



# Clinical trials

How the UK can transform the  
clinical research environment

Autumn 2020



**I'm delighted that the ABPI is publishing its second annual report looking at the clinical trials environment in the UK.**

Since our last report was published in 2019, clinical research has become a topic of public interest in a way we could never have predicted. As the global research community coalesces to find vaccines and treatments for COVID-19, the general public around the world are following every development. In the UK, this is happening against the backdrop of Government and industry preparing for the end of the transition period, where there remains considerable uncertainty.

The UK has responded at an unprecedented pace to get COVID-19 research up and running as quickly as possible, with the life sciences sector, Government and regulators working closely together. Globally, we have seen rapid funding, enhanced partnership opportunities and innovative approaches to designing, delivering and reporting on research, which have brought new opportunities to patients and improved our healthcare decision-making. These new approaches have also shone a light on the possibilities for change that lie ahead.

However, this impressive response has had an impact on research in other disease areas, which has declined over this period. As we seek to define how the UK returns to pre-COVID-19 levels of clinical research and how we can go on to enhance our environment, it is important to understand how the UK clinical research environment has performed. Our report tracks UK clinical research activity in 2018, compared with international competitors, highlighting areas of strength and areas for improvement.

The UK Government has demonstrated a commitment to enhancing the UK clinical research environment, with the Life Sciences Industrial Strategy, Sector Deals and R&D Roadmap providing a platform to address issues that lie in the system. These initiatives and commitments are welcomed by the ABPI and industry. The life sciences sector must be central to the Government's plans to become a science 'superpower' and transformational change in the UK's clinical research environment can help achieve this goal.

Working in partnership with patients and the public, we can learn from our experiences during COVID-19 and position the UK as a leading global destination to conduct clinical research, building an innovative and competitive environment that has patients at the heart.

**Dr Sheuli Porkess**  
**Executive Director, Research, Medical and Innovation**  
The Association of the British Pharmaceutical Industry

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# Executive summary

**Clinical trials are an essential part of the research and development (R&D) process, bringing benefits to patients, the NHS and the economy. For every patient recruited onto a commercial clinical trial between 2016/2017 and 2017/2018, the NHS in England received £9,189 from life sciences companies, and where a trial drug replaced the standard of care treatment, saved £5,813<sup>1</sup>.**

To date, the Life Sciences Industrial Strategy, Sector Deals and R&D Roadmap have laid out commitments to enhancing the UK clinical research environment and have begun to address some of the existing challenges.

The response to the COVID-19 pandemic and the preparations being made for the end of the UK's transition period with the European Union have created an even greater impetus for the transformational change needed as the UK looks to be a global leader in clinical research.

This report looks at how the UK clinical research environment has historically performed, highlighting areas for improvement. The pre-COVID-19 data here from 2018 articulates the UK's performance across phases (I, II and III) and disease areas (Oncology, Nervous System, Cardio-metabolic, Immunology and Infectious diseases). Put in the context of the international landscape, this report highlights where the UK is competitive and where we fall behind other countries.

This report also includes new data from Belgium and Hungary, which gives us additional granularity on performance across Europe.



## What does the data tell us?

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■ The Medicines and Healthcare products Regulatory Agency (MHRA) received 798 applications for commercial clinical trials in 2018<sup>2</sup>.
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■ Since 2017, Phase I clinical trial activity has declined in the UK, with 95 trials initiated in 2018, compared with 117 in 2017. This is a trend seen across European comparators, with the UK maintaining its lead in Europe for Phase I trials.
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■ For Phase II, the UK ranks second globally, with 268 trials initiated in 2018, compared with the USA, ranking first with 1,021 trials initiated.
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■ The UK continues to fall behind global competitors for Phase III clinical trials, with 292 trials initiated in the UK in 2018 – ranking the UK third in Europe behind Germany and Spain.
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■ Oncology remains the UK's strongest research area, with 226 trials initiated in the UK in 2018.
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■ China's clinical research environment has continued to grow across all clinical trial phases, with 234 Phase I, 190 Phase II and 219 Phase III trials initiated in 2018 – a substantial increase in activity compared with 2017.
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■ In 2018/2019, 870,250 people took part in research studies supported by the NIHR Clinical Research Network (CRN)<sup>3</sup>.
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■ As of 9 September, data from the NIHR CRN shows that 45% of studies (2,676) are open to recruitment, with 36% of open studies recruiting since the 1 June<sup>27</sup>.

## Recommendations: How do we supercharge the UK's clinical research environment?

**The UK needs to rebuild and supercharge clinical research by implementing the following actions, in parallel:**

- 1** Restarting and restoring research across the UK and across all disease areas.
- 2** Transforming the UK clinical research environment with investment to increase levels of research beyond pre-COVID levels by:
  - a.** Optimising the processes for setting up and running clinical trials
  - b.** Building a workforce fit for the future with opportunities for all to be involved in research
  - c.** Harnessing the UK's health data to support the efficient design, feasibility, recruitment and conduct of the full range of clinical trials
  - d.** Driving continuing high standards for transparency
  - e.** Creating a regulatory environment which supports innovation in life sciences
- 3** Ensuring that all patients have the opportunity to be involved and engaged with research
- 4** Making research and innovation central to the UK's trade strategy



# Introduction: The time for transformation is now

**Clinical trials are an essential part of the research and development process, ensuring safety and efficacy of potential new medicines and vaccines. Every medicine in the NHS has to be tested in clinical trials before it is used, with development continuing after a medicine is approved for use, to examine longer-term outcomes, and safety and efficacy in routine usage in the ‘real world’.**


Clinical trials rely on the involvement, engagement and participation of patients and public contributors, with over 1 million participants taking part in NIHR-supported health and social care research studies in 2018/2019<sup>3</sup>. By putting patients’ interests at the heart of research, we ensure researcher questions are answered and that the findings of clinical trials have ‘real world’ relevance. We also know that patients treated in hospitals where research is ongoing not only have access to potentially life-saving experimental medicines and vaccines, but will also have better outcomes<sup>4-6</sup>.

Clinical trials also bring direct economic benefits, with research activity attracting substantial industry investment, including the provision of investigative medicines, and supporting the employment of researchers and healthcare professionals.

For every patient recruited onto a commercial clinical trial between 2016/2017 and 2017/2018, the NHS in England received £9,189 from life sciences companies, and where a trial drug replaced the standard of care treatment, saved £5,813<sup>1</sup>.

The pharmaceutical industry invested £4.5 billion in UK R&D in 2018<sup>7</sup>, with global industry predicted to spend \$232.5 billion a year on R&D by 2026<sup>8</sup>. In the UK in 2018, the life sciences industry employed over 240,000 people across 5,870 businesses, generating a turnover of £73.8bn<sup>9</sup>.

The disease area which continues to receive the largest clinical research investment globally is oncology, with other therapy areas such as anti-diabetics, immunosuppressants and vaccines receiving significant R&D investment<sup>8</sup>, with innovations in areas such as cell and gene therapies and genomics offering new ways to treat a range of diseases.



Over  
**1 million**  
participants taking  
part in NIHR-  
supported health and  
social care research  
studies in 2018/2019

With almost 50% of global R&D investment allocated to clinical trials (Phases I–III)<sup>10</sup>, industry invests a substantial amount in clinical research, supporting the development of the medicines and vaccines of the future.

Last year the ABPI's Clinical Trials Report<sup>11</sup> provided a benchmark for clinical research in the UK, with retrospective data articulating the environment in 2017 – a time of uncertainty attributed to the decision by the UK to leave the European Union.

One year on, this report reviews the clinical research activity in the UK in 2018, during which the Withdrawal Agreement was published and endorsed by the EU, setting the UK on a track towards future relationship negotiations.

In 2020, the UK has left the EU and the COVID-19 pandemic has brought mass disruption to global R&D and healthcare systems. As the UK looks ahead, we must reflect on lessons learnt from COVID-19 and embed new ways of working across the clinical research environment, to lock in transformational changes that can benefit the NHS, patients and the public alike. The UK must also ensure that these changes enable future clinical trials to be conducted more efficiently in all disease areas, including COVID-19.

To date, the Life Sciences Industrial Strategy, Sector Deals and Government's commitment to increase R&D investment to 2.4% of GDP have provided a platform for partnership, allowing the sector to work together towards an improved clinical research environment, with many promising initiatives established. However, the step-change needed to transform the UK clinical research environment has yet to come to fruition.

This report presents recommendations that allow us to build on these foundations, to ensure the UK has a globally competitive clinical research environment to conduct commercial clinical research – one that industry can feel confident in and rely on.



**£4.5  
billion**

**invested in UK R&D by the  
pharmaceutical industry in 2018.**



# A benchmark for global clinical research

## Clinical trials at home: What the data shows us for the UK

**Since 2012, commercial clinical research trends in the UK have remained stable, with the total number of clinical trials starting every year, across all phases, averaging 638; with over 75% in Phases II/III (Figure 1).**

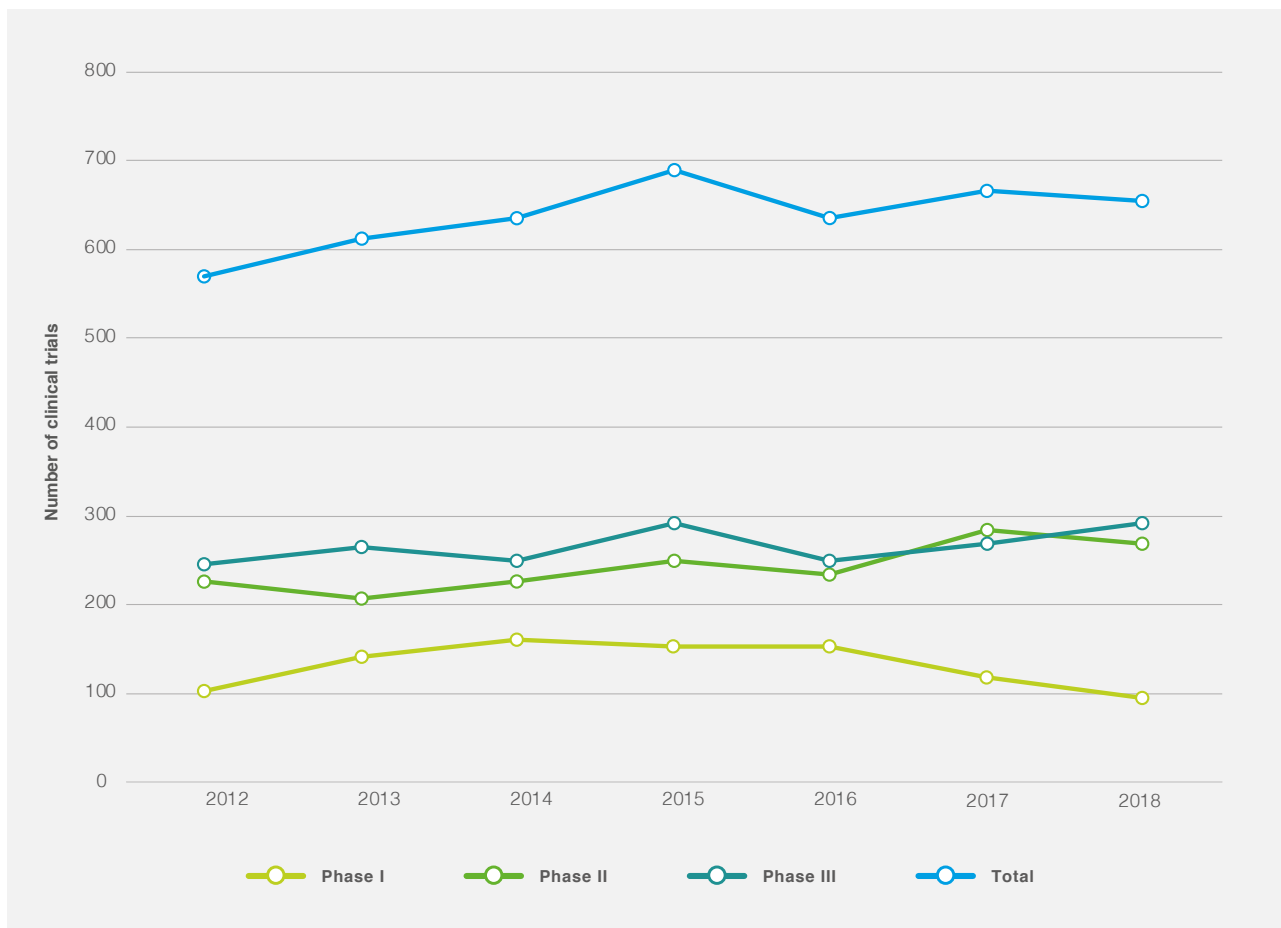
Early clinical research activity in the UK has been on the decline since 2016, with 95 Phase I clinical trials initiated in 2018, compared with 117 in 2017 and 150 in 2016, a decrease of 37%. For Phase II and Phase III clinical trials, activity remains relatively unchanged, with a moderate decrease in Phase II clinical trials initiated in 2018 compared with 2017 (281 in 2017; 268 in 2018) and a moderate increase in Phase III clinical trials initiated in 2018, compared with 2017 (269 in 2017; 292 in 2018) (Figure 1).

