

UK-EU negotiations and clinical research Cancer Research UK recommendations

Summary

Collaboration between the European Union and the United Kingdom on clinical research is a win-win. It drives progress for patients in Europe and across the world, helps our research environments to prosper and thrive, and delivers significant economic benefits.

Cancer Research UK has been working to safeguard this collaboration since the Referendum result. We are the world's largest independent funder of cancer research, committing £546m (€620m) to research in 2018/19 alone. And while we are based in the United Kingdom, we are proud to be part of the thriving pan-European research environment. 28% of our clinical trials take place with at least one EU Member State, and at last count our researchers were partnering with over 400 organisations in the EU.

This paper presents our recommendations to negotiators on how UK-EU collaboration on clinical research can be maintained through the end of the Transition Period and into the future. Cancer Research UK have identified these recommendations by drawing on legal analysis prepared by the University of Sheffield¹ and utilising the expertise of our researchers. We have endeavoured to recognise and respect the mandates of both the EU and UK and draw on precedent, while acknowledging that compromise will be needed from all negotiators to secure the best outcome.

While cancer societies and research organisations across Europe have noted that as-close-as-possible a relationship between the UK and EU is to the benefit of patients and research in both jurisdictions, we appreciate that the UK's exit from the EU will necessitate a reduced level of cooperation than exists at present.²⁻³ However, it is our view that it is the responsibility of all negotiators to protect the interests of patients, health and research in the future relationship. In that spirit, we recommend:

- 1. The Future Relationship Agreement formally recognises that a high level of protection for human health represents a shared value in the UK and EU's regulatory approaches.**
- 2. UK and EU negotiators commit to reducing barriers to UK-EU collaborative clinical research, including the establishment of a Research & Innovation Committee or Working Group to facilitate future cooperation on research (including clinical trials).**
- 3. Full UK association to Horizon Europe, in order to facilitate cross-border collaborative research.**
- 4. UK and EU negotiators commit to cooperate as far as possible on medicines licensing and regulation, patient safety, and minimising barriers to trade, including a best-in-class Mutual Recognition Agreement and the establishment of a Pharmaceuticals Licensing & Regulation Subcommittee or Working Group.**
- 5. Prioritisation of data adequacy status for the UK, with an agreement to be reached before the end of the Transition Period.**

1. Protection of human health as a shared value

Current arrangements for collaboration are based on the EU's internal market and its rules, which create a level-playing field for all market actors that enables innovation driven by fair competition. These rules also create a regulatory 'floor' that provides EU-wide protections to both participants in clinical trials and to patients who use products developed by clinical research.

The EU has a duty to protect human health in its internal market regulation,⁴ as it does in all its activities and policies.⁵ Simultaneously, the UK has given assurances that Brexit will "do no harm" to human health.⁶ However, the House of Commons Health and Social Care Select Committee has noted the omission of health as a regulatory floor from the EU negotiating mandate, and has in response proposed that "the UK should seek to make a shared commitment to protecting health and national health systems part of these negotiations".⁷

- i) **Cancer Research UK recommends that the EU and UK formally recognise in the Future Relationship Agreement that a high level of protection for human health represents a shared value in their regulatory approaches.** This would function similarly to the level-playing field for social and labour protections. The EU and the UK will retain autonomy to develop their domestic regulation of matters pertaining to human health protection,⁸ so long as new rules do not impede trade between the EU and the UK. But, in common with the commitments to maintain and improve social and labour standards,⁹ the EU and the UK should agree a commitment to maintain and improve human health protection.

Such a commitment would provide a basis in the EU-UK Agreement for cooperation in good regulatory practice where necessary to protect human health, including in clinical trials.

2. Clinical research collaboration

Clinical trials play an essential role in determining the effectiveness and safety of new medicines. They also provide patients with access to potentially life-saving treatments that are in development. UK-EU collaboration is critical to delivering many clinical trials, especially those investigating rare and childhood diseases. If this collaboration were reduced, both the UK and EU would risk losing opportunities to innovate and improve patient care.

