



FUTURE OF CLINICAL TRIALS AFTER BREXIT

SLIDE DECK

Introduction

This slide deck outlines the main findings from a project exploring the future of clinical trials out to 2028 in the context of Brexit.

It was commissioned by Cancer Research UK (CRUK) to help them understand how to achieve the best possible outcome for clinical trials as they seek to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.

It took a futures approach based on horizon scanning, trend analysis and scenario planning to understand both the short- and longer-term impacts of Brexit, as well as the drivers that may influence how future trials are conducted, and the world in which trials operate. This approach helped to identify a set of key recommendations: short- or long-term actions that government and the wider sector need to take to ensure the best possible outcome for clinical trials for the benefit of both the UK and the EU.

The project draws on inputs from over 100 contributors from the clinical trials sector including patients, researchers, clinicians, industry, policy makers and regulators in the UK, EU and internationally. We are grateful for the support and participation of all those who generously took part in the interviews, survey and workshop.

“The biggest risk will be outcomes for patients, and what the sector will be able to deliver.”

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1. Key Recommendations

1. Priorities for negotiations

Regulation

- The UK government should continue to seek full regulatory alignment with the forthcoming EU Clinical Trial Regulation (EU CTR). This should include a bespoke agreement for access to the EU portal and database and to ensure the UK can take part in the centralised assessment process.
- Where full alignment with the provisions of the EU CTR is not possible, the UK government should seek a proportionate approach to regulation that balances alignment with the opportunities to innovate.

Access to medicines, Investigational Medicinal Products (IMPs) and devices

- The UK and EU should work to ensure that trade barriers do not impact the availability or movement of new and existing licensed medicines, IMPs and devices after Brexit as this is crucial to maintain standard of care on which to build clinical trials.
- The UK government should continue to seek a close partnership between the MHRA and the EMA. An agreement should be sought to allow EMA marketing authorisation decisions to apply to the UK and equivalent safety standards to be maintained after Brexit
- The UK and EU regulators should ensure equivalence of regulation and standards for certification and testing of IMPs and devices.

Funding

- The UK and EU should agree full UK participation in EU framework programmes with access to funding for clinical research.

Workforce

- The UK Government should negotiate reciprocal arrangements, where possible, to ensure international mobility, as this is seen as a critical aspect of collaboration and research excellence.

2. Actions to maintain UK attractiveness

Regulation

- The UK should adopt a broad strategy to EU and international engagement to ensure it can continue to influence and drive new regulation and standards across Europe and globally, including through partnership with the EMA.

Workforce

- The UK Government should modernise and streamline its global immigration system as this is also seen as a critical aspect of collaboration and research excellence. In particular, a permissive immigration system should be developed that supports the clinical trials, health and research workforce that allows continued movement across borders.

3. Optimising the landscape long-term

Regulation

- UK and EU regulation and regulators will need to adapt to allow for new trial designs, new devices and technologies, and new approaches to data.

Data

- A more streamlined and efficient approach is required in the UK and internationally to allow the effective collection and sharing of anonymised patient and trial data while protecting patients' rights and interests.

Funding

- A long-term strategic approach to funding of clinical trials is necessary in the UK to both ensure investment and to drive collaboration.

Workforce

- The UK needs to invest in a skilled clinical trials workforce to ensure it can maintain its longer-term competitiveness encouraging UK investment.

2. About the project

Brexit has introduced significant short- and long-term uncertainty in a broad set of areas including regulation, access to medicines, IMPs and devices, data, the workforce and funding of clinical trials. The UK faces a future that will be influenced by global shifts in values, demographics, innovation and technological change.

It is redefining the relationship between the UK and EU. Everyone will be affected and the clinical trials sector will need to adapt to the opportunities and challenges associated with Brexit.

However, it is also important that any decisions made today are effective and resilient in the longer-term. To do this it is key to understand both the longer-term impacts of Brexit as well as broader changes that may influence how future trials are conducted, and the world in which trials operate.

To do to this, we used a futures approach to look out to 2028.

We engaged a broad set of participants - an international mix of patients, clinicians, industry, government and regulators - to help participants explore the future of trials before surfacing insights for today.