In addition to this, data from the MHRA gives an insight into the interest in conducting clinical research in the UK. The number of clinical trial applications received since 2016 has remained stable (Figure 2). In 2018, 798 commercial applications were received, comprising 131 Phase I, 630 Phase II/III and 37 Phase IV trial applications (Figure 3). Tracking trends in commercial applications, as further data is published by the MHRA, will help assess commercial interest in the UK clinical research environment over the coming years.

Furthermore, in 2018/19, the NIHR Clinical Research Network (CRN) recruited 870,250 participants to research studies<sup>3</sup>, in particular, succeeding in mobilising the patient and public community in areas such as mental health and dementia, through the NIHR's Mental Health BioResource and the Join Dementia Research service<sup>3</sup>. To further support recruitment to late-phase commercial research, the UK Government also announced the establishment of five Patient Recruitment Centres across England<sup>12</sup>. This investment in late-phase infrastructure should bring new opportunities for commercial sponsors and help grow the UK's Phase III research activity.

It is important to note that the data presented in this report shows the levels of research before the impact of COVID-19, which we know significantly impacted the research environment globally. In the UK, clinical research was proactively paused to help prioritise COVID-19 research and ensure optimal management of COVID-19 patients<sup>13</sup>. Although a framework for restart of non-COVID-19 research has been issued in the UK<sup>14</sup>, there is some evidence that restart has been faster and more successful in other countries, which is discussed later in this report.

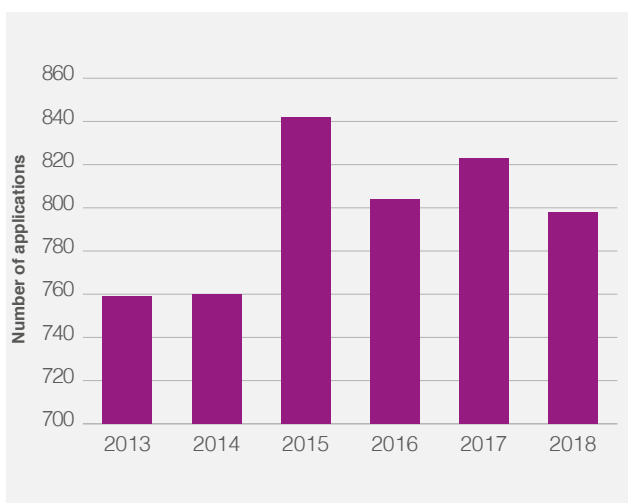
**Figure 1. Number of commercial clinical trials started in the UK, by year and phase (2012-2018)**



Year	Phase I	Phase II	Phase III	Total
<b>2012</b>	102	224	245	571
<b>2013</b>	141	207	265	613
<b>2014</b>	160	226	250	636
<b>2015</b>	152	248	290	690
<b>2016</b>	150	234	250	634
<b>2017</b>	117	281	269	667
<b>2018</b>	95	268	292	655

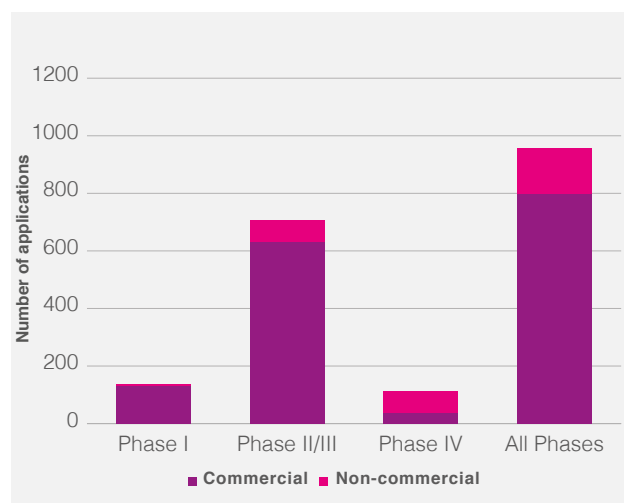
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**Figure 2. Number of commercial clinical trial applications received by MHRA, by year (2013-2018)<sup>2</sup>**



Year	Applications
<b>2013</b>	759
<b>2014</b>	760
<b>2015</b>	842
<b>2016</b>	804
<b>2017</b>	823
<b>2018</b>	798

**Figure 3. Number of clinical trial applications received by MHRA in 2018, by phase and sponsor type<sup>2</sup>**



Phase	Commercial	Non-commercial	Total
<b>Phase I</b>	131	5	136
<b>Phase II/III</b>	630	78	708
<b>Phase IV</b>	37	74	111
<b>All Phases</b>	<b>798</b>	<b>157</b>	<b>955</b>



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## International competition: How the UK compares on the world stage

**From 2017 to 2018, the UK retained its competitive early clinical research environment, ranking first in Europe and third globally for Phase I, with 95 clinical trials initiated in 2018. This trend is echoed in Phase II, with the UK ranking first in Europe and second globally, with 268 trials initiated in 2018 ([Table 1](#) and [Figures 4 & 5](#)).**

Although the UK's ranking for early-phase research remains unchanged, Phase I activity across European countries in 2018 has decreased since 2017. Looking at the UK, Germany and France as examples, the UK initiated 117 Phase I trials in 2017 and 95 in 2018, Germany had 94 trials in 2017 and 68 in 2018, and France had 51 in 2017 and 37 in 2018.

The previous ABPI Clinical Trials Report identified the need for action to improve the late-phase clinical research environment, with the UK ranking behind Germany and Spain in Europe for Phase III clinical trials. This trend has continued in 2018, with the UK ranking third in Europe, again behind Germany and Spain, with 292 Phase III trials initiated in 2018 ([Table 1](#) & [Figure 6](#)); an increase from the 269 trials initiated in 2017.

Globally, the USA continues to dominate the clinical research environment, leading across phases ([Table 1](#) and [Figures 4 - 6](#)) and disease areas ([Figures 7 - 12](#)).

Data from China and Japan allows us to track the ever-growing R&D sector in Asia. Over the last few years, China's clinical research environment has grown across all clinical trial phases, with 234 Phase I, 190 Phase II and 219 Phase III trials initiated in 2018; a substantial increase in activity compared with 2017 (178 Phase I, 146 Phase II and 155 Phase III) ([Table 1](#) and [Figures 4 - 6](#)). In addition to China's increasing focus on R&D<sup>15</sup>, it is also important to note their potential to recruit patients, owing to China having 20% of the world's population<sup>16</sup>, which enables them to recruit large patient cohorts.

This year's new data from Belgium and Hungary shows that both countries are stronger in later-phase clinical research, with 208 and 177 Phase III clinical trials initiated in 2018, respectively. For Phase I and Phase II clinical trials, Belgium initiated 39 Phase I and 125 Phase II trials, with two Phase I and 74 Phase II trials initiated in Hungary. This activity ranks both countries behind many of their European competitors ([Table 1](#) and [Figures 4 - 6](#)).



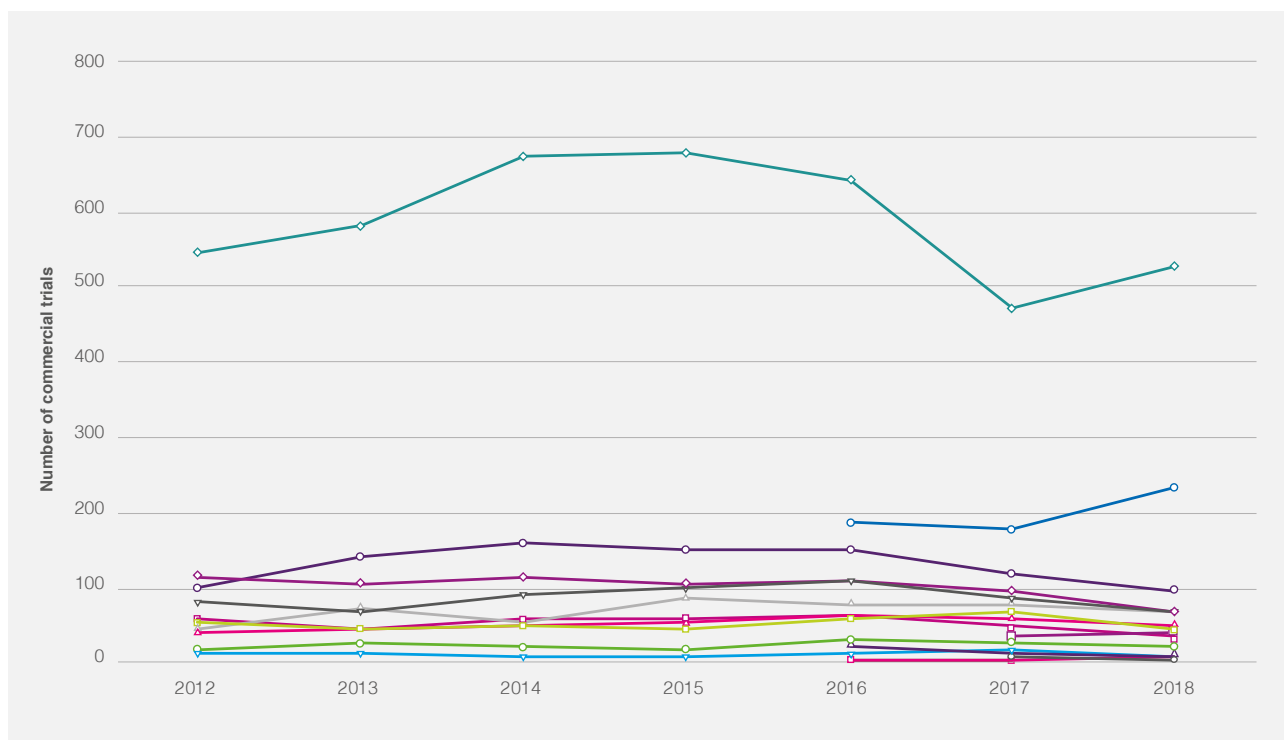
This data demonstrates that between 2017 and 2018, the UK maintained its international competitiveness in early-phase research. However, with only minor improvements seen in later Phase III research, the UK must continue to invest in the clinical research environment, supporting initiatives which boost clinical trial recruitment and grow our global standing across early and late clinical research.

