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DEBATE PACK

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Supporting clinical trials and the UK's future clinical research capability

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This pack has been prepared ahead of the debate to be held in Westminster Hall at 1.30pm on Thursday 23 May 2019 on supporting clinical trials and the UK's future clinical research capability. The subject for the debate has been selected by the Backbench Business Committee and the debate will be opened by Chris Green MP.

Contents

1. Supporting clinical trials and the UK's future clinical research capability

There will be a debate in Westminster Hall on 23 May 2019 on supporting clinical trials and the UK's future clinical research capability. The subject of the debate was selected by the Backbench Business Committee and the debate will be led by Chris Green MP.

In his submission to the Committee, Mr Green highlighted a number of issues that that would be raised in the debate. These included the Government's Industrial Strategy, the impact of immigration policy on clinical trials and the regulation and collaboration on clinical trials after Brexit:

> […] One aspect is the Government's industrial strategy and how it impacts on the life sciences sector as a whole. It is incredibly important to the Government's agenda and what they are doing in getting R&D spend across the UK from 1.7% to 2.4% of GDP and how that is reflected in the interests of the scientific community and life sciences, but specifically how it supports clinical trials.
>
> The Government are looking at their immigration policy, which has a significant impact on clinical trials and the technicians that work within the sector. There is a £30,000 pay threshold for people coming from abroad. We must remember that clinical trials, the life sciences sector and the scientific community as a whole have a very mobile workforce and we need to be able to bring in talent from across the world, so that £30,000 boundary that you have to get over will have an impact. More so, it will have an impact on areas in the north of England. Perhaps in London and the south-east it might not have so much impact, but in the north of England it will have a more significant impact.
>
> Brexit is a significant concern for the clinical trials. The European Union has legislated to change from the clinical trials directive to the clinical trials regulation. We have not yet adopted this, and the EU has not yet adopted it, but having the UK's regulatory framework in sync with the European Union's regulatory framework is of enormous importance, and the Government are not yet doing or saying enough to give a clear direction on what we are going to do in this area.
>
> Also, in terms of clinical trials, especially for rarer diseases and conditions, you need a pool of patients, which the United Kingdom alone could not provide. Therefore, you need collaborations. Yes, you have collaborations internationally, across the world, but our closest partners in so many of these collaborations are in France, Germany—across the European Union— and we don't know whether, post Brexit, we will have access to the databases to be able to share the information that is vital to underpinning what we are doing in the UK. If we do not have access to that, that undermines our sector, and with the doubt that there is at the moment, because the Government are not being as communicative as they might be, over our ongoing agenda in terms of clinical trials and life sciences, we need to

> provide more reassurance to the sector, so I think this debate, at this time, is of great importance.[1]

1.1 Clinical trials in the UK

Clinical trials are the means by which new treatments are tested for effectiveness and safety.[2] More information on the structure and different phases of clinical trials is provided in the following sources:

- NHS, Clinical trials
- MRC Clinical Trials Unit, What is a clinical trial?
- Cancer Research UK, What clinical trials are

The UK is considered a leader in the field of clinical trials. A 2017 report by the Technopolis group (and funded by charities and other medical research funders) The impact of collaboration: the value of UK medical research to EU science and health, highlighted the role of the UK in medical research:

> The UK has one of the largest development pipelines globally, including 500 new biotechnology-based drugs and 600 innovative pharmaceutical product candidates. Looking at existing medicines, around 25% of the world's top 100 prescription medicines were discovered and developed in the UK and three of the five top-selling drugs globally act on a mechanism discovered by UK researchers to combat rheumatoid arthritis and other inflammatory conditions – revolutionising the treatments available. This is testimony to the strength of the UK research system and its ability to translate discoveries into real world solutions.[3]

The report also sets out the UK's active role in EU research work:

> The UK is an important partner in the EU research landscape, contributing to almost 20% of the total research work carried out within EU health programmes between 2007 and 2016. Collaborating in research like this has mutual benefits, particularly in terms of impact. Bibliometric analysis of EU medical and health research publications shows that collaboration with the UK greatly increases the impact of EU26 publications, and vice versa
>
> […]
>
> The UK is active in maintaining Europe's key registries and research networks in rare diseases. The UK co-ordinates the highest number of European registries of all EU member states, including those for childhood lung diseases, Huntington's disease and familial pancreatic cancer. Specialised UK health care providers have taken a significant role in the development of the new European Reference Networks (ERNs): the UK co-ordinates a quarter of the 24 thematic networks and participates in nearly all, thereby pooling knowledge and sharing research expertise. These actions contribute significantly to accelerate innovation in medical

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1 Representations: Backbench Business Tuesday 7 May 2019
2 NHS, Clinical trials
3 Peter Varnai, Maike Rentel, Anoushka Davé, Marika De Scalzi, Wia Timmerman, Cristina Rosemberg-Montes, Paul Simmonds, The impact of collaboration: the value of UK medical research to EU science and health, May 2017

> science and deliver evidence-based treatment to patients across the EU.[4]

There has been recent discussion on how Brexit may impact on the UK's role in research. This is discussed further in section 1.5.

1.2 Regulation of clinical trials

The bodies primarily responsible for regulating clinical trials in the UK are the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority (HRA).

Clinical trials are currently regulated by the EU Clinical Trials Directive[5] which was transposed into UK law by the *Medicines for Human Use (Clinical Trials) Regulations (2004)*.

A new EU Clinical Trials regulation came into force in May 2014 but does not yet apply in Member States. The timing of the application of the regulation is dependent on the establishment of an EU clinical trials portal and database through which all trials will be registered.

The new regulation will implement consistent rules across the EU for conducting clinical trials, it will ensure that information on the authorisation, processes and findings of all EU clinical trials will be publicly available and will introduce a single point submitting information on clinical trials across the EU. The authorisation and monitoring of clinical trials will remain the responsibility of the Member State regulators.

The European Medicines Agency (EMA) report that the key benefits of the new regulation are:

1. Harmonised electronic submission and assessment process for clinical trials conducted in multiple Member States
2. Improved collaboration, information-sharing and decision-making between and within Member States
3. Increased transparency of information on clinical trials
4. Highest standards of safety for all participants in EU clinical trials[6]

More information on the EU Clinical trials regulation is provided in the following sources:

- POSTnote, Regulating Clinical trials, October 2017
- European Medicines Agency, Clinical Trial Regulation
- European Commission, Clinical trials - Regulation EU No 536/2014

Clinical trials are quite closely linked with issues relating to medicines regulation. More information on how medicines are regulated and the

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4 Peter Varnai, Maike Rentel, Anoushka Davé, Marika De Scalzi, Wia Timmerman, Cristina Rosemberg-Montes, Paul Simmonds, The impact of collaboration: the value of UK medical research to EU science and health, May 2017

5 *EC Directive 2001/20/EC "on the approximation of the laws, regulations and administrative provisions of the Member States"*, 4 April 2001.

6 European Medicines Agency, Clinical Trial Regulation [accessed 22 May 2019]

potential impacts of Brexit on this are is discussed in the Commons library briefing paper, Brexit and medicines regulation.

1.3 Industrial Strategy: support for clinical trials

R&D funding

In the Industrial Strategy (November 2017) the Government set a target to "raise total R&D investment to 2.4% of GDP by 2027" and to reach 3% "in the longer term". In 2017, total expenditure on R&D was £34.8 billion, £527 per head, or the equivalent of 1.7% of GDP.[7]

In terms of public investment, the Government committed to invest £12.5 billion public R&D investment by 2021/22:

> Increasing investment in R&D to 2.4 per cent of GDP in a decade is ambitious and will require concerted effort by the government and business. As a first step we will invest an additional £2.3bn over what was previously planned in 2021/22, raising total public investment in R&D to approximately £12.5bn in that year alone. This investment will see public R&D spending increase as a share of GDP every year. It means that we will have raised public investment in R&D from around £9.5bn last year (2016/17) to around £12.5bn in 2021/22. This is an extra £7bn over five years – the biggest ever increase in public funding of R&D.[8]

The House of Commons Science and Technology Select Committee and the Business Energy and Industrial Strategy Committee have both called for the UK Government to set a target to increase (public and private) R&D investment to 3% of GDP.[9] [10]

More information and figures on R&D expenditure overall is provided in the Library briefing paper: research and development expenditure (10 April 2019).

Life Sciences Sector Deal

Specifically relevant to clinical trials, the Industrial Strategy announced the Life Sciences Sector Deal, one of five partnerships between government and industry announced at the time. The Deal followed recommendations made to Government by Sir John Bell in the Life Sciences Industrial Strategy. Two Life Sciences Sector Deals have since been published, in 2017 and 2018.

The Sector Deal is a collaboration including more than 25 organisations from businesses, charities and academia. The Government stated that

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7 See the Library briefing paper: research and development expenditure (10 April 2019).

8 Department for Business, Energy and Industrial Strategy, Industrial Strategy: building a Britain fit for the future, 27 November 2017, page 67.

9 House of Commons Science and Technology Committee, Thirteenth Report of Session 2016–17, Industrial Strategy: science and STEM skills, HC 991,12 April 2017, para 13.

10 House of Commons Business, Energy and Industrial Strategy Committee, Second Report of Session 2016–17, Industrial Strategy: First Review, HC 616, para 103.

the deal included "nearly £500 million" of government investment and £1 billion private sector investment into UK life sciences:

> The deal committed nearly £500 million of government investment into UK life sciences, backed by more than £1 billion of private sector investment, to build on the sector's strengths, help to secure thousands of jobs and ensure that new medicines and technologies are created in the UK.[11]

The first Life Sciences Sector deal was published in 2017 and included the following key Government commitments to "strengthen the environment for clinical trials":

1. We will invest through the National Institute for Health Research in research infrastructure in the NHS. New contracts worth more than £950 million will start over the next 5 years.
2. The Health Research Authority will speed up approvals for clinical trials and reduce the burden on NHS Trust R&D departments.

The 2017 Sector Deal also pointed towards "action underway to streamline approvals processes" such as work ongoing at the HRA to speed up approvals and highlighted initiatives already underway in industry and in collaboration with universities.