“**Brexit could galvanise a new sense of purpose for Clinical Trials, but we need to think deeply about how to make new freedoms advantageous**”

Four phases:

- 1. Horizon scan and interviews.** A broad range of literature was reviewed to identify drivers and trends, as well as weak signals from a wide range of fields, including shaping the future of clinical trials. In parallel, 23 interviews were conducted with a mix of patients, clinicians, industry, government and regulators to identify different perspectives on the future.
- 2. Prioritisation of drivers of change.** An online assessment was conducted to gather sector views on the most important and uncertain drivers of change and to gather additional perspectives.
- 3. Scenario development.** Five alternative scenarios were developed for the future of clinical trials. See Annex B for how this was done, and the resulting scenario narratives.
- 4. Identification of implications and recommendations.** A participative workshop was held with 38 participants to explore the scenarios and explore their implications. Following the workshop, we identified 5 themes - regulation, access to medicines, IMPs and devices, data, funding and the workforce - along with a set of recommendations to help ensure a successful future for trials and a positive outcome for patients.

3. Drivers of Change

Through the horizon scan and interviews a shortlist of 26 drivers of change were identified that were viewed to be important to the future of clinical trials.

These included a broad set of drivers that would have impacts on the Economy, Society and Technology, as well as a set of issues that would effect Regulation, Efficiency and collaboration, Funding and Brexit, and Supply chain and migration.

The 26 drivers were then assessed in an online survey, in particular to identify:

- **Critical issues** High impact and highly uncertain drivers that might impact the sector by 2028
- **Short- and long-term priorities:** important drivers in 0-2 year and 5-10 year time-frames
- **Emerging issues:** important drivers where there was less consensus on the level of impact or uncertainty among respondents. A lack of consensus can help to identify 'weak signals' of change not yet on most people's radar

Legend	
■ Economy	
■ Efficiency and collaboration	
■ Regulation, funding and Brexit	
■ Society and Technology	
■ Supply chain and migration	

Critical issues

- Ease of cross-border collaboration
- Availability of funding for clinical trials, research and innovation
- UK and EU cooperation around development of regulation and policy
- UK participation in EU framework Programmes and funding
- International competitiveness of UK/EU for the conduct of clinical trials
- Alignment of clinical trials regulation
- Transparency and ease of disclosure of trial data between the UK and EU
- Ease of marketing authorisation and parallel distribution
- Efficiency of customs and regulatory checks between UK and EU
- Easy movement of workers and their families between UK and EU
- Alignment of drugs and devices regulation
- UK participation in the EU clinical trials database and portal
- Streamlined approaches to pharmacovigilance
- Strength and volatility of the global economy
- Alignment of data protection regulation
- Coordination and communication between regulators and the clinical trials sector

Short-term priorities (0-2 years)

- Alignment of clinical trials regulation
- Availability of funding for clinical trials, research and innovation
- Easy movement of workers and their families between UK and EU
- Cooperation around development of regulation and policy
- Coordination and communication between regulators and the clinical trials sector

