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Clinical research in the UK: an opportunity for growth

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Foreword

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Clinical trials are an essential part of the research and development (R&D) of new medicines and vaccines, bringing benefits to patients, the NHS and the economy. During the COVID-19 pandemic, the value of clinical trials has become increasingly evident, with research seen as critical to global recovery – refining our public health efforts and enhancing our armoury against COVID-19 and future pandemics.

The pandemic has also significantly impacted the type of clinical trials conducted and how these are designed and delivered. On the positive side, we have seen regulatory flexibilities introduced, digital and remote approaches adopted, and innovative design and delivery models implemented. However, we have also seen the negative effect that a focus on COVID-19 has had on research into other conditions, such as cancer and cardio-metabolic disease. Efforts to restart and recover activity in these areas have varied depending on the impact of the pandemic on individual nations and healthcare systems.

The UK's ability to restart clinical research activity has been primarily dictated by capacity within the NHS, which has been focused on managing COVID-19 and frontline care for thousands of patients. The ability to restore its healthcare system will be critical if the UK is to succeed in embedding new and innovative ways of working and growing its capacity to deliver clinical research.

The Government's UK-wide vision for clinical research delivery puts the NHS and patients front and centre, with the aim to rebuild post-pandemic and create an ecosystem which is globally competitive – one which delivers for UK patients now and in the future. What matters now is the UK's ability to translate these commitments into action and demonstrable change on the ground. Progress is underway to deliver the vision, with support from the ABPI and the pharmaceutical industry as delivery partners of the Recovery, Resilience and Growth Programme.

Continued partnership with industry will be key to the successful delivery of this vision. Commercial clinical research contributes significant economic benefits, generating an estimated income of £355 million for the NHS in England in 2018/2019. Ensuring that implementation of the vision serves to enhance the commercial clinical research environment would therefore help attract further industry investment, delivering on the Government's plan for growth and contributing to the health and wealth of the nation.

Demonstrating our potential for growth is the UK's recent performance in patient recruitment. In 2019, the UK increased its share of patients recruited to global clinical trials, overtaking Italy and equalling Canada with a 2.8% share. In 2020, the UK recruited over 1.3 million participants to clinical research studies supported by the National Institute for Health Research's Clinical Research Network (NIHR CRN) – the largest number ever to take part in NIHR research, primarily driven by recruitment into COVID-19 research studies.

With NHS reform underway, through the establishment of new Integrated Care Systems, and a vision for how the Government will improve the attractiveness of the life science ecosystem, the UK is well placed to build back better. With Governments around the world supercharging their R&D ecosystems in response to the pandemic, the UK must be at the vanguard of this global transformation, implementing sustainable and transformative changes that support growth, innovation and investment.

This report articulates how the UK can maximise the opportunities that lie ahead to rebuild its clinical research environment and grow its commercial portfolio. By benchmarking the UK's clinical trial environment relative to global competitors, this report highlights where the UK is competitive and how we are recovering from the pandemic relative to others, making recommendations for the next phase of implementation on the UK-wide vision for clinical research delivery.

The ABPI and the pharmaceutical industry continue to work in partnership with Government and system partners on enhancing the UK life sciences sector and hope this report is a helpful contribution, as we look to implementation of the Life Sciences Vision.

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Summary: Findings and Recommendations

Findings: What does the data tell us?

- Between 2017 and 2019, an average of 25 participants were treated in Phase I clinical trials and 24 in Phase II/III in the UK. The average for Phase I ranks the UK highly compared with other countries; however, in Phases II-III, countries such as Japan, Spain, Germany and France treat more patients per trial.

- The Medicines and Healthcare products Regulatory Agency (MHRA) assessed a total of 967 clinical trial applications in 2020, of which 110 were COVID-19 studies. Within this total, 777 commercially sponsored applications were assessed, of which 639 were Phase II-III studies.

- The UK initiated 68 commercial COVID clinical trials in 2020, making it the third largest initiator of COVID-19 trials globally, behind only the USA and Brazil.

- The number of commercial clinical trials initiated in the UK continues to decline. In 2017, 667 commercial clinical trials were initiated and in 2020, 508 were initiated, representing a decrease of 24%. Excluding COVID-19 studies, the total in 2020 is 440, representing a decrease of 34% from 2017.

- In 2020/2021 across England, 1,390,483 participants took part in clinical research – almost double the number that took part in 2019/2020. 905,790 of these participants were involved in COVID-19 studies. 35,488 participants were recruited to commercial studies, which equates to a 2.5% share of total recruitment across the NIHR CRN portfolio.
This is a decrease from the 3.9% share in 2019/2020.

- Over 40% of NHS Trusts had non-COVID-19 research studies paused during the first wave of the pandemic, impacting patient access to potentially life-saving treatments. Oncology, which comprises the majority of the UK's research portfolio, was most impacted, with enrolment in May 2020 down 87.5% compared with May 2019.

- The loss of commercial research across NHS Trusts during the pandemic is estimated to have generated a deficit of up to £447 million in total in FY2020/2021.

- The UK continues to lag behind international comparators in recovering enrolment in commercial studies. Enrolment into commercial clinical trials in June 2021 was 15% lower than in June 2019. Spain and Italy have recovered fastest, with enrolment in June 2021 37% and 34% higher than in June 2019, respectively. Enrolment in July 2021 across all countries has been lower than in the preceding months, which may be due to disruption caused by the COVID-19 Delta variant.

- The UK has maintained its European lead in Phase I commercial clinical trial activity. However, activity continues to decline across the continent, with 83 Phase I commercial clinical trials initiated in the UK in 2020, compared with 160 in 2014.

- For Phase II, the UK ranks 5th globally, with 201 trials initiated in 2020, compared with the USA ranking first with 953 trials initiated. For Phase III, the UK continues to fall behind global competitors, with 224 trials initiated in the UK in 2020 – ranking the UK 5th in Europe behind Germany, Spain, Italy and France.

Recommendations: How the UK can rebuild the clinical research environment

1 Embedding clinical research in healthcare

- The new Health and Care Bill 2021-22 should mandate that Integrated Care Systems ensure that NHS organisations, for which they are responsible, conduct and resource clinical research.
- System partners should work together to investigate the infrastructure, workforce efficiencies and resource needs to deliver commercial research studies to time and target.

2 Reforming and streamlining approvals and set-up

- The Medicines and Medical Devices Act 2021 should be used to mandate rapid timelines for regulatory approvals and reform clinical trial regulation, building on the UK's international reputation for pragmatism and innovation.
- Costing and contracting processes need to be made quicker, more transparent and less variable, ensuring the UK delivers on the commitments of the UK-wide vision for clinical research delivery.
- MHRA and HRA should be appropriately resourced to:
  - Deliver fully the MHRA Delivery Plan 2021-2023 and HRA Make it Public Strategy.
  - Address regulatory and operational challenges relating to the Northern Ireland Protocol.
  - Reform the UK research ethics service to create a professionalised, accredited and streamlined offer.
  - Establish a UK clinical trial registry to enhance opportunities for research involvement and participation and support the UK's commitment to research transparency.
  - Deliver new and expanding regulatory and ethics services for clinical trials, including the MHRA's Early Advice Service and the Innovative Licensing and Access Pathway (ILAP), accompanied by guidance for sponsors.

3 Increasing and diversifying patient recruitment to clinical trials

- Clinical research activity should be scaled up across the healthcare system in primary, secondary and tertiary care settings, with collaboration and flexibility in delivery approaches incentivised to maximise opportunities for patient and public involvement and participation.
- UK Government should resource and fully deliver the Data Saves Lives and Genome UK strategies to help harness health data and genomics for clinical trials and clearly articulate to commercial sponsors the offer and services available to support research study feasibility, set-up, recruitment and delivery.
- System partners should work together to pilot community-based projects to support local healthcare systems in building relationships with underserved communities and understanding unmet need relative to local and national demographics.
- Funders and regulators should better coordinate efforts to embed patient and public involvement system-wide, helping researchers and sponsors to navigate and operationalise existing tools and guidance through improved signposting and sharing of case studies.
- UK Government should work with system partners and the Devolved Nations to deliver a public campaign to describe the value of clinical research and enable all patients, members of the public and healthcare professionals to get involved with and participate in research.

4 Adopting innovative clinical trial design and delivery approaches

For the UK to become a test-bed destination for innovation and truly benefit from the efficiencies innovation can bring, the healthcare and research system should work together to:

- Develop and put into practice standardised approaches and guidance for innovative design and delivery of trials.
- Deliver training on innovative design and delivery approaches for ethics committees, regulators, researchers involved in trial design and delivery teams.
- Ensure that digital tools are available to support remote monitoring and virtual trial delivery.
- Communicate internationally how the UK is adopting innovative design and delivery approaches and how this improves trial efficiency.

5 Improving how the UK reports on clinical research performance

UK Government should work with system partners on the development of a UK-wide clinical research dashboard, agreeing the metrics needed to articulate performance across the UK healthcare system and evidence the impact of changes and trends on patients, the NHS and the economy.

Introduction: Maximising benefits for patients, the NHS and the economy

Clinical trials are an essential part of the research and development process, demonstrating safety and efficacy of potential new medicines and vaccines. Development continues after a medicine is initially approved for use, with further studies to examine longer-term outcomes and additional indications, and to monitor safety and efficacy in routine usage in the 'real world'.

Clinical research in the UK is delivered across the healthcare system, with the National Institute for Health Research's Clinical Research Network (NIHR CRN) playing an important role in delivery of trials in England. In 2020/2021, 100% of hospital trusts and 50% of GP practices were involved in recruiting to and delivering clinical research studies, supporting **the recruitment of over 1.3 million participants into research studies through the NIHR CRN.** This included over 900,000 in 101 Urgent Public Health Research COVID-19 studies in England.[1] Recruitment to COVID-19 studies across the Devolved Nations was also significant, with over 66,000 participants recruited to studies in Scotland,[2] 26,000 in Northern Ireland[3] and 5,800 in Wales.[4]

In addition to the fundamental value that clinical research brings to patients, who stand to benefit from receiving potentially life-saving treatments through research participation, there are other significant benefits to be had for the wider patient population, the NHS and the wider economy.

Patients receiving care in research-active hospitals have improved outcomes and improved survival rates[5] and research-active trusts also better manage the treatment and care of patients, resulting in a better patient experience.[6]

For the NHS, trusts that are more research-active benefit from the 'research effect', as described by the Royal College of Physicians. Research participation improves job satisfaction for clinicians, helping them build new transferable skills, preventing burnout and supporting the retention of staff.[7] This drives better care for patients and improved Care Quality Commission ratings.[8]

In terms of benefits for the wider economy, clinical research activity across the NIHR CRN generated **£2.7 billion of gross value added** (GVA) and supported over **47,400 full-time equivalent jobs** in 2018/2019[9].

For commercial clinical research, the NIHR CRN supports researchers across 30 speciality therapy areas and 15 Local Clinical Research Networks (LCRNs). Funded by the Department of Health and Social Care, the CRN provides a network of expertise and leadership and supports the cost of research staff and facilities, to deliver high-quality clinical research.[10] The MHRA estimates that around 85% of all commercially sponsored studies approved by the agency are delivered by the NIHR CRN.[9]

The NHS also benefits directly from commercial clinical trials supported by the NIHR CRN. Between 2016/2017 and 2018/2019, **the NHS received on average over £9,000 per patient recruited** and **saved over £5,800 per patient,** where trial drugs replaced the standard treatment. This yielded a total estimated income of £355 million and total estimated cost saving of £28.6 million in 2018/2019.[9]

COVID-19 has shone a light on these benefits. Treatments and vaccines to combat COVID-19 have been successfully researched and developed through clinical trials, and both healthcare and policy decision-making have been informed by the results of thousands of research studies across the UK and globally. However, a significant proportion of the non-COVID-19 clinical research was paused in the UK during 2020, with a proportional reduction in the direct benefits that commercial trials bring to the NHS.

The NHS received an estimated income of

£355 million

in 2018/2019 from commercial clinical research

The UK is now at a critical inflection point, with COVID-19 and the end of the UK's transition period with the EU providing the impetus for transformation.

With changes to clinical trial regulation underway, using powers enabled by the Medicines & Medical Devices Act 2021,[11] NHS reform on the horizon, with the establishment of new Integrated Care Systems[12,13] and UK-wide momentum behind delivering the vision for clinical research delivery,[49] the UK is well placed to rebuild and grow its clinical research ecosystem – and the time to do so is now.

Pre-pandemic and increasingly so since the pandemic, Governments around the world are supercharging their R&D ecosystems, introducing mechanisms to improve efficiency and building resilience to better meet patient and public health needs. The UK must be at the vanguard of this global movement and must now forge a new path for itself – one which champions the pragmatism and new ways of working seen during the pandemic.

The vision for transforming clinical research is part of the wider Life Sciences Vision, published in July 2021,[14] which acknowledges the opportunities that lie ahead of us and lays out how the UK Government will create an environment in which industry can grow and succeed in the UK, and where patients and the NHS can all benefit.

The ABPI and the pharmaceutical industry welcome Government's dedication to bolstering the UK's life sciences sector and reforming healthcare design and delivery. We believe that by supporting and implementing initiatives which harness and attract industry investment, Government can deliver on its plan for growth as well as improve the health and wealth of the nation.

Harnessing the collaborative approach that has been so successful in addressing the challenges posed by the pandemic, will enable us together to transform the scale of clinical research conducted across the NHS; together with the full range of opportunities described in the Life Sciences Vision, to build a globally competitive destination for industry.

The impact of COVID-19 on clinical research

Global R&D efforts to tackle COVID-19

The UK's strong performance in COVID-19 research has negatively impacted research into other disease areas, more significantly than in other countries.

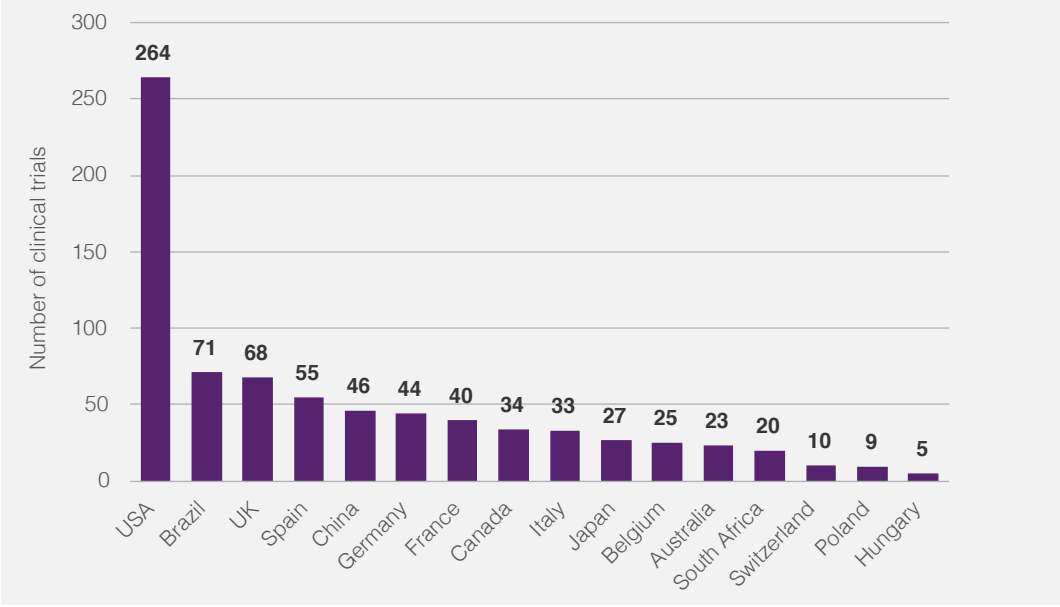
COVID-19 was officially declared a pandemic by the World Health Organisation (WHO) on 12 March 2020, with over 220 million cases and nearly 5 million deaths recorded[15]

In response to the pandemic, we have seen unprecedented global efforts to research and develop new medicines and vaccines to prevent and treat COVID-19 and manage the public health crisis. The global pharmaceutical industry has worked in partnership with academia, Governments and healthcare systems to research and develop over 1,300 products, with over 400 in Phase I-III clinical trials, to treat and/or prevent asymptomatic, moderate and severe COVID-19 in adults, the elderly, children and infants.[16]

In the UK, the Government has badged 95 Urgent Public Health Research (UPHR) studies to date, including 21 commercial studies and several large platform studies including RECOVERY and PRINCIPLE led by the University of Oxford, and REMAP-CAP funded by the EU Commission.[17] In comparison to Europe, the UK has led on commercial R&D activity, with 68 COVID-19 clinical trials initiated in the UK in 2020 (Figure 1).