In December 2018 the Government published the Life Sciences Sector Deal 2 which set out progress made in the Sector Deal and set further Government actions. On clinical trials, the Government set out the following commitments:

> We will further improve the speed and efficiency of clinical trials by:
>
> 1. Establishing 5 centres for late phase commercial research.
> 2. Exploring opportunities to recognise and incentivise NHS Trusts and GP practices acting as participant identification centres.
> 3. Continuing to improve research set-up timelines.
> 4. Addressing challenges in NHS workforce resourcing to deliver commercial research.
>
> We will consolidate our world-leading position in delivering novel and innovative trials by:
>
> 1. Promoting the UK's expertise in designing and delivering innovative trials.
> 2. Enabling industry, including SMEs, and the wider research community to access advice to support innovative trial design.
> 3. Delivering a skills programme to embed expert understanding of how innovative studies can be run across the NHS.

[11] DHSC, BEIS, DIT, Office for Life Sciences, Life Sciences Organisation, £1.3 billion industry/government investment in UK economy and new partnership driving early disease detection, 5 December 2018.

The 2018 Sector Deal 2 report also highlighted the following commitments made by industry under the deal:

> The government's comprehensive plan to improve our clinical research environment has unlocked new commitments from companies:
>
> 1. Celgene provides support for studies and is making a new investment in excess of £7m, with an overall £38m investment.
> 2. With National Institute for Health Research (NIHR) facilitation support, IQVIA Ltd. will invest £24m over 5 years into a fourth UK Prime Site for clinical trials across the North of England.
> 3. IQVIA Ltd. and Genomics England are investing £20m over 5 years to develop services that will enable more efficient drug research.
> 4. The Brain Tumour Charity will invest £2.8m in the Tessa Jowell BRAIN-MATRIX, a trial aimed at increasing opportunities for brain tumour patients to try non-standard treatments.[12]

Further detail on specific progress under the strategy is outlined on pages 27-28 of the report.

1.4 Immigration rules and non-EEA clinical staff

Tier 2 (General) is the main visa route available to employers wishing to recruit a skilled non-EU/EEA worker. Generally speaking, this visa category only caters for jobs that are classed at 'graduate level' (RQF level 6) or above and which pay a minimum of £30,000 per year[13], and for jobs which are on the official Shortage Occupation List. An applicant must show they meet the appropriate salary threshold for their specific role, which in most circumstances must be above £30,000. Appendix J of the Immigration Rules sets out the appropriate salary thresholds for each job code. This means that the salary threshold required for those working on clinical trials varies depending on the type of job the Tier 2 migrant is performing. Evidence received by the Commons Science and Technology Committee explained that using salary as a proxy for skill was an issue 'particularly pronounced for research technicians who do "not exceed the current salary threshold for a 'high-skilled' job"'.[14]

Once the UK leaves the EU the Government intends to implement the *Immigration and Social Security Co-ordination (EU Withdrawal) Bill 2017-19* to end free movement in the UK. The Bill is currently awaiting Report stage and Third Reading on a date to be announced. This means

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12 BEIS, Office for Life Sciences, and Life Sciences Organisation, Life Sciences Sector Deal 2, 5 December 2018, page 9.

13 Subject to certain exceptions (e.g. RQF level 4 for jobs in the creative sector or on the SOL; £20,800 salary threshold for less experienced workers and certain professions)

14 *An immigration system that works for science and* innovation, House of Commons Science and Technology Committee, eighth report of session 2017-19, 19 July 2018, 15

that EU and EEA citizens will require immigration permission to come to the UK for work and other purposes.

The Government set out its proposals for the future immigration system in the Immigration White Paper 'The UK's future skills-based immigration system' in December 2018. The White Paper explains that 'the Government proposes to move to a single, skills-based immigration system, which for economic migration prioritises higher skilled workers.'[15] The Government intends to open up the existing Tier 2 visa category to EU and EEA citizens, while also abolishing the existing cap and lowering the skill threshold to jobs at RFQ3 and higher. The Migration Advisory Committee (the "MAC") recommended that the Government retain the existing salary threshold of £30,000. In response the White Paper explains that the Government will "engage extensively with businesses and employers, consider wider evidence of the impact on the economy, and take into account current pay levels in the UK economy."[16] The Immigration White Paper commits to supporting science, research and innovation with several proposals:

> • Introduction of a new UK Research and Innovation-led scheme to support the temporary movement of scientists and researchers under our Government Authorised Exchange Scheme, for those looking to come to the UK for two years;
>
> • Doubling the number of Tier 1 Exceptional Talent visas, including for top global scientists, to 2,000 a year. This helps to underpin the UK's position as a hub for international collaboration and research excellence;
>
> • Changes to the UK Immigration Rules to waive the Resident Labour Market Test for employers recruiting supernumerary researchers supported by Awards and Fellowships, and members of established research teams who are sponsored by UK Higher Education Institutions and the Research Councils under our main skilled work route;
>
> • Providing an exemption from the usual rules for absences from the UK for scientists and researchers called to assist with humanitarian and environmental crises; and
>
> • Enabling faster switching between our existing Tier 4 student route and highly skilled tier 2 visas, demonstrating our commitment to support those at the early stages of their careers.[17]

1.5 Brexit and clinical trials

In a speech at Jodrell's bank on 21 May 2018, the Prime Minister set out her aims for the future relationship between the UK and the EU on science and research:

> I know how deeply British scientists value their collaboration with colleagues in other countries through EU-organised programmes.

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15 HM Government, 'The UK's future skills-based immigration system', December 2018, 3.3

16 HM Government, 'The UK's future skills-based immigration system', December 2018, 6.24

17 HM Government, 'The UK's future skills-based immigration system', December 2018, 6.7

> And the contribution which UK science makes to those programmes is immense.
>
> I have already said that I want the UK to have a deep science partnership with the European Union, because this is in the interests of scientists and industry right across Europe.
>
> And today I want to spell out that commitment even more clearly.
>
> The United Kingdom would like the option to fully associate ourselves with the excellence-based European science and innovation programmes – including the successor to Horizon 2020 and Euratom R&T.
>
> It is in the mutual interest of the UK and the EU that we should do so.
>
> Of course such an association would involve an appropriate UK financial contribution, which we would willingly make.
>
> In return, we would look to maintain a suitable level of influence in line with that contribution and the benefits we bring.
>
> The UK is ready to discuss these details with the Commission as soon as possible.[18]

Clinical Trials Regulation

The Government have said that they intend to align with the Clinical Trials Regulation (CTR) after the UK leaves the EU. If the legislation comes into force within the implementation period, then this will automatically apply under the provisions of the *EU Withdrawal Act* but if this is not the case, or if the UK leaves without a deal, this will not be automatic. More information was provided by the Under-Secretary of State for Health, Jackie Doyle-Price in March 2019 during a debate on no deal Brexit clinical trials regulations :

> We expect the clinical trials regulation to be implemented in late 2020, and the MHRA, the National Institute for Health Research and the NHS have been working towards the implementation of that regulation since it was agreed in 2014. The withdrawal agreement Bill will give effect to the implementation period in domestic law and will allow EU regulations to continue to apply directly in the UK for this time-limited period. If the clinical trials regulation comes into force during the implementation period, as it is currently expected to, we would expect to apply that to the UK. If however we leave without a deal—this is why we have these regulations—the CTR will not be in force in the EU at that time so will not be incorporated into UK law on exit day; however, we intend to align, where possible, with the CTR without delay when it does come into force, subject of course to the usual parliamentary approvals. But that alignment will happen after 29 March 2019.[19]

The MHRA have previously said that, if the CTR does not come into force in the implementation period the Government has confirmed the UK will remain aligned with the CTR, except in areas where this is not in the UK's control. The two areas where this is not in the UK's control are

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[18] Prime Minister's office, PM speech on science and modern Industrial Strategy: 21 May 2018

[19] Exiting the European Union (Medicines) c1415

the use of a shared central IT portal, and participation in a single assessment model.[20]

The MHRA provides information about what action will need to be taken if the UK is outside the EU network after the implementation period.[21]

No deal Brexit

The February 2019 MHRA document, Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal provides information on what would apply to clinical trials in the event of a no deal Brexit. This sets out that the UK's current participation in the EU regulatory network would not continue and the MHRA would take on the responsibilities currently held by the EU system. The UK's current regulatory system as set out in the 2004 Clinical Trials Directive would remain in place but the Government has said it will re-align with the parts of the EU's CTR legislation that are within the UK's control.

The UK would require the sponsor of a trial to either be in the UK, or in a country on an approved list (which will include all EU countries). However, the EU have set out that in the event of the UK leaving with no deal, sponsors of clinical trials in the EU must be based in the EU.[22]

With regards to publishing clinical trial information, the Government have said that the UK intends to align with the transparency provisions across the EU. Initially, researchers should use the existing international registries to ensure information about the trial is publicly available. However, the MHRA states that "by the time the EU's new portal goes live (as part of the new CTR), the UK will have its own specific hub that would give both the UK patients and researchers a single reference point for all UK trials."

For further information on the impacts of no deal Brexit on clinical trials regulation, see the MHRA guidance.

Comment

Health organisations and other stakeholders have expressed support for close alignment with the EU on clinical trials following Brexit. Concerns have been expressed that a move away from regulatory alignment with the EU could impact on the negatively on clinical trials in the UK.

In its February 2019 report, Brexit and Beyond: Clinical Trials, Wellcome stated that the best option for UK and EU clinical trials was full UK participation in the EU clinical trials system (bold retained from original):

> The **best option for UK and EU clinical trials after Brexit is full UK participation in the EU clinical trials system on a similar basis to Member States**. The UK would implement the EU Clinical Trial Regulation (CTR) and have access to the single EU

20 MHRA, News story: Clinical Trials Regulation, 6 August 2018
21 MHRA, News story: Clinical Trials Regulation, 6 August 2018
22 European Commission, Notice to stakeholders withdrawal of the United Kingdom and EU rules in the field of clinical trials, September 2018

> clinical trials portal and database alongside being a part of relevant regulatory discussions. This would enable the UK to continue its strong relationship with the EU on clinical trials, with access to EU resources, and provide a leadership role for the Medicines and Healthcare products Regulatory Agency (MHRA). The UK and EU should seek to agree this in future relationship negotiations, as it would minimise the burden on researchers, continue to provide access to the widest pool of patients, and allow Europe to use its collective expertise to be a global leader in clinical research**. In the interests of European health and research, both sides will need to be pragmatic in negotiations. A positive first step would be to include clinical trials in negotiations on the future UK–EU research and innovation relationship rather than the economic partnership.**[23]

The report goes on to explore other alternative options for UK and EU clinical trials after Brexit, where there are different levels of alignment and cooperation.[24]

Following the meaningful vote result in parliament in January 2019, The Association of Medical Research Charities expressed concerns about the impact of a no deal Brexit on medical research:

> […]A no-deal Brexit scenario is unacceptable. It would risk patient safety and jeopardise pioneering medical research in the UK.
>
> In a no-deal Brexit, patient access to existing and new medicines as well as opportunities to take part in innovative clinical trials would be at risk. From day one of a no-deal Brexit, delays at borders would impact supply of medicines with the need to enact robust, but inherently risky, contingency plans.
>
> The impact on the UK's world-leading medical research base would also be profound. Collectively, members of the Association of Medical Research Charities fund almost half of all publicly funded medical research nationally as well as over 17,000 researchers. A no-deal Brexit could irreversibly damage our relationship with our most important research partner.
>
> The damaging implications of a no-deal Brexit on patients and medical research must be clear and understood. With time running out we hope a solution can be found to the current stalemate which ensures no damaging impact on patients."[25]

Further comment from health organisations on clinical trials after Brexit is provided in the following sources:

- Brexit Health Alliance, The impact of Brexit: Patient access to medical research, February 2018
- British Medical Association, BMA Brexit briefing: Medical research, December 2018
- Cancer Research UK, The Future of Clinical trials after Brexit, August 2018

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23 Wellcome, Brexit and Beyond: Clinical Trials, February 2019
24 Wellcome, Brexit and Beyond: Clinical Trials, February 2019
25 AMRC, AMRC's response on the outcome of the vote on the Withdrawal Agreement and Political Declaration, January 2019

2. News items

Pharma Times

Brexit will have 'minimal' effect on R&D in UK, says expert

4 April 2019

http://www.pharmatimes.com/news/brexit_will_have_minimal_effect_on_r_and_d_in_uk,_says_expert_1283463

Pharma Times

UK will be 'less attractive' for clinical research post Brexit

13 March 2019

http://www.pharmatimes.com/news/uk_will_be_less_attractive_for_clinical_research_post_brexit_1281279

Telegraph

Medical industry sounds alarm on risks posed by no-deal Brexit

21 February 2019

https://www.telegraph.co.uk/business/2019/02/21/medical-industry-sounds-alarm-risks-posed-no-deal-brexit/

Telegraph

Patients at risk as UK universities fail to disclose results of clinical trials

24 January 2019

https://www.telegraph.co.uk/news/0/patients-risk-uk-universities-fail-disclose-results-clinical/

Nature

How UK scientists are preparing for a chaotic no-deal Brexit

17 January 2019

https://www.nature.com/articles/d41586-019-00191-0

Pharmaceutical Journal

NHS hospital says medical research has been halted because of Brexit uncertainty

10 October 2018

https://www.pharmaceutical-journal.com/news-and-analysis/news/nhs-hospital-says-medical-research-has-been-halted-because-of-brexit-uncertainty/20205555.article?firstPass=false

Pharma Times

MHRA clarifies post-Brexit clinical trials rules

6 August 2018

http://www.pharmatimes.com/news/mhra_clarifies_post-brexit_clinical_trials_rules_1247633

Pharmaceutical Journal

UK may be out of step with Europe on clinical trials regulations after Brexit, minister accepts

16 October 2017

https://www.pharmaceutical-journal.com/news-and-analysis/news/uk-may-be-out-of-step-with-europe-on-clinical-trials-regulations-after-brexit-minister-accepts/20203739.article?firstPass=false

3. Press releases

Medicines and Healthcare Products Regulatory Agency

UK Clinical Trial Pilot Helps Companies Prep for New EU Regulation

20 May 2019

In preparation for the future of clinical trials under EU Clinical Trial Regulation 536/2014, the UK has been running a pilot program for a little more than a year to streamline the submission and review process for applications to run Clinical Trials of Investigational Medicinal Products (CTIMPs).

Under the pilot, which has been run jointly since April 2018 by the UK's Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA), a single CTIMP application can be submitted for the Clinical Trial Authorisation (CTA) and the Research Ethics Committee (REC) opinion.

> The reviews are undertaken independently, but the outcome of the review is co-ordinated to ensure that any requests for further information or changes to documentation are compatible. Applicants receive a single co-ordinated communication to request further information or document changes, and a single communication to confirm the final decision,

HRA said.

The pilot has so far dealt with more than 40 applications.

And as the pilot morphs into a fully fledged program for all trial sponsors, which MHRA said Monday is expected, some sponsors with different departments dealing with CTA and REC submissions may need to make changes as they submit one application dossier for both the CTA and the REC.

> Overall we have seen a significant decrease in MHRA and REC approval timelines which has been welcomed by our clients; the pilot process was straightforward and fitted well into PRA's established processes,

PRA Health Sciences, a contract research organization and participant in the pilot, said.

> One change to the usual approvals service is the 14-day window for updating applications in response to requests for further information from the regulators. The pilot is also developing guidance around clinical trial amendments, which will be important if the combined approval system is launched.

To find out more about the pilot and how to get involved please see the guidance on the HRA website (see link below) or email cwow.admin@nhs.net and include 'combined ways of working pilot' in the subject line, HRA said.

The combined ways of working pilot

Department for Business, Energy & Industrial Strategy, Medical Research Council, Innovate UK, UK Research and Innovation

Investment to transform access to data to help pioneer new patient treatments

The government is backing plans to create new digital innovation hubs, changing the way scientists access NHS data.

6 May 2019

- Digital innovation hubs, part of our modern Industrial Strategy, to be created to transform the way researchers and innovators can access data from the NHS
- innovators will be able to access data more easily and use it in their efforts to find cures and treatments for diseases including cancer and diabetes
- the project may also enable scientists to find ways to diagnose disease earlier, speed up drug development, and give people faster access to more personalised treatments

Plans to transform the way scientists access health data are being backed by £37 million of Industrial Strategy government investment, to pioneer new, faster treatments for patients and new cures for diseases.

The new centres across the UK – known as Digital Innovation Hubs – will enable scientists and innovators to access data from the NHS, universities and social care to deliver more efficient clinical trials. They can use the data to answer the most important and complex questions about people's health in the future.

The centres will make data accessible from some of the UK's major health providers in one place for the first time, including the NHS in England, Scotland, Wales and Northern Ireland. These will allow experts to research the factors behind many familiar common diseases and identify revealing data trends which may help with finding cures or treatments.

The information will go through a de-identification and encryption process to preserve privacy.

Business Secretary Greg Clark said:

> Access to anonymised health data has huge potential to allow us to better understand diseases and develop life-saving new drugs and treatments.
>
> The Digital Innovation Hubs, backed by over £37 million of Industrial Strategy investment, will ensure researchers, innovators and clinicians can access a large quantity of anonymised data responsibly and ethically - allowing them to pioneer new medicines and treatments.
>
> These hubs are a major part of our modern Industrial Strategy, building on the UK's world leading life sciences sector and health service to the benefit of researchers, industry and patients.

The project, led by Health Data Research UK (HDR UK), aims to improve health and care in the UK in areas like speeding up drug development

and giving people faster access to more personalised treatments. It also aims to help in diagnosing diseases earlier and help in wider efforts to find cures and treatments, including for conditions such as cancer.

Health Minister Nicola Blackwood said:

> It is absolutely crucial that researchers are able to access the NHS's world-leading anonymised data so they can develop cutting-edge treatments and solutions to some of healthcare's biggest challenges. This will mean people can receive new medicines quicker and get more timely diagnoses which will ultimately save lives.
>
> As part of our Long Term Plan, we are determined to encourage more innovation in the NHS than ever before so patients benefit from the best medicines and technologies.

A £3 million trial is underway with 10 projects across the UK. In Manchester, patients with already implanted pacemakers and defibrillators will have their health data analysed in real-time to detect signs of deterioration earlier and prevent hospital admissions.

About 1,000 patients with heart failure, being cared for by Manchester Royal Infirmary, already had an implantable device such as a pacemaker or defibrillator which captures information about their health. The project's clinical team used the data to detect signs of deterioration earlier and to transform care for the patient.

The new centres will be selected through a competition and are expected to be established by the end of this year.

They will also be tasked with ensuring responsible access to anonymised health data in a trustworthy and ethical way, by involving patients to ensure that benefits are returned to the NHS for the greater public good.

The £37.5 million investment in Digital Innovation Hubs is a key part of the modern Industrial Strategy, and its Data to Early Diagnosis and Precision Medicine Challenge. Backed by a total of up to £210 million government investment, it aims to combine data and real-world evidence from across the health service to create new products and services to help diagnose diseases earlier and more efficiently.

This also forms part of wider work to ensure the UK remains a world-leader in the life sciences sector, already worth nearly £74 billion to the UK economy. In December 2018, the government agreed a second life sciences sector deal, drawing substantial investment into the sector from across the world, ensuring that the next wave of breakthrough treatments, innovative medical research and technologies, and high skilled jobs are created in Britain.

Professor Andrew Morris, Director of Health Data Research UK, said:

> We are excited about the tremendous opportunities that Digital Innovation Hub Programme brings to the future of health research and innovation in the UK. Working closely with UK Research and Innovation, our focus in delivering these new centres of excellence is first and foremost on ensuring that patients reap the rewards and are reassured that all data are used ethically and responsibly.

> The UK has a high energy community that brings together leading health experts, entrepreneurs and data scientists. When combined with the UK's ability to bring data together from hospitals, patients, public health and laboratories, we can power an open innovation platform that improves the health and care of people living with cancer, diabetes and heart disease and make the UK the place for ethical data research.

Notes to editors

1. The Digital Innovation Hub programme forms part of the modern Industrial Strategy's Data to Early Diagnosis and Precision Medicine Challenge led on behalf of UK Research and Innovation by Health Data Research UK (HDR UK).
2. The investment in Digital Innovation Hubs builds on smaller UK digital innovation projects currently underway and also funded through the Industrial Strategy Challenge Fund (ISCF) that show the exciting potential for larger programmes.
3. For further details about the Digital Innovation Hub Programme visit HDR UK's website.
4. For information about the funding opportunity visit the Medical Research Council (MRC) website.

Medicines Discovery Catapult

New report unveils a thriving service and supply sector for UK medicines discovery

13 May 2019

Driving innovation into state-of-the-art technologies such as Artificial Intelligence and Complex Cell Models is key to maintaining the UK's global competitiveness

Today (13th May 2019), Medicines Discovery Catapult and the BioIndustry Association unveil their 2019 State of the Discovery Nation report, providing new insights into the UK's growing medicines discovery industry.

The report reveals a thriving service and supply sector for the UK in addition to its R&D biotechs. It also highlights two breakthrough technologies set to influence the future of medicines discovery and maintain the UK's global competitiveness.