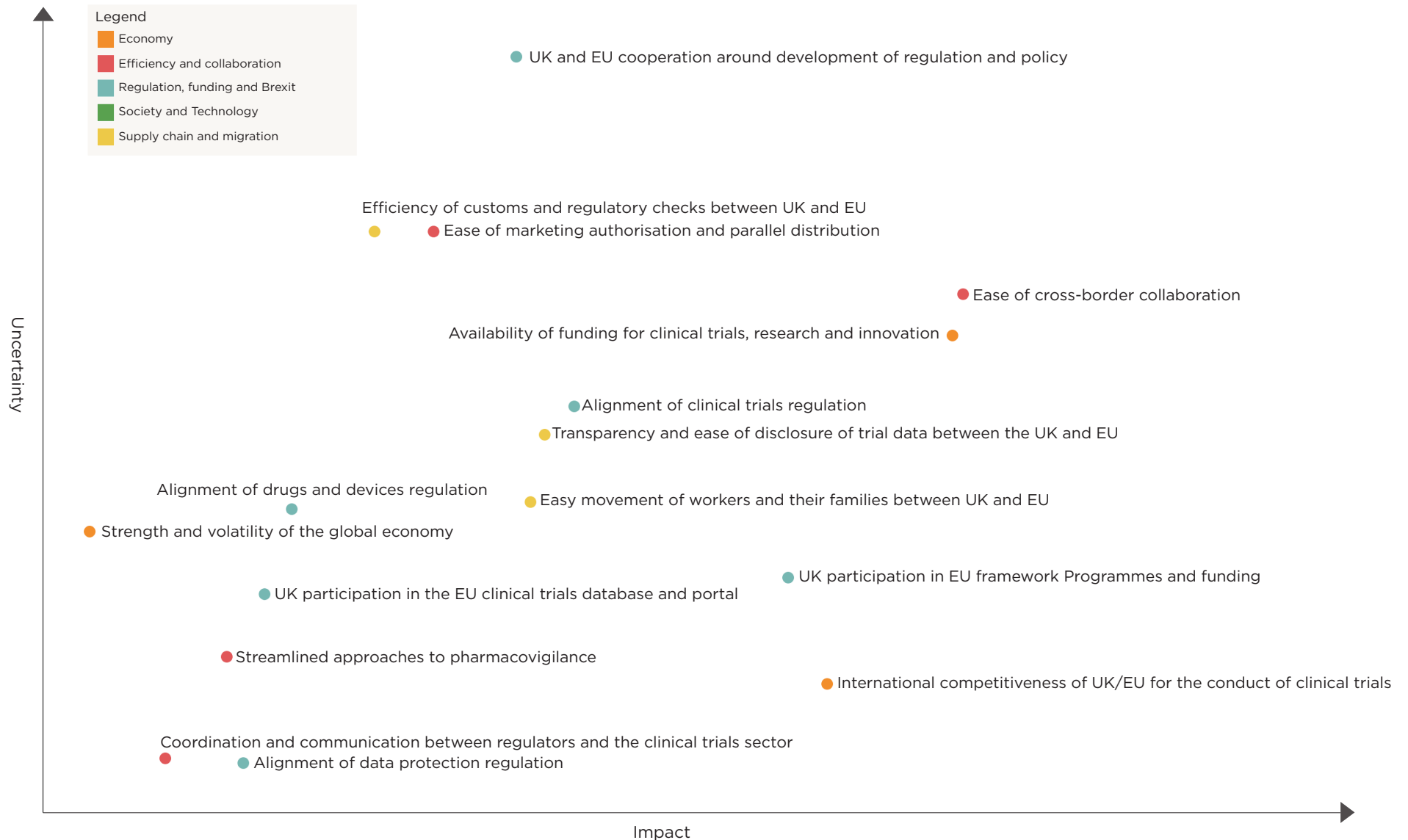
Long-term priorities (5-10 years)

- Availability of funding for clinical trials, research and innovation
- Advances in genomic, personalised and translational medicine
- Transparency and ease of disclosure of clinical trial data between UK and EU
- Ease of cross-border collaboration
- Easy movement of workers and their families between UK and EU
- Alignment of clinical trials regulation
- International competitiveness of UK/EU for the conduct of trials

Emerging issues

- Social attitudes to data, privacy and the transparency of clinical trials
- Patient-centric approaches to trials
- Level of clinical innovation
- Impact of aging and non-communicable disease

3. Drivers of Change: Critical Issues



Drivers prioritised by survey respondents as having greater than average impact and uncertainty

4. Scenario Framework

We chose to consider five scenarios, that would reflect a broad range of possible Brexit outcomes.

