Additional data on clinical trial recruitment

Number of participants recruited to industry research studies in the UK per year, as reported by the NIHR CRN, NRS, HCRW, NICRN, and NICTN (2017/2018-2023/2024)

| Devolved Nation/Local Clinical research network (LCRN) | 2017/18 | 2018/19 | 2019/20 | 2020/21 | 2021/22 | 2022/23 | 2023/24 |
|---|---|---|---|---|---|---|---|
| Scotland | 7,221 | 4,590 | 9,787 | 5,213 | 8,118 | 9,140 | 8,361 |
| Wales | 1,143 | 961 | 838 | 1,147 | 625 | 775 | 786 |
| Northern Ireland | 356 | 144 | 129 | 524 | 200 | 114 | 251 |
| East Midlands | 3,294 | 1,650 | 1,350 | 1,813 | 1,509 | 1,887 | 23,335 |
| East of England | 3,361 | 2,775 | 4,793 | 2,862 | 2,621 | 2,717 | 8,977 |
| Greater Manchester | 3,653 | 4,513 | 3,306 | 3,859 | 4,456 | 3,474 | 8,384 |
| Kent, Surrey and Sussex | 4,888 | 1,576 | 1,016 | 1,372 | 993 | 1,083 | 3,144 |
| North East and North Cumbria | 2,625 | 1,755 | 1,454 | 2,032 | 1,907 | 2,592 | 4,532 |
| North Thames | 4,211 | 6,379 | 2,671 | 4,997 | 3,232 | 2,815 | 11,790 |
| North West Coast | 3,003 | 1,873 | 1,431 | 2,335 | 1,400 | 1,955 | 9,440 |
| North West London | 1,736 | 4,597 | 1,659 | 2,060 | 1,095 | 3,448 | 7,469 |
| South London | 3,018 | 2,862 | 1,972 | 2,717 | 2,402 | 2,467 | 4,676 |
| South West Peninsula | 2,185 | 2,006 | 1,356 | 2,716 | 1,477 | 2,063 | 3,964 |
| Thames Valley and South Midlands | 4,368 | 4,986 | 1,766 | 1,857 | 1,428 | 1,510 | 9,029 |
| Wessex | 1,774 | 2,835 | 1,160 | 1,854 | 1,179 | 1,744 | 9,181 |
| West Midlands | 5,235 | 4,377 | 2,064 | 2,001 | 1,656 | 2,799 | 6,088 |
| West of England | 1,798 | 1,197 | 1,045 | 967 | 1,506 | 1,410 | 14,371 |
| Yorkshire and Humber | 4,411 | 3,170 | 2,625 | 3,231 | 2,726 | 2,571 | 16,413 |
| England-only total | 49,560 | 46,551 | 29,668 | 36,673 | 29,587 | 34,535 | 140,793 |
| UK-wide total | 58,280 | 52,246 | 40,422 | 43,557 | 38,530 | 44,564 | 150,191 |

Number of participants recruited to interventional industry research studies in the UK per year, as reported by the NIHR CRN, NRS, HCRW, NICRN, and NICTN (2017/2018-2023/2024)

| Devolved Nation/Local Clinical research network (LCRN) | 2017/18 | 2018/19 | 2019/20 | 2020/21 | 2021/22 | 2022/23 | 2023/24 |
|---|---|---|---|---|---|---|---|
| Scotland | 6,374 | 3,707 | 8,822 | 3,500 | 7,205 | 4,413 | 3,516 |
| Wales | 485 | 651 | 377 | 898 | 368 | 436 | 441 |
| Northern Ireland | 141 | 119 | 106 | 523 | 119 | 34 | 94 |
| East Midlands | 1,068 | 1,004 | 453 | 1,442 | 1,197 | 1,150 | 1,476 |
| East of England | 1,927 | 1,995 | 1,726 | 1,753 | 1,594 | 1,981 | 1,868 |
| Greater Manchester | 2,758 | 2,854 | 2,302 | 2,990 | 3,086 | 2,249 | 1,560 |
| Kent, Surrey and Sussex | 1,197 | 1,144 | 412 | 671 | 453 | 637 | 744 |
| North East and North Cumbria | 1,304 | 1,244 | 563 | 1,631 | 1,369 | 1,400 | 706 |
| North Thames | 2,281 | 4,345 | 1,443 | 4,278 | 1,752 | 1,861 | 1,585 |
| North West Coast | 914 | 1,028 | 625 | 2,012 | 871 | 1,399 | 1,738 |
| North West London | 913 | 4,179 | 709 | 1,250 | 722 | 634 | 767 |
| South London | 1,368 | 1,344 | 1,123 | 2,209 | 1,650 | 1,760 | 1,082 |
| South West Peninsula | 906 | 1,396 | 644 | 2,153 | 988 | 1,269 | 945 |
| Thames Valley and South Midlands | 3,167 | 1,507 | 1,364 | 1,550 | 886 | 986 | 1,254 |
| Wessex | 873 | 1,218 | 637 | 1,503 | 765 | 1,446 | 1,187 |
| West Midlands | 2,429 | 3,018 | 976 | 1,728 | 959 | 820 | 884 |
| West of England | 630 | 849 | 529 | 717 | 1,064 | 1,187 | 738 |
| Yorkshire and Humber | 2,236 | 2,200 | 1,655 | 2,699 | 1,774 | 2,068 | 1,606 |
| England-only total | 23,971 | 29,325 | 15,161 | 28,586 | 19,130 | 20,847 | 18,140 |
| UK-wide total | 30,971 | 33,802 | 24,466 | 33,507 | 26,822 | 25,730 | 22,191 |

