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“Everything’s harder” but “the spirit of science is still there”:

Understanding how the new UK-EU relationship affects global collaboration in cancer research

2025

University of Southampton

Contents

Reference

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About Cancer Research UK

We’re the world’s leading cancer charity, dedicated to saving and improving lives through our research, influence and information. And we’re the largest charitable funder of cancer research in the world, funding around 50% of all publicly funded cancer research in the UK.

For the past 120 years, we’ve been making discoveries that have saved countless lives and benefited millions of people around the world. Our research has helped prove the link between tobacco and cancer, preventing millions of deaths worldwide. We were a key player in the development of radiotherapy. Our research has played a role in around half of the world’s essential cancer drugs. And our research led to the development of the HPV vaccine.

These developments have been at the heart of the progress that has already seen cancer survival in the UK double in the last 50 years. Our pioneering work is saving lives in the UK and on a global scale. Together we are beating cancer.

CANCER RESEARCH UK

Cancer Research UK is a registered charity in England and Wales (1089464), Scotland (SC041666), the Isle of Man (1103) and Jersey (247)

Hatch

Hatch is based in the School of Healthcare Enterprise and Innovation at the University of Southampton. Hatch specialises in policy research; stakeholder mapping and engagement; pragmatic evidence and literature review; developing meaningful metrics and indicators; building evaluative thinking through learning and development; theory of change development, and undertaking mixed-method theory-led evaluation and research impact assessment.

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List of acronyms

ABPI	Association of the British Pharmaceutical Industry
CRUK	Cancer Research UK
CTA	Common Travel Area
CTD	Clinical Trial Directive
CTIS	Clinical Trials Information System
CTR	Clinical Trial Regulation
CYP	Children and Young People
EAMS	Early Access to Medicines Scheme
EFPIA	European Federation of Pharmaceutical Industries and Associations
EORI	Economic Operators Registration and Identification
EMA	European Medicines Agency
ERDF	European Regional Development Fund
ERC	European Research Council
ESF	European Social Fund
EU	European Union
GB	Great Britain
HEI	Higher Education Institution
HER	Higher Education Research
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IVDs	In-Vitro Diagnostics
LMICs	Low- and middle-income countries
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PRISM	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
A QP	Qualified Person
STEM	Science, Technology, Engineering and Mathematics
TCA	Trade and Cooperation Agreement
UK	United Kingdom
WHO	World Health Organization

Key messages

This collaborative research explored the challenges and opportunities facing science, research, health and care since the introduction of the UK-EU Trade and Cooperation Agreement (from 1 January 2021).

This report shares the detailed and often complex feedback generated through this research within an everchanging political environment. In summary, the research found that:

- The challenges currently being faced are having a direct negative impact on people affected by cancer.
- Access to EU research funding and collaboration opportunities is considered vital for UK cancer research.
- There are significant concerns about the future of UK cancer research, the health and care workforce, and the ability of the UK to attract global talent.
- Regulatory changes have created significant challenges to the delivery of clinical trials involving patients in both the UK and the EU, resulting in delays, additional costs, and complexity. This has a particular impact on rare and children’s cancer trials.
- Regulatory frameworks that are aligned or ”compatible enough” with the EU are pivotal to effective collaboration and innovation. There also exist opportunities for some regulatory divergence to facilitate more innovative research and international investment, as long as key priorities such as data-sharing are protected.
- Concerns continue about the impact of Brexit on the attractiveness and competitiveness of the UK in relation to industry investment within the global market.
- There is great expertise within the UK science base. The desire of researchers to collaborate internationally and the desire of researchers to collaborate with the UK is as strong as ever. But the environment is changing. Those changes have the potential to enhance the UK’s position as a global leader in cancer research and innovation, but much uncertainty remains.
- The issues are interwoven. Consideration needs to be taken when defining and implementing solutions to account for potential knock-on effects (positive and negative) to interrelated challenges.

There are genuine opportunities to enhance the UK science and innovation sector and the delivery of cancer care, but without addressing the existing challenges and ongoing uncertainty, it is unclear if and how these opportunities will come to fruition. While the September 2023 announcement that the UK would be an associated country to Horizon Europe was warmly welcomed and provided relief, it is only one aspect where some clarity has been gained.

There are strong concerns that the full impact of the UK’s exit from the EU will be felt for an extended period of time. This has had–and will continue to have–a lasting legacy for cancer research and the delivery of cancer care.

Executive summary

Background

> **“There has never been a better opportunity to harness research and innovation and international partnerships to speed our ability to prevent, detect and treat cancer for all.”**
>
> - UK US Cancer Summit 2023 (p. 3)

Cancer will affect all of us at some point during our lives. A huge rise in cancer cases is predicted worldwide between 2022 and 2050 (from just under 20 million to over 35 million cases each year) [1]. In the World Health Organization (WHO) European region, cancer cases are expected to rise by 22.5% between 2022 and 2045 [2]. In the UK, 1 in 2 of us will get cancer in our lifetimes [3, p. 944]. Every year, around 2.7 million people in the European Union are diagnosed with cancer [4], and there are substantial inequities; for example, more than 33,000 cases of cancer each year are attributable to deprivation in the UK [5].

But we have made huge progress in the past 50 years. We know that cancer research saves lives and gives people more time with their loved ones. Global collaboration increases the impact of research [6], and it is essential to address this huge global challenge [7]. As the world’s largest charitable funder of cancer research, Cancer Research UK and the US National Cancer Institute co-founded the Cancer Grand Challenges with an international community of partners– now including the Spanish Association Against Cancer, French National Cancer Institute and the Dutch Cancer Society - because “[cancer’s toughest challenges] are the obstacles that continue to impede progress against cancer and that no one scientist, institution or country can solve alone” [8]. While researchers continue to collaborate globally, the political focus on cancer has been strengthened significantly with the US Government’s ongoing Cancer Moonshot [9] since 2017 and the European Union’s Beating Cancer Plan 2019 – 29, which emphasises the need for collegiality across nations [4].

The UK’s evolving political and trading relationship with the European Union has posed well-documented questions for many industries, medical research included. From a research funder’s perspective, CRUK’s research community prioritises partnerships with the United States and Europe, with increasing interest in the Asia Pacific region. In a 2023 survey with CRUK researchers, 10 of the top 15 countries specified for future collaborations were in the EU (plus a further two within the EU’s single market) (CRUK, unpublished data). It is, therefore, vital to understand the impact of Brexit on the environment for research, including further opportunities for international cooperation. “Science does not recognise borders, and everyone wins when the best UK scientists can work with the best in the EU and around the world” [10, column 577].

The cancer research community, including people affected by cancer, set out their priorities for the future UK-EU relationship during negotiations in 2019 and 2020 [11]. Three years after the 2021 EU- UK Trade and Cooperation Agreement, acknowledging the substantial additional challenges of the COVID-19 pandemic, CRUK, in collaboration with Hatch Consulting, set out to explore opportunities and challenges for cancer research in this new and rapidly evolving political and regulatory landscape. During the project, negotiations succeeded on the UK’s association to Horizon Europe, with the UK Government confirming that ”(W)e are determined to do all we can together with our European colleagues to seize this moment, and all it could do to help our brightest minds deliver jobs, growth, and breakthroughs that will make life better for us all” (Press release) [12].

Approach

In collaboration with Cancer Research UK’s Policy Department (Global Policy & Programmes team), Hatch Consulting, part of the University of Southampton, was commissioned to undertake multi-qualitative research in 2023 that aimed to identify the experienced or perceived challenges and opportunities facing UK researchers, specifically the CRUK research community[1]. This research addressed the following research questions:

- What are the challenges, future concerns and opportunities being experienced or perceived by UK researchers, specifically the UK cancer research community, since 1st January 2021?
- What are the challenges, concerns and opportunities facing UK care delivery, specifically cancer care delivery, following the UK’s exit from the EU?

This research focuses on the period after the UK left the European Union on 31 January 2020 (‘post-Brexit’) and the period since the introduction of the UK-EU Trade and Cooperation Agreement (TCA) (from 1 January 2021).

This project employed a multi-method design consisting of a rapid scoping review of academic and grey literature sources; interviews with members of the CRUK research community; workshops with CRUK research community members and staff, and secondary analysis of CRUK’s global collaboration survey qualitative data.

Further detail about the methodology, data and analysis underpinning this research can be found in Supplementary material A of this report.

Key findings

The challenges currently being faced are having a direct negative impact on people affected by cancer

- Delays and increasing costs associated with access to innovative treatments and care have significant implications for people affected by cancer.
- Early access to innovative medicines often comes from clinical trials. Running clinical drug trials has been made more difficult and costly, ultimately negatively impacting patients.
- Paediatric and rare cancer treatment options appear to have been particularly adversely affected. Such studies require international collaboration to recruit patients as well as to access collaborative networks to inform the delivery of care.
- Concerns persist about future access to medicines and patient choice if opportunities for people affected by cancer to participate in innovative trials in the UK are adversely impacted. These concerns stem from ongoing uncertainty about the compatibility of the UK’s future regulatory framework with other regulators, as well as the broader UK environment for research and innovation regarding continuing support for industry investment and remaining internationally competitive.
- The UK’s withdrawal from the EU and subsequent changes to immigration policy are considered to have further contributed to the pre-existing resourcing challenges in the UK health system and, thus, the ability to deliver cancer care and clinical research.
- The evidence review identified legal and regulatory changes that have the potential to impact public health and cancer prevention, such as changes in tobacco control and trade in food and food quality standards. It is unclear if and how changes to regulatory frameworks in this regard could benefit or increase cancer risk to the public.