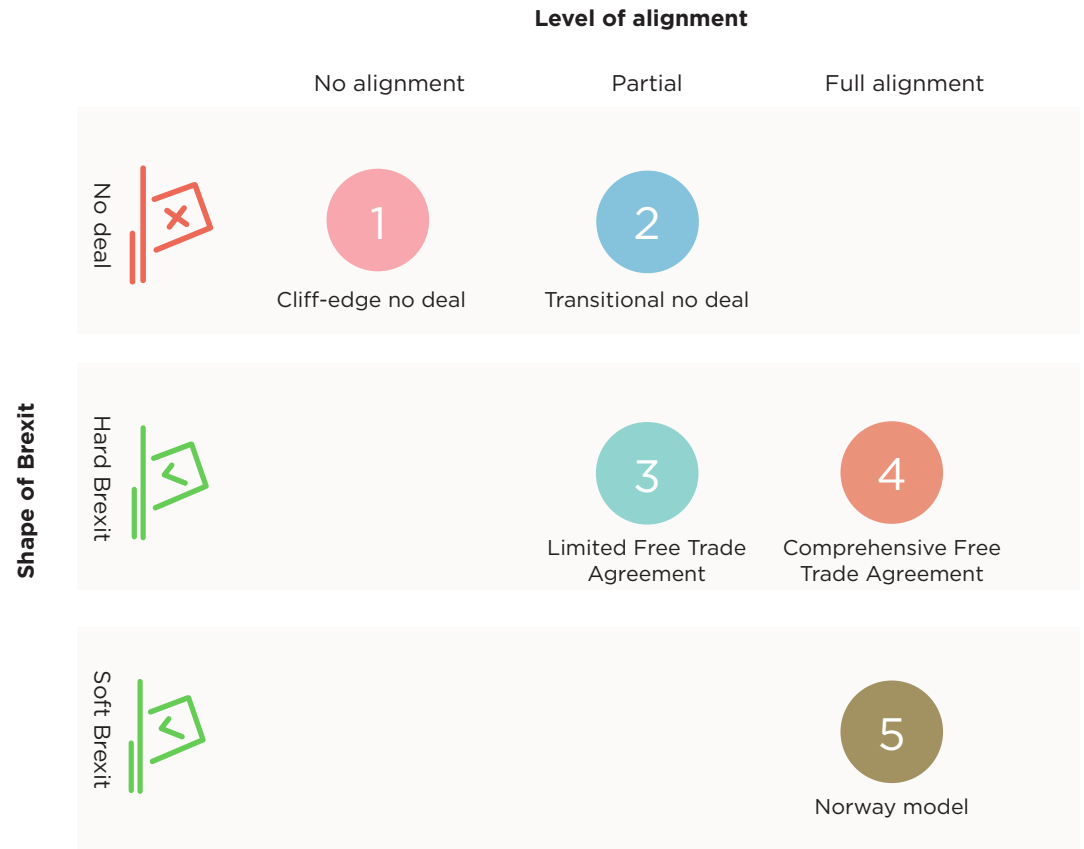
To develop the framework, we started by considering:

- **The shape of Brexit** How different Brexit outcomes might impact the future of clinical trials? What does the post-brexit world look like in 2028? (see Figure 1 for a summary of the different Brexit shapes)
- **The level of regulatory alignment between the UK and EU** Did the UK implement the provisions of the EU CTR? Was a bespoke agreement made to allow the UK to participate in the EU database and portal? And was it possible to stay aligned over time?

A range of outcomes associated with additional drivers were explored.

Level of alignment:

- **Full alignment** assumes a bespoke agreement is agreed between the UK and EU to allow the UK to participate fully in the provisions of the EU CTR and to access the EU portal and database.
- **Partial alignment** assumes that the UK implements the provisions and processes in the EU CTR as far as possible but is unable to access the portal and database as a third country.
- **No alignment** assumes that the UK does not implement the provisions of the EU CTR but keeps existing clinical trials legislation in place. The UK may choose to adopt a bespoke regulatory system or align with an alternative market.



4. Scenario Framework: Shapes of Brexit

No Deal

1. Cliff-edge no deal The UK leaves the EU without any arrangements in place. The UK and EU trade on WTO terms including for drugs. The UK is able to establish its own regulatory standards. Formal freedom of movement ends, but little may change in the short-term. A new UK border system is required from day one, with issues around access to market, regulatory checks and potential damage to supply chains. UK implements legislation and regulation agreed in the Withdrawal bill. Potential negative relationship and lack of cooperation between UK and EU. UK and EU are Third Countries for services. Potential for a FTA between the UK and US, with the UK moving towards US standards over time.

2. Transitional no deal UK and EU negotiate a transitional arrangement beyond that already agreed in principle for instance for an additional 4 years. UK and EU trade on WTO terms. Potential for other bespoke agreements around e.g. data sharing, regulation and citizens' rights. Warmer relations between EU and UK compared to the cliff-edge scenario. The UK may be able to negotiate better than third country access to Framework Programmes and other European institutions. Potential for a trilateral FTA between the UK, EU and US, with the UK moving towards US standards over time.

Hard Brexit

3. UK-EU Free Trade Agreement UK exports to the EU would have to satisfy some rules of origin requirements, and customs measures would increase compared to current Single Market membership. To trade in the EU, UK companies would still need to comply with ECJ legislation and regulation. UK regulations and standards can diverge from those of the EU. UK has reduced access to markets, increased regulatory checks and potential damage to supply chains. The UK may be able to negotiate better than third country access to Framework Programmes and other European institutions. The level of comprehensiveness depends on the final agreement.



We need an extended transition period. Lives matter. Taking as much time as it needs to get this right is really important.