Furthermore, with China moving rapidly towards meeting its goal of becoming a global leader in science and innovation by 2050<sup>17</sup> and European research activity decreasing in 2018 compared with 2017, the European R&D base is at risk of falling behind. The UK must harness its expertise and global partnerships, to leverage further collaborations, investment and access to talent.

**Table 1. Number of commercial clinical trials started in 2018, by phase and country**

Rank	Country	Phase I	Country	Phase II	Country	Phase III
1	USA	526	USA	1021	USA	626
2	China	234	UK	268	Germany	315
3	UK	95	Germany	249	Spain	308
4	Germany	68	Spain	221	UK	292
5	Australia	66	France	200	France	290
6	Japan	66	Japan	198	Canada	289
7	Spain	49	China	190	Italy	264
8	Canada	43	Canada	187	Poland	250
9	Belgium	39	Italy	157	Japan	242
10	France	37	Australia	152	China	219
11	Italy	20	Poland	133	Australia	211
12	Poland	10	Belgium	125	Belgium	208
13	South Africa	6	Hungary	74	Hungary	177
14	Switzerland	6	Switzerland	56	Brazil	123
15	Hungary	2	Brazil	37	Switzerland	101
16	Brazil	No data	South Africa	20	South Africa	77

**Figure 4. Number of commercial clinical trials started by country, Phase I (2012-2018)**



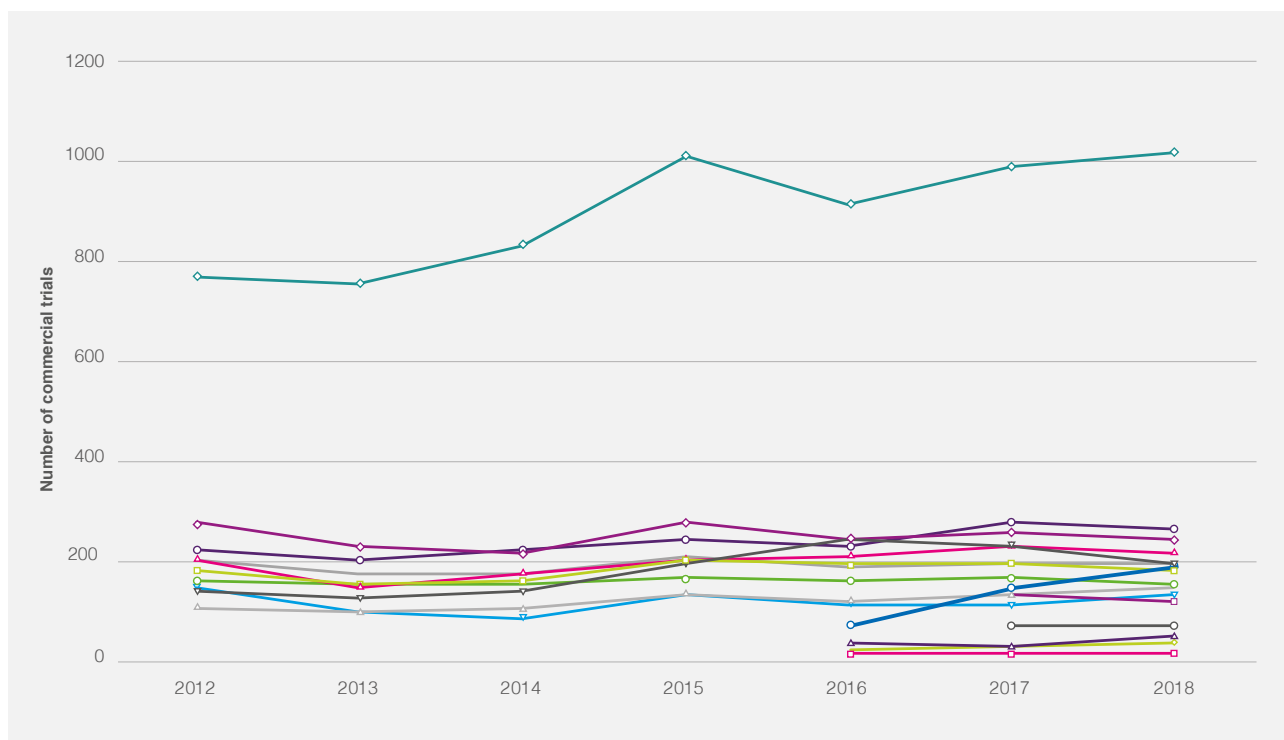
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	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Japan	Australia	China	Brazil	South Africa
<b>2012</b>	102	114	59	19	40	12				547	54	83	45			
<b>2013</b>	141	106	45	27	43	12				583	45	70	73			
<b>2014</b>	160	115	59	20	50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

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**Figure 5. Number of commercial clinical trials started by country, Phase II (2012-2018)**



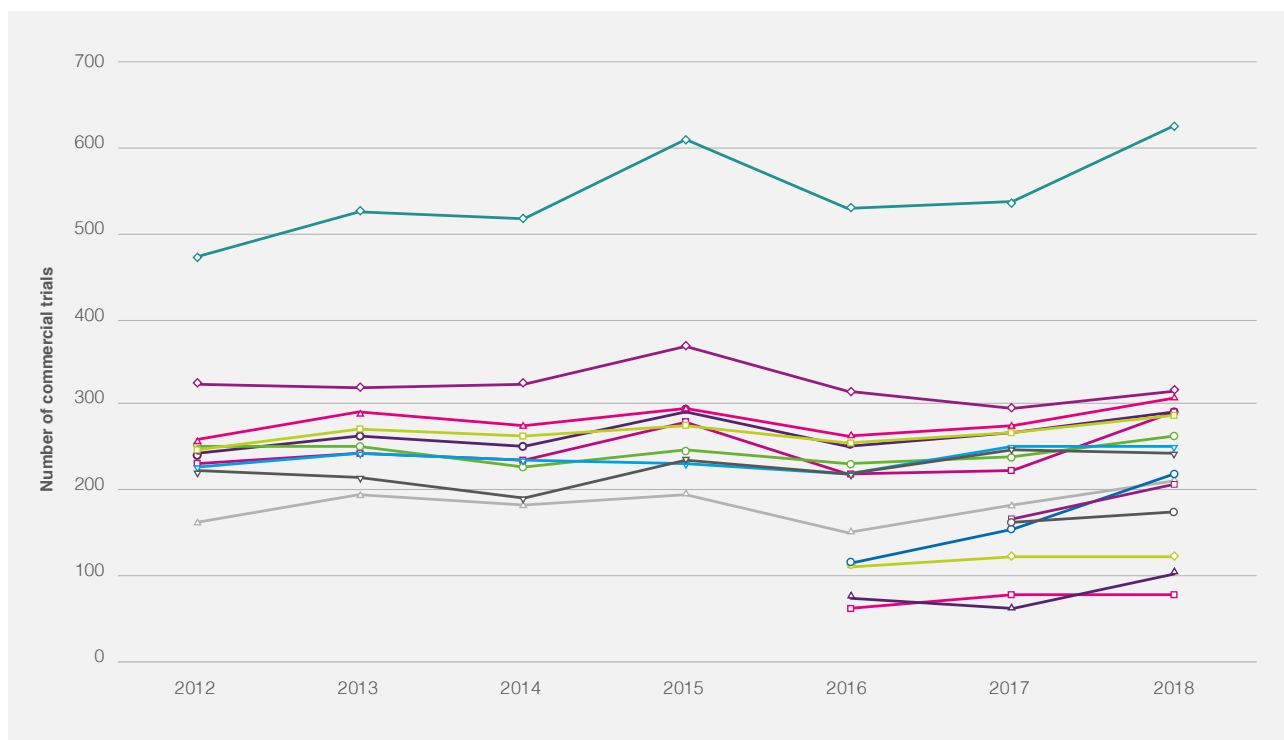
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	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Japan	Australia	China	Brazil	South Africa
<b>2012</b>	224	283	203	161	203	152				767	185	143	111			
<b>2013</b>	207	232	180	157	150	101				757	153	132	100			
<b>2014</b>	226	221	177	156	176	88				833	166	141	110			
<b>2015</b>	248	278	209	168	206	135				1010	206	201	138			
<b>2016</b>	234	243	188	160	212	113	40			913	201	247	119	76	22	17
<b>2017</b>	281	262	198	167	229	112	35	137	72	988	201	229	133	146	30	19
<b>2018</b>	268	249	200	157	221	133	56	125	74	1021	187	198	152	190	37	20

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**Figure 6. Number of commercial clinical trials started by country, Phase III (2012-2018)**



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<b>2012</b>	245	323	233	251	261	229				474	246	225	162			
<b>2013</b>	265	319	244	252	290	243				525	271	215	197			
<b>2014</b>	250	322	237	229	275	237				516	263	192	183			
<b>2015</b>	290	370	281	248	295	230				608	275	235	196			
<b>2016</b>	250	314	221	233	263	218	76			530	255	219	151	113	110	61
<b>2017</b>	269	294	224	241	274	250	64	169	162	536	267	246	183	155	122	77
<b>2018</b>	292	315	290	264	308	250	101	208	177	626	289	242	211	219	123	77

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## Global R&D by disease area: Where does the UK do best?

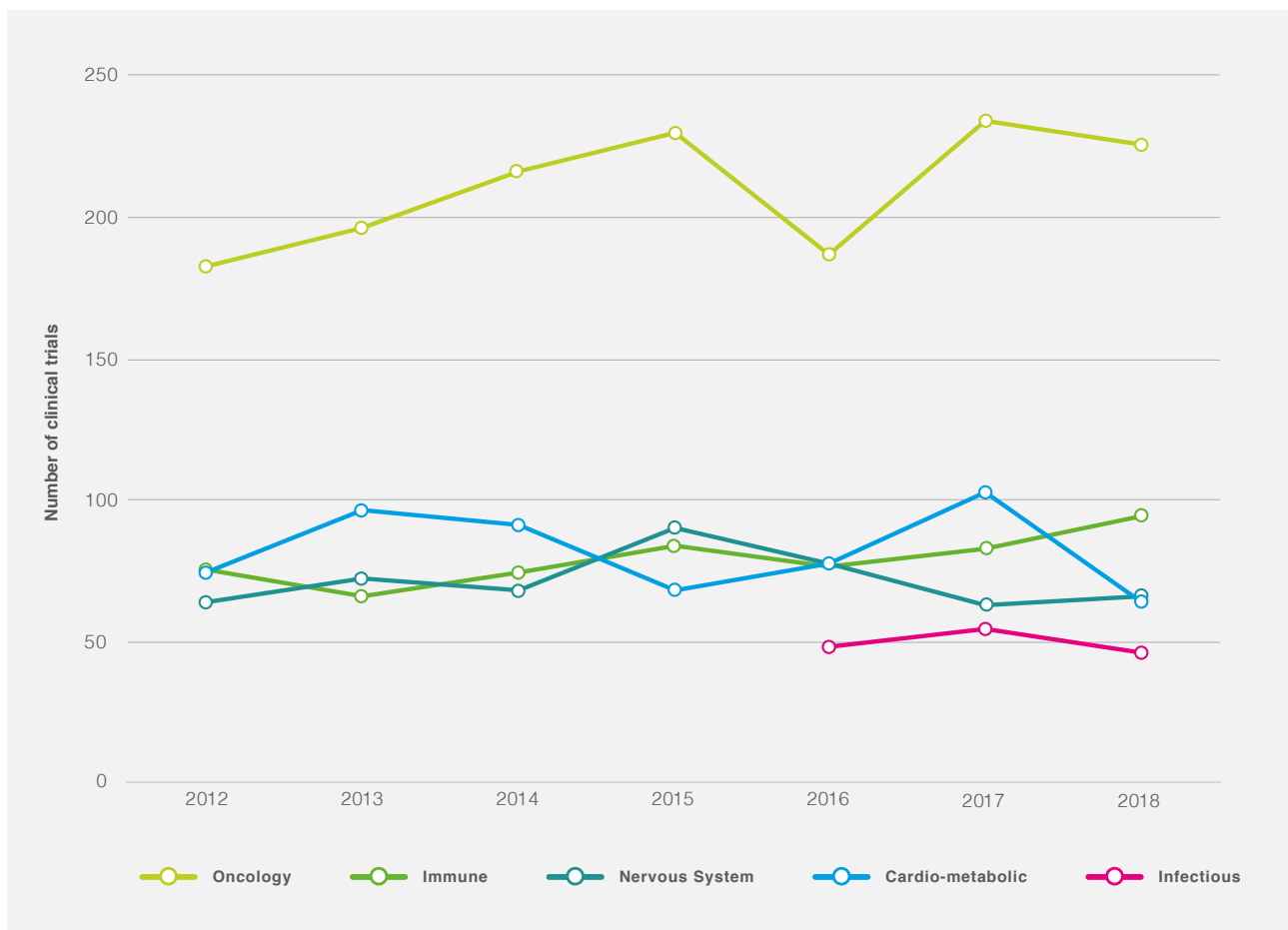
### **Oncology remains the UK's strongest research area, with 226 trials initiated in the UK in 2018 ([Figure 7](#)).**