[1] For the purpose of this research the CRUK research community is defined as ”Any person or those involved in a project in receipt of funding from CRUK since 1st January 2021 (The date the UK-EU Trade and Cooperation Agreement came into effect)”

> **“[My experience has been] just reduced opportunities and having to work so much harder to do everything that we do and ultimately delaying progress for patients. ”**
>
> Focus Group Participant, UK-based, Sep 2023

Access to EU research funding and collaboration opportunities is vital for UK cancer research

- Amongst the cancer research community, concern remains that science and research could continue to be embroiled in any ongoing political bargaining between the UK and the EU.
- The September 2023 announcement that the UK would become an associated country to Horizon Europe from 1st January 2024, providing direct access to EU funding, was warmly welcomed. There was a clear sense of relief that the agreement had been reached, allowing UK-based researchers to continue to participate in and lead research, as with previous programmes.
- There was a perception that the 2019-24 UK Government continued to send ’mixed signals’ to the research community. On the one hand, they appeared committed to funding and supporting UK research, but on the other hand, they were seen to be cutting spending on research and infrastructure.
- The extended period of uncertainty has had, and will continue to have, a lasting impact on UK research and researchers due to lost opportunities for collaborative research during the period of uncertainty about the UK’s Horizon Europe associate status. This occurred at a time when the EU was investing in cancer research as a high priority, with a particular focus on rare cancers.
- While associate status to Horizon Europe was welcomed and seen as significantly better than uncertainty, it was considered to have significant drawbacks, including limitations on the strategic influence of Horizon Europe. However, there was a clear commitment from both UK and EU-based researchers to collaborate wherever they find shared interests and to work around the new barriers wherever possible.
- UK researchers and their research centres are no longer eligible to be part of European Reference Networks (ERNs), such as those focused on children’s cancers. These networks link together specialised centres to share best practice and learning around treatments for rare diseases [13, 14, 15]. This exclusion was widely seen as a loss of highly specialised expertise, especially in rare diseases for which international collaboration is critical [15, 16].

There are significant concerns about the future UK cancer research and health and care workforce and attracting global talent to the UK

- Changes to UK immigration policies limit the ability to attract cancer researchers and health and care workers from the EU to undertake cancer research and deliver cancer care in the UK.
- Multiple additional factors were identified that impact the attractiveness of the UK as a workplace for EU workers. These include new costs (e.g. visas, Immigration Health Surcharge and international fees for EU PhD students), perceptions of a less open and welcoming ’post-Brexit’ UK culture, and uncertainty about career development opportunities and recognition of qualifications.
- The end of freedom of movement between UK-EU students and workers has added time, complexity, and cost, making it harder for British experts to visit the EU and for EU citizens to come to the UK to collaborate, share knowledge and expertise even on a temporary basis, due to changing immigration policy and visa requirements.

- Changes to visa requirements appear to have greatly impacted early-mid career researchers and health and care workers, who are typically on lower pay. Before the UK’s exit from the EU, EU-based researchers were prominent in UK-based cancer research institutes and centres. Post-Brexit, there is a strong sense that EU early career researchers avoid the UK, leaving a gap in the workforce that is not being filled by domestic or non-EU talent.

- For more senior appointments, special provisions for scientists and options such as the ’Global Talent visa’ are considered to be working reasonably well, but the situation is more fragmented for UK scientists seeking to work in the EU [17].

- Suggestions identified to overcome the workforce challenges included the creation of an easier, faster and simpler immigration system; establishing reciprocal agreements to facilitate mobility of researchers and health and care professionals; reducing immigration and visa costs; addressing perceptions that the UK is not welcoming to international workers; and honouring mutual recognition of professional qualifications.

Regulatory frameworks that are aligned or ”compatible enough” are pivotal to effective collaboration and innovation

- The ability to continue to share data easily between countries is hugely important to support effective international collaborations. For the UK and EU, this is underpinned by “data adequacy” decisions.

- Regulatory changes as a result of the UK’s withdrawal from the EU and introduction of the UK-EU TCA have created significant challenges for the delivery of clinical trials in the UK, resulting in delays, additional costs and complexity. Those involved in clinical trial setup require and still hope for more detailed guidance and effective communication regarding existing and future practical changes.

- In the short term, access to medicines and devices has been largely maintained, although specific challenges exist within Northern Ireland. In the long term, there are concerns about how future regulatory divergence away from the EU may hinder access and supply of medicinal products.

- Beyond the EU, with greater regulatory independence, there are opportunities to engage in other global initiatives to support faster access to medicinal products, such as involvement in Project Orbis, and there is scope for regulatory innovation domestically (see p. 53).

The UK environment for science and cancer research

- There is continued respect for the UK’s position as a leader in research and innovation, and there remains a desire from industry and academia to engage and collaborate with the UK. However, concerns persist about the damage to the UK’s position and reputation if the challenges around accessing EU funding, regulatory issues and attracting the best talent continue.

- The UK research landscape is changing with government commitments to new funding for research and innovation and changes to the way in which clinical trials are delivered following the O’Shaughnessy review of commercial clinical trials in the UK [18]. Both have the potential to enhance the UK’s position as a global leader in cancer research and innovation, but much uncertainty remains about how these new initiatives will come to fruition.

- There are mixed views about the impact on industry investment in the UK. Significant concerns exist about future investment and the UK delivering clinical trials if existing challenges, which are causing delays and increased costs, are not addressed. Additionally, concerns were raised if significant divergence arises between EU and UK regulatory frameworks. Conversely, some are optimistic about the UK as an important location for industry to prioritise research and supply medicinal products.

- Concerns were raised that changes to the UK’s regulatory environment and reduced industry investment could limit the health and care system’s ability to procure essential goods and services, potentially reducing patient access to medicines, particularly in Northern Ireland. However, the UK’s position as an attractive early medicines launch destination offers hope for faster access to innovative treatments, benefiting patients, especially those affected by cancer.

- Greater government support is called for to bolster basic research and its ability to be commercialised. Suggested initiatives include fostering stronger links between industry and academia and sufficient funding (equivalent to other European countries) to address the loss of access to EU funds.

- The full impact on UK HEIs remains to be seen but is expected to lead to reduced funding. This could occur directly through lack of access to EU-based funds, loss of research funding, and limited EU student mobility through ERASMUS, and indirectly, as a result of a smaller UK economy.

Discussion and implications

This research highlights a complex and rapidly changing environment, which continued to evolve throughout the duration of this project. Our findings identified significant challenges and uncertainty arising from the changing relationship between the UK and the EU. These challenges impact cancer research and have consequences for those affected by cancer. During these periods of uncertainty and navigating regulatory changes, reliance on goodwill and interpersonal connections has been crucial to ensure collaborative research can continue. However, this reliance raises concerns about sustainability, especially where such connections do not exist or as relationships change and the current research workforce retires.

Despite these challenges, there is optimism and potential for greater EU and global collaboration that could be realised if managed effectively. However, uncertainty and concerns remain. Some in the research community see rejoining the EU as the best possible solution. For most, however, rejoining the EU is thought to be unrealistic, at least in the short term.

The UK rejoining Horizon Europe offers a glimmer of hope for addressing further challenges around funding, regulation, movement of people and the UK’s position as a leader in global research. This holds huge potential for cancer prevention and new treatments that stand to benefit the global effort to beat cancer. However, there is a mixed narrative with regard to regulation. On one hand, there is a huge desire for alignment with regulatory frameworks, whilst, on the other, opportunities to diverge in places where it benefits UK science and innovation have been raised. The question remains whether this balance can really be achieved. Can the UK be regulatory aligned and different?

Moving forward, policy reforms and calls for more transparent and better communication to support the implementation and delivery of cancer research and care are needed. In this research, the research community’s main focus of EU funding centred around Horizon Europe (because of what it represents overall about open- ness to collaboration in addition to the prestigious funding itself), further benefits to UK researchers may come from access to other EU programmes like EU4Health, to which the UK is not associated [19], which provide significant funding for cancer research. If acted upon, the CRUK research community can remain competitive internationally, attract industry investment, and draw the best global talent to the UK.

1. Introduction

UK and EU ambitions for beating cancer

The UK and EU are aligned in their objectives to accelerate progress for people affected by cancer. In the UK, all four nations have cancer/major conditions strategies at varying stages of implementation [20, 21, 22, 23, 24]. See **Figure 1**.

The 2019-24 UK Government had a 10-year Life Sciences Vision with ambitions for the UK to become a “science superpower,” an objective part of a strategic framework that acknowledges the significance of science and technology with the potential to revolutionise healthcare worldwide. One of the primary areas of focus is to ’cure cancer’ [25]. UK-based charity Cancer Research UK (CRUK) continues to help shape and influence agendas for cancer and life sciences policy across the UK and globally, most recently through CRUK’s plans for Longer, Better Lives: A Manifesto for Cancer Research and Care.

Meanwhile the EU published its first cancer plan in 2021 (Europe’s Beating Cancer Plan: A new EU approach to prevention, treatment and care 2021), and cancer is high on the EU’s agenda through a research and innovation-focused cancer mission, funded by programmes such as Horizon Europe and EU4Health (e.g. EU4Health programme 2021-2027 – A vision for a healthier European Union).