Soft Brexit

4. Norway model The UK remains part of the European Economic Area with access to the EU Single Market, but leaves the Customs Union. The UK would have to comply with EU rules on free movement of goods, services, capital and people. It would be able to pursue other FTAs, but would face rules of origin and other Non-Tariff Barriers in trade with the EU, would have to accept EU regulations and contribute to the EU budget, despite being excluded from decision-making. UK is a third country but (like Norway who is attempting to implement the EU CTR) may be able to access the EU CTR.

5. Swiss model The UK remains in the Single market for goods but not services. The UK-EU goods trade would continue to be tariff-free. But non-tariff barriers on trade in services rise. UK is required to contribute to the EU budget and adhere to EU regulations and standards. The UK has no voice in decision-making and would have to accept new regulation from Europe. The UK can negotiate Free trade agreements with other countries. UK is a third country and would need to negotiate a bespoke arrangement to provide access to EU CTR.

6. Customs union covering goods only. The UK maintains a customs union with the EU, but only for goods, not services, while leaving the Single Market. This would restrict the UK's ability to act independently, but would ensure trade with the EU took place free of tariffs and some non-trade barriers, even though non-trade barriers on services would rise. UK a third country.

5. Implications and Recommendations

Following the workshop, five themes were identified as priority areas that would impact the the future of clinical trials out to 2028:

- Regulation
- Access to Medicines, IMPs and devices
- Data
- Funding
- Workforce

A set of recommendations were drawn to help ensure a successful future for trials and a positive outcome for patients.

The high-level implications and recommendations are presented in the next slides, highlighting key aspects where the UK and EU might have different levels of alignment after Brexit.

Regulation

- The UK government should continue to seek full regulatory alignment with the forthcoming EU Clinical Trial Regulation. This should include a bespoke agreement for access to the EU portal and database and to ensure the UK can take part in the centralised assessment process.
- Where full alignment with the provisions of the EU CTR is not possible, the UK government should seek a proportionate approach to regulation that balances alignment with the opportunities to innovate.
- The UK should adopt a broad strategy to EU and international engagement to ensure it can continue to influence and drive new regulation and standards across Europe and globally, including through partnership with the EMA.
- UK and EU regulation and regulators will need to adapt to allow for new trial designs, new devices and technologies, and new approaches to data.

Access to medicines, IMPs and devices

- The UK and EU should work to ensure that trade barriers do not impact the availability or movement of new and existing licensed medicines, IMPs and devices after Brexit
- The UK government should continue to seek a close partnership between the MHRA and the EMA. An agreement should be sought to allow EMA marketing authorisation decisions to apply to the UK and equivalent safety standards to be maintained after Brexit
- The UK and EU regulators should ensure equivalence of regulation and standards for certification and testing of investigational medical products and devices.

Data

- A more streamlined and efficient approach is required in the UK and internationally to allow the effective collection and sharing of anonymised patient and trial data while protecting patients' rights and interests.

Funding

- A The UK and EU should agree full UK participation in EU framework programmes with access to funding for clinical research.
- A long-term strategic approach to funding of clinical trials is necessary in the UK to both ensure investment and to drive collaboration.

Workforce

- The UK Government should negotiate reciprocal arrangements, where possible, to ensure international mobility, as this is seen as a critical aspect of collaboration and research excellence.
- The UK Government should modernise and streamline its global immigration system as this is also seen as a critical aspect of collaboration and research excellence. In particular, a permissive immigration system should be developed that supports the clinical trials, health and research workforce that allows continued movement across borders.
- The UK needs to invest in a skilled clinical trials workforce to ensure it can maintain its longer-term competitiveness encouraging UK investment.