The UK plays a central role in the European clinical research environment, to the benefit of patients across Europe. Despite having just 12.9% of the EU's population,¹⁰ the UK produced 28% of the EU's clinical trial applications between 2008 and 2018.¹¹ Working with the EU is foundational to UK clinical research, with the UK participating in more UK-EU trials (4,883) than UK-only trials (2,864) between 2004 and 2016.¹² UK researchers are strong collaborators, with the UK participating in more pan-EU trials for rare and childhood diseases than any other Member State.¹³ The UK also delivers more phase I trials than any other EU country, developing specialist expertise that EU partners can draw on.¹⁴

Pan-EU trials are currently regulated by the Clinical Trials Directive (2001/20/EC) (CTD), which will be replaced by the EU Clinical Trial Regulation (536/2014) (CTR) in 2022. The UK played a central role in the development of the CTR, which researchers widely expect to be a significant improvement on the CTD. The CTR will be underpinned by a clinical trial database and a centralised clinical trial portal. This infrastructure should coordinate Member State reviews and approvals, accelerate trial set-up, improve safety reporting, and facilitate collaborative research within the EU's internal market.

Challenges

To ensure UK and EU researchers can continue to collaborate on clinical research, whilst recognising that the UK will be outside the internal market, the future relationship will need to minimise practical, legal and financial barriers to running UK-EU clinical trials.

New barriers to collaboration will materialise if UK and EU clinical trial approval processes diverge.¹⁵ Since it is no longer an EU Member State, the UK will not have access to the CTR's centralised clinical trial portal when it comes into operation. A key efficiency gain that will be provided by the portal is the coordinated review of Clinical Trial Applications (CTAs) by participating Member States, which is designed to accelerate trial set-up and facilitate collaborative research. Without access to the portal, the UK and EU CTA review processes will have to run separately, in parallel to each other. If these separate processes do not cooperate, they will eventually begin to diverge. Differences in assessment criteria, approval timelines, and other areas, will increase the administrative burden on researchers and delay the set-up of UK-EU clinical trials. This in turn will reduce collaborative research activity, resulting in fewer trials and a reduction in patient access to new treatments in both the EU and UK.

Another barrier caused by divergence will be an increase in legal costs faced by UK-based sponsors of UK-EU trials. In cases where an EU trial has a non-EU Sponsor, the CTD (and later the CTR) requires sponsors to establish a legal representative in the EU. Evidence from our research community has shown the process of establishing an EU-based legal representative for multi-state trials can range from £20,000 to £300,000 per year, which would be prohibitively expensive for many non-commercial Sponsors (e.g. universities). An increase in legal costs, unless compensated elsewhere, would likely lead to a fall in UK-led pan-European clinical trials, which would negatively impact both the UK and EU. Cancer research would be particularly vulnerable to these costs, as approximately 40% of all UK cancer trials have non-commercial Sponsors.¹⁶ Ultimately both EU and UK patients would have fewer opportunities to participate in trials and benefit from new, potentially life-saving, treatments.

Recommendations

The UK Government has already said it will implement aspects of the CTR “which best suits the interests of UK patients, industry, non-commercial researchers and hospitals”.¹⁷ Cancer Research UK welcomes this, as efforts to maintain consistent regulatory standards will make UK-EU research collaboration easier, which is in the best interests of patients. However, full UK participation in the CTR would be the best long-term outcome for patients across Europe, as UK access to the CTR's entire IT infrastructure would provide the best environment for conducting life-saving EU-UK trials. As a minimum, we encourage UK and EU negotiators to keep the door open for future opportunities to support research collaboration.

- i) **An ideal forum for discussing these future opportunities would be a Research & Innovation Committee or Working Group, similar to that proposed by the Wellcome Trust and Bruegel.**¹⁸ We recommend UK and EU negotiators establish this Subcommittee, which should sit under the proposed Specialised Committee on Regulatory Cooperation,¹⁹ of which the UK-EU Joint Committee²⁰/Partnership Council²¹ would have oversight. The Subcommittee's purpose would be to oversee the UK-EU research relationship (including clinical trials) and make recommendations to the Specialised Committee for ways this relationship could be enhanced within the framework of the Future Relationship.

The Subcommittee structure should be modelled on the EU-Canada Comprehensive Economic Trade Agreement's (CETA's) subcommittees.

