Life Sciences R&D

Rescuing patient access to industry clinical trials in the UK

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.

Executive summary

- Patient access to industry research has fallen dramatically from 50,112 participants recruited to industry clinical trials on the National Institute for Health and Care Research Clinical Research Network (NIHR CRN) in 2017/18 to 28,193 in 2021/22 – a 44% decline.
- Reduced access to interventional industry clinical trials has significant consequences for patients, whose access to innovative treatments is diminishing. This has particularly serious implications for the health outcomes of patients with limited treatment options in routine care, such as people living with rare diseases.
- Consistently slow and variable study set-up timelines are driving this decline. Between 2018 and 2020, the median time between a clinical trial in the UK applying for regulatory approval and that trial delivering its first dose to a participant rose by 25 days to 247 days – placing the UK 7th amongst a basket of comparator countries.
- As a result, the number of industry clinical trials initiated in the UK per year has fallen by 41% between 2017 and 2021. Pharmaceutical companies are increasingly placing their trials in other countries (e.g. Spain and Australia) and reviewing UK research affiliate headcounts. The ABPI's data shows this is already impacting the UK's global rankings, with the UK dropping from 4th in 2017 to 10th in 2021 for Phase III industry clinical trials.
- The decline in patient access to research and industry clinical trial activity points to a clear and serious threat to the long-term future of industry clinical research in the UK – and the benefits it brings to patients, the NHS, and the economy. The Government must act decisively to prevent further decline and stave off this existential threat to the UK life sciences sector and healthcare ecosystem.
- If the system can preserve and grow the UK life sciences sector, it is estimated to yield significant benefits, including an additional £68 billion of GDP for the UK economy from increased R&D investment and a 40% decrease in total attributable burden of disease.

Short-term recommendations

Rapid implementation of the three sets of short-term recommendations below is essential to regaining the UK's competitiveness in industry clinical research, alongside the long-term recommendations in the ABPI's report *Clinical research in the UK: An opportunity for growth*.

I. Prioritise interventional industry clinical trials

1. The Research Reset initiative should accelerate prioritisation of the set-up and delivery of interventional clinical trials of new medicines and vaccines, especially global studies where the UK is competing for participation.
2. NHS England (NHSE) and the devolved administrations should establish mechanisms to improve coordination between companies and study sites.

II. Improve set-up processes for industry clinical trials

3. NHSE and the devolved administrations should introduce a 60-day maximum timeframe, with limited negotiation, for costing and contracting of industry clinical research.
4. NHSE and the devolved administrations should commit to achieving UK-wide use of unmodified model contracts for industry clinical research.
5. NHSE should work at pace to ensure all NHS Trusts in England are committed to adhering to prices generated by the interactive Costing Tool for industry clinical research.
6. NHSE should develop hub-and-spoke model contracts for Integrated Care Systems (ICSs) that cover all providers in an ICS's catchment in a single contract.

III. Leverage industry trials to boost NHS research capacity and culture

7. NHSE and its devolved equivalents should reinvest revenue generated by industry clinical research into increasing the provision of dedicated research time and research training, especially for nurses and other staff critical to delivering clinical trials.
8. NHSE and the devolved administrations should mandate rapid invoicing for all research costs, as current delays in invoicing deprive the NHS of much-needed research revenue.
9. NHSE and the devolved administrations should consistently incorporate research leadership into the role descriptions for NHS R&D Directors, Medical Directors, Directors of Nursing, and Chief Executives.
10. NHSE should incorporate best practices in research finance into its upcoming research guidance for ICSs.
11. NHSE should work with the pharmaceutical industry to co-develop research guidance and research performance metrics for ICSs.

Decline of industry clinical research in the UK

For the *Life Sciences Vision* to be a success, the NHS must become a full innovation partner by delivering the Health and Care Act's mandate for research and achieving the *Future of UK Clinical Research Delivery* ambition to increase the NHS's research capacity.

However, the UK's deteriorating ability to attract and deliver industry clinical trials poses a serious and growing obstacle to delivering on this ambition.