Collectively, this has led to regulatory approval of the repurposed antiviral agent, remdesivir, for the treatment of hospitalised adult and paediatric patients, and the approval of 4 vaccines, with nearly 6 million vaccine doses administered globally to date.[15,18] As vaccines continue to be rolled out internationally, industry's focus has shifted to the development of novel anti-COVID-19 agents, with many novel anti-virals and antibodies in clinical trials.[19]

Figure 1. Number of COVID-19 commercial clinical trials initiated in 2020, by country



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The pandemic's impact on research in other disease areas

While this response has been undoubtedly positive in our efforts to tackle the pandemic, the significant COVID-19 research portfolio in the UK has focused capacity and resourcing away from non-COVID-19 clinical research, with non-COVID-19 research studies paused in over 40% of NHS Trusts during the first wave.[20]

Analysis conducted by UKRD in July 2020 demonstrates that the loss of commercial research across trusts during the pandemic is estimated to generate an **NHS deficit of up to £447 million in total in FY2020/2021**.[21]

Furthermore, patients with other conditions have been significantly impacted, with opportunities to get involved with and participate in potentially life-saving research hindered.

Data from a sample of commercial studies in the UK shows that disruption to the number of patients enrolled in studies has been across all disease areas. The number of enrolled participants plummeted in April 2020, relative to April 2019, during the first wave. Significant disruption remained for several months, with activity seeming to resume from August 2020 onwards (Figure 2).

For oncology, which comprises the majority of the UK's portfolio, enrolment to commercial studies was most impacted in May 2020, with enrolment down 87.5% versus May 2019. Enrolment improved between May 2020 and November 2020, dropping again in January and February 2021 due to the second wave over the winter of 2020/2021 (Figure 2).

Over recent months the UK's vaccination programme has been rolled out rapidly and the COVID-19 burden on hospitals has subsided,[22] allowing staff to return from the frontline and capacity for research to become available. As such, enrolment across all disease areas has been slowly recovering, with enrolment in infectious and immune disease studies seeing the greatest recovery in 2021 (Figure 2).

Since the first wave, the time and duration of subsequent waves has been variable across Europe, with changeable infection and death rates and variable transmission of COVID-19 variants, driving an ever-changing public health policy landscape. This has resulted in variable pandemic recovery from country to country.

Between April and August 2020, the UK was more significantly impacted than other countries, with enrolment down 84% in May 2020 relative to enrolment in May 2019. France, Germany and Spain saw enrolment down between 66% and 71% in May 2020, and in Italy, where the first wave of the pandemic was more severe, enrolment was most greatly impacted in April 2020, down 60% versus April 2019 (Figure 3).

Loss of commercial research during the pandemic estimated to generate an NHS deficit of up to

£477 million

in FY 2020/2021

All countries then experienced a similar reduction in enrolment to commercial studies in January 2021, as a result of the second wave in the winter of 2020/2021, with enrolment down between 5% and 19% relative to January 2019 (Figure 3). This indicates that enrolment was disrupted to a lesser extent during the second wave than in the first wave, likely due to the resilience built into clinical trial protocols and healthcare systems.

Since then, Spain and Italy have recovered the fastest, with enrolment in June 2021 37% and 34% higher than in June 2019, respectively. The UK on the other hand has been unable to recover enrolment to pre-COVID-19 levels, with enrolment in June 2021 15% lower than in June 2019 (Figure 3). Enrolment in July 2021 across all countries has been lower than in the preceding months, which may be due to disruption caused by the COVID-19 Delta variant.

Throughout the pandemic, the NIHR has supported sites and sponsors with restart by publishing guidance and providing additional funding to sites. In May 2020, NIHR published a Restart Framework,[23] which helped sites and sponsors in assessing and prioritising which studies to restart.

This was replaced a year later by the centralised Managed Recovery Process,[24] which has been supporting interventional multi-site studies that require the NIHR CRN to support delivery. This process has supported constructive local dialogue to support restart, with the NIHR CRN reporting in July 2021, that as of 31 March 2021, 81% of previously paused commercial contract studies had restarted.[1]

In addition, the ABPI and Birmingham Health Partners launched a Restart and Recovery Resource, showcasing how Birmingham's Trusts have dealt with the challenges of the pandemic and conducted their restart programme, with the aim of supporting other sites and sponsors in their restart and recovery process.[25]

The UK has also partnered with fellow G7 countries, to improve how vaccine and therapeutic clinical trials are conducted in future pandemics, ensuring more streamlined and coordinated prioritisation, design and delivery to reduce duplication and better generate evidence to inform public health decision-making.[26]

Figure 2: Percentage change in total enrolment for UK non-COVID, commercial studies per month relative to 2019 baseline, by disease area (January 2020-July 2021)

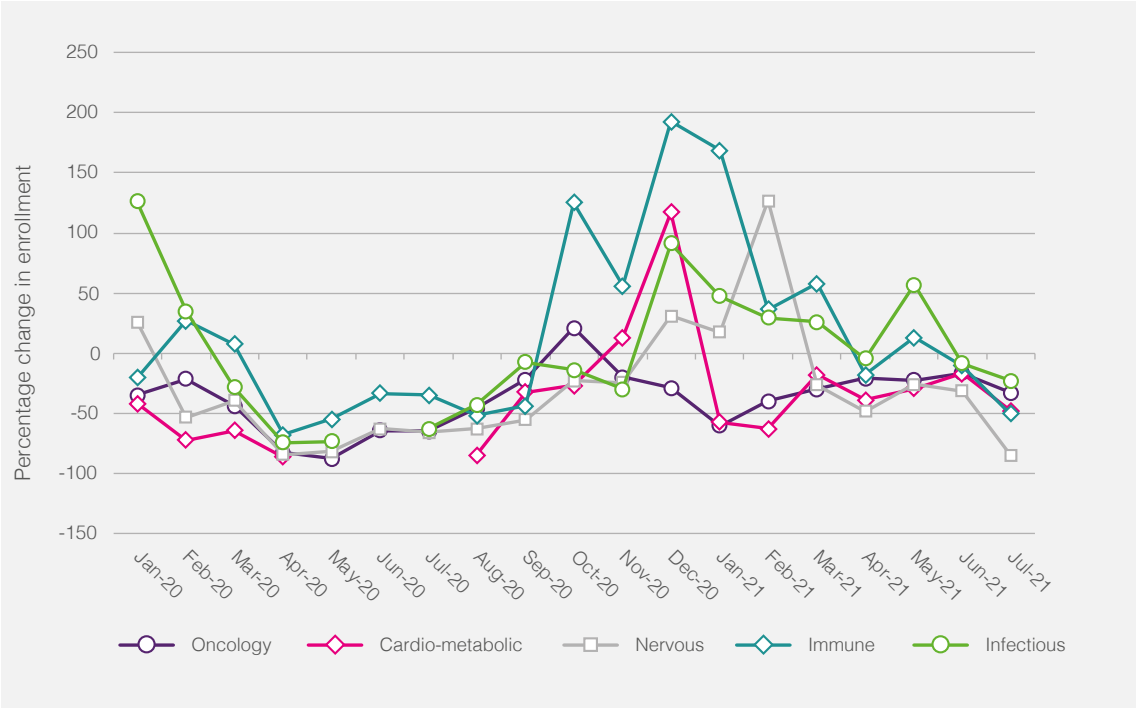
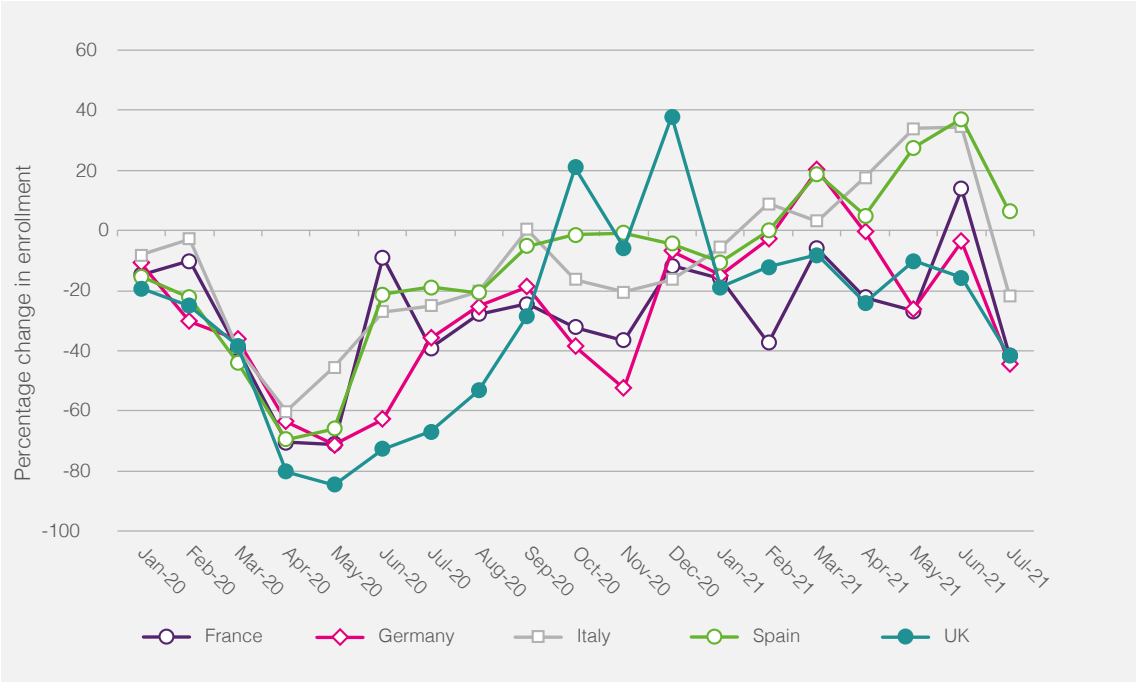


Figure 3: Percentage change in total enrolment for commercial studies per month relative to 2019 baseline, by country (January 2020-July 2021)



See Appendix B for data table and data on percentage change for enrolment broken down by country and disease area.

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The tireless efforts of system partners and research delivery teams is acknowledged and has been welcomed; however, recruitment to non-COVID-19 studies is still slow, with other countries recovering faster than the UK. Some of the challenges which remain include:

- variability and inconsistency in implementing remote monitoring and source document validation across the NHS
- limited workforce availability, with staff stretched across set-up, recruitment, delivery and follow-up activities
- limited access to clinical facilities, with significant disruptions seen in radiology and pharmacy
- lack of transparency on site prioritisation and planning.

In some places, limited capacity for conducting critical safety monitoring may impede study set-up and patient recruitment. In addition to global restart trends looking more promising, some pharmaceutical companies are needing to reassess the allocation of studies to the UK, choosing in some instances to reallocate studies and accompanying headcount, to countries where there is less disruption and greater capacity to deliver.

It is therefore critical that Government and system partners continue to work with sponsors and sites to support the restart of clinical research activity. In particular for global commercial research, supporting studies in setting-up and recruiting to time and target will be critical for the UK's continued participation in multi-country studies; increasing UK participation in these studies will be imperative to support the growth ambition described in the Vision.

Furthermore, as companies plan their global development programmes for the coming years, looking for predictability and reliability in their destinations of choice, transparency will be key. The UK remains an important destination for clinical research and hence the manner in which it manages and communicates progress on recovery will have a direct impact on how global pharmaceutical companies perceive the UK's status and will dictate the UK's ability to grow its clinical research portfolio and attract future investment.

UK performance in clinical research

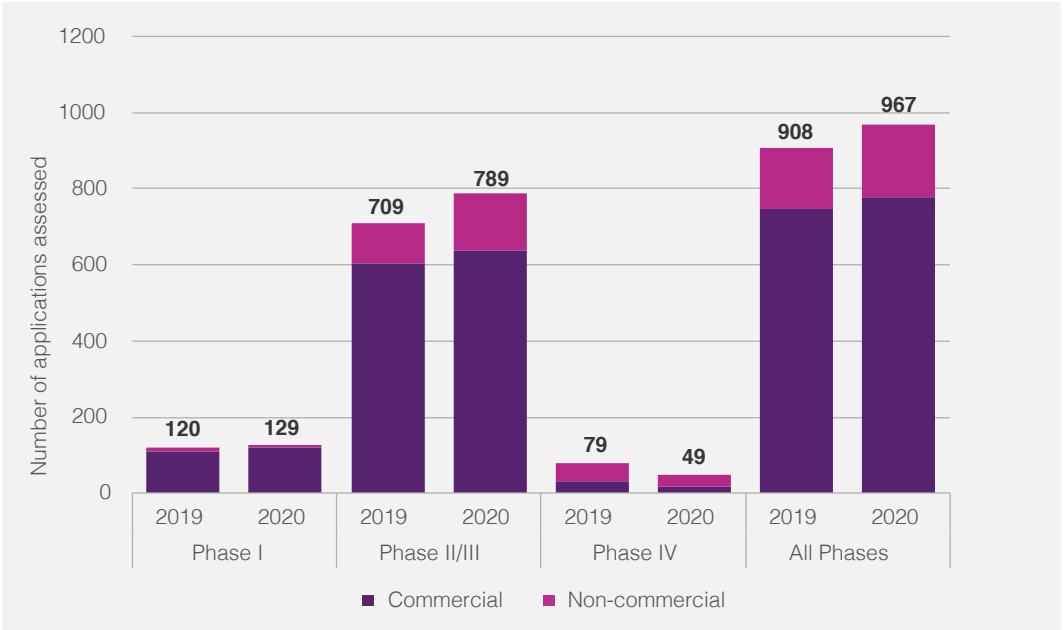
Domestic trends

Industry appetite to conduct clinical trials in the UK has remained relatively constant over recent years, but the numbers of trials initiated and share of global recruits is declining.

Data from the MHRA shows that commercial interest in conducting clinical trials in the UK has remained relatively stable over recent years, with the number of commercially sponsored clinical trial applications assessed since 2013 averaging 788. In 2020, the total number of clinical trial applications assessed by the MHRA was 967, of which 110 (11.4%) were COVID-19 trials (Figure 4).

For commercial, 777 applications were assessed, of which 639 were Phase II/III studies. Commercially sponsored clinical trial applications remain the majority of the MHRA's assessment portfolio, with non-commercial research representing just under 20% of the total number of applications assessed by the MHRA in 2020 (Figure 4).

Figure 4: Number of applications assessed by the MHRA in 2019 and 2020 by phase and sponsor type



See Appendix B for data table

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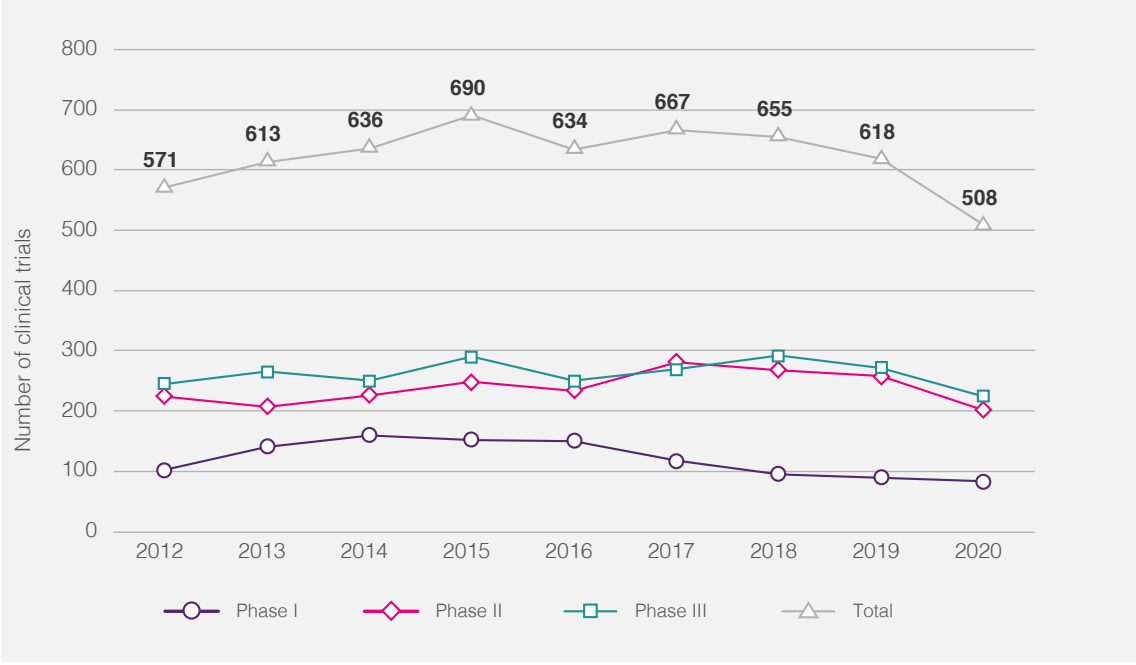
However, despite applications to MHRA remaining relatively stable, the UK is seeing a continued reduction over time in the number of commercial clinical trials initiated.