Despite these aligned missions, the UK’s 2016 decision to withdraw from the EU (”Brexit”) in 2020 and the introduction of the UK- EU Trade and Cooperation agreement in January 2021 (EU exit) have altered the way in which UK and EU-based scientists undertake cancer research and deliver cancer care collaborations. With examples of high-profile obstructions to collaborative research efforts, such as access to Horizon Europe funding, beginning to emerge. This has been further complicated due to the impact of the COVID-19 pandemic.

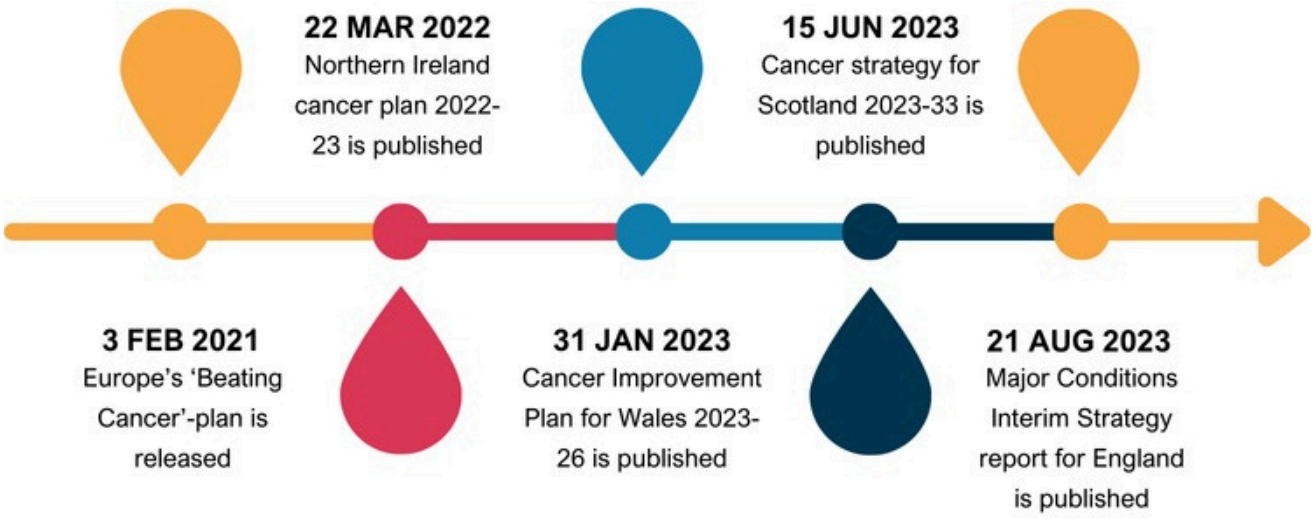

Figure 1: Timeline of key cancer strategy publications for UK and EU since UK exit from the EU

Background to the UK’s withdrawal from the EU

In 2016, after the Brexit referendum, the UK initiated the process of formally leaving the EU. The original deadline for the UK’s withdrawal from the EU was 29th March 2019, which, after many political developments, occurred on 31st January 2020. The transition period was extended until 31st December 2021 to allow for more time to ratify withdrawal agreements. The extension was partly due to complexities relating to the Republic of Ireland as a member of the EU, bordering Northern Ireland and, by that, the rest of the UK. This led to further negotiations between the UK and the EU concerning border control, regulations and policies and how they would apply in terms of maintaining an open border and upholding the Belfast (Good Friday) Agreement (ruling out a hard border) [26].

During the withdrawal agreement (Article 50) negotiations, universities and research communities repeatedly voiced their concern that higher education and research in the UK during the withdrawal process were not given much importance and were overshadowed by other matters [27, 28]. The uncertainty and concerns related to a number of areas:

- Ongoing and future research projects
- Erasmus+ placements
- Principal Investigator status within Horizon 2020 (the EU framework programme immediately preceding Horizon Europe).

Whilst universities expressed uncertainty and asked for assurances, the UK Government emphasised a bright future for UK higher education and research [29].

The health community also formed the Brexit Health Alliance (now known as The UK Alliance for International Health Policy), which made a number of calls for issues with the potential to negatively impact patients to be prioritised during the negotiations of the UK’s exit from the EU, and these were supported by CRUK.

The UK-EU relationship is now embodied in three principal legal agreements:

1. The Withdrawal Agreement, which outlines the terms of the UK’s withdrawal from the EU
2. The UK-EU Trade and Cooperation Agreement (TCA), introduced on 1st January 2021 and formally came into force on 1 May 2021. It sets out the arrangements in areas such as trade in goods and services.
3. The Windsor Framework agreement, which was agreed on the 27th February 2023 and sets out to ensure the smooth movement of trade in the internal market, notably between Great Britain and Northern Ireland and facilitating the movement of goods between Northern Ireland and the Republic of Ireland (EU) without the need for a hard border.

Furthermore, the Common Travel Area (CTA) describes a set of arrangements allowing largely free movement between the UK, Republic of Ireland, Isle of Man and the Channel Islands.

By 2022-23, at a time when approximately one-third of all CRUK-funded clinical trials involved at least on EU country, and CRUK researchers viewed themselves as part of a worldwide research community [30, 31], CRUK wished to get an up-to-date understanding of the challenges and opportunities being faced by the UK and EU cancer researchers. This would help to inform CRUK how best to engage with the UK Government and EU Institutions in this rapidly changing political and regulatory landscape to ensure the research ecosystem is as conducive as possible to cancer research collaboration and care that supports the fastest possible progress to help those affected by cancer.

2. Research aims and objectives

In collaboration with Cancer Research UK’s Policy Department (Global Policy & Programmes team), Hatch conducted multi-qualitative research in 2023 that aimed to identify the experienced or perceived opportunities and challenges facing UK research, specifically focusing on the CRUK research community[2] as well as cancer care delivery. To achieve this aim, this research addresses the following research questions:

- What are the challenges, future concerns and opportunities being experienced or perceived by UK researchers, specifically the UK cancer research community, since 1st January 2021?
- What are the challenges, concerns and opportunities facing UK care delivery, specifically cancer care delivery, following the UK’s exit from the EU?

This research focuses on the period after the UK’s exit from the EU on 31st January 2020, specifically from the introduction of the UK- EU TCA on 1st January 2021 to October 2023, when data collection was completed, while also discussing later policy changes based on published reports (see **Figure 1** Timeline). **Figure 2** presents a timeline of key political agreements during this period and the contextual setting in which the data collection took place. This work builds upon a previous CRUK influencing paper The UK and EU: What people affected by cancer need from the future relationship.

While this research aimed to support CRUK to make specific recommendations for UK-EU relationships, it also sought to contextualise the evidence more broadly. This approach allows CRUK to better understand which bilateral and multilateral foreign policy relationships, including and beyond the EU, are most important for future policy work.

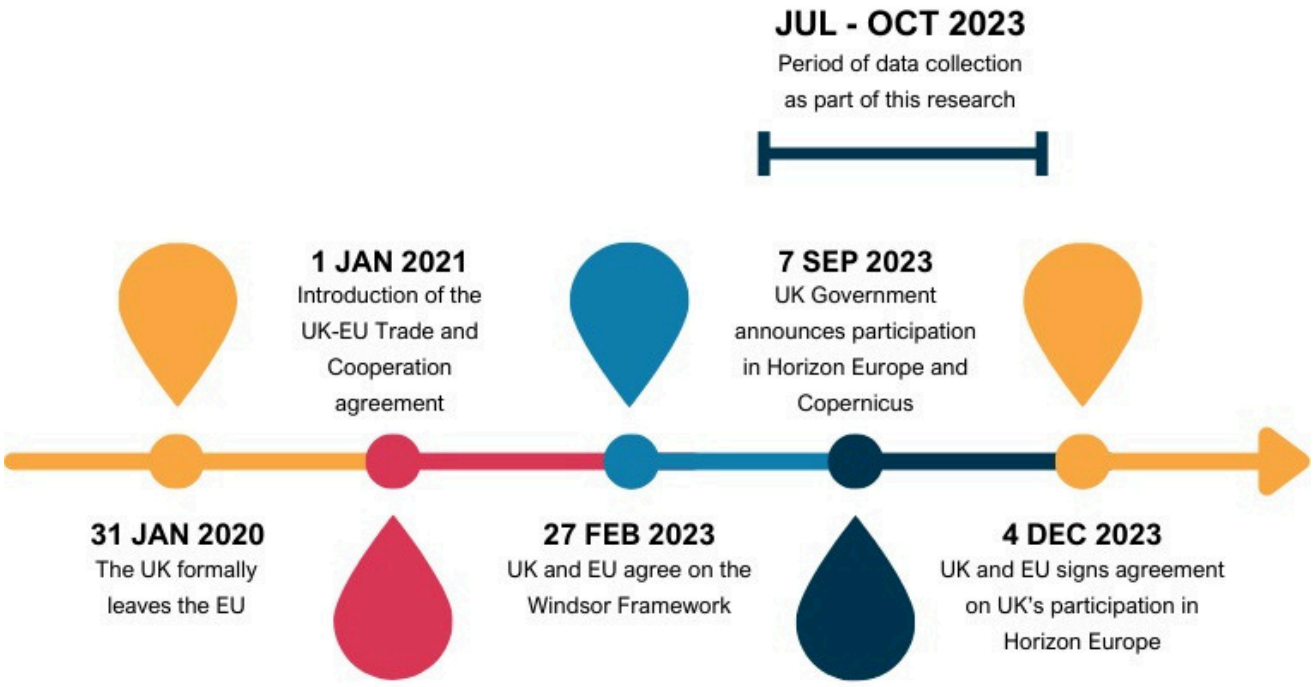

Figure 2: Timeline of key political agreements following the UK’s exit from the EU that have impacted cancer research, health and care, alongside the data collection period for this research