As for other disease areas, the UK is seeing a gradual increase in research activity for diseases of the immune system, with 94 trials initiated in 2018 ([Figure 7](#)), compared with 83 in 2017 and 77 in 2016. Research into diseases of the nervous system and infectious diseases have remained relatively unchanged between 2017 and 2018; however, cardio-metabolic research activity has significantly reduced, with 103 trials initiated in 2017 but only 64 in 2018, a decrease of 38% ([Figure 7](#)). As health challenges such as AMR and the COVID-19 pandemic change our global research portfolios, tracking trends in particular for infectious disease clinical research will be important for understanding global R&D efforts and informing ongoing research prioritisation.

The UK's strong oncology research environment ranks it second in Europe, behind Spain, and fourth globally, with 226 trials initiated in 2018 ([Figure 8](#)). For research in diseases of the nervous system and infectious diseases, the UK leads in Europe, with 66 and 46 clinical trials initiated in 2018, respectively ([Figure 10 & 11](#)). For cardio-metabolic and immune research, Germany leads in Europe, with China, Japan and Canada also performing strongly in these disease areas ([Figure 9](#)). These trends are similar to those seen in 2017.



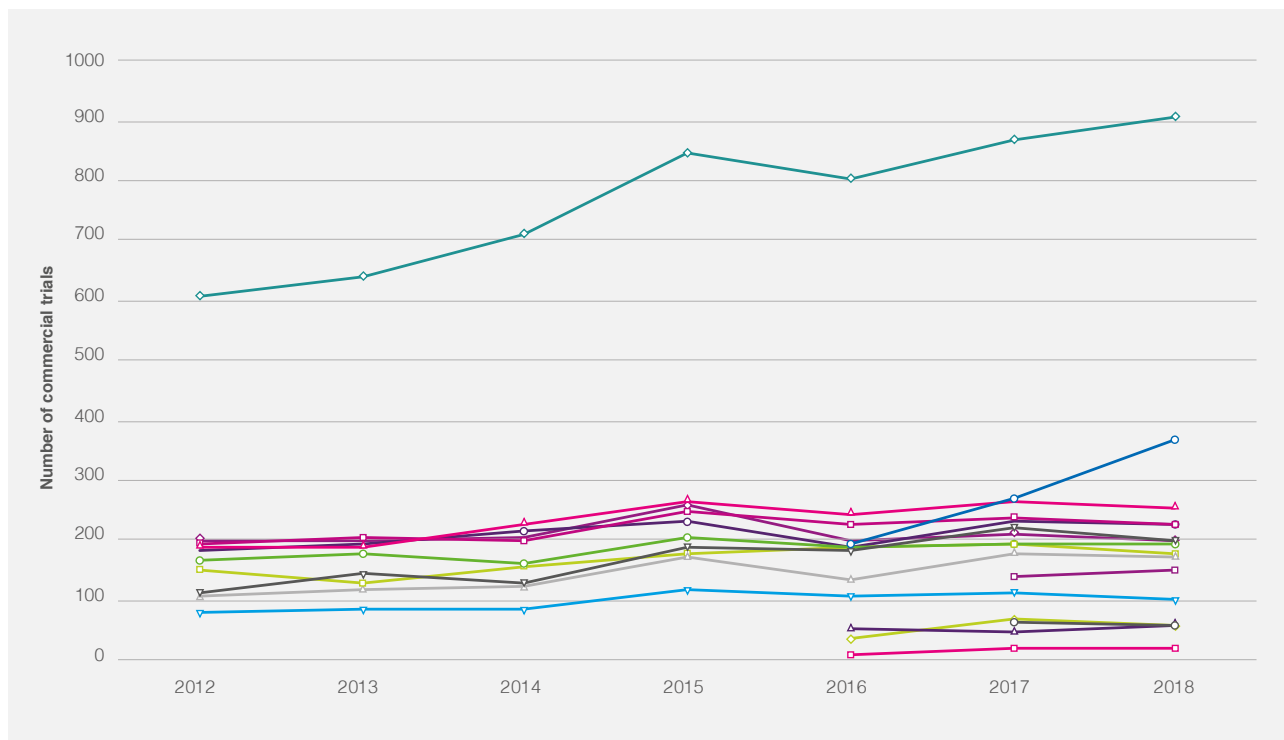
**Figure 7. Number of commercial clinical trials started in the UK, by year and disease area (2012-2018)**



Year	Oncology	Immune	Nervous System	Cardio-metabolic	Infectious
2012	183	76	64	74	
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

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**Figure 8. Number of commercial clinical trials started in oncology, by year and country (2012-2018)**



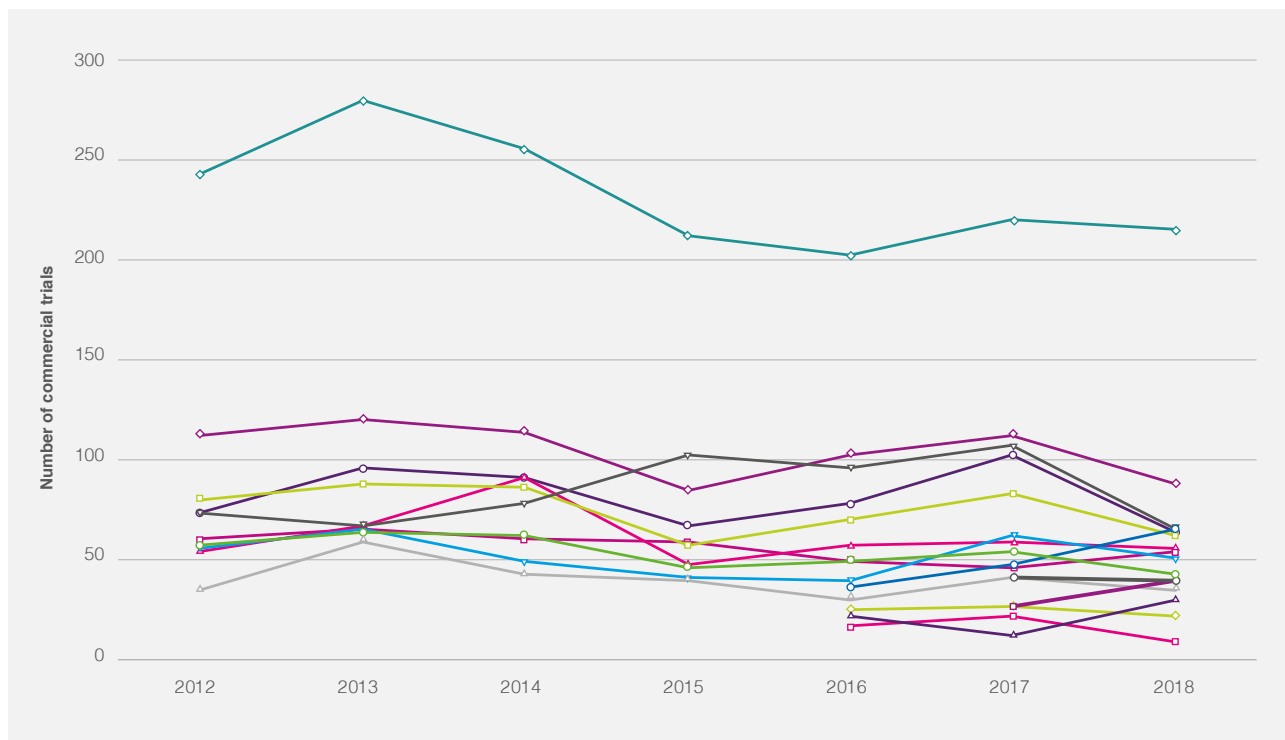
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	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Australia	Japan	China	Brazil	South Africa
<b>2012</b>	183	198	195	166	190	81				607	152	107	115			
<b>2013</b>	196	199	203	178	189	83				639	129	117	143			
<b>2014</b>	216	206	199	161	229	84				711	154	126	131			
<b>2015</b>	230	258	248	207	263	116				846	177	171	188			
<b>2016</b>	187	200	225	189	245	105	55			801	189	134	181	192	39	10
<b>2017</b>	234	213	237	194	264	113	47	142	65	869	196	179	220	270	67	20
<b>2018</b>	226	202	225	196	256	104	60	151	57	907	176	174	200	367	57	18

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**Figure 9. Number of commercial clinical trials started in cardio-metabolic diseases, by year and country (2012-2018)**