UK patient access to industry clinical trials and their treatments has fallen dramatically

In 2021/22, 28,193 participants were recruited to industry clinical trials on the National Institute for Health and Care Research Clinical Research Network (NIHR CRN),[1] which equates to 2.2% of total recruitment to studies on the NIHR CRN. This represents a significant decline from the 50,112 participants recruited to industry trials (5.9% of total recruitment) in 2017/18 (Table 1).

The NIHR's data also shows that fewer than half of industry clinical trials recruit their target number of participants.[2] This inability to consistently meet recruitment targets helps to explain why industry clinical trials in the UK treat fewer participants (on average) than trials in competitor countries (Graph 1).

Reduced access to interventional industry clinical trials – including those developing potentially life-saving or life-enhancing new medicines and vaccines – has significant consequences for patients. This has particularly serious implications for the health outcomes of patients with limited treatment options in routine care, such as people living with rare diseases.

Industry clinical trial activity in the UK is at its lowest point to date

The ABPI's data shows that **the number of industry clinical trials initiated in the UK per year has fallen by 41% between 2017 and 2021**, with oncology clinical trials falling by the same margin. This decline has been most pronounced in Phase III industry trials – those with medicines closest to market – with the number initiated in the UK per year falling by 48% between 2017 and 2021 (Graph 2).

This is resulting in a significant drop in industry clinical trial activity in the UK, with pharmaceutical companies increasingly placing their trials in other countries, such as Spain and Australia, and reviewing UK affiliate research headcounts. The ABPI's data shows this is already impacting the UK's global rankings, **with the UK dropping from 4th globally in 2017 to 10th in 2021 for Phase III industry clinical trials (Tables 2-3).**

Case study 1

In 2021-2022, an ABPI member company was planning two global vaccine studies. The company had experience delivering similar clinical trials in the same indication in the UK. The UK also had enough Clinical Microbiology and Infection (CMI) laboratory capacity to handle the studies' samples, and a sufficient number of eligible patients had been identified to make UK participation possible.

However, while study sites in other countries could recruit 25-30 participants each, sites in the UK said they could only recruit 10-20 and were unable to commit to delivering the studies due to uncertainty over their resources. These factors, combined with concerns over potential delays to imports caused by the risk of licence changes between the UK and EU, resulted in the studies being awarded to other countries.

Case study 2

In 2022, an ABPI member company was planning a global Phase II clinical trial for patients with small-cell lung cancer. Three study sites in the UK were chosen for inclusion in the study.