The research found that service and supply companies account for **80%** of small and medium enterprises (SMEs) in UK medicines discovery, and **90%** of employment. While **20%** of companies are actively focussed on therapeutic product development.

With SMEs at the heart, UK medicines discovery is a large, diverse, vibrant and growing sector. This core biopharma sector alone increased turnover by £3.3bn and created 47 new businesses between 2016 and 2017.

Key insights from the report reveal:

- 300 companies are focussed on discovering potential new medicines; 70% are working in the areas of cancer, anti-infectives and the central nervous system
- 1,200 companies provide vital services and supplies
- Despite their size, SMEs are a critical source of innovation for new medicines; 60% have fewer than 5 staff and 80% have fewer than 20 people within the company

In addition, the BIA's benchmarking report showed that by 2025 the UK could support an additional:

- 33,000 biotech jobs
- 50 biotech companies at early clinical stage

The importance of companies working within the service and supply sector should not be underestimated, they are key to maintaining the UK's global competitiveness in a sector that's critical for UK plc. In 2015, the life sciences industry contributed £30.4 billion in UK GDP, supported 482,000 jobs and contributed £8.6 billion in taxes.

Service and supply companies are an essential part of the industry and include: contract research organisations (CROs), advisory services, consultants as well as organisations that provide to access to state-of-the-art technologies and laboratory capabilities.

They enable the sector to deliver discovery projects that are more predictive and improve R&D productivity, thereby attracting industry investment into R&D in the UK. Improved productivity is integral to the UK's Industrial Strategy which aims to build a Britain fit for the future and raise total R&D investment to 2.4% of GDP by 2027.

Insights from the field of **Artificial Intelligence (AI)** and **Complex Cell Models (CCMs)** reveal that the UK now has an opportunity to apply new cutting-edge science and technology to make medicines discovery more productive.

The report reveals that the medicines discovery community view **AI** as not only one of the current 'hot areas', but integral to improving medicines discovery decision making.

- **90%** of medicines discovery companies confirmed a need for AI
- **75%** of current AI spend is on data access, curation and data labelling
- AI budgets are growing, but the industry is calling for benchmarks and comparisons between AI systems
- Small companies prefer to sell their assets; large companies prefer embarking on partnerships

Medicines discovery generates a huge quantity of complex biological, chemical, clinical and safety information. Data science is critical to making the best decisions on which drugs to optimise or progress.

The report also reveals that **Complex Cell Models (CCMs)** are a trend to watch. They have great potential to make preclinical research more likely to predict a drug's effects in clinical trials.

- UK SMEs are asking for validation of CCMs
- Engagement with regulators is vital to speed up the use of CCMs
- Improving reproducibility and developing validation data are immediate priorities
- Adoption is small-scale and experimental, with regulation the enabler for growth

CCMs, such as 3D biological models and testing systems using human tissue, can provide data that's more relevant to patients than animal tests. Ultimately, they could replace traditional 2D cell cultures and animal testing in pre-clinical research.

Chris Molloy, Chief Executive Officer of Medicines Discovery Catapult, says:

> The UK should be proud of the vibrancy of its medicines discovery community and thriving service and supply sector. The UK cannot conduct medicines discovery without access to this diverse range of skills, technologies and expertise. It is vital that we maintain our global competitiveness and R&D services can be a major sector driving international trade. The report's findings help shape our strategy at MDC and we will continue to strengthen R&D productivity to create new medicines for patients.

Steve Bates OBE, Chief Executive Officer of the BioIndustry Association, says:

> This report shines a light on a key but often overlooked group of companies vital to the life science ecosystem in the UK. Many virtual and small biotechs, as well as established global pharma players, rely on the expertise and capability of UK service providers. As such the economic benefit in jobs and growth in UK life science, especially outside the South East of England, is often delivered via sub-contracting and the provision of services. It's vitally important policy makers understand this network and supply chain as we work together to deliver the UK life science industrial strategy.

Dr Kath Mackay, Director – Ageing Society, Health & Nutrition, Innovate UK says:

> As this report shows, the UK is a global leader in developing medicines. By maintaining and building upon this leadership we can deliver real benefits to patients and for the economy. Innovate UK, working with its health catapults – Medicines Discovery and Cell and Gene Therapy – and now with the centres funded by the Industrial Strategy Challenge Fund, it is bringing together researchers and entrepreneurs to rise to the health challenges of now and those of the future.

Today's report provides confidence that a vibrant and more productive medicines discovery sector will positively impact employment, economic growth and deliver better medicines for patients, faster. This is a key sector for UK plc.Download State of the Discovery Nation 2019 >

Department of Health and Social Care, Department for International Trade, Department for Business, Energy & Industrial Strategy, Office for Life Sciences, Life Sciences Organisation

£1.3 billion industry/government investment in UK economy and new partnership driving early disease detection

The second Life Sciences Sector Deal will support healthcare innovation and back businesses to create high-paid, high-quality jobs.

5 December 2018

- life-saving early disease detection technology to be developed by new partnership between government and industry using artificial intelligence (AI) to develop the next generation of treatments, including a first-of-its-kind national health programme
- the second Life Sciences Sector Deal, with industry investment from 10 companies, will support healthcare innovation and back businesses to create high-paid, high-quality jobs as part of the government's modern Industrial Strategy
- the deal signals a vote of confidence in UK industry, with global biopharmaceutical company UCB investing around £1 billion in research and development, including in a new state-of-the-art facility

Tens of thousands of lives could be saved by pioneering research to detect deadly diseases before symptoms even appear, thanks to a new collaboration between the government and the Life Sciences Industry. The deal will also announce that global biopharmaceutical company UCB is investing £1 billion in research and development, including in a new state-of-the-art facility, continuing the UK's reputation as a world leading base for global life sciences research and industry.

The programme, backed by up to £79 million of government funding, will study 5 million healthy people to develop new diagnostic tests using AI and is part of the government's Life Science's Sector Deal 2, announced today by Businesses Secretary Greg Clark and Health Secretary Matt Hancock.

View the Life Science Sector Deal 2.

The deal, which brings together 10 companies and is backed by wide range of organisations from across the sector, includes more than £1.3 billion of investment between the public and private sectors. It ensures the UK remains in pole position in the treatments of today, while creating the industries and treatments of the future such as genomics and AI-powered diagnosis.

Business Secretary Greg Clark said:

> From the first vaccine to the discovery of DNA, the UK has always been at the forefront of medical endeavour and healthcare innovations. That is why we are building on our unique strengths by placing life sciences at the centre of our modern Industrial

> Strategy, backed by the biggest increase in public research and development investment in UK history.
>
> This is our modern Industrial Strategy in action as we work hand in hand with industry to ensure the UK remains the go-to destination for launching new businesses, new discoveries and treatments to benefit health around the world.
>
> The announcement of UCB's investment in new research and development is a clear vote of confidence in UK life sciences research base and business.

The programme – Accelerating Detection of Disease – will be led by Professor Sir John Bell and brings together the NHS, industry and leading charities including Cancer Research UK, the British Heart Foundation and Alzheimer's Research UK. It will be the largest ever study of its kind collecting such a range of data from healthy volunteers over years. This will help deliver the Early Diagnosis Mission — a key part of the Industrial Strategy's AI and Data Grand Challenge. Businesses will be able to access this funding through UKRI managed competitions.

Researchers will study how the group's health changes, identifying common characteristics to understand how and why diseases develop. The ambition is to empower everyone to understand their risk of developing diseases and take steps to remain healthy for longer. The project will attract investment from global life science companies seeking to develop new diagnostic tools and treatments.

It is estimated that if late stage diagnosis were halved across bowel, ovary, prostate and lung cancer, over 55,500 more people would be diagnosed at an early stage, potentially resulting in 22,500 fewer deaths per year within 5 years of diagnosis.

In a meeting with industry leaders at No10, the Business Secretary announced that as part of the Sector Deal a new £150-200 million research and development facility of global biopharmaceutical company UCB will be built in the UK as part of a total investment of around £1 billion over the next 5 years. The transition to this state-of-the-art facility will support around 650 jobs and further boost the UK's reputation for developing world-leading medical treatments and technologies.

Health Secretary Matt Hancock said:

> I want the UK to have the most advanced health and care system on the planet. Technology and artificial intelligence have the potential to revolutionise healthcare by unlocking the next generation of treatments, diagnosing diseases before symptoms appear and helping patients take greater control of their own health.
>
> Our world-leading plans to map 100,000 genomes is just one example of how innovation can deliver life-changing results for patients and we want to build on its success to provide patients with truly personalised care.

Jean-Christophe Tellier, Chief Executive Officer at UCB, said:

> At UCB, we are proud of our heritage in the UK and I am very pleased to announce our planned investment to support the construction of a major R&D hub in the UK, which will enable us

> to build upon our numerous active collaborations with UK universities, biotechs and medical research charities, and continue our successful track record of bringing innovative medicines discovered in the UK to patients globally
>
> Access to world class talent remains vital to R&D and we therefore look forward to working closely with government to support the full implementation of Sir John Bell's Life Sciences Industrial Strategy, and importantly, to ensure that patients in the UK have quicker access to the innovative medicines researched and developed here.

Professor Sir John Bell said:

> This Sector Deal is another major step forward for the Life Sciences Industrial Strategy in the UK. It has been hugely enabled by government and will initiate new projects that will be a magnet for further investment.
>
> Together, industry, charities, government and the NHS can tackle some of the major challenges to healthcare systems, including ageing and early diagnostics and, in doing so, can grow the economy and demonstrate what a modern Industrial Strategy looks like in action.

Secretary of State for International Trade, Dr Liam Fox MP said:

> The UK remains the leading destination for life sciences inward investment in Europe, second only to the US globally. Major global companies continue to commit to the UK as an investment and operating location.
>
> At home we are also nurturing the next crop of global businesses and future exporters, such as the companies in our thriving cell and gene therapy industry. Last year the UK exported around £30 billion in life sciences products - there is worldwide demand for our innovative products and our excellent services.
>
> As an international economic department, our role is to promote the UK abroad, capitalising on the demand for our goods and services and drive investment into our industries. Our team of HM Trade Commissioners and overseas network are based in 108 markets, providing a vital link for businesses as we seek to make the most of opportunities presented by leaving the European Union.