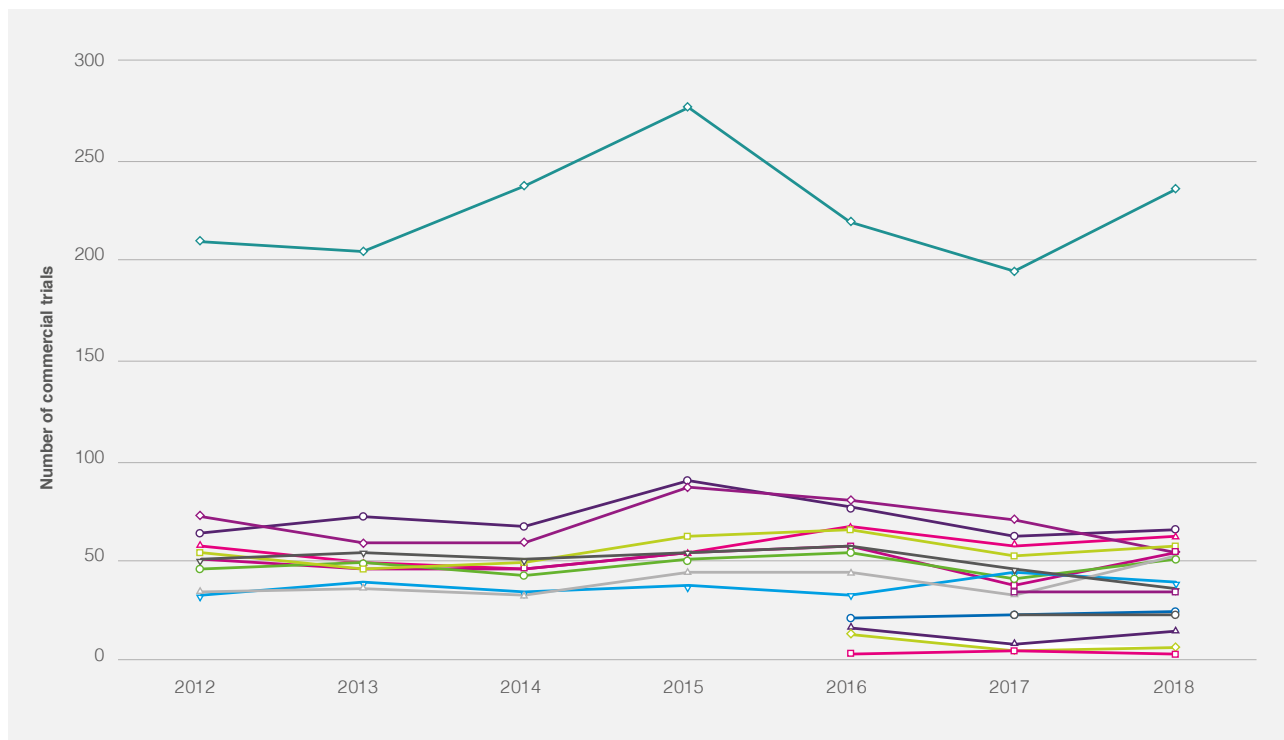
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	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Australia	Japan	China	Brazil	South Africa
<b>2012</b>	74	113	61	58	55	56				242	80	35	74			
<b>2013</b>	96	120	65	64	68	65				280	89	60	67			
<b>2014</b>	91	114	61	63	92	50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

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**Figure 10. Number of commercial clinical trials started in nervous system diseases, by year and country (2012-2018)**



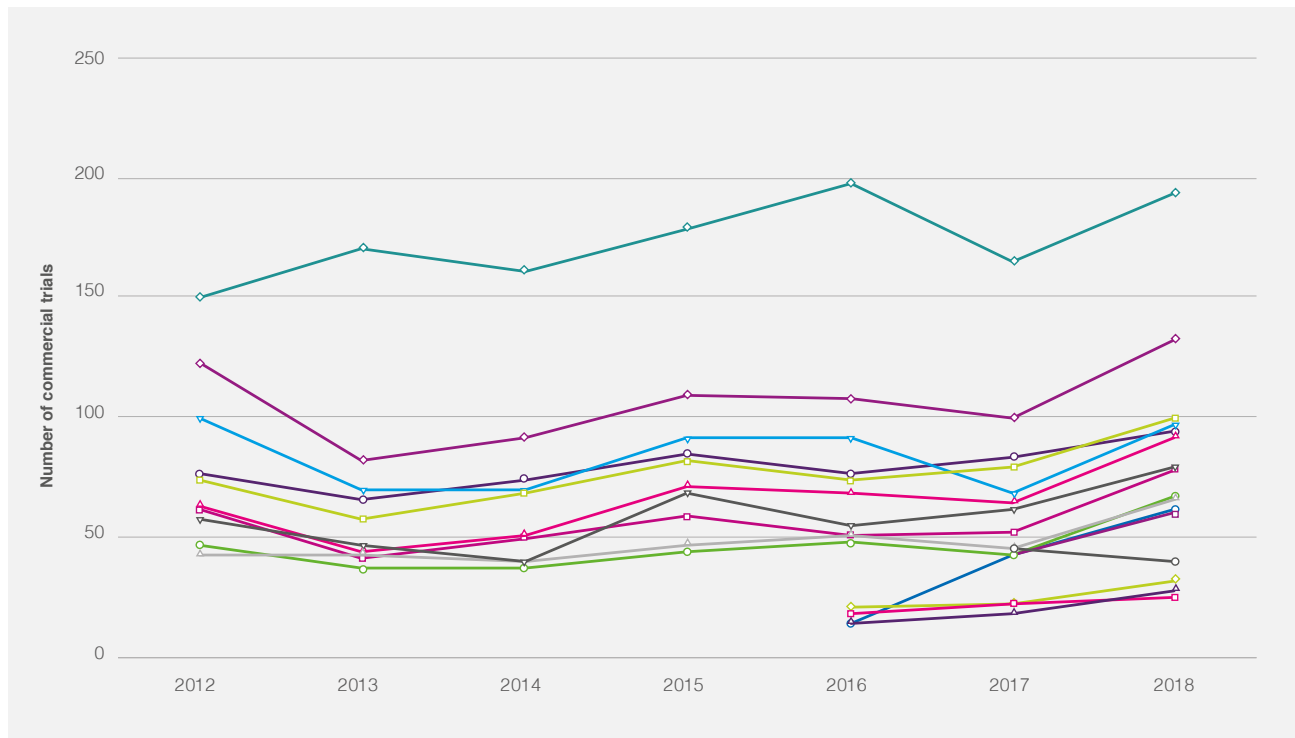
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	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Australia	Japan	China	Brazil	South Africa
<b>2012</b>	64	72	51	47	58	33				210	54	35	51			
<b>2013</b>	72	60	46	49	49	40				205	47	37	54			
<b>2014</b>	68	60	47	43	46	35	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

Access interactive graphs and data on the ABPI website [here](#)

**Figure 11. Number of commercial clinical trials started in immune disorders, by year and country (2012-2018)**



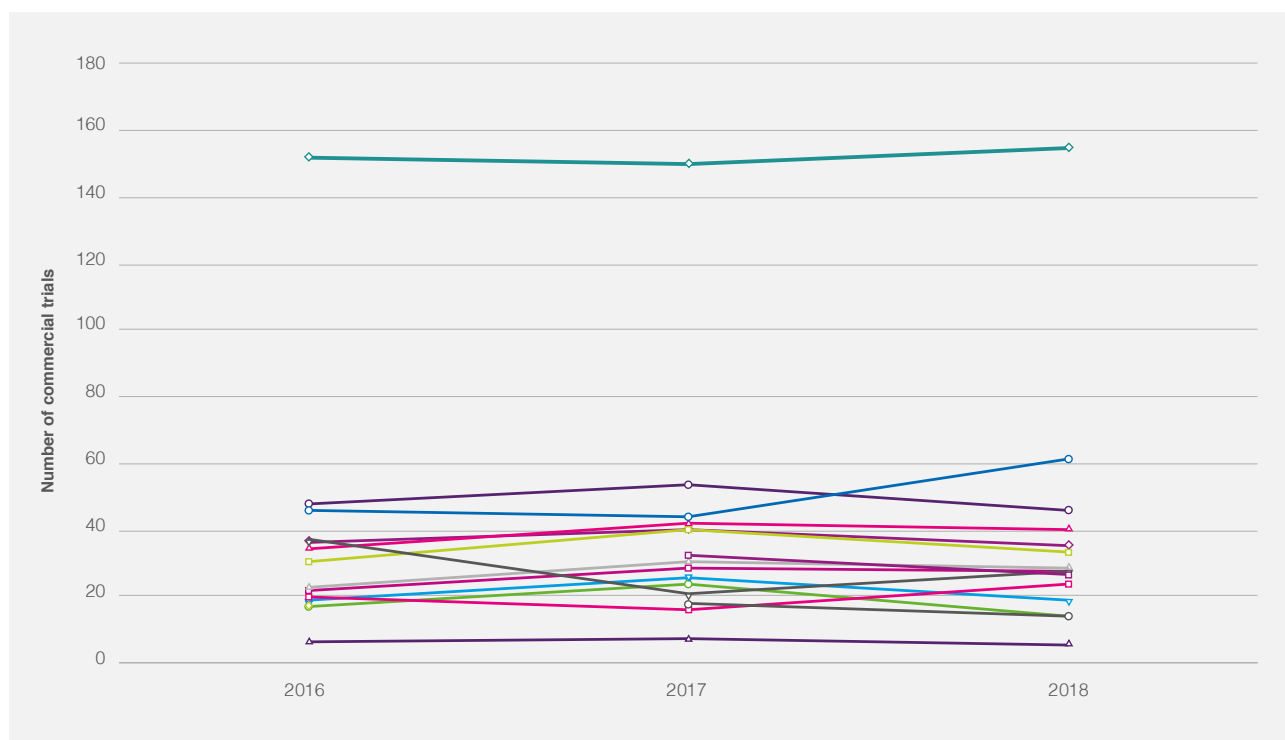
**Key**

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

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

Access interactive graphs and data on the ABPI website [here](#)

**Figure 12. Number of commercial clinical trials started in infectious diseases, by year and country (2012-2018)**



**Key**

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

	UK	Germany	France	Italy	Spain	Poland	Switzerland	Belgium	Hungary	USA	Canada	Australia	Japan	China	Brazil	South Africa
<b>2016</b>	48	36	22	17	34	19	6			152	31	23	37	46	17	20
<b>2017</b>	54	40	29	24	42	26	7	32	18	150	40	31	21	44	9	16
<b>2018</b>	46	35	28	14	40	19	5	27	14	155	33	29	28	61	17	24

Access interactive graphs and data on the ABPI website [here](#)

# Beyond COVID-19: Restart, Recovery and Resilience

## The global R&D response to COVID-19 has been unprecedented in scale and speed, and in terms of collaboration, transparency and translation.

COVID-19 was officially declared a pandemic by the World Health Organization on 12 March 2020. As a critical part of the healthcare community, the global pharmaceutical industry has been committed to playing the biggest possible role in the response to this outbreak.

In the UK, the pharmaceutical industry has created new partnerships with academia, charities, Government and NHS to<sup>18</sup>:

- research medicines and vaccines to fight COVID-19
- mitigate any impact that the global supply chain, manufacturing and transport disruption may have on the availability of medicines and health technologies
- support the opportunities for thousands of highly skilled people to volunteer where most needed
- build capacity for COVID-19 testing and diagnostics.

The UK's COVID-19 R&D response has been impressive, with Government setting up a process for nationally prioritising and approving Urgent Public Health Research studies<sup>19</sup>. The first studies through this process were approved in March, and an ever-increasing number of participants have been recruited since then, to a range of interventional and observational, commercial and non-commercial studies<sup>20</sup>. This response has been made possible through the monumental efforts of patients, the public and research and healthcare staff across the life sciences sector, NHS and Government. Many clinical trials in other non-COVID-19 diseases were also proactively paused<sup>13</sup>, to help prioritise COVID-19 research and ensure optimal management of COVID-19 patients.

We have also seen the adoption of new ways of working in the design, approval, set-up, recruitment and delivery of ongoing COVID-19 and non-COVID-19 clinical trials, which enable greater efficiency and flexibility. Examples include direct-to-patient shipments of investigational medicinal products, digitally-enabled remote approaches, including monitoring of patients, informed consent and electronic signatures<sup>21,22</sup>, the use of data to support healthcare decision-making and research efforts, and the adoption of complex innovative design (CID) and large platform trials<sup>23</sup>, such as RECOVERY. This response has come with the support of national regulators, the Health Research Authority (HRA) and MHRA, with efficient approval and supporting guidance on managing clinical trials, making amendments, acquiring informed consent, pharmacovigilance and inspections<sup>24,25</sup>.

As of 9 September,

# 45%

of studies are open to recruitment, with 35% of open studies recruiting patients since the 1 June.



Since May 2020, the UK has commenced a programme of restarting the paused non-COVID-19 research studies<sup>14</sup>. Despite the NIHR issuing a framework to support decision-making by sites and sponsors, a number of challenges remain, such as patient recruitment, trial oversight via remote or onsite monitoring and lack of available research staff<sup>26,27</sup>. Furthermore, with record high waiting times in England, the NHS' capacity to deliver clinical services and research, for both COVID-19 and non-COVID-19 patients, is limited<sup>28</sup>.