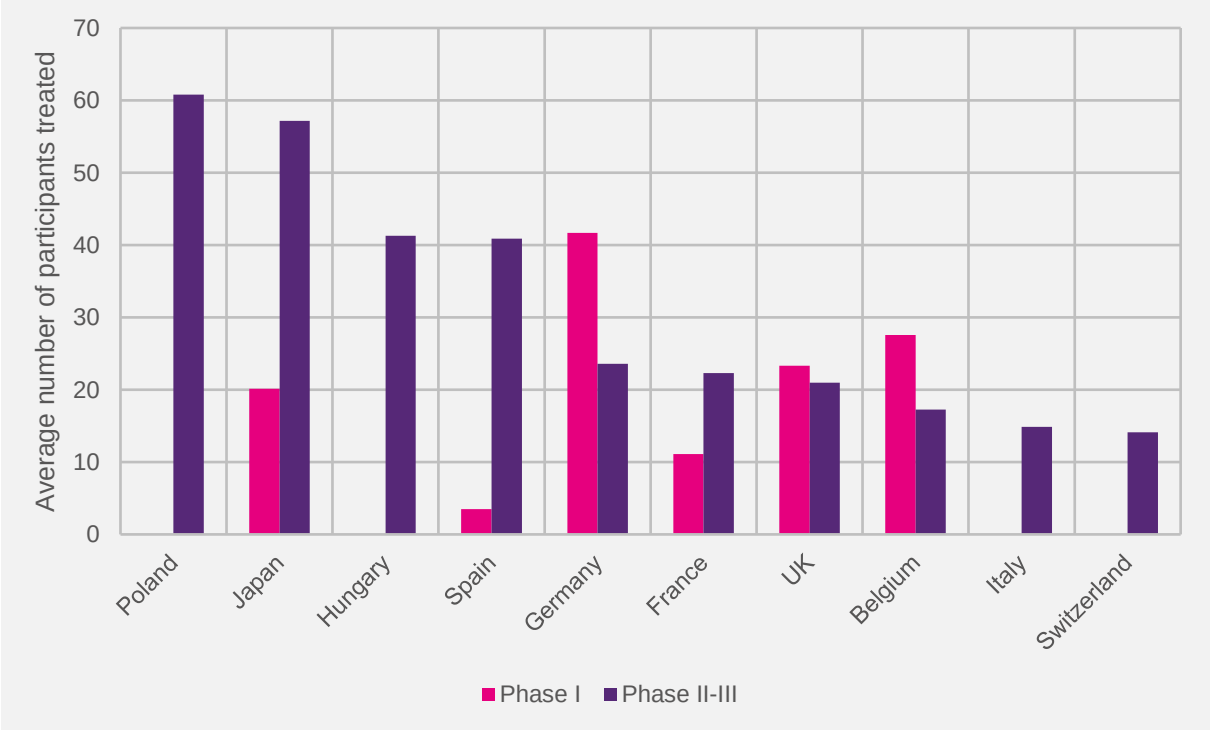
Two of those sites have experienced significant delays in costing and contracting negotiations, resulting from ongoing issues with the NHS's research capacity. For example, one site has not accepted the study document pack, so negotiations have not even started, which means the site is unlikely to be involved in the clinical trial.

Meanwhile, recruitment in other countries participating in the clinical trial is well ahead of schedule, so recruitment is expected to close early. As a result, UK patients with small cell lung cancer will lose the opportunity to access this clinical trial and its potentially life-extending treatment.

Table 1: Number of participant recruits in research studies supported by the NIHR CRN, as reported in NIHR CRN Annual Reports (2017/18-2021/22)

Year	Total recruits	Industry recruits	Industry recruits (% of total)
2017/18	853,904	50,112	5.9%
2018/19	870,250	46,064	5.3%
2019/20	732,176	28,832	3.9%
2020/21	1,390,483	35,488	2.6%
2021/22	1,289,937	28,193	2.2%

Graph 1: Average number of participants treated per industry clinical trial, by country, by phase (2018-2020)



Graph 2: Number of industry clinical trials initiated in the UK per year, by phase (2012-2021)