5. Implications and Recommendations: Regulation


Implication		Full alignment	Partial alignment	No alignment	Recommendation
Regulation	Alignment with the provisions of the EU Clinical Trials Regulation	<p>UK replicates provisions of the EU CTR and negotiates access to the EU portal and database through a bespoke agreement</p> <p>Harmonised approach to trials with minimal barriers</p> <p>UK and EU can cooperate on trials maximising patient participation and access to trials and treatments</p> <p>UK seen as an attractive destination for clinical trials as part of a unified UK and EU market</p>	<p>UK can replicate provisions of the EU CTR but does not have access to the EU portal and database</p> <p>UK facing increased complexity and difficulty to sponsor EU trials, particularly for non-commercial trials and increased barriers to expanding trials internationally</p> <p>Quality and frequency of trials conducted in UK decreases</p> <p>Patients have fewer options and delayed access to trials and/or potential innovative treatments</p> <p>UK a less competitive market for the placement of trials as an 'additional' market outside of the EU</p>	<p>UK and EU clinical trials regulation is not equivalent</p> <p>Increased costs and delays to international trials</p> <p>Quantity of trials conducted in UK decreases</p> <p>Patients have fewer options and delayed access to treatments</p> <p>Potential opportunities to innovate, but UK potentially less competitive compared to Full alignment</p> <p>UK may choose to specialise or align with another international market e.g. USA</p>	<p>The UK Government should continue to seek full regulatory alignment with the forthcoming EU Clinical Trial Regulation. This should include a bespoke agreement for access to the EU portal and database and to ensure the UK can take part in the centralised assessment process</p>
	Access to the EU clinical trials portal and database	<p>A bespoke agreement allows the UK to access the portal and database as a third country</p> <p>Risks where implementation of the EU CTR is delayed, or the portal and database are hard to use</p>	<p>Increased costs and potential time delays if the UK implements a parallel system</p> <p>Parallel systems may still be a barrier to the placement of trials in the UK due to increased administrative costs and duplicate systems</p>	<p>Time delays and costs to implement a bespoke system</p> <p>Different systems require multiple submissions with increased costs and delays</p>	
	Clinical trials sponsorship	<p>A bespoke agreement allows the UK to lead and sponsor trials as a third country</p>	<p>UK researchers and companies cannot sponsor and lead trials without legal representation in the EU to ensure compliance</p> <p>This may increase complexity and costs and result in fewer trials being conducted in the UK</p>	<p>UK researchers and companies cannot sponsor and lead trials without legal representation in the EU to ensure compliance</p> <p>This may increase costs and result in fewer trials being conducted in the UK</p>	
	Supervision and assessment	<p>UK can benefit from the streamlined supervision and assessment process in the EU CTR which should result in reduced clinical trial timelines and costs</p>	<p>Increased costs and barriers where the UK is outside of the supervision and assessment process</p> <p>Likely reduction in the number of EU-UK trials being sponsored in UK</p>	<p>Increased costs and barriers where the UK is outside of the supervision and assessment process</p> <p>UK participates in fewer UK-EU trials</p> <p>UK could become a more international market for clinical trials over time</p>	
	Transparency	<p>Greater transparency of clinical trials benefits patients.</p> <p>Potential barrier to the placement of industry trials.</p>	<p>Less transparency of UK clinical trials with negative impacts on patients.</p>	<p>Less transparency of UK clinical trials with negative impacts on patients.</p>	
	Expansion of trials	<p>UK-only trials can be expanded to include European centres (and vice versa) facilitating patient recruitment and access</p>	<p>Limited ability to expand UK-only trials and to join EU trials already underway</p>	<p>Limited ability to expand UK-only trials and to join EU trials already underway</p>	

 Positive outcome
  Negative outcome
  Risk or uncertainty

5. Implications and Recommendations: Regulation

Implication	Full alignment	Partial alignment	No alignment	Recommendation
UK influence over future regulation and policy	<p>Significant risk that the UK will be subject to EU regulation without significant influence around medicines regulation in EU and new CT guidance</p> <p>Potential to negotiate membership or associated status with the EMA</p> <p>Limited international influence</p>	<p>Significant risk that the UK will be subject to EU regulation without significant influence</p> <p>Limited ability to influence as an observer of the EMA</p> <p>Potential to influence regulation internationally</p>	<p>No formal mechanisms for influencing former EU legislation</p> <p>Critical to build influence internationally</p>	<p>The UK should adopt a broad strategy to EU and international engagement to ensure it can continue to influence and drive new regulation and standards across Europe and globally, including through partnership with the EMA</p>
Innovation	<p>UK automatically inherits new regulation.</p> <p>UK may have limited influence and opportunity to drive innovation.</p> <p>EU bureaucracy may limit the speed at which new regulation can be introduced</p>	<p>UK required to take additional steps to implement new regulation</p> <p>UK likely to have limited influence and opportunity to drive innovation.</p> <p>EU bureaucracy may limit the speed at which new regulation can be introduced.</p> <p>Limited opportunities for divergence.</p>	<p>Outside of the EU, the UK could take an innovative and proportional approach to regulation.</p> <p>Concerns that UK will become too niche, or become a rule-taker from another market e.g. USA</p>	<p>Where full alignment with the provisions of the EU CTR is not possible, the UK Government should seek a proportionate approach to regulation that balances alignment with the opportunities to innovate without compromising patients' safety</p>
Clinical trial design	<p>UK researches can influence and drive development of regulation for adaptive and real- world evidence trials</p> <p>UK aligned with Europe which may limit ability to adopt new approaches or benefit from advances internationally</p>	<p>UK has limited influence for regulation of new trial designs but needs to align with EU legislation</p>	<p>UK is independent and would drive development of regulation for adaptive and real- world evidence trials in the UK or internationally, or benefit from alignment with non- EU countries</p>	<p>UK and EU regulation and regulators will need to adapt to allow for new trial designs, new devices and technologies, and new approaches to data</p>