As of 9 September, data from the NIHR CRN, shows that 45% of studies (2,676) are open to recruitment, with 36% of open studies recruiting since the 1 June<sup>27</sup>.

The ABPI and pharmaceutical industry have been working with Government and the wider sector, in England<sup>14</sup> and the Devolved Administrations<sup>29</sup>, to help identify bottlenecks in restart, share best practice and advise on possible solutions, driven by a shared ambition to successfully navigate the UK through this challenging restart.

While the comparative data presented in this paper describes the pre-COVID-19 clinical research environment, the areas for improvement remain the same, with the need for change merely amplified through the 2020 pandemic. The manner in which we restart clinical research activity is a critical first step in the UK's journey to recovery and will be crucial for the resilience of the healthcare system against any future public health emergencies. An evolution of the NHS is a critical part of this and the ABPI and pharmaceutical companies are committed to working with Government and the life sciences sector to make these changes happen.



# Recommendations

**As the global research environment recovers from COVID-19 and the UK looks towards the end of the transition period, there is an urgent need to embed new ways of working in order to transform the UK clinical research environment.**

In the ABPI's 2019 Clinical Trials Report, we outlined how the UK can build an ecosystem fit for the future of clinical research. This report builds on those recommendations and outlines industry's priorities.

In addition, the ABPI and industry recognise that the role of the NHS is critical here.

As clinical research is delivered in the NHS, the UK must work towards embedding a research culture across our healthcare system. A plan must be

developed for how funding, resources, facilities and workforce will be made available for research, to ensure the NHS has the capacity and resilience to deliver world-class clinical research throughout the UK. We also need to redefine our prioritisation and support the NHS in resuming healthcare services and research in order to address the unmet needs of all patients, including COVID-19 patients.



## 1. Restarting and restoring research across the UK and across all disease areas

There is increasing concern across the research and healthcare sector around the UK's progress on the restart of non-COVID-19 clinical research, which is a critical first step in delivering the changes needed to transform our clinical research environment. Many challenges remain across all parts of our healthcare system, following the COVID-19 pandemic, with a second wave threatening further disruption.

The ABPI and industry appreciate the efforts of NIHR, UKRD and the R&D Forum to restart research and the ongoing support from other organisations, such as HRA and MHRA. However, it is clear that the scale of the challenge requires leadership and a strategic approach from across industry, charity, academia, Government and crucially the NHS.

### Policy recommendations

The UK Government should take urgent action to plan and implement the sustainable restart of non-COVID-19 clinical research at pace and scale, through the following:

- To continue working collaboratively across the sector and with patients and the public, to openly discuss and address the challenges of restart.
- To develop a strategic plan for how the NHS will deliver clinical services and research (COVID-19 and non-COVID-19) sustainably.
- To articulate a leadership commitment across all organisations (DHSC, NIHR and NHS), to restarting non-COVID-19 clinical research with an appropriate timeframe that recognises winter challenges, with a clear message to the NHS, clinical trial sponsors and patients, on the importance of research across all disease areas.

## 2. Transforming the UK clinical research environment with investment to increase levels of research beyond pre-COVID levels

Commitments from the UK Government, in the Life Sciences Industrial Strategy and Sector Deals, commit funding and infrastructure investment to enhance the UK's clinical research environment.

Furthermore, the R&D Roadmap published in July 2020<sup>60</sup>, sets out the ambition to be a global leader in research and innovation infrastructure, with commitments to develop a long-term investment plan and increase public investment in R&D to £22bn by 2024/2025. The role of the pharmaceutical sector is central to delivering on this ambition, with the sector investing more in R&D than any other sector of the UK economy<sup>7</sup>.

To enable the NHS to become the best platform in the world for clinical research and an attractive destination for commercial sponsors, the UK Government must deliver on these commitments, working with industry to ensure they have maximum impact on improving the commercial clinical research environment.

In addition, the nation's largest funder of health and care research, the NIHR, works in partnership with the NHS and the wider life sciences sector, to deliver clinical research in England, including commercial funded research. In 2018/2019, the NIHR centres and facilities supported over 3,500 commercial studies, with over £100m in funding leveraged from industry<sup>30</sup>.

Despite the NIHR's critical role in the UK clinical research environment and the ongoing COVID-19 R&D effort, the NIHR's total spend on infrastructure, research programmes and supporting systems has remained unchanged for the past five years, with an annual budget of around £1 bn, which has also included its annual contribution to Genomics England<sup>31-34</sup>.

Parallel to restarting and restoring research across the UK and across all disease areas, increased investment in the UK's clinical research environment is required to support the transformational changes needed to increase research activity beyond pre-COVID-19 levels. Investment should be directed by:

### a. Optimising the processes for setting up and running clinical trials

Central to the ability of the UK to become a more attractive destination for medical research, is the ability to improve efficiency in approving and setting up trials. Commercial sponsors often experience variable approval timelines, with slow and arduous negotiations around costing and contracting. The UK must be able to offer fast and accurate feasibility, streamlined approvals, globally competitive and harmonised costing and contracting, successful recruitment to time and target, and efficient trial conduct.

**In 2018/2019, the NIHR  
centres and facilities  
supported over**

**3,500  
commercial studies**

For streamlined approvals, much progress has been made with the Combined Ways of Working (CWoW) pilot between HRA and MHRA, set up in April 2018. This initiative brings together a single Clinical Trials of Investigational Medicinal Products (CTIMPs) application for both MHRA's clinical trial authorisation and HRA's research ethics committee (REC) opinion and has succeeded in reducing timelines for regulatory and ethics approval<sup>35,36</sup>. Work to develop the IT infrastructure to support CWoW has however, slowed during the COVID-19 pandemic<sup>37</sup>. Approval timelines have continued to improve during the COVID-19 pandemic, with unprecedented speed seen for both MHRA and HRA.

For costings, the National Directive on Commercial Contract Research Studies<sup>38</sup> commits to harmonising the cost of commercial research, with the National Contract Value Review pilot established to develop a standardised and national approach to costing and contracting for commercial contract research. The process aimed to improve consistency and timelines for study set-up, however was paused due to the COVID-19 pandemic<sup>39</sup>.

## Innovative approaches

**The COVID-19 pandemic has led to innovative and remote approaches in trial delivery, such as delivery of treatments direct to patients' homes.**

With regard to innovative design, the Life Sciences Industrial Strategy and Sector Deals have committed to funding the research infrastructure to support delivery of a range of complex innovative design (CID) clinical trials, with a cross-sector consensus paper describing how the UK can effectively deliver these types of trials<sup>40</sup>. The NIHR, HRA and ECMC have also jointly developed tools and resources to help train and upskill RECs, researchers and the wider community on CID trials<sup>41,42</sup>.

As well as innovative design, the COVID-19 pandemic has led to innovative approaches in trial delivery, including medicines and treatments being delivered direct to patients' homes and remote approaches to patient consultations, patient consent and safety monitoring. With such approaches welcomed and supported by both regulators and sponsors, the question now remains as to whether these flexibilities will be adopted into business-as-usual.

During the COVID-19 pandemic, studies such as the Oxford RECOVERY platform trial tested a range of repurposed medicines as possible COVID-19 treatments in large patient numbers with a simple endpoint<sup>43</sup>. This demonstrated how innovative design and delivery approaches can support recruitment of large patient cohorts and quickly produce robust results to support healthcare delivery decision-making. Support for innovative design and delivery must also span across the full range of trials, including for more complex trials, needed to develop novel treatments.

In developing novel medicines, patient safety is paramount in early-phase trials, where tolerability is routinely explored initially in small patient numbers. Early efficacy studies usually examine a variety of measures and endpoints, again in fairly small numbers and with stringent safety monitoring. Only when there is confidence that the balance between efficacy and safety looks promising is the novel medicine tested in larger numbers, usually comparing several measures with the current standard of care. With the evolving ability to stratify patients into smaller specific sub-groups using biomarkers and through genomic analyses, more complex innovative design trials are needed to generate robust data on a variety of endpoints to support the trend towards precision and personalised medicines.

In the UK, we have the patients, the medical expertise and the research capability to conduct all types of trials and to lead innovation, but we need the system to support efficient set-up, recruitment and conduct of these trials.

Through support and investment, the NIHR, HRA, MHRA and other organisations which drive and facilitate clinical research, can deliver on rolling out the CWoW pilot further and developing their IT infrastructure, establishing a national costing review process, and supporting new ways of designing and delivering clinical trials.



## **b. Building a workforce fit for the future with opportunities for all to be involved in research**

The successful set-up and delivery of research relies on research culture being embedded locally and nationally across the NHS, with supporting infrastructure, capacity and workforce.

To date, the life sciences sector and Government have highlighted the need to enhance the clinical research workforce, with proposals aimed at protecting time for researchers<sup>44</sup>, combating the clinical pharmacology skills shortages<sup>45</sup> and upskilling clinical and non-clinical staff in research<sup>46</sup>. In addition to existing initiatives, transformative solutions are needed to ensure a successful recovery from the COVID-19 pandemic.

Industry welcomes the NHS People Plan<sup>47</sup>, published in July 2020, which highlights how the NHS workforce responded during the COVID-19 pandemic. In particular, NHS staff were able to provide an around-the-clock recruitment service, which patients directly benefited from, with enhanced opportunities to participate in research. The NHS People Plan commits to making the most of the skills across the workforce, including pharmacists, nurses and clinicians, ensuring educational and training programmes are available to support the development of their research skills and understanding.

To secure the step-change needed to build a workforce fit for the future and deliver on the commitments in the NHS People Plan, clinical research needs to be integrated in routine healthcare with opportunities provided for every healthcare professional to take part in research delivery. The Government's Life Science Council's Clinical Research Working Group and other cross-sector groups must continue to work together to provide the driving force needed for this transformative change.

### **c. Harnessing the UK's health data to support the efficient design, feasibility, recruitment and conduct of the full range of clinical trials**

Key aspects of enhancing the UK's clinical research environment are data and digital capability. We must be collecting the right data needed to help answer research questions and help identify the right patients, across all disease areas. This data must also be discoverable and useable, in a well governed and safe environment, with fair value contracting frameworks for researcher access.

Industry recognises that the UK is taking important and positive steps to help digitise and link the UK's health datasets to achieve this goal. One such example is the launch of NHS DigiTrials<sup>48</sup>, the Health Data Research Hub for clinical trials, developed to improve efficiency and effectiveness of clinical trials in the UK. During COVID-19, NHS DigiTrials has continued to support the identification of potential sites and patients and expanded its services to include outcome data, to help understand the dose response of a drug in development.

Communicating the impact and progress of such initiatives and articulating the UK clinical trials data offer, are also both important. The Government's Life Science Council's Clinical Research Working Group is developing a framework to support data custodians in articulating the data offer and services that they provide, to help global industry's understanding and discoverability of UK assets.

As health data is collected from patients and members of the public, and in order for it to be used to support the development of new treatments, patients and members of the public must have trust and confidence that their personal information will be used only in the way that they choose, that it is securely protected when it is used, and that its use will be carefully governed.

Industry is committed to working with Government and the wider research community to ensure that consistently high standards of governance are established and maintained, in order to generate and maintain the trust of patients, the public and other stakeholders, in the use of health data for research.

### **d. Driving continuing high standards for transparency**

Clinical research conducted for the benefit of the public and patients globally, must be available, accessible and understandable. Over the past 10 years, there has been significant progress in registration and reporting of clinical trials, with many pharmaceutical companies leading the way and setting the standard for best practice<sup>49</sup>.