[2] For this research, the CRUK research community is defined as ”Any person or those involved in a project in receipt of funding from CRUK since 1st January 2021 (The date the UK-EU Trade and Cooperation Agreement came into effect)”

3. Methods

The purpose of this research was to identify the challenges and opportunities in cancer research and cancer care delivery as experienced or perceived by the research community, particularly within the CRUK research community, since the UK’s withdrawal from the EU. Please note that suggested solutions have not been assessed in terms of their feasibility or accuracy as part of this research; they are a synthesis of potential considerations as expressed by the research community. To capture a wide range of perspectives and experiences, a multi-qualitative design consisting of the following four approaches was employed:

3.1 Rapid Scoping Review

The aim of the rapid scoping review was to identify and outline key challenges or opportunities encountered by the UK research community in relation to collaboration beyond the UK, with a particular focus on specific nuances relevant to cancer research and care delivery. The review protocol was developed in collaboration with CRUK and included English-language literature published between January 1, 2021, and June 30, 2023, encompassing academic and grey literature sources (see Supplementary material B). The rapid scoping review is referred to as a ”review” throughout this report.

3.2 Interviews with the CRUK research community

The study consisted of 12 semi-structured interviews, each lasting 30 minutes, with purposefully selected key stakeholders from the CRUK research community (see Supplementary material C). The stakeholders were chosen to obtain diverse perspectives within the cancer research ecosystem. Our interview framework (see Supplementary material G) aimed to explore several aspects of UK-EU collaboration in cancer research, such as identifying areas that are working well, areas that could use improvement, and potential concerns for the future that could impact collaboration. Additionally, to gain insight into which countries outside the EU are considered most important for stakeholder collaborations.

3.3 Workshops with CRUK research community and CRUK staff

Three one-hour online workshops were conducted to explore views in small groups. Two of the workshops were with researchers and support staff who received or supported CRUK-funded research, and one was with CRUK staff involved in funding research involving bilateral and multilateral relationships with project teams based in the EU and globally. The format (see Supplementary material D) followed a structure similar to that of the interview framework. However, the workshops allowed for the range of perspectives across a research project or funding activity to be captured and encouraged discussion between the participants.

3.4 Secondary analysis of CRUK global collaboration survey data

Between 8th June - 26th July 2023, CRUK conducted a survey amongst professional subscribers to their mailing list, including CRUK grantees, to gather intelligence about the challenges and issues that cancer scientists are facing or perceiving in global collaboration regarding cancer research. The survey included open-ended questions, and a secondary qualitative analysis was conducted on a subset of these questions (see Supplementary material E). This analysis focused on responses from those who qualified for the ’CRUK Research Community’ definition as described above and consented to share their anonymous survey data with third parties (N=52). The data included a small sample of responses from those primarily based in an EU or EEA country (n=2), with the remaining respondents all based in the UK (n=50).

3.5 Analysis

Data from all sources were combined and analysed thematically using NVivo software. Illustrative quotes were selected from the data sources (workshops, interviews and a survey) to include in the presentation of the results section of the report. Further details about the methods and analysis process can be found in the Supplementary material along with additional supplementary quotes.

4. Results

This section reports the perceived or experienced challenges and opportunities to cancer research and cancer care delivery since the UK’s exit from the EU as identified through the review and expressed by the research community and CRUK research community during the interviews, workshops and survey.

A total of 88 documents were included in the review as part of this report (See supplementary material B.IV). Perhaps unsurprisingly, most were published in 2022 (38/88), followed by those published in 2021 (32/88) and 2023 (18/88), respectively.

The results are presented under four primary interconnected key themes with associated sub-themes. The ’Impact on people affected by cancer’ is presented as a core overarching sub-theme within each of the primary themes. A series of contextual factors are also identified as a separate theme. A summary of the key thematic areas identified in the research is shown in **Figure 3.**

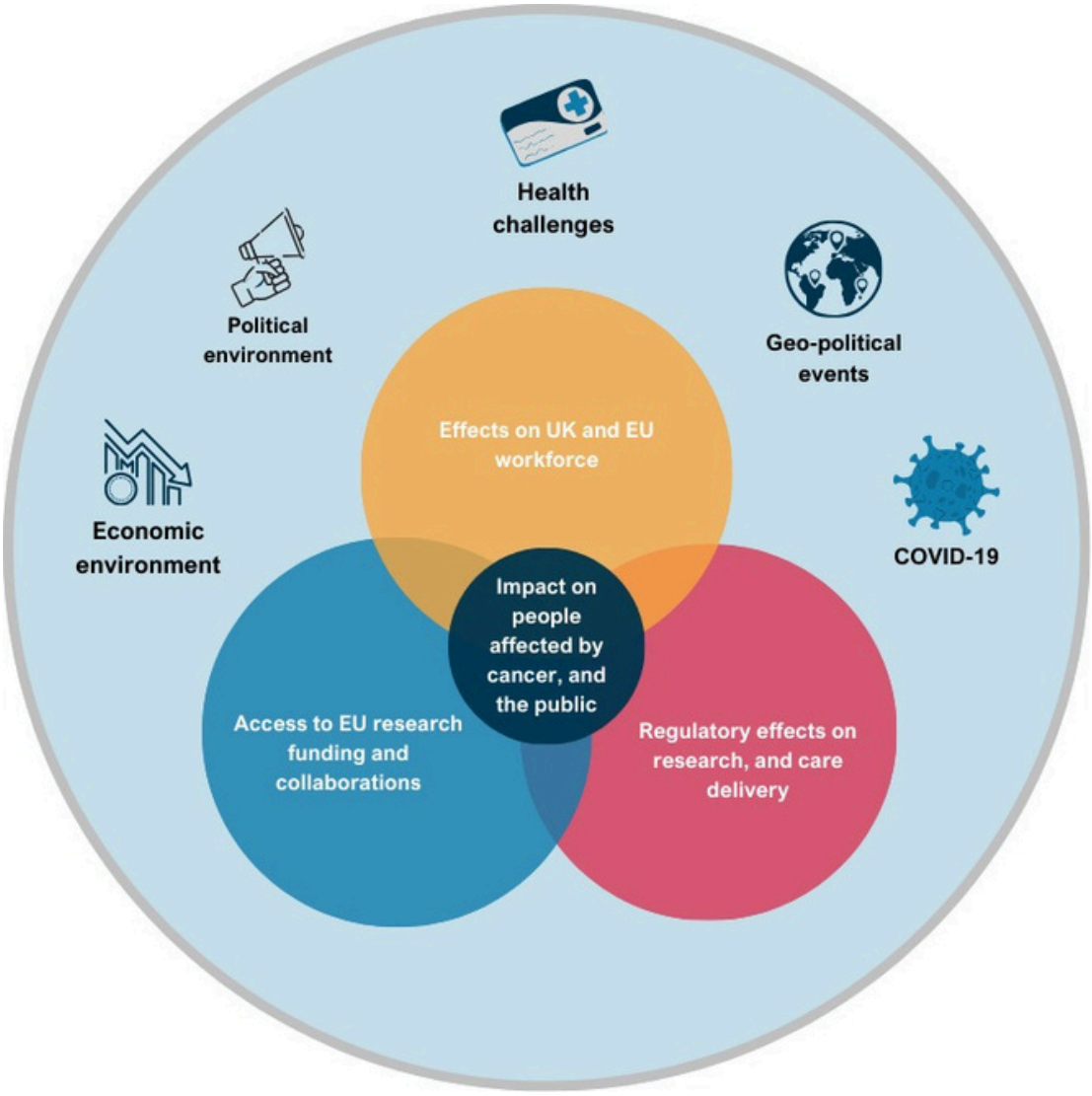

Figure 3: Thematic areas identified as presenting challenges and opportunities to UK cancer care and research

These themes and their sub-themes (**Figure 4**, below) are interconnected with each other and the broader contextual factors identified.