In 2017, 667 commercial clinical trials were initiated and in 2020, 508 were initiated, representing a decrease of 24% (Figure 5). The 2020 total here includes 68 COVID-19 clinical trials, which if excluded brings the total in 2020 to 440, representing a decrease of 34% from 2019. Looking at activity by phase, Phase II and Phase III on average across the years collectively comprise ~80% of all trials initiated, with a consistent decrease in this activity seen since 2017 (Figure 5).

In Phase I, 83 clinical trials were initiated in 2020, with 117 in 2017, representing a decrease of 29%. In Phase II, 201 clinical trials were initiated in 2020, with 281 in 2017, representing a decrease of 28%, and in Phase III, 224 clinical trials were initiated in 2020, with 269 in 2017, representing a decrease of 17% (Figure 5).

Figure 5: Number of commercial clinical trials initiated in the UK per year, by phase (2012-2020)



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In addition to monitoring performance in the initial stages of a clinical trial, it is important to see whether studies in the UK successfully recruit participants; ensuring that clinical research investment translates to benefit for patients.

For commercial studies in 2020/2021, 35,488 participants were recruited across a portfolio of 1,366 studies, with 8 global firsts achieved.[1] This equates to a 2.5% share of total recruitment across the NIHR CRN portfolio and an average of 26 participants recruited per commercial study. Since 2017/2018, this proportion of commercial recruits has been on the decline, with the number of commercial recruits and global firsts decreasing year on year (Table 1).

Table 1: Number of participant recruits in research studies supported by the NIHR CRN, as reported in NIHR CRN Annual Reports (2017/18-2020/21)

Year	Total recruits	Commercial recruits	Commercial (% of total)	Global firsts (no. of studies)
2017/2018	853,904	50,112	5.9%	24
2018/2019	870,250	46,064	5.3%	15
2019/2020	732,176	28,832	3.9%	14
2020/2021	1,390,483	35,488	2.5%	8

International trends: clinical trial initiation

From 2018 to 2020, the UK has retained its competitive early clinical research environment (Phase I); however, is falling behind in later phases (Phase II and III).

For Phase I clinical trials, the UK continues to rank first in Europe, with 83 trials initiated in 2020 (Table 2). Although the UK's ranking for early-phase clinical research remains unchanged, countries across Europe, including the UK, are experiencing a downward trend in activity, with other countries such as Australia and China rising in the ranks (Figure 6).

The UK has seen a decrease of 29% in the number of Phase I trials initiated between 2017 and 2020. Similarly, Germany has seen a 30% decrease, Italy a 20% decrease and France a 4% decrease.

Spain on the other hand, has seen a 22% increase since 2017, with 60 Phase I clinical trials initiated in 2017 and 73 in 2020. Australia ranked 3rd globally in 2020, also saw an increase (+50%) in the number of Phase I trials initiated since 2017 – ranking Australia behind only the USA (1st) and China (2nd) (Table 2, Figure 6).

For Phase II and III clinical trials, the UK ranked 5th globally for Phase II and 7th globally for Phase III in 2020, with European countries such as Germany, Spain, France and Italy outperforming the UK (Table 2). This represents a drop in performance, as the ABPI's previous reports[27,28] showed the UK's ranking for Phase II was 2nd globally in 2017 and 2018, and for Phase III it was 5th (2017) and 4th (2018).

Looking more closely at the number of Phase II and III trials initiated by these countries, the UK, Germany and Italy have all seen a decrease in the number of Phase II and Phase III studies initiated since 2017, while Australia saw an increase in Phase II trials initiated (+10%) and stable levels of activity were seen across the USA, Australia, France and Spain in Phase III trials (Figures 7 and 8).

The declining trend in clinical trial initiation across phases may partly be driven by a change in how clinical trials are being designed, with greater use of platform trials and adaptive designs allowing for multiple treatments or indications to be tested in a single trial, with perhaps fewer traditional simple two-arm comparisons.

Another reason may be the rise in clinical research activity in emerging markets, particularly China. In recent years, China is the only country to have significantly increased clinical research activity across all phases, with an increase of 93% in Phase I, 147% in Phase II and 55% in Phase III trials initiated seen between 2017 and 2020 (Figures 6-8).

As this is 2020 data, a significant contributing factor to bear in mind is also the impact of the pandemic on trial activity, which continues to influence how countries prioritise and manage their COVID-19 and non-COVID-19 portfolios, an aspect which is detailed earlier in this report.

Table 2: Global rankings – Number of commercial clinical trials initiated in 2020 by country by phase

Rank	Country	Phase I	Country	Phase II	Country	Phase III
1	USA	512	USA	953	USA	537
2	China	343	China	361	Spain	273
3	Australia	117	Germany	213	Germany	264
4	**UK**	83	Spain	203	China	241
5	Japan	83	**UK**	201	Italy	229
6	Spain	73	France	164	France	226
7	Germany	66	Japan	164	**UK**	224
8	France	49	Canada	151	Canada	220
9	Canada	47	Australia	146	Japan	218
10	Belgium	35	Italy	132	Poland	194
11	Italy	20	Poland	113	Australia	181
12	Poland	10	Belgium	97	Belgium	158
13	Switzerland	8	Hungary	58	Hungary	152
14	Brazil	7	Brazil	49	Brazil	151
15	South Africa	3	Switzerland	35	Switzerland	67
16	Hungary	2	South Africa	25	South Africa	48

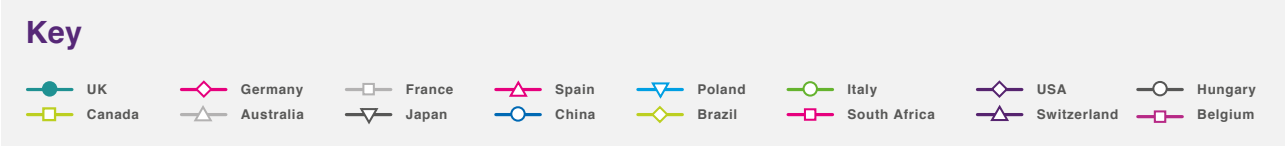


Figure 6: Number of Phase I commercial clinical trials initiated per year, by country (2012-2020)

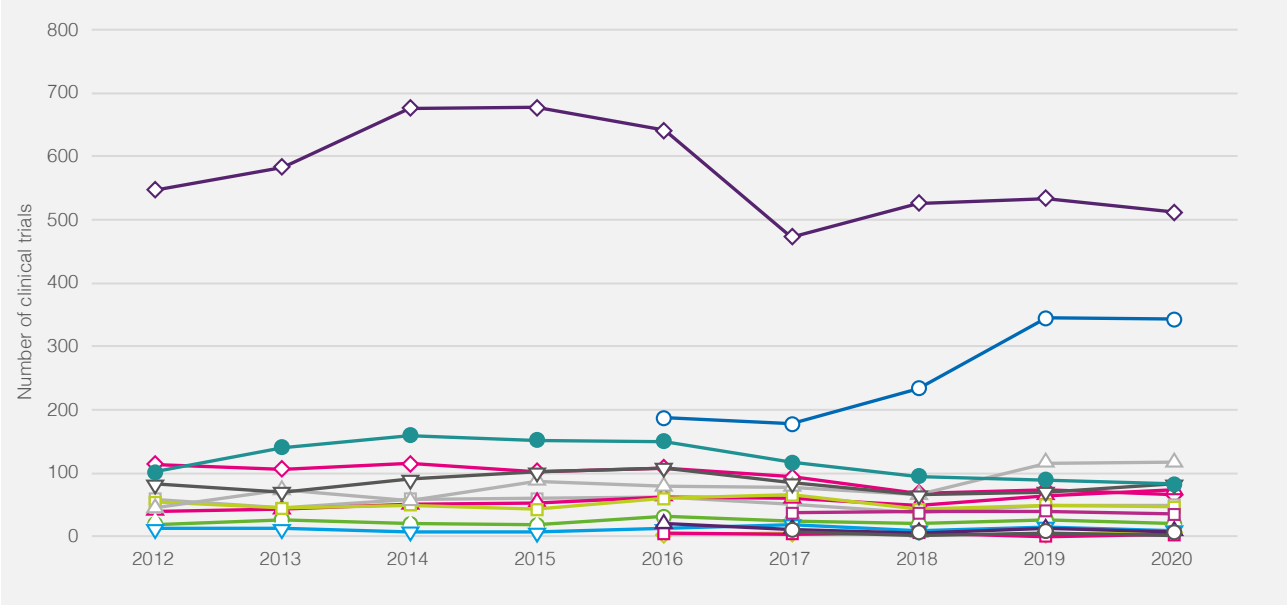
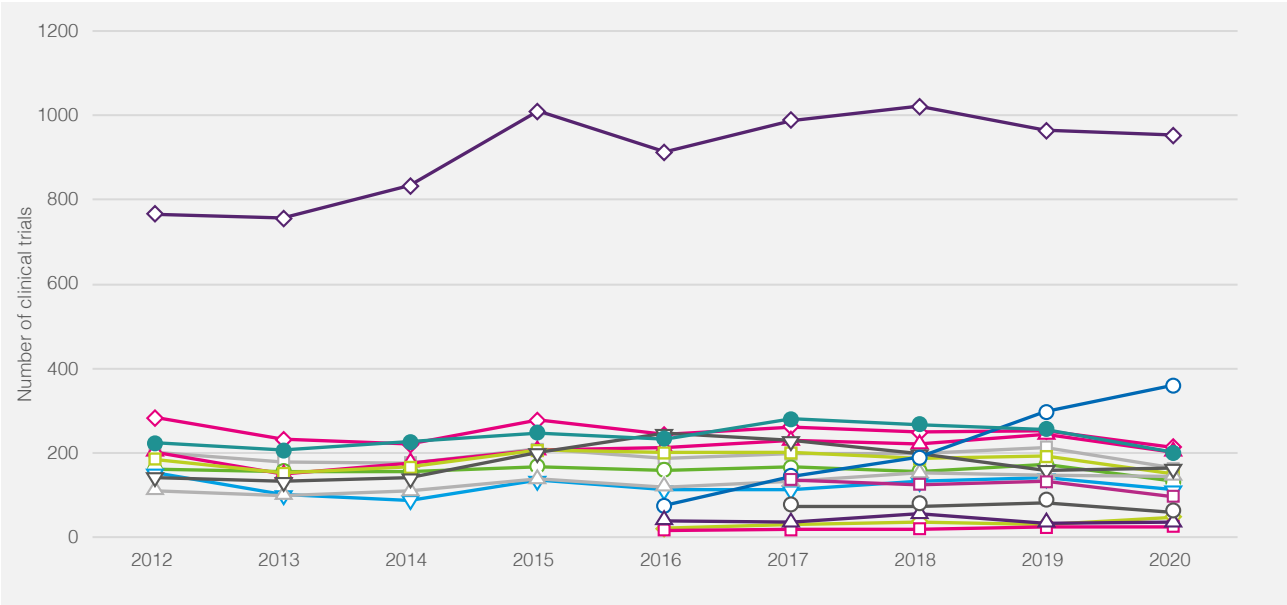


Figure 7: Number of Phase II commercial clinical trials initiated per year, by country (2012-2020)



See Appendix B for data table

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

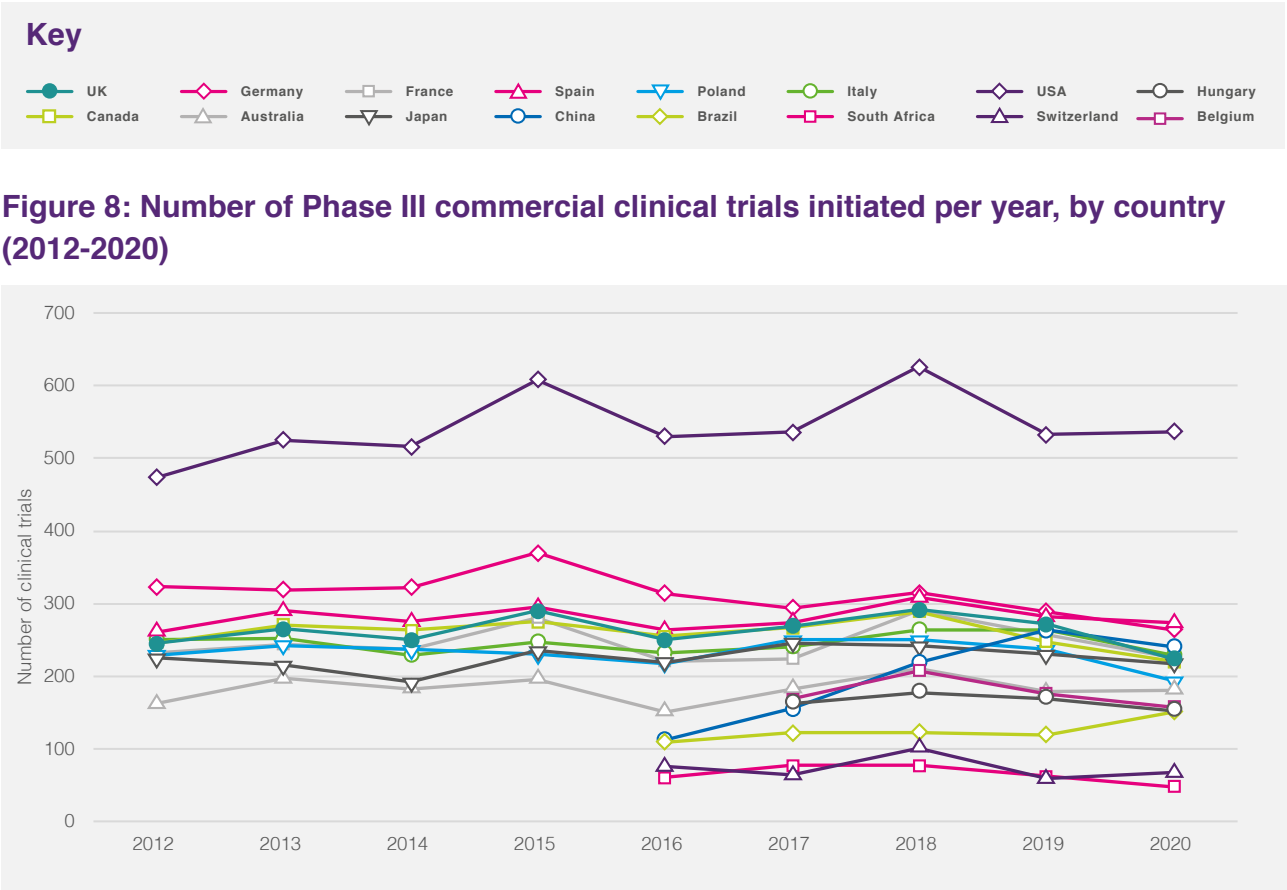


Figure 8: Number of Phase III commercial clinical trials initiated per year, by country (2012-2020)

See Appendix B for data table

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

International trends: clinical trial enrolment

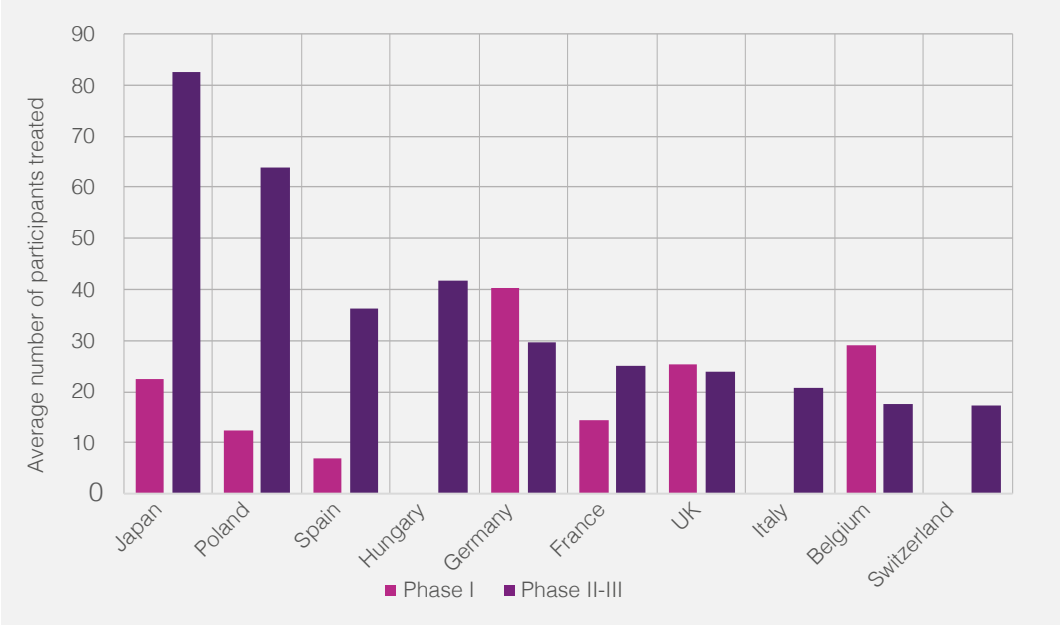
For the first time this year, this report also describes how successful commercial clinical trials are in recruiting and treating participants, in the UK and beyond. Data from a sample of commercial clinical trials in Phase I (healthy volunteers and patients) and Phase II-III (patients) between January 2017 and December 2019, describes the UK's performance relative to key competitors, in terms of average number of participants treated per trial.