Other new announcements as part of the Life Sciences Sector Deal include:

- A further £30 million investment in the UK by healthcare company Roche, including a £20 million investment over 3 years in a precision cancer research partnership with the Christie NHS Foundation Trust in Manchester. This will use cutting-edge genomic technology and big data to accelerate the next generation of digital clinical trials for rare cancers, making the UK a leading global hub for rare cancer trials, potentially benefiting nearly 5,000 patients annually
- Measures to further strengthen the UK environment for clinical research, including through IQVIA investing £24 million facilitated by the National Institute for Health Research in a Prime Site for clinical trials across the North of England, and IQVIA and Genomics England announcing a new £20 million

partnership to enable more efficient drug research and support accelerated discovery of personalised medicines for NHS patients

- Over £80 million of investment in the UK from 5 rapidly growing cell and gene therapy companies. The majority of this investment will be in cutting-edge manufacturing facilities, building on the government investment in advanced therapies manufacturing made in last years' Sector Deal. Autolus have planned to invest a further £50 million to expand its UK presence, including a new global headquarters with laboratories in White City. Oxford BioMedica, Cobra Biologics, and Roslin CT are planning investments of £19 million, £8 million, and £4 million respectively to scale up their UK cell and gene therapy manufacturing facilities. Bellicum, an inward investor, has committed to its first European investment in the UK with £2 million and 20 jobs initially.

Today's announcement builds on the first Life Sciences Sector Deal, published in December 2017. The deal committed nearly £500 million of government investment into UK life sciences, backed by more than £1 billion of private sector investment, to build on the sector's strengths, help to secure thousands of jobs and ensure that new medicines and technologies are created in the UK.

In the last year its achievements have included:

- kick-starting the largest whole genome sequencing project ever undertaken, helping to develop new tests and treatments for cancer and rare diseases
- establishing a network of 5 centres of excellence in digital pathology and radiology to supercharge new diagnostic industries
- Implementing the Accelerated Access Review with government, industry, the NHS and its partners working together to put NHS patients at the forefront of the latest advances in healthcare

It has also been announced today, through the Strategic Priorities Fund, that research programmes will be awarded over £35 million to boost medical science. The first programme will seek to better understand tissue development through the Human Cell Atlas initiative, whilst the second will bring together the physics and biology communities to address key questions in biological and biomedical sciences.

The new Life Sciences Sector Deal further strengthens the UK's world-leading capabilities in the likes of genomic science, Big Data assets and gene and cell therapies, ensuring we are at the forefront of new industries in areas such as genomics and AI-driven diagnostics.

The UK remains the number 1 destination for life sciences inward investment in Europe, ranks number 2 globally behind the US, and has also grown a thriving domestic industry with more than 5,600 companies supporting 240,000 jobs and generating a turnover of around £70 billion per year. All of the top 25 global pharmaceutical companies, and the top 30 global medical technology companies,

operate in the UK. The UK also accounts for 12% of total life sciences academic citations and 18% of the most-cited publications – the second highest share above China, Germany and Canada.

Notes to editors

The up to £79 million Accelerating Detection of Disease programme will be delivered by UK Research and Innovation through the Industrial Strategy Challenge Fund, subject to business case approval and match funding from industry.

UCB is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases in immunology or neurology. The investment around £1 billion over the next 5 years will include £150-200 million to build a new, purpose-built state-of-the-art facility enabling cutting-edge R&D, early manufacturing and commercial operations. The transition to this new facility will support around 650 high-skilled jobs, mainly in scientific research and early manufacturing. The investment will allow UCB to continue their innovative research in areas of unmet patient need, deepen their collaborations with UK organisations, and solidify their position as a leader in UK life sciences. UCB's new facilities will be based in or close to the wider Slough area and will be announced subject to UCB finalising their search for a suitable location and agreed contractual negotiations.

The Ageing Society mission with the modern Industrial Strategy is to ensure that people can enjoy at least 5 extra healthy, independent years of life by 2035, while narrowing the gap between the experience of the richest and poorest.

It is estimated that by 2033 if late stage diagnosis were reduced by 50% across bowel, ovary, prostate and lung cancer, over 55,500 more people would be diagnosed at an early stage, which could result in over 22,500 fewer deaths per year within 5 years of diagnosis. This is calculated by Cancer Research UK based on current distribution of stage at diagnosis for cancers with a recorded stage of disease in England (obtained from Public Health England), cancer incidence projections for 2033 and estimates for 5-year cancer survival by stage.

Using data, artificial intelligence and innovation to transform the prevention, early diagnosis and treatment of chronic diseases is the first mission of the AIand Data Grand Challenge. Success in this mission is one of a number of steps towards saving lives and increasing NHS efficiency by enabling earlier diagnosis and reducing the need for costly late stage treatment. The opportunity - working with academia, the charitable sector, and industry and harnessing the power of AI and data technologies - is considerable. It should lead to a whole new industry of diagnostic and tech companies which would drive UK economic growth.

The Accelerating Detection of Disease project also supports the Ageing Society Grand Challenge mission, which is to ensure that people can enjoy at least 5 extra healthy, independent years of life by 2035, while narrowing the gap between the experience of the richest and poorest.

Association of the British Pharmaceutical Industry

UK Clinical Research Post Brexit

09 Aug 2018

In a week that sees the MHRA and CRUK publish critical information about the UK's clinical research environment post-Brexit, ABPI's Deputy Chief Scientific Officer Dr Sheuli Porkess explores what it means for the pharmaceutical industry.

It's been an important week for clinical research, with two important documents published which should go a long way in helping to support clinical research as the UK leaves the EU.

Cancer Research UK has published a comprehensive report exploring the impact of Brexit on the future of clinical trials as a whole and cancer trials in particular in the UK and EU.

This comes shortly after the MHRA published an important notice regarding the Clinical Trials Regulation and its role in the UK during the implementation period under the terms set out in the draft Withdrawal Agreement.

The new Clinical Trials Regulation is a major step forward. It will enable a streamlined application process, harmonised assessment procedure, single portal for all EU clinical trials and simplified reporting procedures, including for multi-Member State trials. That's why it's good news that even if the new regulation does not come into force during the implementation period, the Government has confirmed UK law will remain aligned with parts of the CTR legislation. This will mean researchers conducting clinical trials can plan with greater certainty.

Today's Cancer Research UK report details short and long-term issues which need to be addressed to support clinical research and patients in the UK. At the ABPI we support these findings.

In 2017, there were 823 applications for commercial clinical trials of medicines in UK. It is in the interests of patients and medicines development for us to find a way to continue to work together in clinical trials. The UK Government's proposals for a new 'Science and Innovation Pact' with the EU say that collaboration enables researchers to work at greater scale than they can in their own countries and the proposals supports this spirit of future science collaboration.

Here is an analysis of some of the key points which are particularly relevant to pharmaceutical companies.

- *Participation in the forthcoming EU regulatory system for clinical trials*. This will support the UK's continued leadership in clinical research. It will allow UK patients to take part in developing new medicines. It is also aligned with the MHRA's notice about the terms of the Brexit implementation period and would avoid longer term disruption in clinical research.
- *Trade barriers should not impact on clinical trials.* It is critical that the UK and EU ensure that trade barriers do not impact the

availability or movement of investigational medicinal products (IMPs), clinical trial supplies and medicines after the UK leaves the EU. 70% of all IMPs in ongoing EU trials are QP released from the UK. It is important to make sure that patients who are participating in trials – both in the UK and the EU - at the time of Brexit are able to continue to get their trial medicines.

- *UK Government should focus on long term funding initiatives.* The UK Government should continue to develop long-term funding initiatives for clinical trials. Trials may be funded by industry, charities, the public sector - or a combination. Mechanisms must be in place for this to happen internationally. The Government's commitment to increase investment in UK R&D to 2.4% of GDP by 2027 is welcome and must be complemented by funding of international collaborations. Implementation of the Life Sciences Industrial Strategy in full is also needed to support the ambitious goals for clinical trials set out within the Strategy.
- *Getting the right talent.* The UK and EU must continue to co-operate and develop new migration arrangements which enable scientists and doctors working on clinical trials to continue to collaborate.

When patients take part in clinical trials, they are helping the patients of the future. We know from our own research this year that clinical research is important to people; two thirds (66 per cent) of British people said they are willing to allow the NHS to use their healthcare data for medical research. This important report sets out just why we must take great care to safeguard the future of clinical research for patients not just in the UK, but across the whole of the EU.

House of Commons Science and Technology Select Committee

Committee proposes a new immigration system for skilled workers post-Brexit

19 July 2018

The Science and Technology Committee calls for visa free travel and permit-free work in the UK for short-term stays for skilled workers, a relaxation of Tier-1 requirements and the removal of the Tier-2 visa cap

- Read the report summary
- Read the report conclusions and recommendations
- Read the full report: An immigration system that works for science and innovation

The Report sets out the Committee's proposal for an immigration system for the science and innovation sector, and skilled workers more generally. The Committee developed the proposals following

Government inaction on the issue and the urgency of the situation facing the UK's science and innovation sector.

Chair's comments

Norman Lamb MP, Chair of the Science and Technology Committee, said:

> Collaboration is crucial to the UK maintaining its position as a science superpower, and it is essential that the UK has an immigration system that facilitates the mobility of the science and innovation community. Delay in confirming how the system will work following Brexit is deeply damaging. Industry and research communities urgently need certainty.
>
> "If the UK wishes to remain open and attractive to the brightest and best global talent following Brexit, it requires an immigration system that allows researchers, technicians, students and innovative entrepreneurs to arrive and work in the UK without facing a burdensome and daunting process.
>
> "Nobody wants to see damage to our economy as a result of restricting the ability of skilled workers to come to this country. This is essential for our future prosperity.

EEA migration to the UK

The Committee's proposed immigration system has been developed to tackle the pressing matter of EEA migration to the UK after we leave the EU, though it sees clear advantages to applying it to non-EEA countries. It:

- Recommends that the Government establishes visa-free and permit-free work in the UK for up to 180 days for skilled workers.
- Proposes that for long-term migration to the UK, a five-year skilled work permit should be established for those with either an offer of employment, a minimum salary that reflects both the going rate for the job, as well as regional, and public/private sector, differences in salary, or third-party sponsorship.
- Sets out the steps that the Government can take now, unilaterally, to the current non-EEA immigration system while negotiations with the EU are ongoing.
- Highlights concerns that the eligibility criteria for the Tier 1 (Exceptional Talent) visa are too stringent and that this has resulted in a poor uptake of the visa.
- Calls on the Government to reinstate the Tier 1 (Post-study work) visa, so that talented, international graduates, who have chosen to study at a UK higher education institution, are able to contribute further to the UK economy through working here.
- Calls on the Government to remove the cap on Tier 2 (General) visas and reduces the cost of making an application.