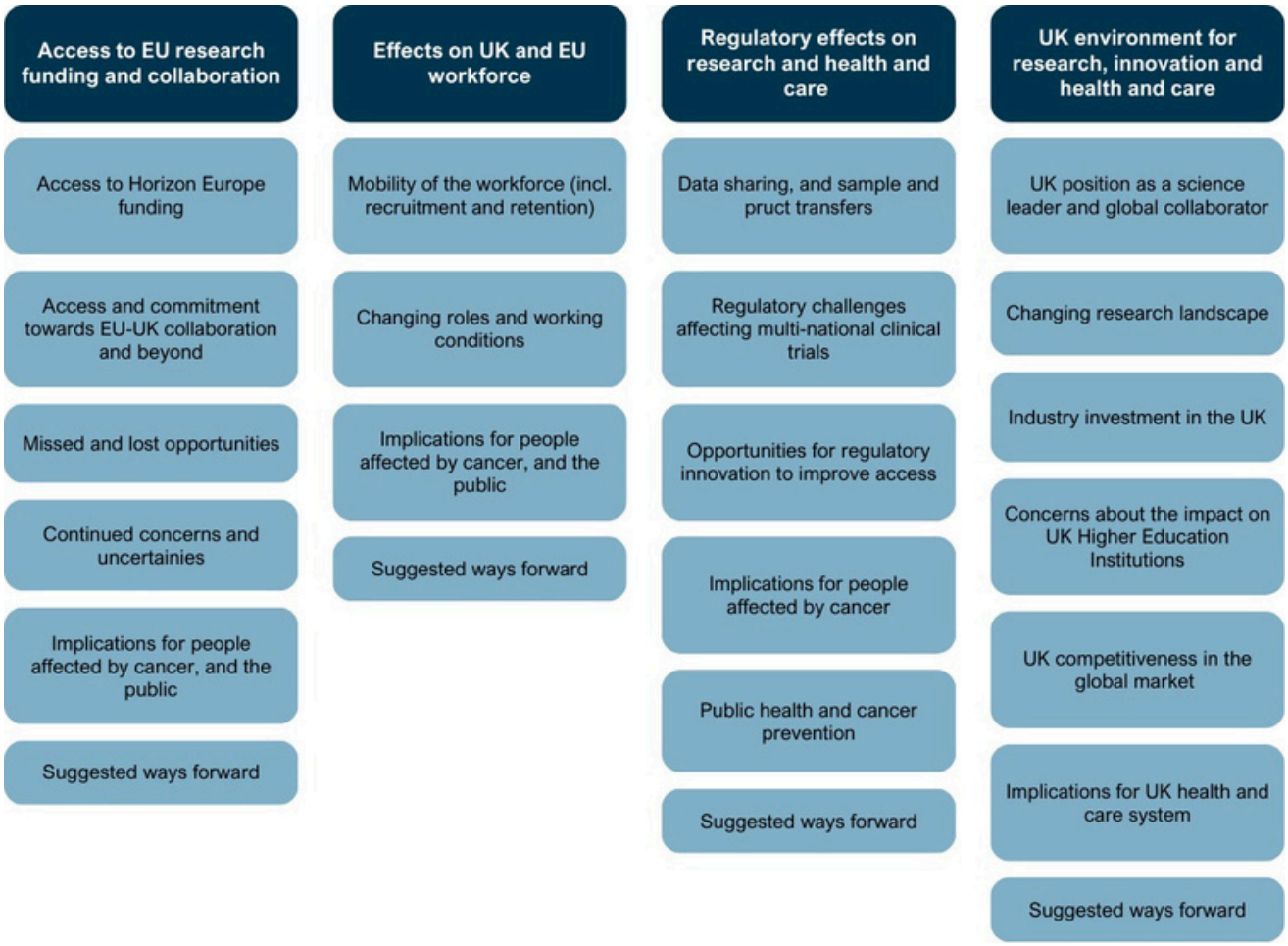

Figure 4: Summary of the thematic areas and sub-themes identified in the research

4.1 Contextual Factors

Since the UK’s exit from the EU and the introduction of the UK- EU TCA, several additional factors were identified which also influenced this period. These factors have also impacted EU-UK collaborative research efforts and the delivery of cancer care, including:

- The ongoing influence of the COVID-19 pandemic [15, 17, 28, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43]
- Turbulent financial and economic situation in the UK, and globally, along with the associated global political instability [33, 36]
- Existing challenges that threaten the future sustainability of health systems [39]
- International geopolitical factors, such as the war in Ukraine [33, 38, 39, 42].

4.2 Access to EU research funding and collaboration

This theme explores how the UK’s withdrawal from the EU and ongoing negotiations have affected UK researchers’ perceived or actual ability to access EU funding and collaboration opportunities.

4.2.1 Access to Horizon Europe funding

Access to Horizon Europe funding emerged as a key narrative in the interviews, survey, and review. Research funded through the Horizon Europe programme and its predecessor, Horizon 2020, such as the European Research Council (ERC), was perceived to be competitive, flexible, innovative, multidisciplinary, and internationally collaborative. This funding was seen as complementary to UK funding schemes, leading to impactful and high-reward research that addresses global challenges [17, 33, 44, 45, 46, 47, 48]. It was noted that Horizon funding was centred on ”excellence” and carried a sense of prestige [27, 28, 44, 46, 49, 50, 51, 52], offering ”a separate peer review system outside [the] UK”. Additionally, the review highlighted specific benefits for basic research and minority subjects, such as archaeology and classics [28, 50].

> **“... you know specifically about the ERC applications, and so these are supposed to be the most prestigious, very top-notch, but also very risky science.”**
>
> Interview Participant, UK-based, Aug 2023

> **“Science and research should transcend countries.”**
>
> Survey Respondent, UK-based, Jul 2023

While most sources spoke of the importance of Horizon Europe in general terms, some specifically mentioned the ERC, Marie Skłodowska-Curie Actions (MSCA), the European Innovation Council (EIC) and the European Institute of Innovation and Technology (EIIT). Moreover, the UK was one of the most successful countries in securing research funding through Horizon 2020, the previous EU framework programme 2014 – 2020, of which the UK was a full member. These successful applications, and EU funding more broadly, were perceived as bringing benefits to UK science departments [27, 28, 34, 37, 50, 51, 52, 53, 54, 55].

> **“It is well known that the UK was consistently securing more EU research funding than what the UK government has contributed to the EU research funding”**
>
> Survey Respondent, UK-based, Jul 2023

The review highlighted uncertainties being experienced around access to EU funding during negotiations on a ”Brexit deal”. Ultimately, the UK Government secured a deal through the TCA that allowed for associate membership, which provided a sense of relief [13, 14, 28, 34, 41, 42, 46, 47, 51, 53, 56, 57, 58, 59, 60, 61, 62, 63, 64]. However, this shifted to a central concern, picked up across all data sources, when negotiations deteriorated due to disagreements over the Northern Ireland Protocol. During this time, the UK’s direct access EU funding was affected [33, 65, 66, 67, 68, 69, 70] with consequences to scientific collaboration across Europe [47, 56] as well as UK and European science [33, 49]. Given these challenges, it was felt that regaining access to EU funding was crucial [17, 33, 49, 56, 71, 72].

> **“The continued uncertainty about the UK’s participation in EU funding schemes is crippling our status on collaborative projects.”**
>
> Survey Respondent, UK-based, Jun 2023

> **“A clear decision that we can participate in Horizon would make life a lot easier, you know, cause it means as new initiatives are being developed, we will be proper partners to it rather than working in parallel.”**
>
> Interview Participant, UK-based, Aug 2023

> **“It is the ERC grants that people are really concerned about more than the other elements. The ERC grants are what every UK researcher seems to want.”**
>
> Focus Group Participant, UK-based, Sep 2023

In September 2023, during the course of primary data collection, an agreement was reached to make the UK an associated country to Horizon Europe from 1st January 2024, providing access to Horizon funding (United Kingdom joins Horizon Europe programme). This was very welcome news to interview and focus group participants, and there was a clear sense of relief that an agreement had been reached, allowing researchers to continue to participate.

> **“I had some four or five people working for me who I wasn’t sure if we’d be able to pay them next month. But anyway, the association with the Horizon Europe programme has now happened, so that hopefully will address those issues and we should be able to get the Horizon funding and access to the sort of the collaborative things that involves, and also the Marie Curie Fellowships, which is all good.”**
>
> Focus Group Participant, UK-based, Oct 2023

During the period of uncertainty, the then UK Government established a backup research scheme called ’Pioneer’ as a UK-based alternative to Horizon Europe, in case an agreement between the UK and Europe was not reached [27, 42, 45, 46, 49, 50, 51, 58, 72, 73]. Under this scheme, the UK would have third-party access to Horizon Europe, allowing participation in research but not leading projects [45, 50]. Pioneer aimed to fund research in the UK and support international collaboration, compensating for any lost Horizon Europe grants with funding from UK Research and Innovation [44, 50, 72].

Sources from the review expressed mixed opinions about the homegrown scheme. On one hand, it was seen as offering several positive opportunities, particularly in providing awards for researchers at various career stages, as well as funding for infrastructure, innovation and international collaboration [17, 45, 58]. It was also felt that having Pioneer was better than having no support at all [46, 72]. Indeed, a number of learned societies contributed to the development of this backup research scheme to ensure an adequate UK provision was made [51].

Despite some appreciation for the Pioneer scheme, many perceived third-party access as a second-best option compared to associate membership in Horizon Europe [42, 51, 58]. Additionally, scrutiny around the finer details of Pioneer revealed concerns [27]. Across all sources of evidence, Pioneer was criticised for potentially

disrupting established networks and partnerships built through Horizon 2020 [45, 46, 49, 50, 58, 74] as well as uncertainties around funding, and cost-effectiveness, for the scheme [27, 45, 50, 51, 58]. Unlike funding associated to Horizon membership, any homegrown scheme would require going through frequent spending reviews [45]. Moreover, some doubted whether the ambitions of Pioneer would be realised in practice [50].