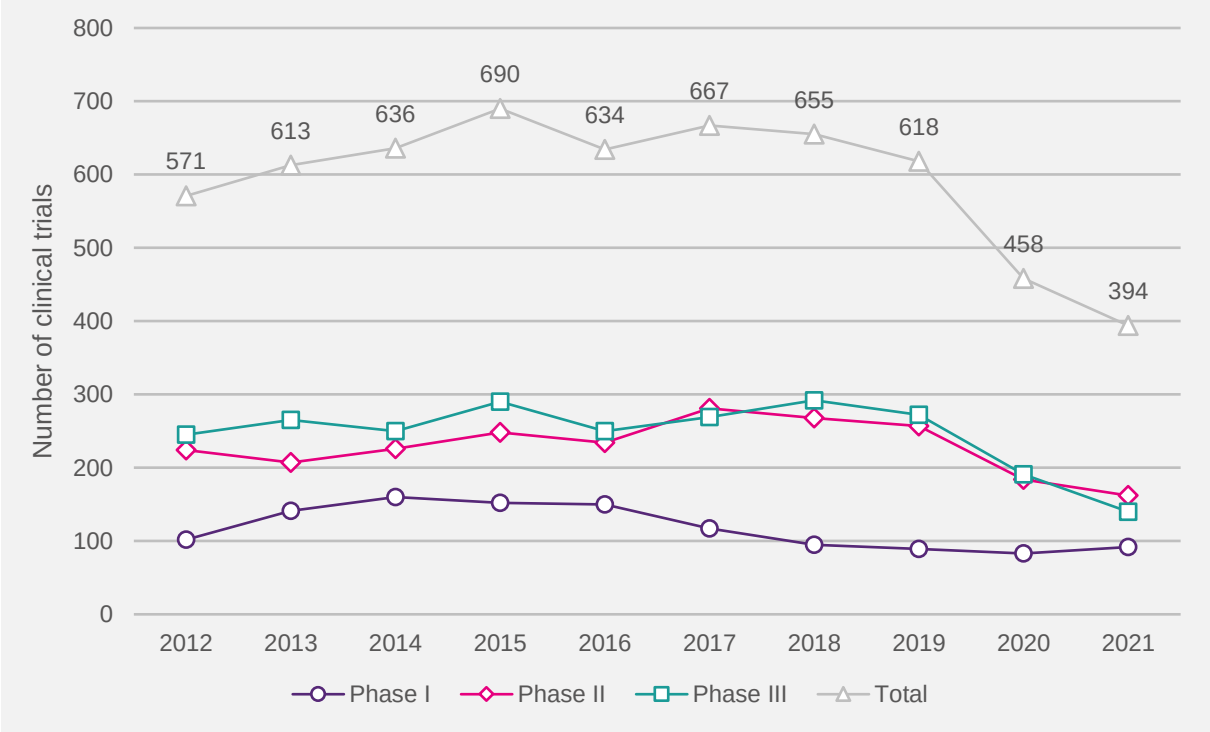


Table 2: Global rankings – Number of industry clinical trials initiated in 2021, by country, by phase

Rank	Country	Phase I	Country	Phase II	Country	Phase III
1	USA	505	USA	1016	USA	478
2	China	395	China	478	China	271
3	Australia	107	Spain	194	Spain	217
4	**UK**	92	Australia	169	Japan	190
5	Japan	81	Japan	168	Germany	181
6	Spain	62	**UK**	162	Canada	170
7	Germany	46	Canada	159	France	165
8	Canada	42	Germany	152	Poland	158
9	France	35	France	152	Italy	156
10	Belgium	31	Italy	138	**UK**	140

Table 3: Global rankings – Number of industry clinical trials initiated in 2017, by country, by phase

Rank	Country	Phase I	Country	Phase II	Country	Phase III
1	USA	473	USA	988	USA	536
2	China	178	**UK**	281	Germany	294
3	**UK**	117	Germany	262	Spain	274
4	Germany	94	Spain	229	**UK**	269
5	Japan	85	Japan	229	Canada	267
6	Australia	78	Canada	201	Poland	250
7	Canada	66	France	198	Japan	246
8	Spain	60	Italy	167	Italy	241
9	France	51	China	146	France	224
10	Belgium	37	Belgium	137	Australia	183

Recommendations

The decline in patient access to research and industry clinical trial activity points to a clear and serious threat to the long-term future of industry clinical research in the UK – and the benefits it brings to patients, the NHS, and the economy.

The Government must act decisively to prevent further decline and stave off this existential threat to the UK life sciences sector and healthcare ecosystem. Below, the ABPI has set out three sets of actions the Government can support the NHS to take in the next six months to stabilise and increase industry clinical trial activity in the UK.

I. Prioritise interventional industry clinical trials

In the Government's words: "the number of studies in the NHS is now higher than ever before."[3]

This glut of studies has placed unprecedented demands on the NHS's research capacity, which is simultaneously being constrained by record waiting lists[4] and increased staff fatigue and turnover.[5] This mismatch between demand and supply of clinical research has left the system overloaded and inefficient, resulting in the number of clinical trials stuck in set-up rising well above pre-pandemic levels. Consequently, it is increasingly challenging for the NHS to set up and deliver interventional industry clinical trials within the timeframes expected of a globally-competitive and innovative destination for pharmaceutical R&D.