Number of participants recruited to observational industry research studies in the UK per year, as reported by the NIHR CRN, NRS, HCRW, NICRN, and NICTN (2017/18-2023/2024)

| Devolved Nation/Local Clinical research network (LCRN) | 2017/18 | 2018/19 | 2019/20 | 2020/21 | 2021/22 | 2022/23 | 2023/24 |
|---|---|---|---|---|---|---|---|
| Scotland | 847 | 883 | 965 | 1,713 | 913 | 4,727 | 4,845 |
| Wales | 658 | 310 | 461 | 249 | 257 | 339 | 345 |
| Northern Ireland | 215 | 25 | 23 | 1 | 81 | 80 | 157 |
| East Midlands | 2,226 | 646 | 897 | 371 | 312 | 737 | 21,859 |
| East of England | 1,434 | 780 | 3,067 | 1,109 | 1,027 | 736 | 7,109 |
| Greater Manchester | 895 | 1,659 | 1,004 | 869 | 1,370 | 1,225 | 6,824 |
| Kent, Surrey and Sussex | 3,691 | 432 | 604 | 701 | 540 | 446 | 2,400 |
| North East and North Cumbria | 1,321 | 511 | 891 | 401 | 538 | 1,192 | 3,826 |
| North Thames | 1,930 | 2,034 | 1,228 | 719 | 1,480 | 954 | 10,205 |
| North West Coast | 2,089 | 845 | 806 | 323 | 529 | 556 | 7,702 |
| North West London | 823 | 418 | 950 | 810 | 373 | 2,814 | 6,702 |
| South London | 1,650 | 1,518 | 849 | 508 | 752 | 707 | 3,594 |
| South West Peninsula | 1,279 | 610 | 712 | 563 | 489 | 794 | 3,019 |
| Thames Valley and South Midlands | 1,201 | 3,479 | 402 | 307 | 542 | 524 | 7,775 |
| Wessex | 901 | 1,617 | 523 | 351 | 414 | 298 | 7,994 |
| West Midlands | 2,806 | 1,359 | 1,088 | 273 | 697 | 1,979 | 5,204 |
| West of England | 1,168 | 348 | 516 | 250 | 442 | 223 | 13,633 |
| Yorkshire and Humber | 2,175 | 970 | 970 | 532 | 952 | 503 | 14,807 |
| England-only total | 25,589 | 17,226 | 14,507 | 8,087 | 10,457 | 13,688 | 122,653 |
| UK-wide total | 27,309 | 18,444 | 15,956 | 10,050 | 11,708 | 18,834 | 128,000 |

Number of participants recruited to research studies in England per year, as reported by the NIHR (2017/2018-2023/2024)

| Year | Total recruitment | Industry recruitment | Industry recruitment (per cent of total recruitment) |
|---|---|---|---|
| 2017/18 | 808,523 | 49,560 | 6.1 per cent |
| 2018/19 | 973,145 | 46,551 | 4.8 per cent |
| 2019/20 | 834,703 | 29,668 | 3.6 per cent |
| 2020/21 | 2,293,386 | 36,673 | 1.6 per cent |
| 2021/22 | 1,470,975 | 29,587 | 2.0 per cent |
| 2022/23 | 1,068,877 | 34,535 | 3.2 per cent |
| 2023/24 | 1,096,405 | 140,793 | 12.8 per cent |