> **“... the ERC programme is about excellence. You know, it is about global excellence. And my concern with that is, you know, we’re not going to be part of the ERC, but we’re going to have some kind of substitute for that. It’s very easy in a relatively small country for these things to become politicized”**
>
> Interview Participant, UK-based, Aug 2023

> **“ERC funding and Marie Curie fellowships have been a boon to UK science, which we are currently shut out from. Homegrown initiatives offer nothing in the way of establishing links with science abroad and would be controlled by the same small group of gatekeepers that control all other UK science, in stark contrast to the broad base reviewing used by the EU. A recipe for more of the same, uninspiring science.”**
>
> Survey Respondent, UK-based, Jun 2023

While access to Horizon Europe was the primary concern across all sources, the review and interviews highlighted access concerns to other EU funding programmes that were important to the UK research community as they often provided financial leverage – their relevance to cancer research and care delivery is provided in the brackets. Other EU programmes mentioned include: the European Infrastructure Consortium (ERIC - a legal instrument to support research) [60], European Regional Development Fund (ERDF, one of the priorities is equal access to health care) and the European Social Fund [36] (ESF - supports workforce skills and social inclusion). Additionally, the European Innovative Health Initiative (funds projects relevant to cancer), Euratom Research and Training (is relevant to the use of radiation in cancer treatment), and the Copernicus programme (data from Earth observation systems supports environmental and behavioural research of non-communicable diseases including cancer), were also highlighted [60]. Finally, access to funding from the European Investment Bank [27] (which has supported commercial cancer research and development through loans, and has financed UK universities) was seen as important.

> **“We’ve got a heads up of a European Innovative Health Initiative grant that’s coming through. That would be absolutely perfect for us to lead... I think you could put a really strong grant in, but I didn’t know if UK can participate at the moment or in the future. What I think will happen is we’ll develop it on mainland Europe, we won’t develop it in the UK”**
>
> Interview Participant, UK-based, Aug 2023

The previous government established homegrown schemes, such as the UK Shared Prosperity Fund (UK-SPF - designed among other things to reduce health inequalities, increase health equity and involve the public health community)to replace EU funding such as the European Regional Development Fund (ERDF) and European Social Fund (ESF), and the Advanced Research and Innovation Agency (ARIA - R&D funding across all disciplines aimed at long-term breakthroughs), to overcome some of the losses from lack of access [60]. However, UKSPF has been criticised for not being as extensive or effective in supporting the different regional needs as the ERDF, together with concerns about the experience of the department managing the fund [27] (see subsection 4.5).

4.2.2 Access and commitment towards EU-UK collaboration and beyond

The benefits associated with collaboration in research were reported across all sources. Researchers in the interviews and survey reported that such collaborations provided benefits in terms of access to expertise, technology/tools/facilities [37], drugs, samples or access to cancer trials:

> **“So in the context of our collaboration, it means that we have access to these trials that otherwise wouldn’t be available with access to drugs via those partnerships”**
>
> Interview Participant, UK-based, Oct 2023

> **“we ask people with certain expertise to help with certain methodologies or maybe even a technology that we don’t have and just reach out to them in that way to assist with an ongoing study we ask people with certain expertise to help with certain methodologies or maybe even a technology that we don’t have and just reach out to them in that way to assist with an ongoing study”**
>
> Interview Participant, UK-based, Aug 2023

The review identified other benefits that collaboration offers to research: it enhances the impact of research [27], provides mechanisms for peer review, and facilitates recruitment from a broader pool of patients into clinical trials. This is especially important for rare cancers, leading to bigger benefits:

> **“if every other European country have got five patients, each with the same disease type, treated with the same drugs, with a similar sort of benefit, it makes total sense to pull those data together. And then the rare becomes not so rare, and we’ve got a much bigger data set and that’s a much stronger argument for publications. But importantly for reimbursement with the regulatory agencies who are willing to see those data from other countries as well. So there, there has been a move to try and get all these studies working together across Europe”**
>
> Interview Participant, UK-based, Oct 2023

All sources emphasised the need for, and importance of, international research collaboration [57, 69]. The review, along with the interviews and surveys, highlighted the advantages of EU-UK collaboration [37, 41, 72], which benefits both the EU and the UK [33, 37, 49]. The interviewees also stressed the importance of forming partnerships on a global scale, not just with the EU, in cancer research. Many of them were already involved in large multi-national cancer research trials or networks.

> **“So I think particularly when you’re thinking about clinical problems and this particular problem with early onset cancers, we really need to think about this, not just because we’re no longer part of the EU, but how can we create relationships on a very global perspective.”**
>
> Interview Participant, UK-based, Aug 2023

However, some researchers highlighted challenges in collaborating with colleagues in the United States of America (USA) due to practical issues such as time zone differences and misalignment of healthcare systems

and regulations. As a result, they found it more appealing to work with collaborators closer to home in the EU.

> **“Americans collaborate with each other because there’s enough people and enough, uh, you know, high quality research that a lot of the times they don’t have to look outside. And so you know, in that and it’s also closer to home”**
>
> Interview Participant, UK-based, Aug 2023

> **“when we collaborate with the US, it’s a lot more compromise and because of the way the clinical trial regulations are implemented in the US compared to UK and Europe, we do have quite substantial barriers that we’re trying to find ways [to overcome]”**
>
> Interview Participant, UK-based, Aug 2023

All sources indicated that the UK’s withdrawal from the EU and ongoing negotiations were jeopardising UK researchers’ ability to collaborate with their EU counterparts [15, 17, 34, 37, 41, 42, 49, 54, 56, 58, 60, 62, 63, 66, 70, 71, 74, 75]. Access to Horizon Europe funding was not just about prestigious funding; it was felt to be an important enabler to research collaborations [46, 48, 52]. There was concern that new ’homemade’ funding schemes may not replicate this support in the same way [56]. In addition, legal and regulatory changes (see subsection 4.4) pose additional challenges, which could hinder effective collaboration with EU researchers.

The interviews, focus groups, and survey responses revealed that UK-based researchers had mixed experiences on how Brexit and the ongoing negotiations had impacted their collaborations with EU researchers and networks of excellence. On the one hand, researchers felt that their involvement in EU networks had changed because there are:

> **“more red tape, less trust and fewer exchanges”**
>
> Survey Respondent, UK-based, Jun 2023

> **“the cooperative networks, all the sort of the collaboration networks that’s also, I mean, as part of Horizon Europe, now I think we have access to some of those things that we were not necessarily officially shut out of, but the perception was that it wasn’t a good idea to have UK people on them, even if maybe we weren’t officially shut out of them just because of the perception of the UK situation”**
>
> Focus Group Participant, UK-based, Oct 2023

Despite these changes, all sources noted the ongoing passion, willingness and importance of collaboration between UK and EU researchers [41]. Researchers reported continued mutual respect and enduring partnerships, showcasing the collaborative spirit of research. Sources noted that UK-based researchers remained engaged in EU networks and consortiums, often taking leadership positions [41]. Some interviewees mentioned that day-to-day collaborations hadn’t changed much, with networking and collaboration continuing through conferences and virtual platforms:

> **“I think we’ve got good personal connections with colleagues around Europe and the globe, and therefore, that will always stand us in good stead to continue to collaborate and try and work around some of the challenges.”**
>
> Interview Participant, UK-based, Oct 2023

> **“There continues to be a willingness to collaborate and for UK institutions to be involved in multinational collaborations with EU countries. The motivation to collaborate is still present.”**
>
> Survey Respondent, UK-based, Jun 2023

Some sources noted that the withdrawal of the UK from the EU and the changes within the EU presented potential opportunities to collaborate differently or foster new collaborations [34]. Other sources mentioned that EU and UK policies, as well as local schemes [34, 37, 50], have been established to ensure that research collaboration between the UK and the EU, and beyond, remains important. This sometimes meant remaining part of EU funding mechanisms [28] or engaging with EU researchers on schemes co-funded by UK-based organisations like Cancer Research UK:

> **“we’re seeing EU partners very interested in looking beyond Europe, so you know, Cancer Research UK has joined a kind of G7 cancer alliance with our Cancer Grand Challenge programme. You know, it’s working internationally, and we’re seeing EU partners interested in kind of funding beyond their borders”**
>
> Focus Group Participant, UK-based, Sep 2023

> **“...something remarkable from the side of CRUK, it could have been the opposite. That once you have the Brexit, they would have focused more on funding only projects with British investigators and not other countries and actually has been normally opposite [...] Efforts are even at the level of brainstorming for specific areas to invest”**
>
> Interview Participant, EU-based, Sep 2023

4.2.3 Missed and lost opportunities

Across all the sources, there was a general sense of loss or reduced collaboration opportunities and funding as a result of the UK’s withdrawal from the EU and ongoing negotiations [15, 17, 27, 33, 47, 52, 66, 70, 74, 76]. Many sources spoke of lost research that relied on collaboration because of legal and regulatory changes brought about by the withdrawal agreement and ongoing ’Brexit deal’ [28, 63] (see subsection 4.4). There was also a noted loss of UK-based research leadership across EU funded projects [17, 50, 53] and opportunities for young or early career researchers (ECRs) [17] (see subsection 4.3).

Specifically, participants in the interviews and focus groups, as well as the review, spoke of lost opportunities for involvement in EU collaborative research grant applications [33] and exclusion from EU networks and consortia [53, 62]. Due to uncertainties around the status of the UK in accessing and eligibility for EU

funding (see subsubsection 4.2.1), UK-based researchers were often left out of applications [46, 53, 62, 63].