For Phase I trials, which are generally small and single-centre, the average number of participants treated per trial in the UK was 25, with only Belgium and Germany treating significantly more individuals, 29 and 40 respectively (Figure 9).

For Phase II-III trials, the number of participants treated per trial in the UK was 24 – an average lower than Japan, Poland, Spain, Hungary, Germany and France. In particular, the average number of patients treated per trial in Japan was threefold higher (83 treated) than in the UK. Across the UK's European competitors, Spain, Germany and France all treated a significantly higher number of patients per trial, with Italy ranking behind the UK, with 21 patients treated (Figure 9).

Collectively, the data on trials initiated and patients treated demonstrates that not only are more later-phase clinical trials being initiated in countries such as Spain and Germany, but more patients are accessing treatments through clinical trial participation, with the UK under-performing in both respects.

Figure 9: Average number of participants treated per commercial trial, by country (2017-2019)



See Appendix B for data table

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Clinical trials by disease area: domestic and international trends

Between 2017 and 2019, the UK has seen a year-on-year decrease in the number of commercial clinical trials initiated across all disease areas, oncology (-18%), immune system conditions (-10%), nervous system conditions (-11%), cardio-metabolic conditions (-19%), infectious diseases (-11%).

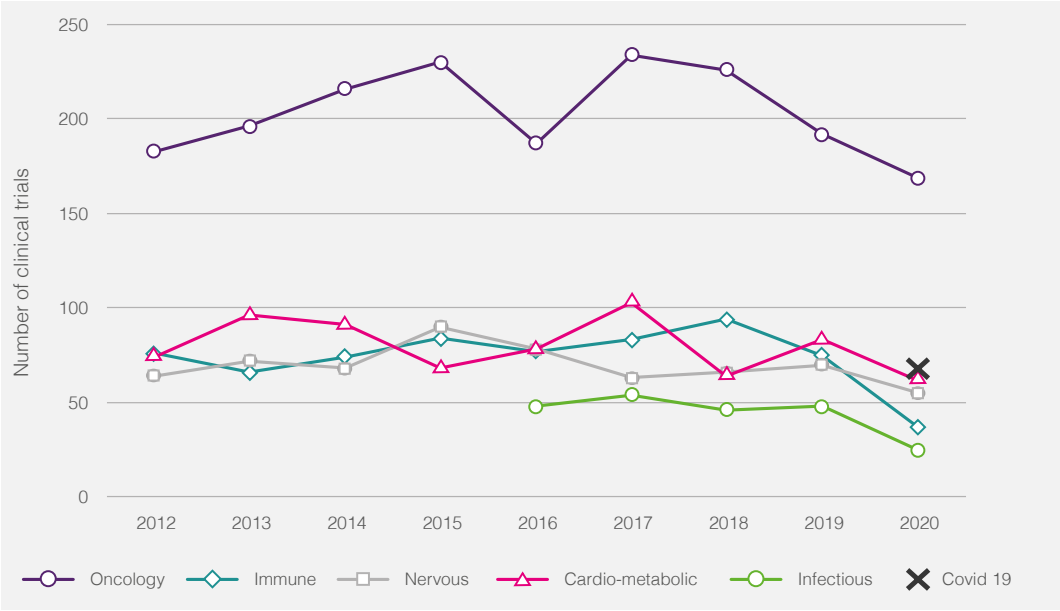
Despite remaining the major driver for the sector's growth, the UK has seen a decrease of 18% in the number of commercial oncology clinical trials initiated between 2017 and 2019, with 234 initiated in 2017 and 192 in 2019 (Figure 10).

Due to the disproportionate impact of COVID-19 on patients with cardio-metabolic conditions,[29] the decline in cardio-metabolic research activity is concerning. Recovery of this portfolio will be important in limiting the impact of COVID-19 and future pandemics on patients with these conditions.

During 2020, most countries observed a reduction in activity across disease areas (Appendix C, Figures A-E), largely due to the widespread need to resource the unprecedented demand for frontline care and rapid set-up of COVID-19 R&D programmes. However, some countries managed to grow their non-COVID-19 portfolio during the pandemic.

For example, Australia saw a 13% increase in the number of oncology trials initiated between 2019 and 2020 (Appendix C, Figure A) and China expanded its infectious disease portfolio by 18% (Appendix C, Figure E). Case studies in this report explore some of the contributing factors for these countries' success, identifying policy solutions which the UK could adopt as part of its efforts to deliver against the ambitions laid out in the UK-wide vision for clinical research delivery.

Figure 10: Number of commercial clinical trials initiated in the UK per year, by disease area (2012-2020)



See Appendix B for data table

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

Prior to the pandemic, specific policy and funding initiatives were established in the UK to help reverse some of these declining trends and address emerging health challenges. Initiatives in multimorbidities, dementia and disease prevention are helping to maintain the UK's position as a key player in tackling global health challenges and ensuring UK patients have the opportunity to access potentially life-saving treatments (Boxes 1-4).

1 Cell and Gene Therapy Catapult

The Cell and Gene Therapy Catapult is a centre of excellence to support the growth of cell and gene therapy R&D in the UK. With over 330 employees focusing on cell and gene therapy technologies, it offers leading-edge capability, technology and innovation, to enable companies to take products into and through clinical trials. Its aim is to make the UK the most attractive choice for the development and commercialisation of advanced therapies. Since the establishment of the Catapult in 2012, the UK's advanced therapy R&D sector has seen year-on-year growth, with 154 trials ongoing in the UK in 2020 – equating to an approximate share of 12% of all advanced therapy trials in progress globally.[30]

3 Join Dementia Research

To help the over 850,000 people in the UK living with dementia, the NIHR, Alzheimer's Research UK, Alzheimer's Scotland and the Alzheimer's Society set up Join Dementia Research. The service enables people to register their interest in participating in dementia research, with over 50,000 participants joining a study since the service was launched in 2015.[35] With new studies being added every week and over 500 studies using the service to date, Join Dementia Research is an example of how research study registries can help provide greater opportunities for participation by connecting researchers with those living with chronic conditions, in order to find the right patient at the right time for the right trial.

2 Tacking Multimorbidity at scale

Tackling multimorbidity – individuals with multiple chronic conditions – has been identified as a national and international research priority, due to the reduced life expectancy and increased need for health services.[31,32] The UK's £20million 'Tackling Multimorbidity at Scale' funding initiative, supported by the NIHR, Medical Research Council (MRC) and Economic and Social Research Council (ESRC), was set up to create multi-disciplinary research collaboratives and improve involvement of those living with multimorbidities.[33] COVID-19 has highlighted the urgent need to address the rise in patients living with multiple diseases and the UK must continue to bring together players across Government, the life sciences sector and medical profession to tackle this. The industry has an important role to play as part of this collaborative effort, with the ABPI partnering with Birmingham Health Partners to support the development, deployment and evaluation of new medicines and better manage multimorbidities.[34]

4 UK Prevention Research Partnership

The UK Prevention Research Partnership (UKPRP) was established in 2017 to improve population health and reduce health inequalities through the prevention of non-communicable diseases (NCDs) such as heart disease, cancer and respiratory conditions.[83] The UKPRP funds the setting-up of cross-sectoral, interdisciplinary research teams and networks to develop preventive interventions, practices and policies, with guidance to support the inclusion of industry partners. UKPRP is supported by CRUK, BHF, UKRI, Wellcome, The Health Foundation, NIHR and the Devolved Nations. With a shift in healthcare delivery moving from disease treatment to disease prevention, initiatives such as these will help the UK remain ahead of the curve, as global R&D undergoes this paradigm shift.

Australia: Developing a world-class environment for early-phase clinical trials

Australia is fast becoming the preferred destination of choice for early-phase clinical trials, with specific expertise, financial incentives and streamlined processes making it attractive to emerging innovators and pharma. How has Australia carved out a reputation for itself in the early-phase clinical trial space?

Streamlining ethics and regulatory processes

Australia has one of the fastest ethics and regulatory review processes in the world for early-phase trials. The National Health and Medical Research Council, which accredits over 200 Human Research Ethics Committees (HRECs), set up two initiatives to streamline ethics approvals. The National Approach to Single Ethical Review[36] and National Certification Scheme[37] which recognise and enable single ethical and scientific review of multi-centre research studies, with tools and guidance materials, including standardised patient information, consent forms and HREC letters, developed to support the process. The Therapeutic Goods Administration (TGA) has also established a digital Clinical Trial Notification (CTN) Scheme,[38] through which the majority of commercial clinical trial approvals are performed. This scheme supports rapid regulatory and ethics approval, which sees the HRECs performing both scientific and ethical review of the trial application. Ethics review also occurs parallel to site set-up, streamlining the process further.

Providing financial rebates

The R&D Tax Incentive (RDTI) is a significant policy influencing decisions to undertake clinical trials in Australia. The RDTI is seen as a globally competitive incentive for Australia-based and global companies to conduct R&D, including clinical trials (Phases I-III); members of AusBiotech stated in a 2019 survey, that the RDTI has helped successfully advance drugs for conditions such as influenza, and driven growth in R&D activity over recent years.[39,40]

Building resilience during the pandemic

At the COVID-19 pandemic, whilst most facilities around the world were closing their doors, 100% of Australia's Phase I units remained open, allowing for trial activity to continue.[41] This was likely due to Australia's low COVID-19 burden, relative to other countries who were more significantly impacted by the pandemic.

China: Creating a new development landscape to supercharge clinical research

China is radically changing its clinical development landscape, resulting in streamlined regulatory processes, expanded trial delivery capacity and increased activity in areas of innovation. How has China fuelled clinical trial growth and effectively integrated itself into the global development process?

Regulatory reforms

In 2019, the National Medical Product Administration (NMPA) joined the International Council for Harmonisation of Technical Requirements for Human Use (ICH),[42] highlighting the shift towards greater international alignment. China also updated its investigational new drug review procedure, helping to reduce regulatory timelines for the approval of clinical trial applications from over 250 days to 60 days, with clinical trials considered automatically approved if no comments were received from the regulator. In order to manage a growing number of applications, the NMPA also increased the number of drug reviewers from 70 in 2015 to 800 in 2017, with a priority placed on the review of products for critical conditions.[43]

Increased capacity for clinical research delivery

Alongside regulatory reform, capacity to deliver clinical trials to international quality has increased, with over 880 clinical trial institutes registered in 2019, an increase of 185% since 2016.[44] Matched with the proliferation of domestic and international biotech and pharmaceutical companies conducting clinical research and large patient pools, China is an attractive destination for commercial sponsors, with capacity rapidly expanding to deliver an ever-growing portfolio.

Supporting innovative research

An example of China's pro-innovation approach is its investment in becoming a world-leading destination to conduct cell and gene therapy (CGT) research. In 2020, China had more than 1,000 clinical trials completed or underway, ranking it second globally. This is in part driven by the rapidly growing CGT biotech sector, whereby local biotech companies in collaboration with research organisations, industry, venture capitals and government are establishing industry standards, supporting manufacturing capability and scale-up and facilitating research collaborations.[45] Supported by improved regulatory and technical guidance for pre-clinical and clinical R&D, China is fast becoming a mature ecosystem for CGT clinical trials.

Spain: A national effort to systematically and sustainably reform clinical research

In the past decade, Spain has become one of the top destinations of choice in Europe to conduct clinical trials, with increased investment and greater speed and efficiency, underpinned by an improved collaborative pro-research culture. How have Spain's system-wide efforts helped pivot them to a world-leading clinical research destination?

Government commitment to increasing R&D investment

In 2021, Spain's Ministry of Science and Innovation announced a 59% boost to its annual budget, allocating €3.2 billion to R&D as part of the Government's 2021-27 Science, Technology and Innovation Strategy, which aims to double investment in R&D, in order to bring the percentage of GDP spend on R&D to 2.12% by 2027 from 1.25% at present.[46] This comes as part of Spain's pro-science agenda under Prime Minister Sanchez who, since coming to power in 2018, has championed science and innovation and introduced measures to restore Spain's research system following the 2008 financial crisis.[47]

Leading the way in Europe on regulatory reform to streamline clinical trial approvals and site set-up

In 2016, Spain became the first country to transpose the EU Clinical Trial Regulation into national legislation, operationalising the regulation through the set-up of the Research Ethics Committees with Medicines (CEIm) and Spanish Clinical Studies Registry, to increase research transparency and simplify clinical trial approvals. This limits ethics questions to one round, with a maximum of 5 days to respond and a target of 60 days for regulatory and ethics approvals. Costing and contracting has also been streamlined, with negotiations conducted in parallel to regulatory and ethics approvals and a reduction in contracting timelines seen, from 117 days in 2016 to 90 days in 2020.[48] With no set-up fees and expected timelines from protocol received to first patient first visit of around 4 months, Spain has established a speedy and competitive process for clinical trial approval and study set-up.

Nationwide public-private consortia to track clinical trial performance

In the early 2000s, the Spanish trade association Farma Industria identified the need to transform the Spanish clinical research environment, which was losing competitiveness. Working with the clinical research community, it established the BEST Strategic Consortia Project, bringing together the private and public sector to develop an integrated platform to measure clinical trial performance in Spain.

The resulting BD Metrics platform reports against key metrics relevant to volume, efficiency and quality, with engagement from 6 public research groups, 52 hospitals and 60 pharmaceutical companies. Spanning 13 of the 17 regions in Spain, this platform reports on a significant proportion of the country's portfolio, with annual reports providing a 'single-truth' on performance, uniting the nation in areas of strength and areas in need of improvement.[48]

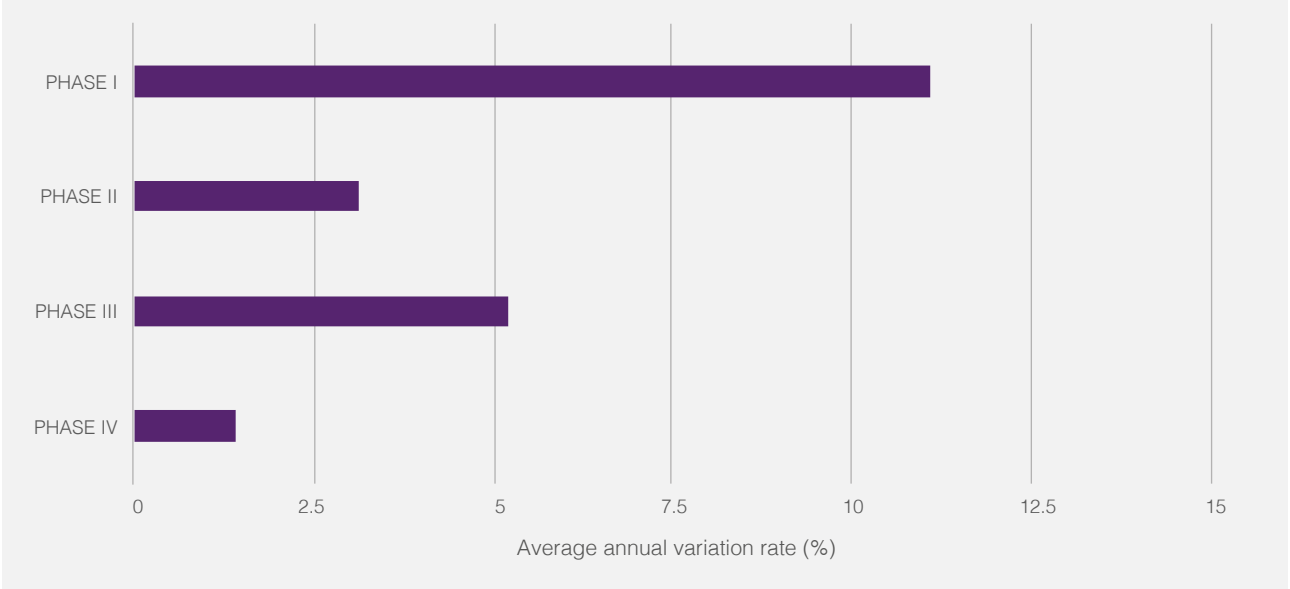
In addition to reporting on performance metrics for clinical trial approval and set-up timelines, the platform tracks recruitment and overall clinical research investment.