 Positive outcome
  Negative outcome
  Risk or uncertainty


We need to keep contributing to the research agenda of the EU and continue to drive and influence the agenda.

5. Implications and Recommendations: Access to Medicines, IMP's and devices

Implication	Full alignment	Partial alignment	No alignment	Recommendation	
Trade barriers	<p>Outcome dependent on the shape of Brexit.</p> <p>Products may be subject to new tariff or non-tariff barriers resulting in raising costs</p> <p>? Increased costs and inefficiencies to the movement of materials, including supplies for clinical research, and medical radioisotopes.</p>			The UK and EU should work to ensure that trade barriers do not impact the availability or movement of new and existing licensed medicines, IMPs and devices after Brexit as this is crucial to maintain standard of care on which to build clinical trials.	
Access to medicines, IMPs and devices	Marketing authorisation	<p>UK participates in EU marketing authorisation processes</p> <p>Aggregation of data for market authorisation supports rare and paediatric diseases</p> <p>✓ Rapid access to drugs authorised in Europe</p> <p>UK benefits from parallel distribution of medicine and IMPs</p> <p>UK and EU can share signals and safety information for Pharmacovigilance</p>	<p>✗ UK may be able to participate in EU marketing authorisation processes</p> <p>Potential delays in access to and availability of medicines and IMPs</p> <p>✗ UK unable to benefit from parallel distribution, raising costs of some medicines</p> <p>Additional costs and delays in sharing safety data</p>	<p>✗ UK unable to participate in marketing authorisation process</p> <p>Significant delays to the availability and access to drugs</p> <p>No parallel distribution resulting in increased costs</p> <p>Barriers to the placement of trials</p> <p>Additional costs and delays in sharing safety data</p>	The UK government should continue to seek a close partnership between the MHRA and the EMA. An agreement should be sought to allow EMA marketing authorisation decisions to apply to the UK and equivalent safety standards to be maintained after Brexit
	Medical products and devices	<p>✓ UK adopts EU regulation for medical products including GMP, GDP.</p> <p>Mutual recognition of standards, certification requirements and Qualified Persons</p> <p>No additional testing requirements.</p> <p>Free movement of medical products (including IMPs) and devices.</p>	<p>? UK adopts EU regulation for medical products including GMP, GDP.</p> <p>Equivalence of standards and certification but no mutual recognition.</p> <p>Additional barriers to the import and export of IMPs between the UK and EU.</p>	<p>✗ UK and EU standards diverge.</p> <p>No recognition of standards and certification.</p> <p>Significant additional barriers to the import and export of medical products, IMPs and devices between the UK and EU.</p>	The UK and EU regulators should ensure equivalence of regulation and standards for certification and testing of IMPs and devices.

✓ Positive outcome
 ✗ Negative outcome
 ? Risk or uncertainty



If you limit the drugs that are used and are available for patients – the standard or care may be different to other countries. Patients may not be able to access drugs and solutions may be limited