Norman Lamb MP, Chair of the Science and Technology Committee, said:

> Our framework details a sustainable and enforceable system of immigration which should form the basis of further detailed work by the Government with the science and innovation community. Ultimately, it sets out the basis for an immigration policy that promotes the UK as the go-to place for science and innovation, and one that facilitates the global movement of talent into the UK.

The Committee's proposal rests on the following principles:

- support individuals with different types and levels of skill, and who are at different career stages, as well as their dependants;
- facilitate both long-term and short-term stays in the UK;
- enable further travel, outside the UK, for research purposes, without it harming an individual's ability to apply for indefinite leave to remain;
- an efficient, streamlined and low-cost application process for employees and employers;
- readily recruit highly skilled people, wherever they are from, without being subject to an annual limit; and
- assess skills in a way that is not wholly reliant on salary as a proxy for skill.

Background information

In its earlier Report, Brexit, science and innovation, the Committee recommended that the Migration Advisory Committee "bring forward its conclusions in relation to the immigration arrangements needed to support science and innovation" in order for the Government to "build these into a science and innovation agreement with the EU by October 2018 or earlier if possible".

This recommendation was rejected by the Government. The Committee subsequently decided to take the proactive step of developing its own proposals for an immigration system that works for science and innovation.

This week the 'Together Science Can' campaign published its report on 'Supporting researchers to move internationally: a profile of visa systems'.

Data was compiled by the law firm Fragomen to examine the immigration routes available to researchers, from PhD students to established academics, across 22 countries (including the UK) chosen to represent a variety of established and emerging research communities.

The report found that half of the countries' systems reviewed had a dedicated immigration route for researchers.

House of Lords Science and Technology Committee

Government must do more to implement the Life Sciences Industrial Strategy

26 April 2018

The House of Lords Science and Technology Committee's report 'Life Sciences Industrial Strategy: Who's driving the bus?' raises serious concerns about the Government's commitment to delivering the strategy which has so far been "wholly inadequate" and recommends there should be sweeping simplification of its implementation arrangements.

- Report: Life Sciences Industrial Strategy: Who's driving the bus? (HTML)
- Report: Life Sciences Industrial Strategy: Who's driving the bus? (PDF)
- Evidence volume: Life Sciences Industrial Strategy: Who's driving the bus? (PDF 12.68 MB)
- Inquiry: Life Sciences and the Industrial Strategy
- Science and Technology Committee

Overview

The success of the life sciences sector is vital to the UK economy and the health and wellbeing of the population. The report focusses on the issues that require immediate action to ensure the development and expansion of the sector.

Over the course of the inquiry, the Committee has uncovered complicated arrangements for strategy's implementation and a lack of clear authority and accountability. This raises questions about the Government's commitment to implementing the Life Sciences Industrial Strategy.

Chairman

Lord Patel, Chairman of the Committee said:

> If implemented correctly the Life Sciences Industrial Strategy will make a major contribution to the future economic prosperity of the UK but what became clear throughout our inquiry is that it stands little chance of success without a detailed plan for implementation and clear lines of authority, responsibility and accountability.
>
> The Government has an opportunity right now to get ahead of international competition. It can, and must, take bold steps to secure the future growth and expansion of the life sciences sector. This is even more vital as the UK prepares for life outside the European Union.

Key findings from the report

The Life Sciences Industrial Strategy has already secured the commitment of the business, charity and academic communities. But

the central role of the NHS in the life sciences means only the Government can take the lead.

The Committee recommends there should be a single body with complete oversight the implementation of the strategy called the Life Sciences Governing Body. The Business, Energy and Industrial Strategy Secretary and the Health and Social Care Secretary must ensure this Body has the cross-Government backing it needs to do its work.

The Government has failed to engage the NHS effectively even though the NHS is critical to the delivery of the strategy. As a result, the NHS's commitment to the strategy has so far been incoherent, uncoordinated and ineffective. It does not currently have the capacity to rise to the challenge of its implementation and current NHS structures stifle innovation.

The Committee urges the NHS to give greater priority to the uptake and spread of innovation and to rewarding clinicians and managers who make such adoption successful. The Government should explore how it can offer financial incentives to those NHS trusts that adopt and spread proven innovations.

House of Commons Science and Technology Committee

Committee calls for early deal for science and research

21 March 2018

The Science and Technology Committee publishes its report on Brexit, science and innovation. The report sets out the Committee's views on the priorities for the science and innovation sector in future negotiations with the EU, ahead of the European Council Summit this week.

- Read the report summary
- Read the report conclusions and recommendations
- Read the full report: Brexit, science and innovation
- Watch the Brexit: Science and Innovation summit

The evidence included within the report was gathered during the Committee's Brexit: Science and Innovation summit on 22 February 2018.

Recommendation: An early deal for science

The Committee calls for an early deal for science and research with the EU – to be in place by October 2018 or earlier if possible. The report argues that negotiating a deal on science is a 'win-win' for the UK and the EU, and so getting an early agreement could set a positive tone for other elements of the negotiations.

However, if there were to be a protracted delay in agreeing this, it would have unfortunate effects, and it cannot be taken for granted that the UK will retain its leadership position in science and innovation. The

Committee concludes that reaching an agreement on this should now be as important to the Government as addressing the question of security.

Recommendation: Participation in Framework Programme 9

The Committee is concerned that the Government's default position does not appear to be that the UK will participate in Framework Programme 9 (FP9) – the EU's next flagship research funding programme.

The Committee recognises that if the price of taking part is too high, or the focus on excellence is diluted, then a change in approach might be warranted, but calls on the Government to state clearly that it intends to secure Associated Country status for FP9.

Recommendation: Clarity for EU students from 2019

The Committee has also called on the Government to clarify the status of students applying to study in the UK in 2019, given that many universities will soon be distributing information about the 2019 academic year.

Chair's comments

Norman Lamb MP, Chair of the Science and Technology Committee, said:

> The UK's science and innovation sector is in a strong position as the UK enters the Brexit negotiations. The UK is home to four of the world's top ten universities and the Government has committed to raising funding by £4.7 billion by 2021. But we can't take it for granted that we will retain this world-leading position. A concerning lack of clarity remains over access to funding, association with regulatory bodies, and immigration policies.
>
> Cooperation on science and innovation is a 'win-win' for the UK and the EU. An early deal would provide assurances to researchers, students and academics, and could set a positive tone for future negotiations. It is crucial that the Government acts swiftly. If it fails to do so both sides could suffer considerably as a result.

Department for Business, Energy & Industrial Strategy

Government and life sciences sector agree transformative sector deal

Business Secretary Greg Clark and Health Secretary Jeremy Hunt announce a Sector Deal with the life sciences sector.

6 December 2017

- Business Secretary Greg Clark and Health Secretary Jeremy Hunt have today (Wednesday 6 December) announced a Sector Deal with the life sciences sector

- significant investment by 25 organisations from across the sector and supported by government will ensure the UK is at the forefront of developing new innovative treatments and medical technologies that improve patient lives
- the transformative Sector Deal gives the life sciences sector and government an agreed set of strategic goals that will ensure the UK builds on its exceptional reputation for science and research, genomics and clinical trials

A transformative Sector Deal between the UK life sciences sector and the government has today (Wednesday 6 December) been announced. This draws substantial investment into the sector from across the world, ensuring that the next wave of breakthrough treatments, innovative medical research and technologies, and high skilled jobs are created in Britain.

A key part of the Industrial Strategy White Paper, the Life Sciences Sector Deal sets out an agreed strategic vision, built on co-investment, for the government and UK life sciences that will modernise the industry, boost businesses large and small within it, and ensure the sector is perfectly positioned to respond to the challenges and opportunities of demographic change and pioneering research and development.

The deal brings together a number of significant commitments and investments into the UK by 25 global organisations from across the sector, including a major investment by global healthcare firm MSD, known as Merck and Co. Inc. in the US. The investment by MSD will include a new world-leading life sciences discovery research facility and headquarters in the UK, supporting 950 jobs including 150 new high-skilled and high-value research roles.

Business Secretary Greg Clark said:

> Across the world, advances in science and technology are transforming the way we live our lives. Nowhere is innovation more life-changing than in medicine, healthcare and its associated fields.
>
> New discoveries and the applications of new technologies are making diagnoses earlier and more accurate, making new treatments available and existing ones more effective; and making care more beneficial and comforting.
>
> The United Kingdom is extraordinarily well-placed to play a leading role in this revolution in the life sciences. Our universities and research institutes rank among the best in the world. They nurture and attract some of the most inventive people on earth.
>
> We are home to many of the most successful global life sciences businesses and we are also a hotbed of new businesses – springing up to bring new discoveries and techniques to a wider market. Our National Health Service is a prized national asset – the nation's biggest employer and a deep source of learning and of translating discoveries into care.
>
> That is what our Industrial Strategy sets out to support and achieve. So it is appropriate that the first Sector Deal of our Industrial Strategy should be with the life sciences sector.

Health Secretary Jeremy Hunt said:

> The UK has a huge amount to offer the life sciences sector, combining globally renowned scientific research bases with our world leading NHS which allows innovators to test and refine products at scale.
>
> Today proves that life science organisations of all sizes will continue to grow and thrive in the coming years, which means NHS patients will continue to be at the front of the queue for new treatments.

The government and industry have worked extensively since the launch of the Industrial Strategy green paper to secure the deal, with Professor Sir John Bell convening industry involvement in the deal. Yesterday evening, representatives from the companies involved in the deal attended an event at 10 Downing Street to celebrate the success of the sector, attended by Business Secretary Greg Clark and Health Secretary Jeremy Hunt.

Secretary of State for International Trade, Dr Liam Fox said:

> Today's deal is a clear signal to life science investors around the world that the UK is open for business and a world leader in scientific innovation. The Department for International Trade has provided dedicated support to make this investment possible, and that offer is available to all investors through our global network.
>
> As an international economic department our role is to promote the UK as a premier destination to invest, and we are ready to work with potential investors to secure our capital requirements for infrastructure, regeneration and innovative projects in every part of the country.

Regius Professor of Medicine, University of Oxford, Professor Sir John Bell said:

> This Life Sciences Sector Deal demonstrates how powerful it can be to have industry, the NHS, the research community and charities all working together to provide important new insights that can lead to the discovery and implementation of novel innovations for healthcare.
>
> It represents a significant change in both pace and culture that I hope will lead to a flow of such investments into the future.