Number of participants recruited to interventional clinical trials in England per year, as reported by the NIHR (2017/2018-2023/2024)

| Year | Total recruitment | Industry recruitment | Industry recruitment (per cent of total recruitment) |
|---|---|---|---|
| 2017/18 | 232,229 | 23,971 | 10.3 per cent |
| 2018/19 | 263,676 | 29,325 | 11.1 per cent |
| 2019/20 | 238,203 | 15,161 | 6.4 per cent |
| 2020/21 | 906,409 | 28,586 | 3.2 per cent |
| 2021/22 | 551,000 | 19,130 | 3.5 per cent |
| 2022/23 | 383,868 | 20,847 | 5.4 per cent |
| 2023/24 | 376,607 | 18,140 | 4.8 per cent |

# Appendix 2: System partner acronyms

**NIHR CRN:** National Institute for Health and Care Research Clinical Research Network

**NIHR RDN:** National Institute for Health and Care Research Research Delivery Network

**NRS:** NHS Research Scotland

**HCRW:** Health and Care Research Wales

**NICRN:** Northern Ireland Clinical Research Network

**NICTN:** Northern Ireland Cancer Trial Network

# Endnotes


1 The Association of the British Pharmaceutical Industry, 'Getting back on track: Restoring the UK's global position in industry clinical trials', 2023, available here.

2 Department of Health and Social Care, 2023, 'Full government response to the Lord O'Shaughnessy review into commercial clinical trials', available here.

3 The Association of the British Pharmaceutical Industry, 'Getting back on track: Restoring the UK's global position in industry clinical trials', 2023, available here.

4 The Association of the British Pharmaceutical Industry, '2024 Voluntary Scheme agreement published', 2023, available here.

5 EFPIA, 'Assessing the clinical trial ecosystem in Europe', 2024, available here.

6 Cell and Gene Therapy Catapult, 'Clinical Trials Database 2023 – Highlights', 2024, available here.

7 Ibid.

8 EFPIA, 'Assessing the clinical trial ecosystem in Europe', 2024, available here.

9 Ibid.

10 Ibid.

11 The Association of the British Pharmaceutical Industry, 'Getting back on track: Restoring the UK's global position in industry clinical trials', 2023, available here.

12 Medicines & Healthcare products Regulatory Agency, 'Performance Metrics: Assessment of Clinical Trial Authorisation Applications, Clinical Investigations and Amendments', 2024, available here.

13 bid.

14 NIHR for Industry blog on LinkedIn October 24, available here.

15 Department of Health and Social Care, 'UK Clinical Research Delivery Performance Indicators Report', 2024, available here.

16 Ibid.

17 Ibid.

18 Ibid.

19 Cancer Research UK, '2023 Survey of the UK Clinical Research Workforce', 2023, available here.

20 Medical Schools Council, 'Clinical academic survey', 2024, available here.

21 The Royal College of Radiologists, 'Clinical Radiology Workforce Census", 2023, available here.

22 Frontier Economics, 'The value of industry clinical trials report', 2024, available here.

23 Ibid.

24 IQVIA Institute for Human Data Science, 'Rethinking Clinical Trial Country Prioritization', 2024, available here.

25 EFPIA, 'Assessing the clinical trial ecosystem in Europe', 2024, available here.

26 Campaign for Science and Engineering, 'CaSE's Guide to R&D on the Doorstep', 2024, available here.

27 Association of the British Pharmaceutical Industry, 'Getting back on track: Restoring the UK's global position in industry clinical trials', 2023, available here.

28 NHS England, 'Multi-professional practice-based research capabilities framework', 2024, available here.

29 NHS England, 'Report of a UK survey of pharmacy professionals' involvement in research', 2024, available here.

30 Department of Health and Social Care, 'UK Clinical Research Delivery Performance Indicators Report', 2024, available here.

31 The Association of the British Pharmaceutical Industry, 'Getting back on track: Restoring the UK's global position in industry clinical trials', 2023, available here.

32 EFPIA, 'Assessing the clinical trial ecosystem in Europe', 2024, available here.

33 Lightning Health, 'Germany Medical Research Act 2024: Updates to drug pricing and reimbursement', 2024, available here.

34 Frontier Economics, 'The value of industry clinical trials report', 2024, available here.

35 Lord Darzi, 'Independent investigation of the National Health Service in England', 2024, available here.

## About the ABPI

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines.

We represent companies of all sizes who invest in discovering the medicines of the future. Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

**The Association of the British Pharmaceutical Industry**

A company limited by guarantee registered in England & Wales number 09826787

Registered office 2nd Floor Goldings House, Hay's Galleria, 2 Hay's Lane, London, SE1 2HB

RMI-0180-1224

Trusted Information Creator
Patient Information Forum