- ii) **A priority discussion for the Research & Innovation Subcommittee or Working Group should be mutual recognition of clinical trial Sponsors.** This will be necessary if, as expected, the CTR requires trial Sponsors from Third Countries to establish legal representation in the EU. A Mutual Recognition Agreement for UK, EU and EEA Sponsors would prevent the financial barriers this is expected to bring, thereby safeguarding UK-EU clinical trials with Sponsors based in the UK and the benefits these bring to EU and UK patients, confirming a shared commitment to a high level of protection for human health.
- iii) **We recommend the Subcommittee explores ways UK-based trial sponsors could access the centralised portal, when implemented, whilst maintaining the integrity of the EU internal market.** As noted above, having access to the CTR's IT infrastructure would better facilitate UK-EU collaborative clinical research by accelerating trial set-up and expediting the sharing of trial information. This will improve access to in-development treatments for patients across Europe, again making a reality the EU's and UK's shared commitment to a high level of protection for human health.

3. Horizon Europe

Joint-EU research is supported by the EU's Research Framework Programme, Horizon 2020, which provides funding and networking opportunities in order to increase innovation through collaboration. This support plays a vital role in cancer research and is responsible for many world-leading trials – such as the Paediatric Hepatic International Tumour Trial (PHITT)²² – which would not be feasible without international collaboration.

UK-based researchers derive significant benefit from EU networks of funding and expertise, and in turn add considerable value. These collaborative links are vital for clinical research into cancer, an area in which the UK excels.²³ Nearly 50% of all UK cancer research is international²⁴ and 28% of the trials Cancer Research UK supports take place with at least one EU Member State.²⁵

UK and EU researchers have more impact when they work together. Collaborative UK-EU medical and health research publications receive 24% and 44% more citations than their UK-only and EU-only counterparts.²⁶ The UK plays a central role in these collaborative publications, producing almost 20% of the research carried out within EU health programmes between 2007 and 2016.²⁷

Challenges

Horizon 2020 will end this year and be replaced by Horizon Europe, a 7-year programme worth nearly €100 billion, in 2021.²⁸ The UK is scheduled to be a Third Country by the time Horizon Europe comes into force and will thus have to seek associated status to retain a high level of access to EU research funding and infrastructure. Association represents an invaluable opportunity for research initiatives that rely on international collaboration to develop new treatments, especially for rare and childhood diseases. Cancer research would be particularly benefitted by UK association to Horizon Europe, as the programme features a 'cancer mission' designed to improve the prevention, diagnosis and treatment of cancer across Europe.²⁹

Third Country participation is necessarily different from that of EU Member States. The terms of association for Third Countries to Horizon Europe have not yet been finalised, but potentially include limited participation in, or exclusion from, certain parts of the Programme. These could include single-beneficiary schemes, such as European Research Council Funding, or areas with geopolitical sensitivities.³⁰ The exact terms of how the UK contributes and benefits financially will also need to be decided.

There has also been discussion of additional criteria for Third Countries seeking associated status to Horizon Europe, potentially including recognition of intellectual property rights and rules around the mobility of researchers.³¹ While association discussions are outside the scope of negotiations on the future relationship, the terms of the relationship between the UK and EU are likely to have a bearing on UK association to Horizon Europe.

Recommendations

We welcome the UK Government's intention to explore association to Union Programmes, including Horizon Europe.³²

- i) **We recommend the UK Government follow through on this intention and seek association with Horizon Europe as a Third Country, ideally to begin on 1 January 2021, or as soon as Horizon Europe begins thereafter.** This view has been echoed widely throughout the medical research charity sector and across a variety of disease areas.³³⁻³⁴

While terms of UK association to the Programme will be decided outside of negotiations, negotiators should ensure the UK-EU relationship is one which facilitates full association. A Research & Innovation Subcommittee or Working Group, as recommended above, would be well placed to help facilitate this relationship – as spelled out by the Wellcome Trust and Bruegel.³⁵

4. Medicines regulation, safety and movement

“The UK and EU are stronger when they work together to improve public health. In the European Medicines Agency, MHRA expertise and capacity is crucial. For the UK, full participation in the EMA allows swift access to the newest medicines and treatments. A continued strong relationship will benefit patients across Europe and we must not allow political barriers to get in the way of this.”

Thomas Lönngren, Executive Director of the EMA (2001-2010)

UK-EU collaboration in the evaluation and monitoring of medicines entering their markets accelerates patient access to innovative treatments and helps protect patient safety.