Key themes of the deal

The deal sets out a plan for key priorities for the sector going forward, with a vision and strategy that are aligned to the pillars of the Industrial Strategy and the themes of Sir John Bell's Life Sciences Industrial Strategy. It includes action on the technologies of the future and the evolution of clinical trials, alongside government support for direct and indirect investment to support growth.

Each theme sets out a programme of action:

Research

Building on the UK's position as a world leader in biomedical discovery with major inward investments, including MSD announcing a new state-of-the-art R&D hub in London.

Technologies of the future

The deal outlines plans to grow the UK's international reputation for pioneering early diagnostics and genomics programmes, with a government investment from the Industrial Strategy Challenge Fund of up to £210 million, subject to business case. This will contribute to the genomics programme in partnership with organisations including GSK and AstraZeneca and launch a trail-blazing AI programme to develop digital pathology and radiology programmes in partnership with industry, embedded in the NHS.

The evolution of UK clinical trials capabilities

Ensuring that the UK continues to lead the world with its clinical trials, through innovative new trials platforms and investments in the UK's digital evidence collection abilities, combined with a progressive regulatory system. The Medicines Company is today announcing new trials that will use novel methodologies.

Business environment

The government has committed £162 million, through the first wave of the Industrial Strategy Challenge Fund, to develop innovative medicines manufacturing infrastructure and enable SMEs to manufacture advanced therapies. This includes 2 new national centres – Medicines Manufacturing Innovation Centre and a Vaccines centre – adding to the existing national centres and 3 advanced therapy treatment centres co-located in hospitals across the UK as well as funding for viral vectors.

Investment across the UK

The UK has a number of world-class life sciences clusters across the country and today's deal delivers on the Industrial Strategy's aim to distribute growth and opportunity across the country, with pioneering investments in Manchester, Leeds, Sheffield, Glasgow, South Wales and the South East.

The Sector Deal, published on GOV.UK at 9am, sets out full details of the agreed strategy with details of each investment coming into the UK. It includes:

- MSD: a commitment by MSD to establish a state-of-the-art life sciences discovery research facility in London, focussed on early bioscience discovery and entrepreneurial innovation; MSD believes that locating a research facility in London will expand its opportunity to engage with leading researchers in the UK and Europe
- Johnson & Johnson: one of the Janssen Pharmaceutical Companies of Johnson & Johnson, Janssen Pharmaceutica NV, and the University of Oxford intend to collaborate on novel clinical trial methodologies in the UK; these would include platform trials, focused on mental health disorders such as depression
- Medicines Company: The Medicines Company has initiated 2 projects – one with the University of Oxford to perform a large

multinational cardiovascular disease clinical trial and another with The Greater Manchester Health and Social Care Partnership to improve the understanding, management and economics of cardiovascular disease

- GSK and AstraZeneca: significant investments by GSK and AstraZeneca in initiatives to harness advances in genetic research in the development of medicines

Government announced in August £162 million of funding focused on medicines manufacturing from the first wave of the Industrial Strategy Challenge Fund (ISCF) and an additional £86 million as part of the response to the Accelerated Access Review. Building on this, as part of the Industrial Strategy white paper, government committed through ISCF's Wave 2 up to £210 million, dependent on businesses cases, for early diagnostics programmes including funding for genomics research and using AI with digital pathology and radiology.

Dr Roger M. Perlmutter, President of MSD Research Laboratories said:

> For more than a century, MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases.
>
> The announcement of our plans to bring a new Discovery Centre to London, as part of the Life Sciences Sector Deal, will enable us to collaborate with scientists conducting promising emerging science in the UK.
>
> Our new site will combine MSD's powerful and proven R&D engine with the cutting edge technologies and deep discovery capabilities afforded by the biomedical research community in the golden triangle of London-Oxford-Cambridge as well as access to the continental European life science ecosystem.

Dr Richard Mason, Head of Johnson & Johnson Innovation, EMEA said:

> At Johnson & Johnson we collaborate with the brightest minds in every field to drive innovation, change and transformation in healthcare.
>
> We are proud to be part of today's sector deal, demonstrating our commitment to UK life sciences and to ensuring that the UK remains at the forefront of new innovations.
>
> Our partnership with Oxford University will focus on mental health disorders, which is a priority area of focus for the NHS.

Phil Thomson, President, Global Affairs, GSK, said:

> The UK has a world class life sciences sector, but that will only continue to thrive through a strong partnership of government, industry and academia.
>
> This Sector Deal contains a number of very practical commitments to strengthen the UK's life science base and make it more attractive to international investment in areas such as clinical trials and high-tech research.
>
> Ultimately, this should provide benefits to the economy and create jobs. We look forward to seeing further initiatives result from this strategy for the sector.

Mene Pangalos, Executive Vice-President, Innovative Medicines and Early Development (IMED) Biotech Unit and Business Development, at AstraZeneca, said:

> Establishing the UK as a global leader in genomics and precision medicine closely aligns with AstraZeneca's ongoing research programmes and ambitions for the future of medicine.
>
> The UK is one of the best places in the world for cutting-edge science, as is reflected in AstraZeneca's investment of £500 million in our new strategic R&D centre and global headquarters in Cambridge.
>
> The Life Sciences Sector Deal will complement the work of our existing partnerships with Genomics England and others to analyse two million genomes by 2026, helping us to unlock the full benefits that targeted medicines present for patients and the NHS.

Clive Meanwell, Chief Executive Officer, The Medicines Company, said

> Our exciting and productive partnerships with the University of Oxford and with The Greater Manchester Health and Social Care Partnership demonstrate the significant potential for The Life Sciences Industrial Strategy to drive growth through new forms of collaboration.
>
> We also believe that our work with these two groups demonstrates the UK's unique capabilities in clinical trials and in digital healthcare data systems which are rapidly emerging as critical capabilities in the life-science sector worldwide.

Peter Ellingworth, Chief Executive Officer, ABHI, said

> I welcome today's announcement and with continued government backing, the UK will be a world leader in developing new medical treatments and technologies in the life sciences.
>
> This deal will not only benefit the MedTech sector, but the healthcare system and the economy as a whole. If we are to ensure the value our industry provides is realised, high levels of sustained NHS collaboration will be crucial to its success.

Mike Thompson, Chief Executive Officer, ABPI, said:

> Today's announcements are a great start towards industry and government working together to deliver the long-term strategic roadmap set out in the Life Sciences Industrial Strategy.
>
> These are smart investments for the future that acknowledge the government's willingness to build upon the UK's global strength in R&D, our leadership in new technologies such as genomic medicine and the potential that exists in making the best use of health data.
>
> If we get this right - if the Life Sciences Industrial Strategy is implemented in full - the UK can open itself up to be at the forefront of cutting-edge clinical research. NHS hospitals will reap the benefits of global clinical trials and the financial rewards they bring; doctors can prescribe the latest treatments and patients will get the best standard of care. This ecosystem will deliver for everyone.
>
> Next year could be a transformative year for the NHS as we work together to deliver this innovation to underpin a more productive health service.

Royal College of Physicians

Brexit: What does it mean for medical research?

12 April 2017

Brexit: medical research FAQs

Brexit: What does it mean for medical research? is part of a series of briefings produced by the Royal College of Physicians (RCP) outlining key statistics on topics surrounding Brexit negotiations and beyond.

Medical research in brief

Funding – the UK is considered a world leader in medical research, having produced around 25 of the top 100 prescription treatments.[1] The UK currently benefits from access to research funding from EU funding programmes such as Horizon 2020 and the Innovative Medicines Initiative.

Clinical trials – the UK is very successful at conducting clinical trials, sponsoring around 1,500 trials that include other EU countries – half of these will still be occurring in 2019.[2] Particularly for rare disease trials, it is important to collaborate internationally, as there are not enough patients within one country alone.

Access to new treatments – although the Medicines and Healthcare Products Regulatory Agency regulates medicines in the UK, there is a Europe-wide system of collaboration to approve drugs and ensure safety through the European Medicines Agency. This ensures that one drug can be licenced for the whole of Europe. Europe also cooperates on new medical devices through the Conformité Européene (CE) marking system which confirms that the device conforms to health and safety standards. Both of these ensure efficiency and efficacy of treatments for patients.

What does this mean for patients?

Innovation and progress is not possible without funding, and it can take many years between funding and outcome, so reducing funding now has a negative effect for the future. The medical research conducted in the UK is world-leading and we know that patients are keen to be part of this – 89% of people said they would be willing to participate in a clinical trial if diagnosed with a condition.[3]

Without large-scale drug or medical device approval processes the approval of drugs and devices could be delayed, resulting in slower access to new treatments for patients.

89% of people said they would be willing to participate in a clinical trial if diagnosed with a condition

Recommendations

- The UK should negotiate continued access to funding, or provide equivalent replacement funding for research so that patients have access to the best care in the future.

- The UK's exit from the EU must not impact patients' ability to participate in high-quality research.
- Continued collaboration on drug regulation between the EMA and MHRA to ensure that patients do not experience delays accessing treatments and industry is still incentivised to conduct research in the UK.

References

1 The Impact of Collaboration: The Value of UK Medical Research to EU Science and Health, Cancer Research UK, 2017 http://www.cancerresearchuk.org/sites/default/files/main_report_v8.pdf

2 European Federation of Pharmaceutical Industries and Associations, Brexit Survey Results, 2017. doi:10.13140/RG.2.2.26796.05768.

3 NIHR Survey, 2014 https://www.nihr.ac.uk/news/nine-out-of-ten-people-would-take-part-incli...

Downloads

Brexit - What does it mean for medical research? 423.42 KB

4. Parliamentary material

Debates

Lords debate - Life Sciences Industrial Strategy (Science and Technology Committee Report)

HL Deb 23 October 2018 | Volume 793 c802-

http://bit.ly/2ONxc03

Commons debate - Brexit, Science and Innovation (Science and Technology Committee Report)

HC Deb 06 September 2018 | Vol 646 c368-

http://bit.ly/2NYFRYP

PQs

Immigration: Research

Asked by: Lake, Ben

To ask the Secretary of State for the Home Department, what assessment he has made of the potential effect of proposals for a salary threshold in the immigration White Paper on scientific research occupations.