The COVID-19 pandemic has highlighted the benefit of rapid and robust dissemination of research findings that are widely and easily accessible, such as the results from the RECOVERY trial, regarding dexamethasone and hydroxychloroquine, helping to inform clinical practice<sup>50</sup>. This should set the standard for how research in the UK is communicated, ensuring that a shift towards rapid dissemination does not jeopardise robust analysis or the process of peer review.

The UK is now taking strides towards a more open and transparent research environment, with the Government's International Research and Innovation Strategy highlighting a commitment to greater openness in research<sup>51</sup>, and a review underway of UKRI's open access policy<sup>52</sup>. The ABPI believes greater openness can support better collaborations between industry and academia, helping speed up the translation of promising discoveries into development in clinical trials.

The HRA also published its Make it Public strategy<sup>53</sup>, outlining their plans to make transparency straightforward and research findings more public. The ABPI and industry welcome this strategy, in particular the commitments around ensuring all

clinical trials that take place in the UK are registered and supporting best practice through guidance, support and clear communication. At the end of the UK's transition period, we must have mechanisms in place to support the registration and reporting of clinical trials for all research, both commercial and non-commercial, conducted in the UK.

#### **e. Creating a regulatory environment which supports innovation in life sciences**

The COVID-19 pandemic has highlighted that the UK can deliver clinical research at pace and at scale, with agile and flexible approaches<sup>21,22</sup>. The pharmaceutical industry has welcomed this approach, in particular the streamlined approvals and guidance from UK regulators, MHRA and HRA<sup>24,25</sup>.

These approaches, coupled with the highest standards of patient safety in our regulatory and clinical research environment, are important factors for global pharmaceutical companies when considering investment in clinical research. The Medicines and Medical Devices Bill<sup>54</sup> offers the opportunity for secondary legislation to drive changes that could help anchor more clinical research activity in the UK and bring further benefits and opportunities to the NHS and UK patients. Consultation with industry will be essential to identify which changes and flexibilities can have the maximum impact whilst maintaining the highest standards of patient safety.

The Government's R&D Roadmap acknowledges innovative regulation as a key area of opportunity and with other global regulators seeking to modernise regulations post-COVID-19, the UK should seize this short window of opportunity to build upon the UK's reputation as a global thought leader in innovative regulation.

#### **Policy recommendations**

The UK Government should increase investment for the National Institute for Health Research (NIHR), Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA) and other organisations which drive and facilitate clinical research across the UK, in order to support the changes in the system needed to transform our clinical research environment.



### 3. Ensuring that all patients have the opportunity to be involved and engaged with research

COVID-19 has had a significant impact on society, not least on health and medical research and healthcare systems. With the ambition to research and develop new treatments and vaccines for COVID-19, which work for all in society, there is a critical need to ensure patient and public involvement and engagement is embedded across the research environment.

Prior to the pandemic, much progress had been made in the UK and beyond to articulate the value of patient and public involvement and engagement, share best practice and equip the research community with tools and resources to support such activities, including but not limited to, the UK Standards for Public Involvement<sup>55</sup>, guidance on joint working for industry and charities<sup>56,57</sup>, and the EU initiative, PARADIGM<sup>58</sup>.

In the early stages of the pandemic, a limited number of COVID-19 research applications to the HRA included patient and public involvement and engagement activities in their research plans. This has improved, with HRA providing a new service for those looking to conduct patient and public involvement and engagement activities for COVID-19 research<sup>61</sup>; however, as the UK prepares for a potential second wave of the disease, it remains unclear how embedded the public voice is in planning and recovery.

Furthermore, with a growing body of evidence demonstrating the differential impact COVID-19 has on black, Asian and minority ethnic (BAME) people, it is essential that we support BAME communities in engaging and participating in COVID-19 research. The ABPI and industry welcome NIHR efforts to fund research into understanding the disproportionate impact on BAME communities<sup>59</sup>; however, the life sciences sector and Government must work together to ensure system-wide diversity and inclusion of research participants and contributors.

The Government's R&D Roadmap<sup>60</sup> commits to levelling up R&D across the UK by lowering barriers to participation and supporting increased collaboration at a local level. This is an opportunity to maximise the opportunities for involvement engagement and participation in research of new medicines and vaccines, and deliver the greatest societal benefit for all patients and members of the public, across England and the devolved administrations.

#### Policy recommendations

The research community must continue to work with Government, funders, and the public, to tackle issues around diversity and inclusion, ensuring all patients across the UK have the opportunity to be involved and engaged with research.

## 4. Making research and innovation central to the UK's trade strategy

The COVID-19 pandemic has demonstrated the benefit of collaboration and partnership in science, research and innovation, with academia, charity, industry and Government working together at pace, nationally and internationally, to develop new medicines and vaccines for COVID-19.

In particular, delivery of multi-site and multi-country clinical trials and the sharing of data have been of critical importance to the global COVID-19 R&D effort. As clinical trials are a key part of the global research ecosystem, not just for COVID-19, the UK should continue participating in international clinical trials.

As countries look to recover from COVID-19 and rebuild research environments, especially for other diseases, such as cancer and rare diseases, the UK should build on existing partnerships, growing its collaborative and competitive research base and scoping out opportunities with other leading research hubs, such as the USA and Asia.

Furthermore, to ensure that the UK retains its position as a global hub for life sciences, the movement of highly-skilled people is vital. The UK's intent to develop a new immigration system to allow for the best and brightest scientists from the EU and the rest of the world to travel to and work in the UK, is welcomed.

### Policy recommendations

- The UK Government must provide clear guidance on the operational environment at the end of the UK's transition period with the EU, to ensure sponsors can continue conducting their clinical trials in the UK and beyond, with minimal disruption.
- The UK Government must agree a deal with the EU that establishes close cooperation on research and innovation, to ensure the UK has the best opportunity to collaborate and lead internationally with other regulators.
- The UK Government should do everything it can, to secure research and innovation at the heart of the UK trade strategy and ensure that international research collaborations feature in its 'Global Britain' strategy.
- The UK Government should include the movement of researchers in its trade strategy, ensuring that researchers of varying levels and experience contribute to the UK's success in research and innovation and UK-based scientists benefit from working and studying abroad.

# Conclusion

**The pharmaceutical industry operates globally and companies will continue to place their investment where they feel confident that their research can be efficiently and successfully delivered.**

Countries capable of approving and setting up cost-effective clinical trials efficiently and delivering on patient recruitment targets, whilst maintaining high patient safety standards, will succeed in attracting commercial investment in their clinical research environments.

By embracing new and innovative approaches to clinical research design, delivery, and regulation, including data and digital technologies, the UK has the opportunity to transform how clinical trials are conducted and to maximise benefits for the NHS, patients and the economy.

A key part of this transformation will be bringing the NHS into the 21st century, with state-of-the-art infrastructure and a research culture that is embedded in daily processes and across the workforce.

Following the COVID-19 pandemic, the UK must address the immediate challenges that lie ahead, ensuring that as it takes the stage on an international platform in 2021, the right interventions are implemented to deliver on its commitment of becoming a 'science superpower'.



# References

1. National Institute for Health Research. Impact and Value of the NIHR Clinical Research Network 2019 [Internet]. 2019 [cited 2020 Aug 20]. Available from: <https://www.nihr.ac.uk/documents/impact-and-value-of-the-nihr-clinical-research-network-2019-infographic-summarising-key-findings/22486>
2. Medicines and Healthcare products Regulatory Agency. Clinical trials for medicines: authorisation assessment performance [Internet]. GOV.UK. 2020 [cited 2020 Aug 4]. Available from: <https://www.gov.uk/government/publications/clinical-trials-for-medicines-authorisation-assessment-performance>
3. National Institute for Health Research. NIHR Annual Report 2018/2019 [Internet]. 2020. Available from: <https://www.nihr.ac.uk/documents/annual-report-20182019/24559>
4. Hanney S, Soper B, Jones T, Boaz A. Benefits from clinicians and healthcare organisations engaging in research. *BMJ*. 2015 Dec 23;351:h6931.
5. Ozdemir BA, Karthikesalingam A, Sinha S, Poloniecki JD, Hinchliffe RJ, Thompson MM, et al. Research activity and the association with mortality. *PLoS One*. 2015 Feb;10(2):e0118253.
6. Downing A, Morris EJ, Corrigan N, Sebag-Montefiore D, Finan PJ, Thomas JD, et al. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. *Gut*. 2017;66(1): 89–96.
7. Office for National Statistics. Gross domestic expenditure on research and development, UK: 2018 [Internet]. 2020 [cited 2020 Aug 4]. Available from: <https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/bulletins/ukgrossdomesticexpenditureonresearchanddevelopment/2018>
8. EvaluatePharma. EvaluatePharma World Preview 2020, Outlook to 2026 [Internet]. Evaluate.com. 2020 [cited 2020 Aug 4]. Available from: <https://www.evaluate.com/thought-leadership/pharma/evaluatepharma-world-preview-2020-outlook-2026>
9. Office for National Statistics. Business enterprise research and development, UK: 2018 [Internet]. 2019. Available from: <https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2018>
10. European Federation of Pharmaceutical Industries and Associations. The Pharmaceutical Industry in Figures – Key Data 2020 [Internet]. 2020. Available from: [https://efpia.eu/media/554521/efpia\\_pharmafigures\\_2020\\_web.pdf](https://efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf)
11. Association of the British Pharmaceutical Industry. Clinical trials: How the UK is researching medicines of the future [Internet]. 2019 [cited 2020 Aug 4]. Available from: <https://www.abpi.org.uk/publications/clinical-trials-how-the-uk-is-researching-medicines-of-the-future/>
12. National Institute for Health Research. National Patient Recruitment Centres [Internet]. 2020 [cited 2020 Aug 7]. Available from: <https://www.nihr.ac.uk/explore-nihr/support/national-patient-recruitment-centres.htm>
13. National Institute for Health Research. DHSC issues guidance on the impact of COVID-19 on research funded or supported by NIHR [Internet]. 2020 [cited 2020 Sep 9]. Available from: <https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-on-covid-19-on-research-funded-or-supported-by-nihr/24469>
14. National Institute for Health Research. Supporting the restart of paused NIHR research activities [Internet]. 2020 [cited 2020 Aug 12]. Available from: <https://www.nihr.ac.uk/news/supporting-the-restart-of-paused-nihr-research-activities/24890>
15. Veugelers R. The challenge of China's rise as a science and technology powerhouse | Bruegel [Internet]. 2017. Available from: <https://bruegel.org/2017/07/the-challenge-of-chinas-rise-as-a-science-and-technology-powerhouse/>
16. Lu L, Zhang Y, Guyatt G, Tang C, Xu N. How to fulfil China's potential for carrying out clinical trials [Internet]. *The BMJ Opinion*. 2018. Available from: [https://blogs.bmj.com/bmj/2018/10/15/fulfil-chinas-potential-clinical-trials/#\\_ftn3](https://blogs.bmj.com/bmj/2018/10/15/fulfil-chinas-potential-clinical-trials/#_ftn3)
17. Bruegel. China is the world's new science and technology powerhouse [Internet]. 2017 [cited 2020 Aug 7]. Available from: <https://www.bruegel.org/2017/08/china-is-the-worlds-new-science-and-technology-powerhouse/>
18. Association of the British Pharmaceutical Industry. Responding to COVID-19 [Internet]. 2020 [cited 2020 Aug 12]. Available from: <https://www.abpi.org.uk/medicine-discovery/covid-19/>
19. National Institute for Health Research. Prioritised support for urgent COVID-19 research [Internet]. 2020 [cited 2020 Aug 12]. Available from: <https://www.nihr.ac.uk/covid-19/prioritised-support-for-urgent-covid-19-research.htm>
20. National Institute for Health Research. Urgent Public Health COVID-19 Studies [Internet]. 2020 [cited 2020 Aug 12]. Available from: <https://www.nihr.ac.uk/covid-studies/>
21. TransCelerate Biopharma. Beyond COVID-19: Modernizing Clinical Trial Conduct [Internet]. TransCelerate Biopharma; 2020. Available from: [http://transceleratebiopharmainc.com/wp-content/uploads/2020/07/TransCelerate\\_Beyond-COVID19\\_Modernizing-Clinical-Trial-Conduct\\_July-2020.pdf](http://transceleratebiopharmainc.com/wp-content/uploads/2020/07/TransCelerate_Beyond-COVID19_Modernizing-Clinical-Trial-Conduct_July-2020.pdf)