The European Medicines Agency's (EMA's) centralised marketing authorisation process provides a route for companies to access the entire EU pharmaceuticals market based on one regulatory submission. EU and EEA countries' national medicines regulators work together to assess these submissions, and this system allows faster patient access to new medicines across the EU. The Medicines and Healthcare Products Regulatory Agency (MHRA) has historically been a major contributor to the EMA's centralised marketing authorisation process, acting as Scientific Advice Co-ordinator in at least 20% of centralised licensing applications between 2008 and 2016.³⁶

The EMA also oversees monitoring of medicines safety (pharmacovigilance) at an EU level. Collaboration between EU and EEA national regulators, coordinated via the EMA, allows them to quickly identify, share, and act on possible threats to patient safety. This includes information on Suspected Unexpected Serious Adverse Reactions (SUSARs) during clinical trials, which regulators can share to raise concerns about a new medicine's safety. The MHRA has been an integral part of this activity and was responsible for 21% of safety signals identified by an EU or EEA member state between mid-2012 and mid-2017.³⁷

In addition, the EMA is responsible for establishing and enforcing EU-wide standards on a range of other medicines regulatory issues with implications for patient safety, such as Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). These standards apply to both licensed medicines and to Investigational Medicinal Products (IMPs). It is supported in this work by national medicines regulators, such as the MHRA, who provide domestic monitoring and oversight of these standards in medicines manufacturing and supply.

Challenges

When EU internal market law no longer applies in the UK, EU-UK collaboration on the certification and monitoring of GMP compliance will be interrupted. This would put at risk timely patient access to medicines. Before medicines can be released for use, they must be assessed and certified by a Qualified Person (QP) to confirm GMP compliance. This applies both to licensed medicines and IMPs – medicines being tested or used as a reference in a clinical trial, including placebos and licensed products being used in a different form or for a different purpose. In 2018, 70% of IMPs in ongoing EU trials were QP released from the UK.³⁸

In the absence of an agreement between the EU and UK establishing equivalence of GMP standards and QP status, manufacturers would be required to undertake batch testing of medicines to prove GMP compliance separately in the UK and the EU. This will add to the administrative burden on manufacturers and slow the movement of medicines between the UK and EU. Every month, 37 million packs of medicine move from the EU to the UK, and 45 million from the UK to the EU, so this would have a significant impact for patients in both the UK and the EU.³⁹ Any delays in this process could particularly affect products with a short shelf life, including radiopharmaceutical products and possibly cell therapy type products such as CAR T-cell therapy.

Following the Transition Period, unless otherwise agreed, companies will have to submit separate marketing authorisation applications to the MHRA in the UK, and to the EMA in the EU. The relative sizes of the EU and UK pharmaceutical markets mean companies are likely to submit applications for new drugs to the EMA before the MHRA – meaning UK patients could face slower access to the latest medicines.⁴⁰ This will particularly impact authorisation of, and access to, medicines for rare and childhood cancer populations, where the unique need for specialist incentives to develop and market new drugs is already acknowledged in specific EU legislation (the Paediatric Regulation EC 1901/2006 and Orphan Regulation EC 141/2000).

On the EU side, as has been noted by the Executive Director of the EMA,⁴¹ loss of the MHRA's expertise and resource capacity in the EMA's centralised marketing authorisation process could mean that EMA decision-making slows down, at least in the short-term, similarly delaying EU patient access to new innovations.

Likewise, after the Transition Period, the MHRA will cease to be integrated into the EMA's pharmacovigilance systems, since these are currently restricted to EU and EEA Member States. This risks a fall in standards of patient protection; it has been suggested that loss of this integration could cause delays of 1-2 months in picking up new safety signals,⁴² even if the EU and UK agree to confidentially share pharmacovigilance data (in a similar way to existing confidentiality agreements between the EMA and regulators in countries like Australia and Canada).