Data from the latest 2020 report shows that around 88% of commercial trials successfully recruit participants, with only ~12% failing to recruit.

As for investment, the report shows that 60% of investment in Spanish R&D was spent on clinical trials (€714m) in 2019, with 50% of investment in Phase III studies, and oncology and diseases relating to the nervous and immune system dominating the portfolio.[48] By tracking investment, the report articulates how that expenditure has changed over time, showing that in the last 10 years, clinical research investment has grown from €446 million in 2009 to €714 million in 2019, with Phase I and Phase III seeing the greatest growth (Figure 11).[48]

By evidencing the positive impact nationwide initiatives are having on clinical research performance through a single narrative, supported by the whole ecosystem, Spain has developed a culture of collaboration and transparency. As Europe looks to recover and grow its research ecosystem following the pandemic, Spain is likely to remain a destination of choice for the pharmaceutical industry and wider clinical research community, who have confidence in the reliability, cost-effectiveness and quality of the clinical research being conducted.

Figure 11: Average annual variation rate in clinical research investment in Spain, by phase (2009-2019)



Recommendations

Delivering the UK-wide vision for clinical research delivery

Acknowledging the current challenges with restart and looking ahead to longer-term recovery, the Government published a UK-wide vision for clinical research delivery in March 2021.[49] This vision lays out how the UK will develop a more patient-centred, pro-innovation and digitally-enabled clinical research environment, building on lessons learnt from the COVID-19 pandemic and progress made since the Life Sciences Industrial Strategy[50] and Sector Deals.[51,52]

The vision puts the NHS and patients front and centre, with the aim to create an ecosystem which is globally competitive and delivers for UK patients now and in the future. This vision is the product of collaborative efforts under the Recovery, Resilience and Growth (RRG) Programme, which has engagement from industry, academia, governments (including the Devolved Nations), patients, researchers and the NHS – presenting a truly aligned ambition for UK clinical research.

The ABPI is a delivery partner on the RRG Programme, which is now charged with supporting the development of implementation plans to deliver against the vision.

The first implementation plan,[53] outlining activities in Year 1 2020/2021, was published in June 2021 and represents the first step in delivering against the vision. Supported by £64 million investment, it sets out how the UK will work in partnership to:

- continue managing recovery of multi-site studies in order to fully restart its non-COVID-19 clinical research portfolio
- deliver on existing initiatives to make clinical research in the UK more streamlined and effective
- begin to deliver on the longer-term goal of growing and rebuilding the UK clinical research ecosystem through new ambitious initiatives.

The five recommendations set out below are intended to build out a level of detail which we and our members believe needs to be appropriately resourced and funded through development of a multi-year implementation plan. Although they address areas for improvement across the entire research environment, they also reflect the views of ABPI members about the specific improvements that industry needs to see to increase the attractiveness of the UK as a prime destination for clinical research, namely more streamlined and efficient approvals; costing and contracting; faster and more reliable recruitment of patients to target; and the ability to conduct innovative design and delivery of clinical trials.

Recommendations

1 Embedding clinical research in healthcare

The UK-wide vision for clinical research delivery outlines that the 'NHS will be encouraged to put delivery of research at the heart of everything they do, making it an essential and rewarding part of effective patient care'. The forthcoming Health and Care Bill provides a once-in-a-decade opportunity to embed research in England's new Integrated Care Systems (ICSs), by putting this ambition on a statutory footing.

The Health and Social Care Act 2012[54] does not mandate clinical research activity, stating only that there is a duty for Clinical Commissioning Groups (CCGs) to 'promote' research. This has hindered the NHS' ability to prioritise the resourcing and delivery of research, acting as a major impediment to improving the UK's clinical research environment over the last decade. A strengthened legislative mandate is therefore needed, and it is critical that the opportunity presented by this Bill is not missed.

ICSs are being established as the strategic leaders for the NHS and its partner organisations in England, accountable for the system-wide delivery of integrated care. By mandating research as part of the ICSs, we can ensure that across the organisations for which they are responsible, clinical research is resourced and conducted, delivering benefits including improved patient outcomes,[5] greater patient confidence in the care received[6], increased staff satisfaction and retention,[7] reduced staff burnout,[55] improved CQC ratings[8] and greater economic benefits for the NHS and the broader economy.[9]

With disparities in the opportunities for patients to engage in and participate in research, reported for geographic location[7, 55], socioeconomic background[57] and ethnicity,[58–61] the introduction of a legislative mandate could also help deliver on the Government's levelling-up agenda and commitment to address health inequalities.[62]

It is important to stress that the NHS is currently relatively under-resourced, with the UK spending less per capita on healthcare than its European counterparts.[63] Therefore while legislation plays a critical role in the successful delivery of the UK-wide vision for clinical research delivery, it must be accompanied with investment in infrastructure and workforce across NHS R&D and supporting departments. This will enable research to become part of day-to-day healthcare delivery throughout the NHS, removing barriers which currently exist, such as staff shortages and time for healthcare professionals to engage in research, and helping to reduce regional inequalities.

A positive research culture is also key, with the response to COVID-19 demonstrating that when the system comes together to deliver on a shared ambition, it can deliver high-quality clinical research which addresses unmet need and supports policy and healthcare decision-making in an efficient and timely manner.

With more patients, NHS staff and sites engaging in research than ever before during the pandemic and a shift towards a more research-active culture in the NHS, we now have a unique opportunity to embed a research culture into other disease areas and more equally across the UK healthcare system.

Recommendations:

- The new Health and Care Bill 2021-22 should mandate that Integrated Care Systems ensure that NHS organisations, for which they are responsible, conduct and resource clinical research.
- System partners should work together to investigate the infrastructure, workforce efficiencies and resource needs to deliver commercial research studies to time and target, exploring standardised models for assessing capacity within trusts and methods of raising awareness of the benefits of commercial research, with the aim of embedding these approaches across the new Integrated Care Systems.

2 Reforming and streamlining approvals and set-up

During the COVID-19 pandemic, the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Research Authority (HRA) received international recognition for their rapid approvals and pragmatic approaches to clinical research set-up and delivery. Building on these successes and following the end of the UK's transition period with the EU, now is the time to adopt new regulatory frameworks to better support the research studies of tomorrow.

In 2021, the MHRA and HRA already started piloting and establishing new services and expanding existing services, including:

- piloting a fast-track research ethics review for non-COVID-19 global and Phase I clinical trials of medicines, showing ethics decisions can be made 50% faster[64–66]
- expanding the Combined Ways of Working (CWoW) combined review service to all Clinical Trials of an Investigational Medicinal Product (CTIMP)s submitted from 1 January 2022[67]
- launching the Innovative Licensing and Access Pathway (ILAP) to reduce the time to market for innovative medicines[68]

The ABPI and pharmaceutical companies welcome this progress and continue to work with the MHRA and HRA on legislative changes under the Medicines and Medical Devices Act 2021 (MMDA),[11] the ongoing review of the research ethics service and implementation of the MHRA Delivery Plan 2021-2023.[69]

Going forward, the UK should use both legislative and non-legislative levers to overhaul clinical trial regulation and approvals processes, with efforts conducted in parallel with international reforms.

In particular, the revision of ICH E6 Good Clinical Practice[70] and enforcement of the EU Clinical Trial Regulation 536/2014 from 31 January 2022[71] will bring about changes to the international landscape which global pharmaceutical companies will need to comply with.

The UK must therefore continue to contribute to and monitor the international regulatory landscape, maintaining a position at the leading edge – setting global standards for pragmatic and innovative regulation whilst ensuring multi-country clinical trials can continue to be conducted in the UK to global expectations and standards.

Despite these improvements, consistent costing and efficient contracting remains the most significant bottleneck in study set-up, acting to counter the UK's speedy approvals processes.

To ensure a transparent and standardised approach to research costing, NHSE/I introduced the National Contract Value Review Process (NCVR) in 2019/2020. Piloted initially with selected sites and studies, the national roll-out was paused due to the pandemic. The process has, however, been implemented by the NIHR Patient Recruitment Centres[72] since their establishment in 2020. As part of the implementation of the UK-wide vision for clinical research delivery, efforts to roll out the process nationwide have resumed, with NHSE/I working with system partners and the Devolved Nations to amend and enhance the process and review how the approach can be adopted across the UK.

On contracting, the 2020/2021 implementation plan for the UK-wide vision for clinical research delivery commits to expanding the range of model UK contracts agreed with industry and the NHS, including a template to support innovative trial delivery through hub-and-spoke models. This is being led by the HRA and the Four Nations Contracting Group, with input from the ABPI and pharmaceutical companies.

If the UK is to succeed in streamlining the clinical trial process, it must focus its efforts on addressing costing and contracting. Regulators are making significant improvements to the approvals process and now the same must happen for study set-up. Negotiations must be limited, transparency of costs improved and cost variance across sites minimised, in order to bring the UK in line with other countries where site set-up is simpler, quicker and more predictable. For example, France has a mandated contract template which cannot be negotiated, accompanied with a comprehensive list of costed items. Costing is negotiated by a single coordinating site, with other sites given limited time for negotiation. As costing and contracting occurs in parallel to regulatory and ethics approvals, France is one of the quickest countries for approvals and study set-up.

Recommendations:

- The Medicines and Medical Devices Act 2021 should be used to mandate rapid timelines for regulatory approvals and reform clinical trial regulation, building on the UK's international reputation for pragmatism and innovation.
- Costing and contracting processes need to be made quicker, more transparent and less variable. There should be a simple efficient process to enable approved trials to be set up quickly, and ensure the UK delivers on the commitments of the UK-wide vision for clinical research delivery.
- MHRA and HRA should be appropriately resourced to:
  - Deliver fully the MHRA Delivery Plan 2021-2023 and HRA Make it Public Strategy.
  - Address regulatory and operational challenges relating to the Northern Ireland Protocol.
  - Reform the UK research ethics service to create a professionalised, accredited and streamlined offer.
  - Establish a UK clinical trial registry to enhance opportunities for research involvement and participation and support the UK's commitment to research transparency.
  - Deliver new and expanding regulatory and ethics services for clinical trials, including the MHRA's Early Advice Service and ILAP, accompanied by guidance for sponsors.

Recommendations

3 Increasing and diversifying patient recruitment to clinical trials

Statistics from the Office for Life Sciences show the UK's share of patients recruited to global studies was just under 3% in 2019, ranking the UK 5th among global comparators.[73]

The share of patients recruited in countries with comparable population sizes, such as Germany, France and Spain, is much higher than the UK's,[73] with some companies seeing recruitment share as high as 7–8% for some studies. Whilst the UK's share of global recruits has been on the decline since 2015, Spain has seen a year-on-year increase,[73] particularly in Phase I and Phase III studies.[48]

Diversity across those involved and participating is also lacking, with clinical trials failing to include under-served groups, such as women of child-bearing age, socio-economically disadvantaged individuals, people living with multimorbidities or disabilities and those from ethnic minority backgrounds.[74–77]

The lack of proportionate representation in clinical trials has become increasingly evident during the COVID-19 pandemic. Despite a wealth of evidence showing that COVID-19 disproportionately affected people from ethnic minority backgrounds,[77, 78] only 9.26% of participants involved in COVID-19 studies across the UK were from ethnic minority backgrounds, below the UK population average of 13.8%.[80] With a diverse population of over 60 million, the UK has the potential to offer the opportunity to get involved with and participate in research to a much wider range of patients and the public, helping to improve inclusion in research, capture a greater share of global recruits and in doing so help address health inequalities. Clearly more needs to be done to ensure that any eligible patient has the opportunity to participate in a relevant clinical trial wherever they live; the process of identifying and inviting individuals should be further streamlined.

To help increase and diversify patient recruitment to clinical trials, the NIHR has established five Patient Recruitment Centres[72] to support commercial, late-phase clinical trials, and published the INCLUDE guidance which provides a roadmap for funders, researchers and delivery teams as they design and assess clinical research proposals, suggesting intervention points to improve inclusion.[84] This is amongst other commitments in the 2020/2021 implementation plan for the UK-wide vision for clinical research[53] aimed at improving opportunities for UK patients to get involved with and participate in clinical research.

To ensure that through every patient and public interaction with the healthcare system there is an opportunity to engage with and participate in research, the ABPI proposes the following recommendations.

Recommendations:

- Clinical research activity should be scaled up across the healthcare system in primary, secondary and tertiary care settings, with collaboration and flexibility in delivery approaches incentivised to maximise opportunities for patient and public involvement and participation.
- UK Government should resource and fully deliver the Data Saves Lives and Genome UK strategies to help harness health data and genomics for clinical trials and clearly articulate to commercial sponsors the offer and services available to support research study feasibility, set-up, recruitment and delivery.
- System partners should work together to pilot community-based projects to support local healthcare systems in building relationships with underserved communities and understanding unmet need relative to local and national demographics.
- Funders and regulators should better coordinate efforts to embed patient and public involvement system-wide, helping researchers and sponsors to navigate and operationalise existing tools and guidance through improved signposting and sharing of case studies.
- UK Government should work with system partners and the Devolved Nations to deliver a public campaign to describe the value of clinical research and enable all patients, members of the public and healthcare professionals to get involved with and participate in research.

4 Adopting innovative clinical trial design and delivery approaches

The COVID-19 pandemic has changed how we design and deliver clinical research. Platform trials, including SOLIDARITY, RECOVERY, PRINCIPLE and REMAP-CAP, compared multiple treatments in parallel using a single master protocol and recruited thousands of patients over hundreds of sites, collectively developing the evidence base needed to inform how repurposed medicines could be used to treat hospitalised and recovering patients.

The shift to remote trial delivery and monitoring is another example of innovative approaches seen during the pandemic. Difficulties in conducting face-to-face operations led to evolved ways of working for clinical trial monitors, with development of systems and software by third-party providers supporting sites and sponsors to conduct remote monitoring and changes in regulatory guidance to support these approaches. Home-based healthcare has changed how treatment as part of a clinical trial is delivered, with increased use of mobile nursing and direct-to-patient shipment of investigational medicinal products (IMPs). Similar to remote monitoring, sponsors have responded by using third-party providers to deliver IMPs and meet staffing requirements.

Great efficiencies can be had from these approaches, including more effective working within research study teams, more efficient data analysis, increased convenience for research participants, improved patient and public engagement and participation, and greater opportunities for diverse and representative involvement leading to potentially greater validity of the evidence generated.[81] The RELIEVE IBS-D trial, for example, based in the NIHR Patient Recruitment Centre in Newcastle, which is testing a new treatment for Irritable Bowel Syndrome and Diarrhoea (IBS-D), has used a virtual approach to recruitment, increasing speed of recruitment by 67%.[82]

As remote approaches do not, however, meet the needs of all patients, particularly those who may lack access to digital tools or those requiring personal contact, the clinical research systems of tomorrow will need a toolkit of approaches and competencies in order to meet patient preferences and truly maximise speed and efficiency.

The UK is currently leading the way on the innovation and digitalisation of clinical research, with NIHR guidance for remote trial delivery and a consensus statement on effective delivery of complex innovative design trials published.[82,85] However, innovative capability across the UK is not widespread, with little standardisation, and evidence on the applicability of these approaches to the wider portfolio is lacking. In order to better support this evolution, the UK must help the research community put this guidance into practice and evolve its NHS infrastructure, workforce models and regulatory landscape, demonstrating that the system is ready and clear benefits are to be had from placing trials in a more agile and innovative environment.