5. Implications and Recommendations: Data, Funding and the Workforce

Implication	Full alignment	Partial alignment	No alignment	Recommendation
Data	<p>✓ Data protection remains aligned between UK and EU</p> <p>UK influences new standards and approaches to data sharing</p> <p>Permissive environment for real-world evidence</p> <p>Effective patient recruitment</p>	<p>✗ UK likely to remain aligned with EU data protection</p> <p>Lack of influence may limit UK's ability to drive new standards and approaches</p> <p>UK may be unable to participate in databases</p>	<p>✗ UK and EU regulation may diverge with negative impacts on the ability for data sharing, patient recruitment, pharmacovigilance and trials</p> <p>Opportunity to innovate</p>	<p>A more streamlined and efficient approach is required in the UK and internationally to allow the effective collection and sharing of anonymised patient and trial data while protecting patients' rights and interests.</p>
Funding	<p>✓ UK can participate in EU Framework programmes and funding either as an Associated country or through a bilateral agreement</p>	<p>✗ UK can participate in EU framework programmes as a Third Country but is unlikely to be eligible for funding</p> <p>New strategies may be required to support funding and investment in the longer-term</p>	<p>✗ UK can participate in EU framework programmes as a Third Country but is ineligible for funding</p> <p>New strategies will be required to support funding and investment in the longer-term</p>	<p>The UK and EU should agree full UK participation in EU framework programmes with access to funding for clinical research.</p> <p>A long-term strategic approach to funding of clinical trials is necessary in the UK to both ensure investment and to drive collaboration.</p>
Workforce	<p>✗ Short-term uncertainty likely to persist until Brexit outcome known with negative impacts on workforce.</p> <p>Freedom of movement of UK workers within the EU, and the reverse, is likely to be impacted in almost all Brexit scenarios with negative impacts on the availability of skilled workers in trials and the health sector.</p> <p>Negative impact on UK talent and international competitiveness</p> <p>Opportunities to harmonise migration internationally.</p>			<p>The UK Government should negotiate reciprocal arrangements, where possible, to ensure international mobility, as this is seen as a critical aspect of collaboration and research excellence.</p> <p>The UK Government should modernise and streamline its global immigration system as this is also seen as a critical aspect of collaboration and research excellence. In particular, a permissive immigration system should be developed that supports the clinical trials, health and research workforce that allows continued movement across borders.</p> <p>The UK needs to invest in a skilled clinical trials workforce to ensure it can maintain its longer-term competitiveness encouraging UK investment.</p>

✓ Positive outcome
 ✗ Negative outcome
 ? Risk or uncertainty



We need to be able to attract the brightest minds to innovate and staff to deliver. It's already difficult to recruit high quality triallists and trial delivery is affected by resource issues in the NHS

6. Conclusions

- The implications and recommendations outlined in this report are those that participants surfaced as critical to address as the UK and EU work towards a positive future for trials: a future where patients have the best possible outcomes and benefit from a thriving clinical trials sector.
- As the UK and EU engage in phase II negotiations, the sector needs to ensure that clinical trials and patients remain a priority for both UK and EU governments.
- Regulatory alignment will not be sufficient to ensure the best possible outcome. The UK will need special agreements to access the EU portal and database and to simplify UK's ability to simplify UK ability to lead and sponsor trials. It will also need to ensure it can fully participate in pharmacovigilance databases and seek mutual recognition for standards and certification.
- Without this, standards and access to patient care could be impacted, and industry disincentivised from setting up and running trials in the UK.
- A systemic and strategic approach is needed, one that will help to meet future opportunities and challenges as well as those apparent today.
- Until the outcome of Brexit is known it remains critical to prepare for alternative outcomes. In particular for a no deal scenario where the UK may end up outside the EU, without a transition period.



If we don't have new ideas, therapies, devices then the sector won't advance. In the NHS we have a perfect test put with patients who are keen to participate in innovative treatment and trial design



If we are not aligned, our data counts for nothing. Why would we do trials if data counts for nothing?

No regrets strategies

- UK government should invest in an NHS that is fit for the future, one with a unified data infrastructure, a strong workforce and a focus on research.
- The sector should do more to communicate the economic and social value of trials and ensure its prominence in phase II negotiations.
- UK government should develop a long-term, strategic vision for the clinical trials sector that provides early and ongoing assurance for UK clinical trials.
- It will be critical to ensure a smooth transition to any new arrangements to minimise disruption to patients and trials, resulting from new systems.
- The UK should develop an approach to immigration and mobility that will support clinical trials and the broader health and life sciences sector.

7. Acknowledgements

Interviewees

Adrienne Clarke	GlaxoSmithKline
Angela McFarlane	IQVIA
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Toby Toward	Immunocore
Virginia Acha	Merck

Workshop Participants

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Bettina Ryll	Melanoma Patient Network Europe
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Christiane Abouzeid	BioIndustry Association (BIA)
Christos Gatsios	Office for Life Sciences
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