The ABPI has consistently supported cross-sector efforts to restart and recover the UK's entire clinical research portfolio via the Restart Framework, Managed Recovery, and Research Reset initiatives. However, these initiatives have failed to improve the volume and performance of interventional studies at the pace needed. Unless clinical research capacity is focused on delivering interventional studies, the system will continue to be overloaded and inefficient, furthering the decline of industry clinical research in the UK.

To prevent this outcome, the Research Reset initiative must accelerate efforts to:

- Prioritise the supply of research capacity to high-priority interventional clinical trials of new medicines and vaccines;
- Reduce demand on capacity by withdrawing NIHR CRN support from underperforming or completed studies.

Currently, there is limited system-wide coordination between funders of clinical trials and study sites, which has made it challenging to match demand and capacity. To address this barrier to prioritisation, the mechanisms that facilitate coordination between companies planning clinical trials and study sites with capacity to deliver them must be improved.

Prioritisation recommendations:

1. The Research Reset initiative should accelerate prioritisation of the set-up and delivery of interventional clinical trials of new medicines and vaccines, especially global studies where the UK is competing for participation.

2. NHSE and the devolved administrations – in coordination with the ABPI and other life sciences sector stakeholders – should establish mechanisms to improve coordination between companies and study sites. These mechanisms should be designed with the aim of:

- Ensuring companies are well informed when seeking study sites with available capacity to deliver their planned clinical trial;
- Ensuring study sites are well informed when deciding whether to agree to deliver industry clinical trials;
- Ensuring companies have visibility of where their clinical trial sits in a site's queue of studies, which will help inform decisions on whether to continue trials struggling to meet set-up milestones or recruitment targets.

II. Improve set-up processes for industry clinical trials

In 2020, the UK's median time between a clinical trial applying for regulatory approval and that trial delivering its first dose to a participant was 247 days (placing the UK 7th amongst a basket of comparator countries), an increase of 25 days compared to 222 days in 2018.[6] For comparison, the USA had a median of 155 days and ranked 1st amongst the comparators.[6]

The UK has already made considerable progress to accelerate clinical trial approvals, with MHRA-HRA combined review[3] and fast-track ethics review[7] halving their respective approval times. The upcoming reforms to the UK's clinical trial regulation offer further opportunities for improvement, and the ABPI welcomes the MHRA's commitment to co-develop the regulation's guidance with industry and other life sciences sector stakeholders.

However, costing and contracting remains a key bottleneck to rapid and reliable study set-up that undermines the UK's global competitiveness in industry clinical research.

Whilst the ABPI welcomes the relaunch of the National Contract Value Review (NCVR), only 41% of NHS Trusts in England have committed to adhere to prices generated by the interactive Costing Tool[8] – the basis of the NCVR's plans to streamline costing and contracting.

Meanwhile, the UK's competitors have taken bold steps to significantly reduce timeframes for costing and contracting industry clinical trials. Spain, for example, reduced its contracting timelines from 117 days in 2016 to 90 days in 2020[9] by moving to a system of nationwide model contracts that cannot be negotiated or altered. France also has a mandated model contract that cannot be negotiated and is now one of the fastest countries for clinical trial approval and set-up.[10]

Given the urgent need to stabilise industry clinical research activity in the UK, NHSE and the devolved administrations must use the first phase of the NCVR to make rapid progress towards streamlining costing and contracting of industry clinical research across all four nations.

Set-up process recommendations:

3. NHSE and the devolved administrations should introduce a 60-day maximum timeframe, with limited negotiation, for costing and contracting of industry clinical research.

4. NHSE and the devolved administrations should commit to achieving UK-wide use of unmodified model contracts for industry clinical research, which should be aligned across all four nations and periodically reviewed in consultation with industry.

5. NHSE should work at pace to ensure all NHS Trusts in England are committed to adhering to prices generated by the interactive Costing Tool for industry clinical research.

6. NHSE should develop hub-and-spoke model contracts for ICSs that cover all providers in an ICS's catchment in a single contract.