> **“So in the [redacted] consortium, we’re an associate partner because we can’t access… we haven’t, to date, been able to access the Horizon money”**
>
> Focus Group Participant, UK-based, Oct 2023

> **“But I think that yes, the short answer is that you know, for some years actually we have not been able to make proposals with collaborations with UK, with British investigators ”**
>
> Interview Participant, EU-based, Sep 2023

During the two and a half years when UK researchers were unable to participate in the Horizon Programme, newly successful ERC grant holders had to choose between moving to an EU university or giving up their EU funding [17, 44, 49, 51, 55, 56, 57, 67]. Although the UK Government, through UKRI, agreed to match the funding [17, 64], some ERC grantees left the UK [44, 51, 61]. Many of those who stayed and had their grant cancelled felt that the prestige of an ERC grant could not be matched by any UK alternative and this was seen as a detrimental loss [17, 44, 49]. Moreover, there was a drop in the number of MSCA grants acquired post-Brexit [53], indicating that UK institutions became less attractive due to uncertainties around immigration policies (see subsection 4.3).

> **“Funding streams like ERC of greater prestige than anything provided by the UK [...] have been cut off”**
>
> Survey Participant, EU-based, Jun 2023

While researchers expressed relief when the UK gained associate membership of Horizon Europe, there was a continued sense of loss. UK research and expertise can no longer influence the strategic direction of funding [34, 60, 62], as it could when the UK was a full member.

> **“So we can access the funds, but you know, as a country, we have absolutely no say in how those programmes develop. But, you know, we’ve regained our sovereignty, so we can sit on the sidelines and have no influence.”**
>
> Focus Group Participant, UK-based, Oct 2023

4.2.4 Continued concerns and uncertainties

Throughout all the sources analysed, uncertainties were described around the UK’s involvement in EU-funded programmes. Sources in the review highlighted a lack of clarity on how access to Horizon would be paid for [60, 75].

Within the interviews and focus groups, there was a concern that UK science and research could continue to be embroiled in any ongoing political bargaining, affecting the UK’s future access to Horizon. Others questioned how being an associate member of Horizon would work in practice:

> **“Nevertheless, we have to see, you know, at the end, how this agreement works on the real basis, right?”**
>
> Interview Participant, EU-based, Sep 2023

> **“I do have concerns that it could be used as a political football on either side again in the future, which would introduce more uncertainty and the uncertainty is a real killer.”**
>
> Focus Group Participant, UK-based, Oct 2023

Despite regaining access to Horizon, there are concerns about the long-term implications that spanned those periods of uncertainty [48, 50, 52, 53, 77]. These concerns centre on the UK’s position and reputation as a scientific leader [50, 60] (see subsection 4.5), as well as its ability to attract research talent [41, 44, 70] and long-term residence for EU researchers who come to the UK to live and work [34, 63] (see subsection 4.3).

Changes in legal and regulatory frameworks raised concerns about reduced or lost opportunities as well as potential implications for future ongoing collaboration [34, 37, 47, 49, 56, 69]. As one focus group member highlighted, these changes might make EU-EU collaboration much easier than collaboration with the UK (see subsection 4.4).

> **“If there’s an opportunity for our EU partners to partner more easily with other countries within Europe, then I guess the appetite to engage with the UK has the potential to decrease”**
>
> Focus Group Participant, UK-based, Sep 2023

4.2.5 Implications for people affected by cancer and public from loss of collaboration

Since the UK is no longer part of the reciprocal cross-border healthcare arrangements, interview participants observed that UK researchers and hospitals are no longer eligible to form part of European Reference Networks (ERNs). These networks connect together specialised centres to share best practice and learn. Although there remains significant overlap with UK cancer policies, there have been mixed experiences regarding the UK contribution to the EU Beating Cancer Plan’s activities, especially given the networks’ success in addressing rare diseases, which cannot be solved by one state alone [15, 16].

> **“But one of the things that we’ve had to step away from is the European Reference Networks [...] and hospitals in the UK were part of that and, of course, it was an absolute rule that you had to be an EU Member State [or Norway] to be part of it.”**
>
> Interview Participant, UK-based, Aug 2023

A further lost opportunity with implications for people with cancer, as noted within the interviews, is the ability for UK research and clinical expertise to inform and support the implementation of the European Union’s Beating Cancer Plan. The EU plan includes recommendations believed to benefit cancer care across the Euro-

pean geographical region and beyond. Although there remains significant overlap with UK cancer policies, there have been mixed experiences regarding UK contribution to EU Beating Cancer Plan’s activities.

While members of CRUK’s research community continue to contribute to pan-European discussions in their areas of expertise, some have experienced a confusing disconnect. UK-based researchers and clinicians can support their EU colleagues – and in some cases take on official leadership roles – but they find they are excluded from other fora. This inconsistency, coupled with doubts among EU-based researchers about the ability of the UK to contribute, was viewed as potentially harmful to future collaborative efforts.

> **“...and another opportunity that we may lose because of the Brexit is, you know, the responsibility that the European Parliament has taken with the Beating Cancer plan... So for the first time [...] you don’t have competences.”**
>
> Interview Participant, EU-based, Sep 2023

> **“[...] our results are informing the “European Beating Cancer Plan”, so I am in connection with all the agencies dealing with Cancer.”**
>
> Interview Participant, UK-based, Sep 2023

Further implications for patient care result from a loss of low-cost capital from European Investment Bank loans [36]. These loans historically provided financing for some NHS infrastructure projects in the UK [15]. Additionally, as the UK is no longer part of the European Atomic Energy Community (known as Euroatom) [37], there are concerns that there may be implications for radioisotope access for cancer treatment:

> **“I don’t know how much material impact that’s had on radioisotope supply directly. I know there’s a shortage of radioisotopes. I think a lot of the cyclotrons that produce them are going offline. But I think some people feel that our lack of association with Euroatom was also a factor.”**
>
> Focus Group Participant, UK-based, Sep 2023

All sources highlighted the importance of collaboration in addressing rare and paediatric cancers, as well as precision medicine. These fields inherently require access to larger and more numerous trials to gather sufficient patient numbers [41, 78]. Collaborating on these larger trials provides a stronger, more robust data set, which can support a stronger case for ”reimbursement with regulatory agencies who are willing to look at data from other countries” [sic]. UK-EU collaboration on these trials was considered crucial to ensure patients have access to treatments and trials available across the EU. Any barriers that hinder UK collaboration on such projects were viewed unfavourably:

> **“I think that by not being in the EU anymore, a lot of the researchers, and I think in particular we’re thinking about the paediatric space, there’s a lot of initiatives that are going on where they’re getting funding from, you know, like the European Commission to do these massive projects and where we’re constantly seeing that the UK is of course not part of that.”**
>
> Focus Group Participant, UK-based, Sep 2023

4.2.6 Suggested ways forward

Across all sources analysed, a number of considerations and suggestions for the future were proposed. These aim to potentially help overcome challenges related to accessing future EU funding and collaboration opportunities.

Clear support and funding from the UK’s government and research sponsors was considered essential to support research collaboration with the EU [34, 37, 50, 52, 54, 69], and beyond, to remove barriers [46] and create a collaborative ’cross-border research community’ [61].

> **“Clear support from the government that they are behind the idea of scientific and medical collaboration internationally and including with EU countries. If they really back progress in these areas of research then they need to make this clear.”**
>
> Survey Participant, UK-based, Jul 2023

> **“The Government and funding agencies need to make decisions on how to manage relationships with researchers in other countries and be seen to back these with appropriate funding.”**
>
> Survey Participant, UK-based, Jul 2023

Some sources felt it was important that both the EU and UK sides to continue to ensure UK access to Horizon Europe and other future EU funding programmes.

> **“I think that the priority should be that we [EU] keep alternative mechanisms to secure that UK funds these projects and that British investigators also can access to these programmes”**
>
> Interview Participant, EU-based, Sep 2023

Others felt that UK funders had a role and should provide opportunities to showcase UK research projects to an international audience to help to create collaborative opportunities.

> **“More UK-based CRUK-sponsored conferences or events to showcase CRUK-funded projects and bring international experts into the UK to foster new collaborations.”**
>
> Survey Participant, UK-based, Jul 2023

4.3 Effects on UK and EU workforce

This theme covers the challenges and opportunities relating to research and the health and care workforce. It primarily focuses on the challenges facing the UK research and health and care workforce, but also considers the impact on the EU workforce in some instances.

4.3.1 Mobility of the workforce

The main sub-theme within the ’Effects on UK and EU Workforce’ theme was the challenges related to workforce mobility and the UK’s ability to attract and retain EU talent. Within the interviews and survey responses, the challenges focused primarily on the mobility of the research workforce. However, there were also refer- ences to the health and care workforce, predominantly from the review sources. Challenges regarding other roles important to the research and health and care sectors (e.g. in Regulation) were mentioned across all sources.

Multiple sources in the review raised concerns about the apparent decline in the number of EU citizens applying to work or working in the UK’s health and care sector [15, 32, 35, 36, 39, 76, 79, 80, 81], as well as researchers and scientists in, or applying for, UK-based roles [27, 44, 49, 52, 54, 63, 73], following the Brexit vote.