22. TransCelerate Biopharma. Modernizing Clinical Trial Conduct: Continuity Solution Case Studies [Internet]. TransCelerate Biopharma; 2020. Available from: [http://transceleratebiopharmainc.com/wp-content/uploads/2020/07/TransCelerate\\_Modernizing-Clinical-Trial-Conduct\\_Continuity-Solution-Case-Studies\\_July-2020.pdf](http://transceleratebiopharmainc.com/wp-content/uploads/2020/07/TransCelerate_Modernizing-Clinical-Trial-Conduct_Continuity-Solution-Case-Studies_July-2020.pdf)
23. Mullard A. COVID-19 platform trial delivers. *Nat Rev Drug Discov*. 2020 Jul 7;19(8):501–501.
24. Health Research Authority. COVID-19 research [Internet]. Health Research Authority. 2020 [cited 2020 Aug 12]. Available from: <https://www.hra.nhs.uk/covid-19-research/>
25. Medicines and Healthcare products Regulatory Agency. MHRA guidance on coronavirus (COVID-19) [Internet]. GOV.UK. 2020 [cited 2020 Aug 12]. Available from: <https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19>
26. National Institute for Health Research. NIHR shares first update on implementation of the Restart Framework [Internet]. 2020 [cited 2020 Sep 14]. Available from: <https://www.nihr.ac.uk/news/nihr-shares-progress-on-implementation-of-the-restart-framework/25193>
27. National Institute for Health Research. NIHR shares third monthly update on implementation of the Restart Framework [Internet]. 2020 [cited 2020 Sep 17]. Available from: <https://www.nihr.ac.uk/news/nihr-shares-third-monthly-update-on-implementation-of-the-restart-framework/25650>
28. Griffin S. Covid-19: Waiting times in England reach record highs. *BMJ* [Internet]. 2020 Sep 11 [cited 2020 Sep 14];370. Available from: <https://www.bmj.com/content/370/bmj.m3557>
29. Chief Scientist Office. CSO Statement on the Restart Framework [Internet]. 2020 [cited 2020 Aug 12]. Available from: <https://www.scot.nhs.uk/cso-statement-on-the-restart-framework/>
30. National Institute for Health Research. NIHR publishes latest Annual Report [Internet]. 2020 [cited 2020 Aug 21]. Available from: <https://www.nihr.ac.uk/news/nihr-publishes-latest-annual-report/24524>
31. National Institute for Health Research. Research Performance 2015/2016 [Internet]. 2017. Available from: <https://www.nihr.ac.uk/documents/about-us/our-contribution-to-research/research-performance/NIHR-Annual-Report-2015-16.pdf>
32. National Institute for Health Research. Research Performance 2016/2017 [Internet]. 2018. Available from: <https://www.nihr.ac.uk/documents/about-us/our-contribution-to-research/research-performance/NIHR-ANNUAL-REPORT-2016-17.pdf>
33. National Institute for Health Research. Research Performance 2017/2018 [Internet]. 2019. Available from: <https://www.nihr.ac.uk/documents/about-us/our-contribution-to-research/research-performance/NIHR-Annual-Report-2017-18.pdf>
34. National Institute for Health Research. Research performance 2018/2019 [Internet]. 2020 [cited 2020 Sep 9]. Available from: <https://www.nihr.ac.uk/about-us/our-contribution-to-research/research-performance/>
35. Health Research Authority. The Combined Ways of Working pilot: one year on [Internet]. Health Research Authority. 2019 [cited 2020 Aug 28]. Available from: <https://www.hra.nhs.uk/about-us/news-updates/combined-ways-working-pilot-one-year/>
36. Health Research Authority. How the combined ways of working pilot is already making an impact [Internet]. Health Research Authority. 2020 [cited 2020 Aug 28]. Available from: <https://www.hra.nhs.uk/about-us/news-updates/combined-ways-working-pilot-one-year/>
37. Health Research Authority. Combined Ways of Working [Internet]. 2020. Available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working/>
38. National Institute for Health Research. National Directive on Commercial Contract Research Studies [Internet]. 2019. Available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/>
39. National Institute for Health Research. Faster costing and contracting | NIHR [Internet]. 2020 [cited 2020 Aug 28]. Available from: <https://www.nihr.ac.uk/partners-and-industry/industry/run-your-study-in-the-nhs/faster-costing-and-contracting.htm>
40. Blagden SP, Billingham L, Brown LC, Buckland SW, Cooper AM, Ellis S, et al. Effective delivery of Complex Innovative Design (CID) cancer trials – A consensus statement. *Br J Cancer*. 2020 Feb;122(4):473–82.

41. National Institute for Health Research. Delivering complex and innovative trials [Internet]. 2020 [cited 2020 Aug 28]. Available from: <https://www.nihr.ac.uk/partners-and-industry/industry/run-your-study-in-the-nhs/complex-innovative-trials.htm>
42. Health Research Authority. New podcast series looking at innovative trial design launches [Internet]. Health Research Authority. 2020 [cited 2020 Aug 28]. Available from: <https://www.hra.nhs.uk/about-us/news-updates/new-podcast-series-looking-innovative-trial-design-launches/>
43. University of Oxford. Welcome – RECOVERY Trial [Internet]. 2020 [cited 2020 Aug 28]. Available from: <https://www.hra.nhs.uk/about-us/news-updates/new-podcast-series-looking-innovative-trial-design-launches/>
44. The Academy of Medical Sciences. Enhancing the NHS-academia interface [Internet]. 2020 [cited 2020 Sep 9]. Available from: <https://acmedsci.ac.uk/policy/policy-projects/nhs-academia-interface>
45. British Pharmacological Society. Clinical Pharmacology Skills Alliance launched to combat clinical pharmacology skills shortage [Internet]. 2017 [cited 2020 Sep 9]. Available from: <https://www.bps.ac.uk/news-events/news/articles/2017/clinical-pharmacology-skills-alliance-launched-to>
46. Royal College of General Practitioners. Research Ready® [Internet]. 2020 [cited 2020 Sep 9]. Available from: <https://www.rcgp.org.uk/clinical-and-research/our-programmes/research-facilitation-and-support/research-ready-self-accreditation.aspx>
47. National Health Service. We are the NHS: People Plan for 2020/2021 [Internet]. 2020 [cited 2020 Sep 9]. Available from: <https://www.england.nhs.uk/ournhspeople/>
48. Health Data Research UK. NHS DigiTrials – The Health Data Research Hub for Clinical Trials [Internet]. Health Data Research UK. 2019 [cited 2020 Aug 28]. Available from: <https://www.hdruk.ac.uk/help-with-your-data/our-hubs-across-the-uk/nhs-digitrial/>
49. Deane B, Porkess S. Clinical trial transparency update: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved in Europe in 2014. CMRA [Internet]. 2018 Jan [cited 2019 Jul 31];34(7). Available from: <https://www.tandfonline.com/doi/full/10.1080/0307995.2017.1415057>
50. RECOVERY Collaborative Group. Results – RECOVERY Trial [Internet]. 2020 [cited 2020 Jul 21]. Available from: <https://www.recoverytrial.net/results>
51. HM Government. International Research and Innovation Strategy [Internet]. 2019. Available from: <https://www.gov.uk/government/publications/uk-international-research-and-innovation-strategy>
52. UK Research and Innovation. Open Access Review [Internet]. 2020 [cited 2020 Aug 28]. Available from: <https://www.ukri.org/funding/information-for-award-holders/open-access/open-access-review/>
53. Health Research Authority. Make it Public: transparency and openness in health and social care research [Internet]. Health Research Authority. 2020 [cited 2020 Aug 28]. Available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/make-it-public-transparency-and-openness-health-and-social-care-research/>
54. UK Parliament. Medicines and Medical Devices Bill 2019-21 [Internet]. 2020 [cited 2020 Sep 14]. Available from: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency/make-it-public-transparency-and-openness-health-and-social-care-research/>
55. Public Health Agency, Health and Care Research Wales, Chief Scientist Office (Scotland), National Institute for Health Research. UK Standards for Public Involvement [Internet]. 2018 [cited 2020 Sep 14]. Available from: <https://sites.google.com/nihr.ac.uk/pi-standards/home>
56. The Association of the British Pharmaceutical Industry. Working with patients and patient organisations – a sourcebook for industry [Internet]. 2019 [cited 2019 Jul 31]. Available from: <https://www.abpi.org.uk/publications/working-with-patients-and-patient-organisations-a-sourcebook-for-industry/>
57. Shared Learning Group on Involvement and Charities Research Involvement Group. Supporting involvement in industry-led research: guidance for charities [Internet]. 2019 [cited 2019 Jul 31]. Available from: [http://slginvolvement.org.uk/wp-content/uploads/2019/09/Supporting-PPI-in-industry-led-research\\_Guidance-for-Charities\\_CRIG-HRCI-public.pdf](http://slginvolvement.org.uk/wp-content/uploads/2019/09/Supporting-PPI-in-industry-led-research_Guidance-for-Charities_CRIG-HRCI-public.pdf)
58. Innovative Medicines Initiative. PARADIGM [Internet]. 2020 [cited 2019 Jul 31]. Available from: <https://imi-paradigm.eu/>
59. National Institute for Health Research. Multimillion investment in new research projects to investigate higher COVID-19 risk among certain ethnic groups [Internet]. 2020 [cited 2020 Aug 21]. Available from: <https://www.nihr.ac.uk/news/multimillion-investment-in-new-research-projects-to-investigate-higher-covid-19-risk-among-certain-ethnic-groups/25333>
60. Department for Business, Energy & Industrial Strategy. UK Research and Development Roadmap [Internet]. GOV.UK. 2020 [cited 2020 Sep 15]. Available from: <https://www.gov.uk/government/publications/uk-research-and-development-roadmap>
61. Health Research Authority. New public involvement service for COVID-19 studies. 2020. <https://www.hra.nhs.uk/about-us/news-updates/new-public-involvement-service-covid-19-studies/>

## Appendix A: Data collection methodology

Data was collected from Cortellis Clinical Trial Intelligence, Clarivate Analytics, using the following criteria:

- For trial start date 1 January 2012 – 31 December 2018, countries: Australia, Canada, France, Germany, Italy, Japan, Poland, Spain, Switzerland, UK, and USA
- For trial start date 1 January 2016 – 31 December 2018, countries: Brazil, China, South Africa, Switzerland
- For trial start date 1 January 2017 – 31 December 2018, countries: Belgium and Hungary
- Phase of study: Phase I, Phase II or Phase III
- Disease area: Oncology, Nervous System, Cardio-metabolic, Immunology and Infectious diseases
- 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.

Note that data from Cortellis Clinical Trial Intelligence, Clarivate, is regularly updated. The data in this report, was collected on 28 February 2020 and hence may be different from historic and future datasets.

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