III. Leverage industry trials to boost NHS research capacity and culture

Limitations in the NHS's research capacity are a well-documented[11] reason why the UK fails to consistently meet clinical trial recruitment targets.[2]

The Royal College of Physicians found that 57% of all physicians want to be involved in research, but 53% of all physicians said they were unable to because they lacked dedicated research time.[12] The pandemic has further reduced the NHS's research capacity by increasing rates of sickness and fatigue amongst NHS staff,[5] causing staff shortages in research delivery, pathology, and radiology teams that the Institute of Cancer Research found contributed to a 59% fall in patient recruitment to cancer trials in 2020/21.[13]

Yet industry clinical trials generate revenue for the NHS (an average of £9,000 per patient recruited)[11] [10] that could be reinvested into research capacity, so industry research should be self-sustaining and unconstrained by capacity – in theory.

In practice, the relationship between the revenue generated by industry clinical research and the reinvestment of that revenue into a site's research capacity is untethered, as research delivery teams are often unsure how much research revenue will be reinvested into their capacity. This obscurity deprives the NHS of research capacity that it could use to deliver more research that, in turn, would generate much-needed additional revenue[10] and improve job satisfaction and retention rates amongst its staff.[14]

Given the unprecedented challenges posed by record waiting lists[4] and staff vacancies,[15] the NHS cannot afford to allow revenue generated by industry clinical research not to be reinvested in its research capacity.

Finally, the NHS must treat research as a core part of healthcare delivery, as now mandated in the Health & Care Act, to ensure clinical trials can leverage the NHS's capacity to transform patient care and outcomes.

Outside of research-active Trusts, clinical research is frequently described as a "nice to have"[11] that draws scarce resources away from routine care, rather than driving long-term improvements in its quality and efficiency. This view of research filters throughout the NHS workforce – 44% of NHS staff say they are unsure if research is a priority in their Board's clinical strategy[11] – and undermines staff's support (and capacity) for delivering clinical trials.

The ABPI welcomes the Government's Future of UK Clinical Research Delivery Phase 2 Implementation Plan and its commitments to improve NHS research culture, through the use of research metrics and performance incentives. However, the rapid decline in industry clinical trials demonstrates the need for urgent action to strengthen research leadership and accountability in the NHS.

Capacity & culture recommendations:

7. NHSE and its devolved equivalents should reinvest revenue generated by industry clinical research into increasing the provision of dedicated research time and research training, especially for nurses and other staff critical to delivering clinical trials.

8. NHSE and the devolved administrations should mandate rapid invoicing for all research costs, as current delays in invoicing deprive the NHS of much-needed research revenue.

9. NHSE and the devolved administrations should consistently incorporate research leadership (ownership and championing of one's research function) into the role descriptions for NHS R&D Directors, Medical Directors, Directors of Nursing, and Chief Executives.

10. NHSE should incorporate best practices in research finance into its upcoming research guidance for ICSs. This guidance should help increase the visibility of revenue generated by industry clinical research and set an expectation that the majority of that revenue is reinvested into the NHS's research workforce and infrastructure.

11. NHSE should work with the pharmaceutical industry to co-develop research guidance and research performance metrics for ICSs.

Conclusion

Whilst the challenges facing industry clinical trials in the UK are great, the benefits of overcoming them and strengthening the UK's clinical research environment are greater.

The ABPI-PwC report published in June 2022 quantifies the benefits the UK could realise across health, GDP, and employment, as well as NHS revenues and cost savings if the Life Sciences Vision were to be fully implemented. These include:

- The NHS generating an additional £165 million in revenue and £32 million in cost savings per year if recruitment to industry clinical trials in the UK rose to be on par with Spain.
- The UK generating £68.1 billion in additional GDP over the next 30 years if the UK pharmaceutical industry's spending on R&D rose to be on par with the US.
- Reducing the total attributable burden of disease by 40% if the Life Sciences Vision healthcare missions make progress tackling the UK's most pressing disease areas.

To realise these benefits, all system partners must act decisively to implement the short-term recommendations contained in this paper and engage in broader, strategic discussions with industry to create the long-term policy frameworks needed to deliver the Life Sciences Vision.

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