Recommendations

Following the Transition Period, the UK has the option to unilaterally continue to recognise marketing authorisations granted by the EMA as valid. However, this is only a partial solution as it would not allow the MHRA to contribute its resource and expertise to the EMA's centralised authorisation process, which has proven valuable in accelerating patient access to new medicines. We therefore encourage UK and EU negotiators to adopt a long-term perspective when considering how medicines regulation, safety and movement will function in the Future Relationship. The commitment outlined in the Political Declaration to explore cooperation between UK authorities and the EMA is welcome and should be built upon.⁴³

- i) **As a first step, we recommend negotiators establish a confidentiality agreement between the MHRA and EMA as soon as possible.** The content of this agreement should be modelled on the EMA's existing agreements with regulators in countries such as Australia, Switzerland, Canada, and the United States. We are confident this can be delivered quickly and will provide a foundation for the MHRA-EMA relationship after the Transition Period ends. However, this alone will not be enough to safeguard as far as possible patient safety and access to new medicines across Europe.
- ii) **We therefore recommend UK and EU negotiators build on this agreement by establishing a Pharmaceuticals Licensing & Regulation Subcommittee or Working Group.** This would also sit under the proposed Specialised Committee on Regulatory Cooperation and be modelled on the CETA subcommittee structure. This Subcommittee would explore options for the fullest possible pragmatic participation of the MHRA in the EMA's marketing authorisation processes. These discussions would embody the UK and EU's shared commitment to the value of protecting human health; whilst also recognising that, as a non-EU member, the UK cannot fully participate in the internal market's structures.

We acknowledge that the initial basis for pragmatic participation will (out of necessity) be less than the position before 31 January 2020. **We recommend that the UK and EU seek to deepen this position over time, using the Subcommittee as a forum.** Ultimately, Cancer Research UK would wish to see full MHRA participation in these processes, on a similar basis to EEA countries' regulators, as our evidence shows that this would be the best outcome for patients across the EU and UK.

- iii) **We recommend negotiators agree a Protocol on the mutual recognition of GMP standards, compliance and enforcement, along the lines of the equivalent protocol in the CETA.**⁴⁴ This should include waiving of batch testing of medicines and IMPs on entry into their respective territories and mutual recognition of Qualified Persons, in line with existing MRAs the EMA has negotiated with other countries' regulators.

This will help ensure the movement of medicines and IMPs between the EU and the UK is as swift and frictionless as possible and would be compatible with broader global trends for overall regulatory harmonisation on GMP. Monitoring of the implementation of the Protocol could be overseen by the Pharmaceuticals Subcommittee or Working Group we recommend, in an equivalent fashion to the role played by the Joint Sectoral Group on Pharmaceuticals under CETA.

- iv) The Pharmaceuticals Licensing & Regulation Subcommittee or Working Group should also, over time, consider options for the MHRA's integration into the EMA's pharmacovigilance systems, and broader opportunities for collaboration on patient safety and regulatory issues.** Again, we acknowledge that the initial position will provide less patient protection than before 31 January 2020, but we recommend that the Subcommittee or Working Group should operate with an ambition to enhance this integration and collaboration over time.

5. Data sharing

UK and EU researchers and regulators benefit from having access to each other's data, as this facilitates the development and approval of new treatments. Without this data, both the EU and UK risk losing capacity to develop and authorise new medicines quickly and safely, in turn hampering efforts to improve patient care across Europe.

Data transfers are essential for running joint UK-EU clinical trials, as they need to routinely send patient data and test results across international borders from trial sites to researchers conducting analysis. This cross-border exchange provides the foundation for modern-day innovation, as these collaborative trials form the majority of clinical trials conducted in the UK, France, Germany, Italy, the Netherlands, Poland, and Spain.⁴⁵ Clinical trials investigating rare and childhood diseases are particularly reliant on international data for patient recruitment, as individual countries often lack the requisite number of patients and must recruit abroad to make up the gap. The importance of international data driving patient recruitment is expected to grow even further, as future trials will increasingly use innovative research methods that group patients by specific and rare genetic profiles.

Once a clinical trial is completed and its findings are used to authorise a new treatment, data sharing between the UK and EU remains essential. As noted in the previous section, the MHRA is a significant contributor to the EMA's work in monitoring patient safety. Confidentiality agreements, such as those the EMA has with Australia, Canada, and the US, allow confidential information on medicines safety (including SUSARs) to be further exchanged between regulators in these countries. Similarly, the EMA's Mutual Recognition Agreements (MRAs) on GMP with Third Countries, together with specific provisions in EU trade agreements (such as the CETA Protocol on Pharmaceuticals), also allow the findings of GMP inspections to be shared.