Recommendation:
For the UK to become a test-bed destination for innovation and truly benefit from the efficiencies innovation can bring, the healthcare and research system should work together to:

- Develop and put into practice standardised approaches and guidance for innovative design and delivery of clinical trials.
- Deliver training on innovative design and delivery approaches for ethics committees, regulators, researchers involved in trial design and delivery teams.
- Ensure that digital tools are available to support remote monitoring and virtual trial delivery.
- Communicate internationally how the UK is adopting innovative design and delivery approaches and how this improves trial efficiency.

5 Improving how the UK reports on clinical research performance

The UK currently does not report clinical research performance in a systematic and coordinated manner, with differential data collection and reporting independently carried out by system partners. As global pharmaceutical companies see the UK as a single destination for clinical research, it is important that we can present a unified and coherent picture on performance – one which chimes with their internal global performance metrics and reflects the system's recovery following COVID-19.

For global pharmaceutical companies, what matters is being able to demonstrate commercial research activity over time (e.g. number of studies by phase and disease area), rapid approval and site set-up timelines (e.g. clinical trial application to first patient first visit), recruitment relative to global and national targets and allocations, and cost per patient as an indication of cost-effectiveness relative to quality of delivery.

Building on the Life Science Council's Clinical Research Working Group's work on clinical research metrics, the ABPI proposes the development of a UK-wide Clinical Research Dashboard which reports on metrics relating to (i) Speed and efficiency; (ii) Volume; (iii) Quality; (iv) Innovation; and (v) Impact.

The UK already has some robust metrics which the dashboard would need to include, such as those published by the MHRA on the assessment of clinical trial applications, by the HRA on ethics approval timelines, by the NIHR on clinical research activity and by the Office for Life Sciences on share of patients recruited to global studies. It could also draw on metrics already reported by system partners such as the ABPI, on commercial clinical trial activity, and the Cell and Gene Therapy Catapult, on advanced therapy clinical trial activity.

The ABPI proposes the development of a UK-wide Clinical Research Dashboard with metrics on:

1. **Speed and efficiency**
2. **Volume**
3. **Quality**
4. **Innovation**
5. **Impact**

Demonstrating that the UK healthcare system is equipped and ready to deliver novel and innovative design trials in emerging areas, also helps global decision-making around where to place clinical trials, particularly for companies branching out into new therapy areas, new target populations or new modalities and approaches.

Quality and impact metrics are critical for the accurate evaluation of the delivery quality and benefit to patients, the economy and the NHS, yet these are the metrics in most need of development. The NIHR Value and Impact Report in 2019[9] has been an excellent source of evidence on the economic benefits of clinical research to the NHS; however it has not been conducted with regular frequency and fails to articulate the systematic benefits to patients, both participating in clinical trials and receiving routine care – evidence which primarily lies in the peer-reviewed literature for specific diseases.

For impact in particular, it will be important to articulate how clinical research activity, and the value it brings, translates through to evaluation, uptake and patient access. Ensuring the research we do translates to improved standard of care and better treatments for patients, is critical in keeping the UK healthcare system in pace with global developments.

As the UK progresses with implementation of the UK-wide vision for clinical research and the establishment of the new Integrated Care Systems, it will be important that this approach to performance monitoring and reporting is adopted across the UK.

Recommendation:
UK Government should work with system partners on the development of a UK-wide clinical research dashboard, agreeing the metrics needed to articulate performance across the UK healthcare system and evidence the impact of changes and trends on patients, the NHS and the economy.

Conclusion

The UK Government is dedicated to bolstering the UK's life sciences sector and reforming healthcare delivery, with the Life Sciences Vision emphasising the importance of enhancing the clinical research environment as part of that.

This report shows that the UK clinical research environment has the potential to grow and evolve, adopting lessons learnt from the pandemic and addressing key bottlenecks in the system, to build the ecosystem into one which is more attractive to the global pharmaceutical industry.

In order to attract more commercial clinical research investment, deliver against the Government's plan for growth and open up opportunities for patient participation, the UK must generate more capacity for conducting clinical research throughout the NHS, embed research in routine clinical care and focus on delivering improvements in key areas including:

- streamlined and efficient approvals, costing and contracting
- faster and more reliable recruitment of patients to time and target
- improved capability to deliver innovative design and delivery trials.

As we look to the immediate recovery needed following the pandemic and the longer-term ambition of growth, the UK is at a critical inflection point, with COVID-19 and the end of the transition period with the EU providing an impetus for transformation.

The UK must maximise on the opportunities which lie ahead and work hand-in-hand with industry to successfully translate these ambitions into tangible and sustainable changes across the life sciences sector – bringing value not only to global industry, but to the NHS, patients and wider economy.

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Appendix A: Data collection methodology

For the number of commercial clinical trials initiated, data was collected from Cortellis Clinical Trial Intelligence, Clarivate Analytics, using the following criteria:

- For trial start date 1 January 2012 – 31 December 2020, countries: Australia, Canada, France, Germany, Italy, Japan, Poland, Spain, Switzerland, UK, and USA
- For trial start date 1 January 2016 – 31 December 2020, countries: Brazil, China, South Africa, Switzerland
- For trial start date 1 January 2017 – 31 December 2020, countries: Belgium and Hungary
- Phase of study: Phase I, Phase II or Phase III
- Disease area: Oncology, Nervous System, Cardio-metabolic, Immunology, Infectious diseases (excluding COVID-19) and COVID-19
- Only commercial trials related to pharmaceutical drug development and molecular/biological entities were included.
- Collaborative trials were only included if one or more partners was a commercial organisation.
- Trials across multiple therapy areas were only included in their main therapy area.

For the number of patients treated for commercial clinical trials, proprietary data was collected from CMR Global Clinical Performance Metrics, Clarivate Analytics, using the following criteria:

- Commercial clinical trials completing treatment between 1 January 2017 and 31 December 2019
- Phase I data included both healthy volunteers and patients.
- Terminated clinical trials were excluded.
- CMR confidentiality rules are defined as any metric result with contributing data from less than five records or three companies.
    - "N/A" indicates where data cannot be shown.
    - "Rest of TAs" indicates all the therapeutic areas where data cannot be shown.

Please note that data gathered from Clarivate Analytics is regularly updated and hence the data shown here is accurate as of the date of collection (1 July 2021) and may differ from historic and future datasets.

For COVID-19 impact analysis, proprietary data was collected in 2,659 commercial studies from across 473 sponsors, from Medidata Acorn AI. Only data that meets Medidata's data-sharing agreements is included here. Definitions are as such:

- Number of studies (n): Total number of studies enrolling one or more patients throughout the time period covered, by country or disease area.
- Enrolled patient: A patient who has been enrolled or randomised to an active study. Patients who were screened multiple times for the same study and eventually enrolled, are counted as enrolled once.
- Number of enrolled patients: Total enrolled patients across studies in each disease group or country per month.
- Baseline enrolment: Monthly baseline enrolment is determined as the total patients enrolled for the respective month in 2019 for a specific disease group and country.
- Percentage change from baseline enrolment: Percentage change in total enrolment for each disease group and country for a month compared to total enrolment for the same month in 2019 for that disease group and country.

Please note that data gathered from Medidata is regularly updated and hence the data shown here is accurate as of the date of collection (27 August 2021) and may differ from historic and future datasets.

Appendix B: Data tables

Data table 1: Percentage change in total enrolment for UK commercial studies per month relative to 2019 baseline, by disease area (January 2020-July 2021)

	Oncology	Cardio-metabolic	Nervous	Immune	Infectious
Jan-20	-34.7	-41.5	26.1	-20	126.3
Feb-20	-21.1	-72.2	-53.3	27.3	35.3
Mar-20	-43.4	-64.3	-39.1	7.9	-28.3
Apr-20	-82.4	-86.2	-84	-67.5	-73.9
May-20	-87.5	**	-81.5	-54.8	-73
Jun-20	-64.1	**	-62.5	-33.3	**
Jul-20	-64.6	**	-65.6	-34.6	-62.5
Aug-20	-45.7	-84.4	-62.5	-51.5	-42.9
Sep-20	-21.9	-32.3	-55	-43.5	-7.3
Oct-20	20.9	-26.7	-22.6	125	-14
Nov-20	-19.8	12.9	-24.1	55.8	-29.8
Dec-20	-28.9	117.4	31.3	192.3	91.4
Jan-21	-60	-56.9	17.4	168.6	47.4
Feb-21	-39.8	-62.5	126.7	36.4	29.4
Mar-21	-29.7	-17.9	-26.1	57.9	26.1
Apr-21	-20.8	-38.5	-48	-17.5	-4.3
May-21	-22.3	-29.2	-25.9	12.9	56.8
Jun-21	-16	-16.7	-31.3	-10.3	-8.3
Jul-21	-32.9	-47.8	-84.4	-50	-22.5

** Proprietary data excluded as per Medidata's data-sharing agreement

Data table 2: Percentage change in total enrolment for commercial studies per month relative to 2019 baseline, by country (January 2020-July 2021)

	UK	France	Germany	Spain	Italy
Jan-20	-19.2	-14.7	-10.7	-15.3	-8.2
Feb-20	-24.9	-10.2	-30.1	-22.1	-2.8
Mar-20	-38.3	-39.4	-36.2	-43.8	-38.8
Apr-20	-80.1	-70.5	-63.4	-69.5	-60.1
May-20	-84.6	-71	-71.2	-65.8	-45.4
Jun-20	-72.6	-8.9	-62.7	-21.2	-27
Jul-20	-66.9	-39.1	-35.7	-18.9	-24.9
Aug-20	-53.2	-27.8	-25.2	-20.6	-20.2
Sep-20	-28.3	-24.5	-18.6	-5.2	0.4
Oct-20	21.1	-32.2	-38.5	-1.4	-16.3
Nov-20	-5.7	-36.4	-52.4	-0.8	-20.5
Dec-20	37.9	-11.7	-6.8	-4.4	-16.2
Jan-21	-18.8	-15.9	-14.9	-10.4	-5.6
Feb-21	-12.1	-37.4	-2.9	0	8.9
Mar-21	-8.1	-6	20.2	18.8	3.1
Apr-21	-23.9	-22.2	-0.5	5	17.7
May-21	-10	-26.8	-25.9	27.5	33.8
Jun-21	-15.6	13.9	-3.7	37.1	34.4
Jul-21	-41.7	-41.5	-44.3	6.3	-21.7

Data table 3: Number of applications assessed by MHRA in 2019 and 2020 by phase and sponsor type

	Phase I		Phase II/III		Phase IV		All Phases	
	2019	2020	2019	2020	2019	2020	2019	2020
Commercial	111	121	604	639	33	17	748	777
Non-commercial	9	8	105	150	46	32	160	190
Total	120	129	709	789	79	49	908	967

Data table 4: Number of commercial clinical trials initiated in the UK per year, by phase (2012-2020

	Phase I	Phase II	Phase III	Total
2012	102	224	245	571
2013	141	207	265	613
2014	160	226	250	636
2015	152	248	290	690
2016	150	234	250	634
2017	117	281	269	667
2018	95	268	292	655
2019	89	257	272	618
2020	83	201	224	508

Data table 5: Number of Phase I commercial clinical trials initiated per year, by country (2012-2020)

	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	102	114	59	19	40	12	547	54	45	83						
2013	141	106	45	27	43	12	583	45	73	70						
2014	160	115	59	20	50	8	676	49	56	90						
2015	152	103	60	18	53	7	677	43	87	102						
2016	150	108	62	31	63	12	641	60	79	108	187	3	5	20		
2017	117	94	51	25	60	19	473	66	78	85	178	5	4	11	37	7
2018	95	68	37	20	49	10	526	43	66	66	234		6	6	39	2
2019	89	74	49	27	65	15	534	49	116	70	345	3	0	12	40	5
2020	83	66	49	20	73	10	512	47	117	83	343	7	3	8	35	2

Data table 6: Number of Phase II commercial clinical trials initiated per year, by country (2012-2020)

	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	224	283	203	161	203	152	767	185	111	143						
2013	207	232	180	157	150	101	757	153	100	132						
2014	226	221	177	156	176	88	833	166	110	141						
2015	248	278	209	168	206	135	1010	206	138	201						
2016	234	243	188	160	212	113	913	201	119	247	76	22	17	40		
2017	281	262	198	167	229	112	988	201	133	229	146	30	19	35	137	72
2018	268	249	200	157	221	133	1021	187	152	198	190	37	20	56	125	74
2019	257	252	214	173	243	141	964	192	148	160	298	32	24	34	133	82
2020	201	213	164	132	203	113	953	151	146	164	361	49	25	35	97	58

Data table 7: Number of Phase III commercial clinical trials initiated per year, by country (2012-2020)

	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	245	323	233	251	261	229	474	246	162	225						
2013	265	319	244	252	290	243	525	271	197	215						
2014	250	322	237	229	275	237	516	263	183	192						
2015	290	370	281	248	295	230	608	275	196	235						
2016	250	314	221	233	263	218	530	255	151	219	113	110	61	76		
2017	269	294	224	241	274	250	536	267	183	246	155	122	77	64	169	162
2018	292	315	290	264	308	250	626	289	211	242	219	123	77	101	208	177
2019	272	289	258	263	282	237	533	248	179	230	263	120	62	59	176	169
2020	224	264	226	229	273	194	537	220	181	218	241	151	48	67	158	152

Data table 8: Average number of participants treated per commercial trial, by country (2017-2019)

	Average number of participants treated	
Country	Phase I	Phase II-III
UK	25.44	23.82
Japan	22.53	82.58
Poland	12.44	63.97
Spain	6.83	36.24
Hungary		41.64
Germany	40.26	29.5
France	14.41	25.18
Italy		20.63
Belgium	28.96	17.71
Switzerland		17.33

Data table 9: Number of commercial clinical trials initiated in the UK per year, by disease area (2012-2020)

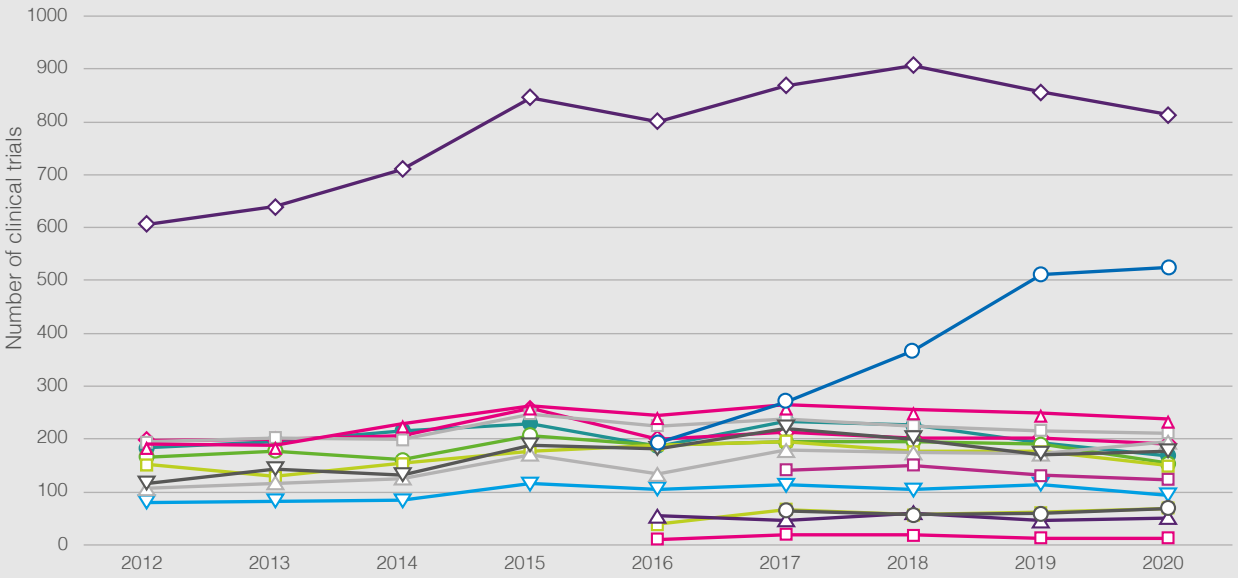
	Oncology	Immune	Nervous	Cardio-metabolic	Infectious (excl. COVID-19)	COVID-19
2012						
2013	196	66	72	96		
2014	216	74	68	91		
2015	230	84	90	68		
2016	187	77	78	78	48	
2017	234	83	63	103	54	
2018	226	94	66	64	46	
2019	192	75	70	83	48	
2020	169	37	55	62	25	68