Answering member: Caroline Nokes | Department: Home Office

The Government is committed to developing a future borders and immigration system that will cater for all sectors of the UK, including for those who make a very valuable contribution to our scientific community

As part of his Spring Statement on 13 March, my Rt Hon Friend the Chancellor of the Exchequer announced that PhD level occupations, which includes scientists and researchers, will be exempt from the Tier 2 (General) cap. In addition, he announced that those same occupations will be exempt from our rules on absences from the UK, ensuring that they can take part in research activities overseas without impacting adversely on settlement applications where absences from the UK are taken into account. The Government intends to give effect to this change later this year

The Migration Advisory Committee recommended retaining the minimum salary threshold at £30,000. However, we have been clear that we want to engage with businesses and employers as to what salary threshold should be set. Currently, graduate entry jobs are already subject to a lower salary threshold and we will continue with that approach – and we are considering whether some occupations, such as

those recognised on the Shortage Occupation List, should be subject to a lower salary threshold.

We have launched engagement over 2019 with a wide range of stakeholders across the UK, including the science and research sectors, and we will be listening to their views on the key proposals in the White Paper before taking final policy decisions on the future system, which will be implemented after 2021.

HC Deb 28 March 2019 | PQ 234799

Medicine: Research

Asked by: Smith, Laura

To ask the Secretary of State for Business, Energy and Industrial Strategy, what recent steps he has taken to ensure the transparency of all publicly funded medical research.

Answering member: Chris Skidmore | Department: Department for Business, Energy and Industrial Strategy

The Department is committed to transparency in publicly funded research, including medical research. This is primarily delivered through UK Research and Innovation (UKRI), as a BEIS partner organisation.

UKRI and its Councils have a long-term commitment to make the research process and findings as open, understandable and reproducible as possible, whilst respecting ethical considerations and necessary exceptions. All UKRI research awards are published on Gateway to Research, along with information on outputs and research papers, and papers relating to medical research are accessible to all via the open access repository EuropePMC. UKRI is also currently progressing the commitment to transparent research in all disciplines through the UKRI Open Access Review, which aims to increase access to publicly funded research.

Within UKRI, the Medical Research Council (MRC) uses additional funding conditions for clinical trials and intervention studies which require the registration of all clinical trials and that all results (positive and negative) are publicly available in a timely way, usually within 12 months.

Looking wider, UKRI is also working with Universities UK and other stakeholders to revise and strengthen the Concordat to Support Research Integrity, including attention to transparency and open communication of research methods, analysis, and the sharing of negative or null results.

The transparency of research funded by other government departments, and their bodies, is not covered in this response.

HC Deb 11 March 2019 | PQ 228672

Medicine: Research

Asked by: Timms, Stephen

To ask the Secretary of State for Business, Energy and Industrial Strategy, what steps his Department is taking to ensure that UK clinical research organisations maintain their competitiveness in the event that their access to the EU market is restricted after the UK leaves the EU.

Answering member: Mr Sam Gyimah | Department: Department for Business, Energy and Industrial Strategy

The NIHR provides the support, expertise and facilities that the NHS needs to undertake world-leading clinical trials funded by the NIHR, and other public, charity and life sciences industry partners, by funding a range of infrastructure facilities and the Clinical Research Network (CRN). The CRN provides the infrastructure that allows high-quality clinical research funded by the life-sciences industry, including CROs, to be undertaken throughout the NHS. Through NIHR and its partners, and by close collaboration with the life sciences sector and industry, the Government will ensure that the UK remains one of the best places in the world for research, science and innovation.

HC Deb 26 June 2018 | PQ 156324

Medicine: Research

Asked by: Timms, Stephen

To ask the Secretary of State for Business, Energy and Industrial Strategy, what estimate his Department has made of the value of the UK research in medicines generated by early phase clinical research organisations.

Answering member: Mr Sam Gyimah | Department: Department for Business, Energy and Industrial Strategy

The Department has not made an estimate of the overall value of research in medicines generated by early-phase clinical research organisations. However, there are several reports which have evaluated the return on investment in different areas, including an independent study funded by the Medical Research Council (MRC), Wellcome, the National Institute for Health Research (NIHR) and Arthritis Research UK on musculoskeletal disease research (published January 2018).

MRC, which is part of UK Research and Innovation, supports translational research and experimental medicine. Pre-clinical research and early clinical testing is supported through the Developmental Funding Pathway Scheme to which the MRC commits up to £30 million per year, CROs may be included in MRC grants on a fee for service basis. The scheme is part of the Biomedical Catalyst programme funded in partnership with Innovate UK. Experimental medicine is a strategic priority for the MRC and can be supported across the research portfolio and industry partnerships, such as the MRC-Industry Asset Sharing Initiative.

The DHSC-funded NIHR invests over £1 billion annually to fund translational, clinical and applied health research spanning the whole innovation pathway. This includes support for research infrastructure in the NHS providing the expertise and facilities the NHS needs for first-class research which health and life sciences researchers, including CROs, can access at any stage of the clinical development process. The main NIHR-funded research infrastructure in the NHS which supports early translational (experimental medicine) clinical trials are the NIHR Biomedical Research Centres and NIHR Clinical Research Facilities. In 2016/17, NIHR funding of £928 million was announced for new NIHR BRCs and NIHR CRFs for 5 years from April 2017. These schemes have seen year-on-year increases in the number of early phase trials (including first-in-human and up to and including phase II) since 2010: from 602 early phase studies in 2010/11 to 2,870 in 2016/17.

HC Deb 26 June 2018 | PQ 156323

Clinical Trials and *Research*

Asked by: Berger, Luciana

To ask the Secretary of State for Business, Energy and Industrial Strategy, whether he has made an economic assessment of the (a) value of early-phase research and (b) inward investment generated by early-phase trials.

Answering member: Mr Sam Gyimah | Department: Department for Business, Energy and Industrial Strategy

The Industrial Strategy White Paper sets out the central role of science and innovation in meeting the UK's productivity challenge. The UK economy gets a high rate of return for our investment in Science – 20% per annum in perpetuity. The UK research base is highly productive in terms of article and citation outputs per researcher and per pound spend on R&D. With only 0.9% of the global population, 4.1% of researchers, the UK accounts for 6.3% of research articles, 10.7% of citations and 15.2% of the most highly-cited research articles. The UK draws in proportionally more internationally mobile investment in Research & Development than other large countries. For further information: http://oecd.org/sti/msti

HC Deb 22 May 2018 | PQ 145318

Clinical Trials

Asked by: Green, Chris

To ask the Secretary of State for Health, what steps the Government is taking to improve the UK's clinical trials base capacity over the next five years.

Answering member: Jackie Doyle-Price | Department: Department of Health

The Government continues to take steps to improve the United Kingdom's clinical trials base capacity.

The National Institute for Health Research (NIHR) provides significant investment to support the UK's clinical trials base and has transformed the health research environment in the UK. This investment includes the England-wide NIHR Clinical Research Network which provides the infrastructure in the National Health Service to deliver clinical trials and other well designed studies. NIHR also provides funding to support Clinical Trial Units. These specialist units support researchers in the design, conduct, analysis and publication of clinical trials and other well-designed studies.

The NIHR also supports capacity development through personal and infrastructure training awards, which includes supporting the development of a highlight skilled research and trials workforce through funding for NIHR Clinical Trials Fellowships. The NIHR has recently published a review of NIHR academic training. The report is available at:

www.nihr.ac.uk/our-faculty/strategic-review-of-training.htm

In 2016/17 the NIHR committed to invest £981 million over the next five years in research infrastructure in the NHS in England, providing the expertise and facilities the NHS needs to undertake health research and clinical studies. This includes funding for NIHR Biomedical Research Centres, NIHR Clinical Research Facilities and Experimental Cancer Medicine Centres.

The Medical Research Council (MRC) supports a number of activities and initiatives which aim to improve the UK clinical trials capacity. The MRC Clinical Trials Unit at University College London provides expertise in novel clinical trial methodology including complex stratified medicine trials and contributes to capacity building through training programmes and conferences. The MRC Hub for Trials Methodology Research Network supports the development of trials methodology research in the UK through leadership and developing guidance for trialists to improve the design, conduct and reporting of clinical trials and support for PhD Studentships to grow national capacity. The MRC's Regulatory Support Centre supports the research community with appropriate interpretation and implementation of regulatory requirements.

The Government has also noted the recommendations in Sir John Bell's Life Sciences Industrial Strategy regarding improving UK clinical trial capabilities and will consider them, along with other recommendations, as part of the ongoing sector deal process. The strategy is available at:

www.gov.uk/government/publications/life-sciences-industrial-strategy

HC Deb 01 November 2017 | PQ 109237

5. Useful links and further reading

Supporting clinical trials and the UK's future clinical research capability – Cancer Research UK briefing for Westminster Hall debate

https://www.cancerresearchuk.org/sites/default/files/cruk_briefing_-_westminster_hall_debate_on_clinical_trials.pdf

Cancer Research UK's policy statement on the future of clinical trials as the UK exits the EU August 2018

https://www.cancerresearchuk.org/sites/default/files/policy_statement_on_future_of_clinical_trials_as_the_uk_exits_the_eu.pdf

Wellcome *Regulation of clinical trials: Brexit and beyond* February 2019

https://wellcome.ac.uk/reports/regulation-clinical-trials-brexit-and-beyond

Industrial Strategy Life Sciences Sector Deal 2017

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/666359/171206_Industrial_Strategy_Life_Sciences_SD_Accessible_PDF_DPS.pdf

Medicines and Healthcare Products Regulatory Agency *Clinical Trials Regulation: Update on the Clinical Trials Regulation during the implementation period* August 2018

https://www.gov.uk/government/news/clinical-trials-regulation

Clinical Trials - *A Report From The Ministerial Industry Strategy Group Clinical Research Working Group* January 2018

https://www.abpi.org.uk/media/4650/clinical-trials-in-the-uk-report-jan-2018.pdf

House of Commons Science and Technology Committee current enquiry *Balance and effectiveness of research and innovation spending*

https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2017/research-innovation-spending-17-19/

House of Commons Science and Technology Committee report *An immigration system that works for science and innovation* HC1061 2017/19 July 2018

https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1061/1061.pdf

Government response HC1661 2017019 October 2018

https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1661/1661.pdf

House of Commons Science and Technology Committee report *Brexit, science and innovation* 21 March 2018 HC705 2017-19

https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/705/705.pdf

Government response HC 1008 2017-19

https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/1008/1008.pdf

House of Lords Science and Technology Committee *Life Sciences Industrial Strategy: Who's driving the bus?* HL 115 2017–19

https://publications.parliament.uk/pa/ld201719/ldselect/ldsctech/115/115.pdf

Wellcome *This is a pivotal moment for clinical trial regulations* 15 February 2019

https://wellcome.ac.uk/news/pivotal-moment-clinical-trial-regulations

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