Challenges

To ensure data sharing between the UK and EU can continue, the UK will need to receive data adequacy status from the European Commission. This status is essential for EU/EEA authorities to exchange data with Third Countries. If the UK did not receive data adequacy status, this would create immediate barriers to EU-UK collaboration, with an increased risk of long-term barriers being erected.

UK and EU researchers involved in collaborative trials would face immediate challenges. In order to exchange personal data, such as test results and patient information, researchers would need to invest time and money instituting additional legal safeguards. This would apply to collaborative trials already underway and future trials looking to recruit patients outside the trial sponsor's country. These legal barriers and costs may discourage collaboration, leading to both the EU and UK losing out on opportunities to innovate and improve patient care. It is therefore in the best interests of all patients that UK and EU researchers be allowed to continue exchanging data - an essential part of collaborative research.

UK and EU regulators would be similarly affected if negotiators did not agree a confidentiality agreement and an agreement (either via a MRA or protocol in the wider trade arrangement) to collaborate on GMP compliance and enforcement. The absence of such agreements would create additional legal barriers to sharing data and collaboratively monitoring medicine safety. The consequence of this would be reduced visibility of medicine safety issues and a potentially increased risk to patient safety across the UK and EU.

Recommendations

To prevent unnecessary barriers to collaboration being erected, Cancer Research UK has outlined three steps negotiators can take to ensure the UK and EU can continue to exchange data whilst maintaining high standards of data protection.

- i) The European Commission and UK Government should work together to ensure the UK receives data adequacy status before the Transition Period ends.** We welcome the UK's decision to recognise the adequacy of the EU's data protection law,⁴⁶ and the European Commission's stated intention to take a data adequacy decision for the UK's data protection law as soon as possible after transition.⁴⁷ We also welcome the readiness of the European Data Protection Supervisor to consider any draft adequacy decision from the European Commission in as expeditious a manner as possible.⁴⁸
- ii) As recommended in the previous section, the MHRA and EMA should negotiate a Protocol on the mutual recognition of GMP compliance, as well as a confidentiality agreement modelled on the EMA's existing agreements with regulators in countries such as Australia, Switzerland, Canada and the US.** In addition, the Pharmaceuticals Subcommittee or Working Group we recommend in the previous section should work towards UK integration into the EudraGMDP database, to allow the UK to contribute to EU processes for monitoring GMP and GDP compliance. These steps would provide an important framework for the sharing of data between regulators, which will help protect patient safety.
- iii) Negotiators should establish a Data Protection & Exchange Subcommittee or Working Group.** This subcommittee would oversee and review the implementation of the UK's and EU's data adequacy status and the MHRA-EMA confidentiality agreement (as well as other similar agreements in other industry sectors). It too would sit under the proposed Specialised Committee on Regulatory Cooperation and be modelled on the CETA subcommittee structure.

Appendix

Case Study: Paediatric Hepatic International Tumour Trial

The Paediatric Hepatic International Tumour Trial (PHITT) investigates the success of different therapeutic techniques for patients suffering from rare liver cancers that account for 1% of paediatric tumours. PHITT is part of a larger collaborative international project called the Children's Liver Tumour European Research Network (ChiLTERN). The trial is being coordinated by the University of Birmingham's Cancer Research UK Clinical Trial's Unit (CTU) and is subsequently being conducted in 13 other European countries.

This project is funded 100% by EU sources via the Horizon 2020 programme and ChiLTERN has received almost 8 million euros from EU grants to carry out this clinical trial. At the forefront of this clinical trial is the University of Birmingham's CTU, one of the UK's largest cancer trials units, translating cutting edge science into improved patient care for over 30 years.

Professor Keith Wheatley, the project lead for ChiLTERN, says "Importantly, the EU funding allows us to develop and deliver the trial and associated studies contemporaneously in all EU participating countries rather than having a disconnected approach whereby each country identifies its own funding stream. The amount of funding needed to undertake this project would not be available from a single source funder within one country. Hence, the Horizon 2020 funding provided by the EU commission is imperative to such a multi-country collaboration."

The Chiltern project is truly collaborative with expert teams from throughout Europe leading sub-sections of the project. The PHITT trial will see the single largest clinical trial ever undertaken in this patient population.

For rare cancers like paediatric liver cancer it is crucial to carry out work collaboratively. If the UK and EU work alongside each other in this research area, it will allow the flow of expertise, ensure a greater source of funding is available and therefore enable progress to be made at pace.

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