Appendix C: Commercial clinical trial activity by disease area

Key

UK, Germany, France, Spain, Poland, Italy, USA, Hungary, Canada, Australia, Japan, China, Brazil, South Africa, Switzerland, Belgium

Figure A: Number of oncology commercial clinical trials initiated per year, by country (2012-2020)



	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	183	198	195	166	190	81	607	152	107	115						
2013	196	199	203	178	189	83	639	129	117	143						
2014	216	206	199	161	229	84	711	154	126	131						
2015	230	258	248	207	263	116	846	177	171	188						
2016	187	200	225	189	245	105	801	189	134	181	192	39	10	55		
2017	234	213	237	194	264	113	869	196	179	220	270	67	20	47	142	65
2018	226	202	225	196	256	104	907	176	174	200	367	57	18	60	151	57
2019	192	203	216	190	250	114	856	176	172	171	512	61	13	45	131	59
2020	169	191	211	154	239	94	813	149	195	176	525	69	13	51	123	69

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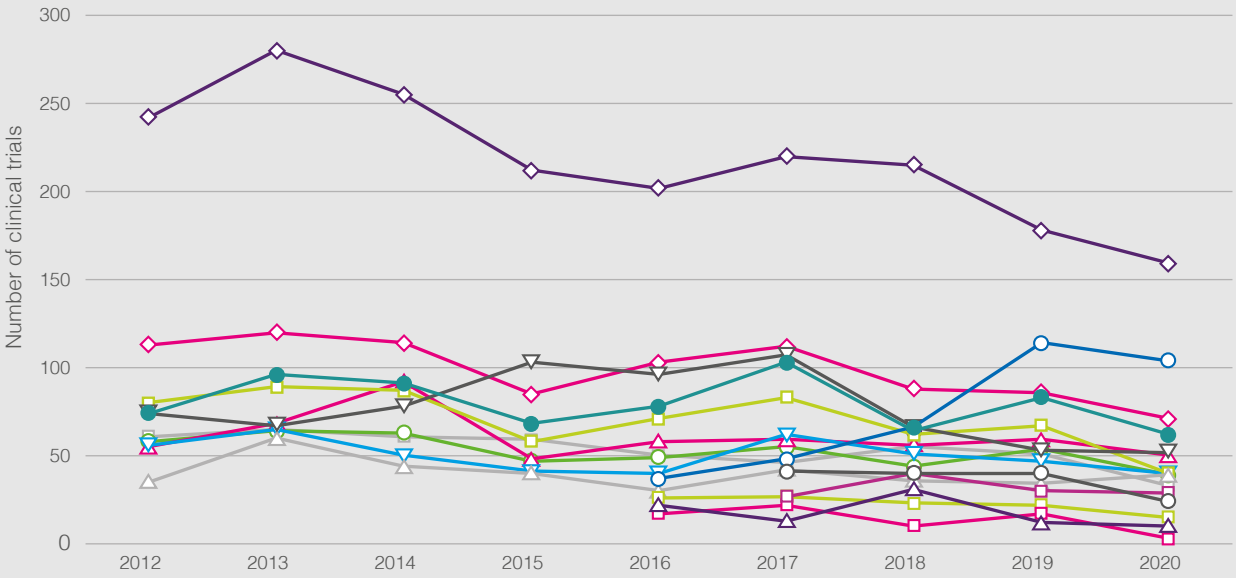
Key

UK, Germany, France, Spain, Poland, Italy, USA, Hungary, Canada, Australia, Japan, China, Brazil, South Africa, Switzerland, Belgium

Figure B: Number of cardio-metabolic commercial clinical trials initiated per year, by country (2012-2020)



	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	74	113	61	58	55	56	242	80	35	74						
2013	96	120	65	64	68	65	280	89	60	67						
2014	91	114	61	63	92	50	255	87	44	78						
2015	68	85	59	47	48	41	212	58	40	103						
2016	78	103	50	49	58	40	202	71	30	96	37	26	17	22		
2017	103	112	46	55	59	62	220	83	42	107	48	27	22	13	27	41
2018	64	88	55	44	56	51	215	62	36	66	66	23	10	31	40	40
2019	83	86	51	54	59	47	178	67	34	53	114	22	17	12	30	40
2020	62	71	33	39	50	40	159	40	39	52	104	15	3	10	29	24

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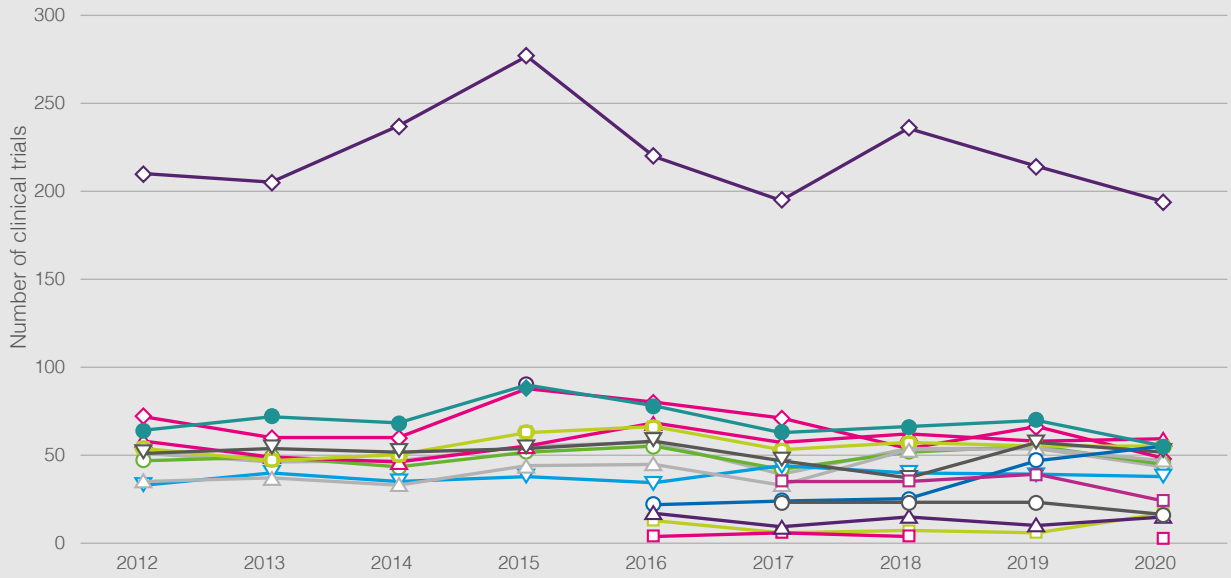
Key

UK, Germany, France, Spain, Poland, Italy, USA, Hungary, Canada, Australia, Japan, China, Brazil, South Africa, Switzerland, Belgium

Figure C: Number of nervous commercial clinical trials initiated per year, by country (2012-2020)



	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	64	72	51	47	58	33	210	54	35	51						
2013	72	60	46	49	49	40	205	47	37	54						
2014	68	60	47	43	46	35	237	50	33	52						
2015	90	88	55	52	55	38	277	63	44	54						
2016	78	80	57	55	68	34	220	66	45	58	22	13	4	17		
2017	63	71	39	42	57	44	195	53	33	47	24	6	6	9	35	23
2018	66	54	54	52	62	40	236	57	53	37	25	7	4	15	35	23
2019	70	66	54	55	58	39	214	55	54	57	47	6		10	39	23
2020	55	48	43	45	59	38	194	55	47	52	55	17	3	15	24	16

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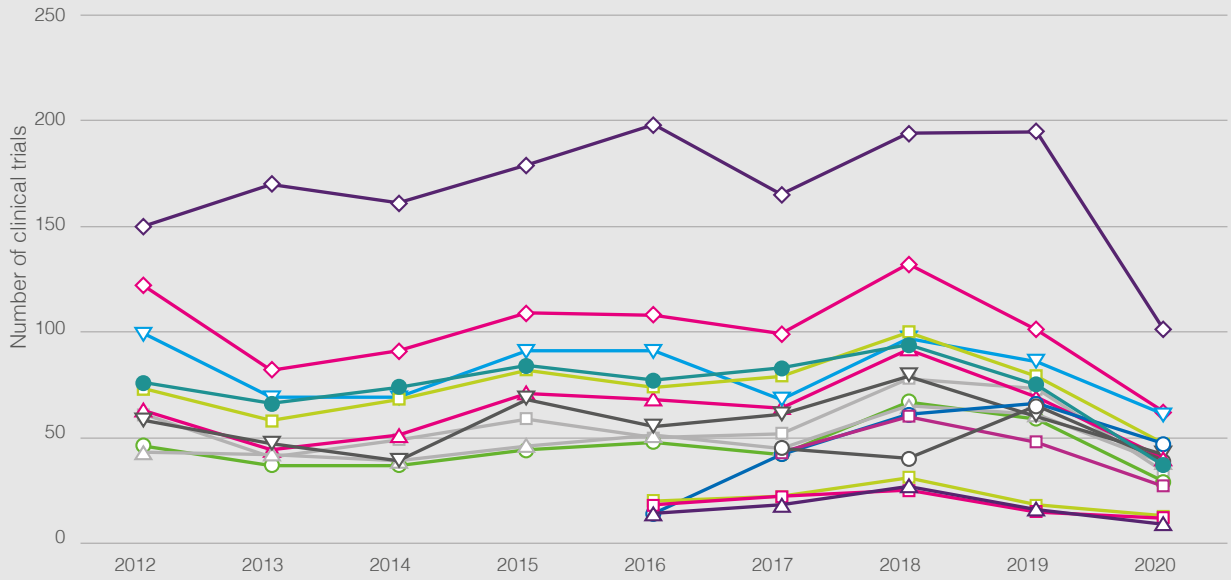
Key

UK, Germany, France, Spain, Poland, Italy, USA, Hungary, Canada, Australia, Japan, China, Brazil, South Africa, Switzerland, Belgium

Figure D: Number of immune commercial clinical trials initiated per year, by country (2012-2020)



	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2012	76	122	61	46	63	99	150	73	43	58						
2013	66	82	41	37	44	69	170	58	42	47						
2014	74	91	49	37	51	69	161	68	39	39						
2015	84	109	59	44	71	91	179	82	46	68						
2016	77	108	50	48	68	91	198	74	51	55	14	20	18	14		
2017	83	99	52	42	64	68	165	79	45	61	42	22	22	18	43	45
2018	94	132	78	67	92	97	194	100	65	79	61	31	25	27	60	40
2019	75	101	73	59	69	86	195	79	61	60	66	18	15	16	48	65
2020	37	62	34	29	40	61	101	47	38	42	47	13	12	9	27	39

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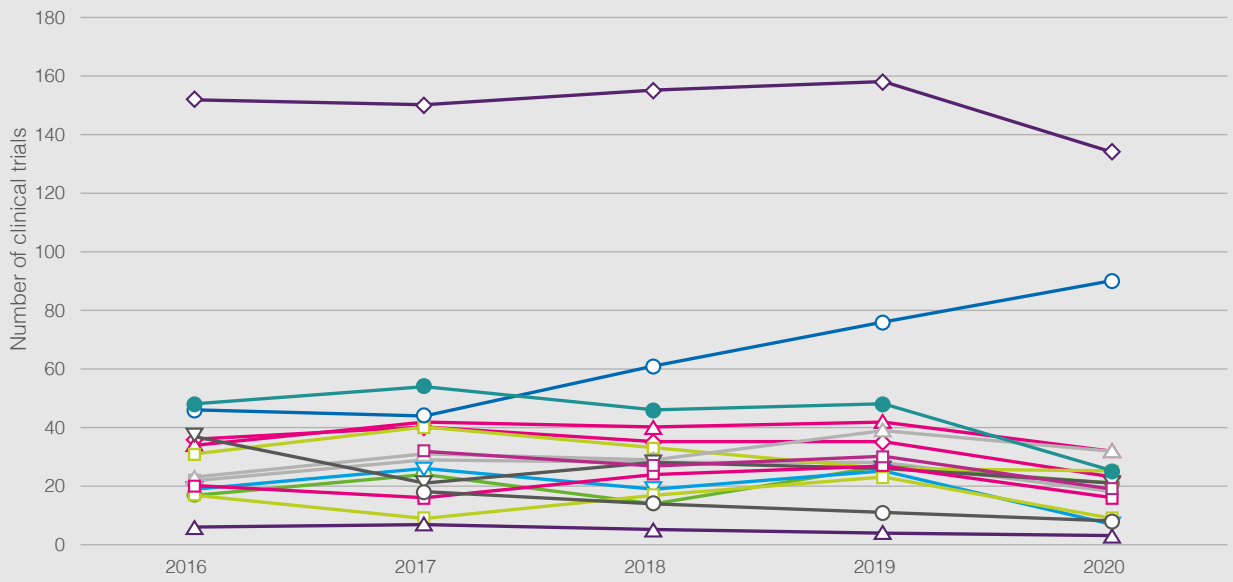
Key

UK, Germany, France, Spain, Poland, Italy, USA, Hungary, Canada, Australia, Japan, China, Brazil, South Africa, Switzerland, Belgium

Figure E: Number of infectious commercial clinical trials initiated per year, by country (2012-2020)



	UK	Germany	France	Italy	Spain	Poland	USA	Canada	Australia	Japan	China	Brazil	South Africa	Switzerland	Belgium	Hungary
2016	48	36	22	17	34	19	152	31	23	37	46	17	20	6		
2017	54	40	29	24	42	26	150	40	31	21	44	9	16	7	32	18
2018	46	35	28	14	40	19	155	33	29	28	61	17	24	5	27	14
2019	48	35	28	27	42	25	158	26	39	26	76	23	27	4	30	11
2020	25	23	18	21	32	7	134	25	32	21	90	9	16	3	19	8

Note: this data does not include COVID-19 clinical trials

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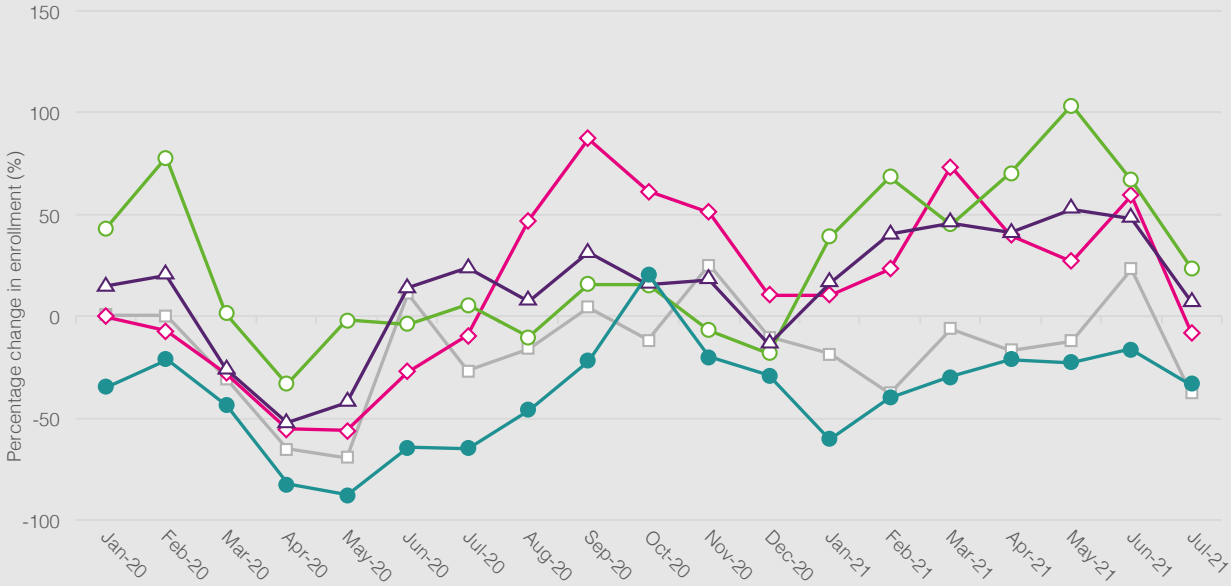
Appendix D: COVID-19 impact on enrolment by disease area

Key

Figure F: Percentage change in enrolment for commercial oncology studies per month relative to 2019 baseline, by country (January 2020-July 2021)



	UK	France	Germany	Italy	Spain
Jan-20	-34.7	0.7	0	43	14.6
Feb-20	-21.1	0.3	-7.1	78.1	20.4
Mar-20	-43.4	-30.5	-27.7	1.7	-25.9
Apr-20	-82.4	-64.9	-55.1	-32.9	-52.3
May-20	-87.5	-69.1	-56	-1.7	-42.1
Jun-20	-64.1	11.5	-27	-3.7	14.2
Jul-20	-64.6	-26.6	-9.3	5.8	23.6
Aug-20	-45.7	-15.6	47.3	-10.2	7.5
Sep-20	-21.9	4.5	87.3	16	31.5
Oct-20	20.9	-11.5	61.4	15.5	15.9
Nov-20	-19.8	25.4	51.2	-6.6	18.3
Dec-20	-28.9	-10.3	10.5	-18.1	-13.3
Jan-21	-60	-18.3	10.6	39.1	16.6
Feb-21	-39.8	-37.5	23.5	68.4	40.5
Mar-21	-29.7	-6	73.3	45.1	46.1
Apr-21	-20.8	-16.3	39.8	70.5	41
May-21	-22.3	-12.1	27.2	103.4	52.6
Jun-21	-16	23.4	59.5	66.9	48.2
Jul-21	-32.9	-37.7	-7.8	23.9	7.1

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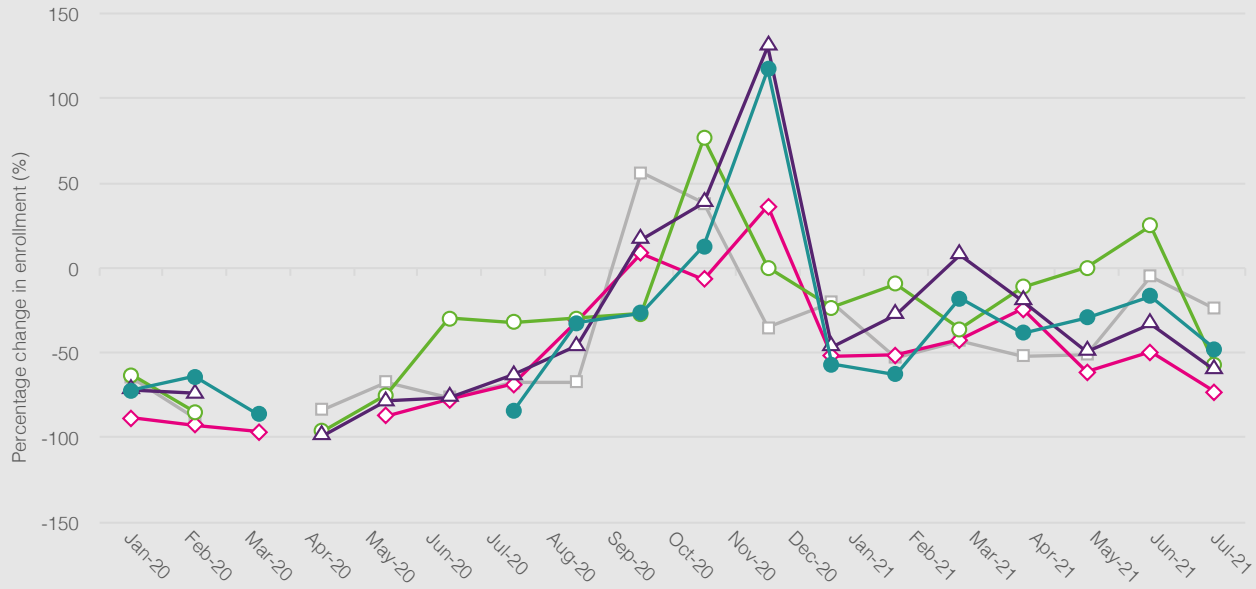
Key

UK Germany France Spain Italy

Figure G: Percentage change in enrolment for commercial cardio-metabolic studies per month relative to 2019 baseline, by country (January 2020-July 2021)



	UK	France	Germany	Italy	Spain
Jan-20	-41.5	-75.9	-76	-59.4	-56.3
Feb-20	-72.2	-64.7	-88.5	-63.2	-71.6
Mar-20	-64.3	-88.5	-92.7	-84.8	-74
Apr-20	-86.2		-96.5		
May-20		-83.7		-96.1	-98.7
Jun-20		-67.4	-87.1	-75	-78.6
Jul-20		-76.2	-77.5	-29.5	-76.3
Aug-20	-84.4	-67.6	-68.8	-32.1	-63.4
Sep-20	-32.3	-67.2	-31.1	-29.8	-45.8
Oct-20	-26.7	56	8.7	-26.9	16.7
Nov-20	12.9	38.1	-6.5	76.7	38.7
Dec-20	117.4	-35	36.4	0	130.8
Jan-21	-56.9	-20.4	-51.9	-23.4	-46.7
Feb-21	-62.5	-52.9	-51.5	-9.2	-27.3
Mar-21	-17.9	-42.6	-42.3	-35.9	7.6
Apr-21	-38.5	-51.8	-24.4	-11.3	-19.4
May-21	-29.2	-51	-61.3	0	-49.4
Jun-21	-16.7	-4.7	-49.4	25	-33
Jul-21	-47.8	-23.8	-73	-56.8	-59.9

** Proprietary data excluded as per Medidata's data sharing agreements

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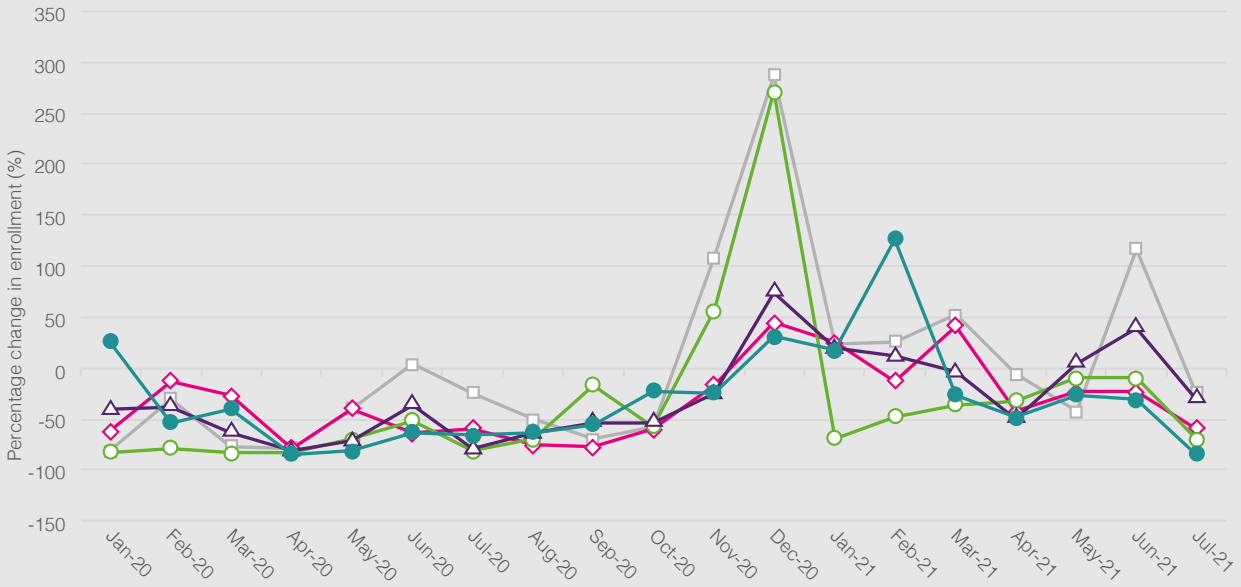
Key

UK Germany France Spain Italy

Figure H: Percentage change in enrolment for commercial nervous studies per month relative to 2019 baseline, by country (January 2020-July 2021)



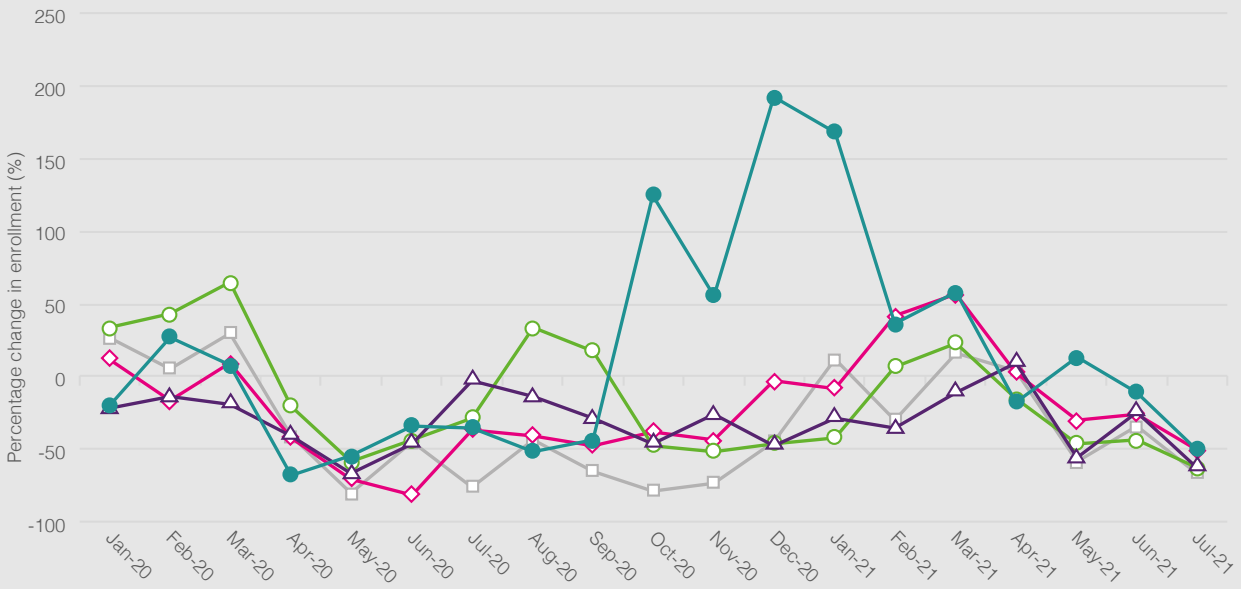
	UK	France	Germany	Italy	Spain
Jan-20	26.1	-81.6	-61.5	-82	-40.3
Feb-20	-53.3	-29.6	-12.2	-78	-37.3
Mar-20	-39.1	-76.2	-26.8	-83.3	-62.4
Apr-20	-84	-78.8	-77.9	-82.9	-81.4
May-20	-81.5	-39.4	-40	-70	-71.6
Jun-20	-62.5	4.3	-63.5	-50.9	-36.1
Jul-20	-65.6	-24	-58.5	-81.7	-79.1
Aug-20	-62.5	-50	-75.6	-69.2	-63.8
Sep-20	-55	-69.4	-77.8	-16.7	-52.8
Oct-20	-22.6	-57.8	-59.6	-56.7	-53.1
Nov-20	-24.1	108.3	-16.7	56.3	-25
Dec-20	31.3	287.5	45	271.4	75
Jan-21	17.4	23.7	25.6	-68.9	19.4
Feb-21	126.7	25.9	-12.2	-47.5	11.9
Mar-21	-26.1	52.4	41.5	-35.6	-3.7
Apr-21	-48	-6.1	-42.6	-31.4	-48.8
May-21	-25.9	-42.4	-23.3	-10	5.4
Jun-21	-31.3	117.4	-23.1	-9.4	39.3
Jul-21	-84.4	-24	-58.5	-70	-29.9

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

Key

UK Germany France Spain Italy

Figure I: Percentage change in enrolment for commercial immune studies per month relative to 2019 baseline, by country (January 2020-July 2021)



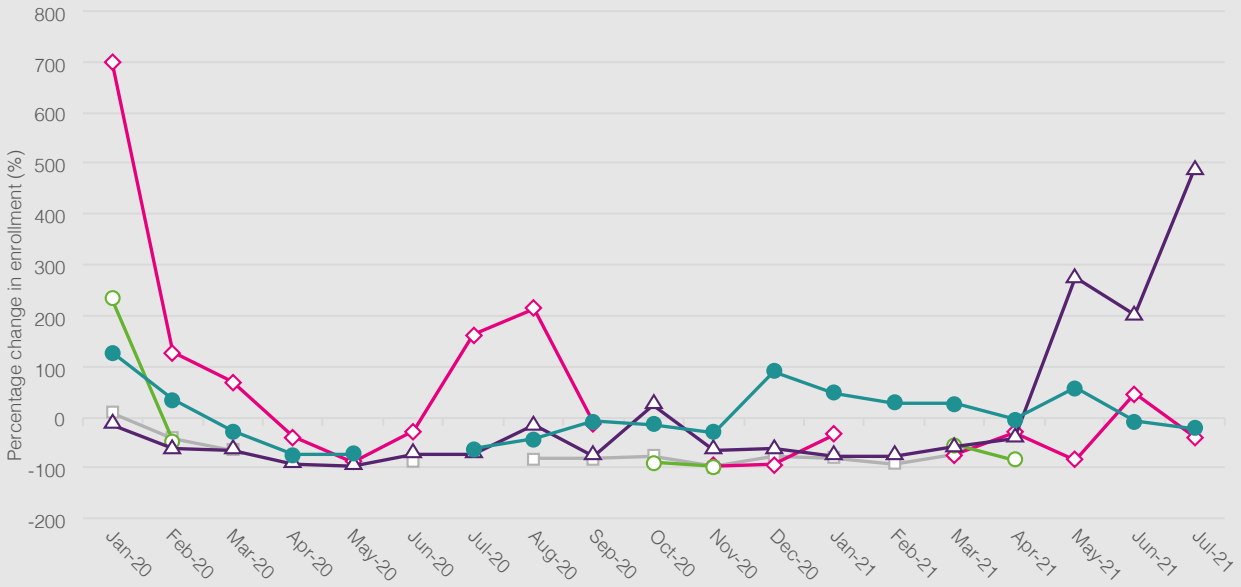
	UK	France	Germany	Italy	Spain
Jan-20	-20	26.9	12.2	33.3	-22
Feb-20	27.3	5.4	-16.8	42.9	-13.8
Mar-20	7.9	30	9.4	64.7	-18.8
Apr-20	-67.5	-40.9	-41.7	-20	-40
May-20	-54.8	-80.6	-70.1	-58.3	-66.7
Jun-20	-33.3	-44.8	-81.1	-43.5	-45.7
Jul-20	-34.6	-75.5	-36.6	-28.1	-2.1
Aug-20	-51.5	-43.8	-40	33.3	-13.8
Sep-20	-43.5	-65	-47.3	17.9	-28.6
Oct-20	125	-78.5	-37.5	-47.4	-45.6
Nov-20	55.8	-73.1	-43.5	-51.4	-25.8
Dec-20	192.3	-44.4	-3.2	-45.5	-47.2
Jan-21	168.6	11.5	-7.6	-41.7	-28
Feb-21	36.4	-29.7	42	7.1	-35.4
Mar-21	57.9	16.7	56.6	23.5	-10.4
Apr-21	-17.5	4.5	3.3	-15	10
May-21	12.9	-58.3	-29.9	-45.8	-56.3
Jun-21	-10.3	-34.5	-25.4	-43.5	-23.9
Jul-21	-50	-66	-50.7	-62.5	-61.7

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

Key

UK Germany France Spain Italy

Figure J: Percentage change in enrolment for commercial infectious disease studies per month relative to 2019 baseline, by country (January 2020-July 2021)



	UK	France	Germany	Italy	Spain
Jan-20	126.3	10	700	233.3	-14.3
Feb-20	35.3	-40.9	127.8	-47.4	-62.7
Mar-20	-28.3	-64.3	68.8		-65.1
Apr-20	-73.9		-40		-91.7
May-20	-73		-88.1		-95.2
Jun-20		-86.4	-27.3		-72.7
Jul-20	-62.5		161.5		-71.9
Aug-20	-42.9	-81.3	214.3		-16.7
Sep-20	-7.3	-81	-12.5		-76.2
Oct-20	-14	-75.8		-88.6	25
Nov-20	-29.8	-96.5	-96.1	-97.3	-63.5
Dec-20	91.4	-76.9	-94.2		-62.1
Jan-21	47.4	-80	-33.3		-76.2
Feb-21	29.4	-90.9			-76.3
Mar-21	26.1	-71.4	-75	-55.6	-58.1
Apr-21	-4.3		-30	-83.3	-41.7
May-21	56.8		-83.3		273.8
Jun-21	-8.3		45.5		200
Jul-21	-22.5		-38.5		487.5

** Proprietary data excluded as per Medidata's data sharing agreements

Access interactive graphs and data on the ABPI website: https://www.abpi.org.uk/facts-and-figures/

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