The survey responses, interviews, and workshops frequently raised concerns about the movement of people. Specific examples noted a decline in the number of EU applications and appointments to UK-based PhD studentships and Post-Doctoral roles in the lead-up to and following the UK’s withdrawal from the EU. Recruitment of EU-based talent to the UK was seen as being important for attracting the best talent and creating a competitive and diverse workforce. The loss of research talent is anticipated to have implications for UK Universities and higher education institutions’ (HEIs) ability to secure funding and conduct research longer-term [34, 41, 51, 60, 82].

> **“Recruitment is highly problematic. EU-originating post-docs avoid the UK - these were the majority of my workforce in the past; now, we struggle to find anyone from the EU willing to come to a top UK cancer institute. In addition, we have not been able to make up this talent from elsewhere in the world.”**
>
> Survey Respondent, UK-based, Jun 2023

4.3.1.1 Changes to immigration policy and visa requirements

Since 31st December 2020, changes to immigration policy and visa requirements have ended freedom of movement between the UK and EU for students and workers, except for Irish citizens under the Common Travel Area (CTA). As a result, EU citizens now need a visa to work and study in the UK, and the same applies to British workers seeking employment in an EU country. These changes were largely described as having a negative impact, adding time, complexity, and costs for students, workers, and employers, while making it harder to attract and retain the best talent in the UK [14, 15, 27, 33, 36, 42, 44, 58, 66, 83]. For EU citizens already based in the UK, changes to immigration rules and uncertainties about their future rights, and those of their families, were identified as factors in deciding to leave the UK [35, 44, 74, 76].

> **“The change in status for Europeans [EU citizens], albeit it’s now equivalent to the rest of the world, has had a massive impact on the UK scientific workforce.”**
>
> Focus Group Participant, UK-based, Jul 2023

For senior appointments to the UK, special provisions for scientists such as the ’Global Talent Visa’ were considered to be working reasonably well [28, 63]. However, the process is more fragmented for UK scientists seeking to work in the EU [53, 59].

> **“It is very difficult to hire UK nationals as staff. The preference is for Swiss and EU nationals. Nationals from the UK are now grouped with the rest of the world and very very challenging to employ.”**
>
> Survey Participant, EU-based, Jun 2023

For the research community, who are often hired on temporary contracts, the visa requirements were felt to add additional uncertainty and administrative burden. They must ensure they have the correct visa for their stay, which includes worries around what they can do while living in the UK (e.g. starting a family without the right visa).

4.3.1.2 Immigration Health Surcharge (IHS) also referred to as the NHS Surcharge

Health and care workers who are eligible for a health and care worker visa (and their dependents) do not need to pay the surcharge, which was welcomed [76]. However, all other researchers (including PhD students) and non-clinical roles (and their dependents) coming to the UK must pay the IHS in addition to visa costs, depending on the type of immigration status being applied for. This expense is not always covered by funding or their prospective employer and can, therefore, be off-putting [50, 52], particularly since it must be paid upfront in full for the duration of the visa.

> **“The other challenge is the loss of the collaborative agreement for healthcare in that people if you work for the NHS, it doesn’t apply, but if you have an honorary NHS contract or work for a university, you have to pay a huge upfront payment for access to healthcare. And I think that has absolutely crippled that movement of people and recruitment...”**
>
> Interview Participant, UK-based, Aug 2023

4.3.1.3 International Fees for EU PhD Students

A further cost implication for PhD students applying from the EU is that their change in ’freedom of movement’ status now makes them liable for international tuition fees, whereas previously, they would have been covered by national fees. Depending on the arrangements in place, this now makes hiring EU PhD students significantly more expensive for employing institutions, charities and individuals [50, 63]. For certain areas (e.g. cancer immunology, bioinformatics and data science), this is considered to particularly impact their ability to hire the best and future talent by significantly diminishing the applicant pool.

> **“I can’t recruit EU PhD students due to the fact that University applies international student fees and has limited international fellowships available”**
>
> Survey Respondent, UK-based, Jun 2023

4.3.1.4 Uncertainties around UK being the best place for career development

The increased cost and complexity associated with coming to work in the UK, combined with uncertainties around future access to important EU funding (see subsection 4.2) is perceived to be deterring talented scienti-

sts from coming to or staying in the UK, making it harder to fill vacant posts [50, 82].

> **“As an EU citizen, not being applicable to a lot of EU funding or collaborations where I can continue to work in the UK with a co-PI in another country has led to fellowship issues which have directly influenced me to leave my current position within the next three months as I have another opportunity available to me.”**
>
> Survey Participant, UK-based, Jun 2023

Equally, for health and care professionals involved in clinical research and cancer care delivery, uncertainty extended post-Brexit about the recognition of qualifications and was felt to be a potential barrier to working in the UK [13, 34, 76, 79]. This issue was expected to be particularly challenging for the movement of workforce between Northern Ireland and the Republic of Ireland [15]. The TCA allowed for the development of new mechanisms for mutual recognition of professional qualifications [13], which could replicate previous EU provisions, but these mechanisms must demonstrate positive economic value, and while this is particularly relevant for Northern Ireland, the EU and UK negotiating objectives did not fully align with the needs of the UK’s health system [15]. Furthermore, there were concerns that a lack of automatic recognition of UK qualifications in the EU could deter international students and training professionals from coming to the UK to study, due to reduced opportunities once qualified [15].

4.3.1.5 Perceptions of UK culture post-Brexit

The nature of the Brexit vote, together with changes to immigration policy, left EU workers living and working in the UK feeling unwelcome and affecting their sense of identity and belonging in the UK [76, 82]. This may be a reason for considering leaving the country. Furthermore, perceptions of UK culture following the decision to leave the EU were felt to continue to impact both EU and UK citizens’ feelings about the UK as a place to live and work.

> **“I guess as part of this [the UK] has come to be seen as being a place that’s inherently not friendly to foreign researchers or particularly not to European Union researchers, so I think that also puts people off, you know. Nobody wants to come work somewhere where they’re not welcome.”**
>
> Focus Group Participant, UK-based, Oct 2023

4.3.1.6 Mobility across the career pathway

Challenges to workforce mobility were identified across the research career pathway, from PhD researchers conducting cancer research projects (including clinical trials in the NHS) to senior appointments and hiring health and care staff in the UK. These challenges were generally considered to have the greatest impact on more junior and lower-paid roles, such as PhD studentships, ECRs, nurses and social care workers [71] due to the associated costs and certain roles being ineligible under new visa requirements (see paragraph 4.3.1.1) [15, 32]. Sources highlighted difficulties taking up substantial posts and travelling between the UK and EU, even on a temporary basis, such as no longer participating in the ERASMUS scheme [13] (see subsection 4.5). Additionally, as described in Amsen, 2022 [17], it is felt to be harder for British scientists to visit the EU or EU citizens to come to the UK for even short-term working visits and collaborations to share knowledge and learn from one another.

4.3.1.7 Contextual factors

Recruitment challenges were recognized as not solely the result of changes following the introduction of the UK-EU TCA. Many staff shortages, particularly in healthcare, preceded the UK’s exit from the EU and other contextual factors, such as the COVID-19 pandemic and the cost of living crisis [15, 36, 43, 76] are also thought to have further compounded the impact on the movement of people. However, it is considered to have exacerbated the situation and contributed to a growing decline in particular pathways such as Cardiothoracic surgery and anaesthetics [39], STEM fields [50], nuclear medicine [84], clinical scientists [85], nursing, and social care [15, 32, 36, 39].

> **“I was thinking about another student I had...this person had to stop her PhD because of the cost of living in London, because this is another problem you know, this kind of reception we are facing that makes the cost of living in London much worse, both, I must say for PhD student, but also for staff members.”**
>
> Interview Participant, UK-based, Sep 2023

4.3.1.8 Workforce issues at the UK MHRA

Workforce issues at the UK MHRA were highlighted as having been impacted by the UK’s withdrawal from the EU, contributing to delays in receiving timely regulatory approvals for clinical trials (see subsection 4.4). Anecdotally, interview and workshop participants perceived the relocation of the European Medicines Agency (EMA) from its location alongside the UK MHRA in London to Amsterdam, due to the UK’s withdrawal from the EU [33] to have caused a temporary lack of resources and expertise within the UK MHRA, whilst new staff were recruited and trained.

> **“We’ve always been quite an expensive environment to do clinical trials, but now we’re expensive and we’re slow and part of it is because we’ve lost all this staff, who probably went from, you know, the MHRA in London to the offices in the Netherlands and that you know, we’re losing a lot of momentum. ”**
>
> Interview Participant, UK-based, Aug 2023

While the review highlighted under-resourcing at MHRA [18], particularly in relation to approval backlogs and industry confidence, our review did not identify direct evidence linking this under-resourcing to staff loss resulting from the EMA relocation.

4.3.2 Changing roles and working conditions

For researchers that continue to work in the UK, the introduction of the UK-EU TCA brought about changes to their ways of working and placed increased demands on individuals and roles as a result [16, 34, 43, 63, 76, 86]. Interview, workshop, and survey participants reported an increased workload, more administrative duties and additional time needed to prepare paperwork for relevant regulatory approvals, transfer of materials, and establish cross-country collaborative agreements compared to the period before the UK EU TCA.

> **“[Q66 What are the key barriers to your research projects..?] Significant increase in paper-work and time to import goods, components and consumables from the EU.”**
>
> Survey Respondent, UK-based, Sep 2023

Changes to roles were also raised, particularly in terms of needing to navigate and advise on regulatory changes affecting research delivery. This was especially the case in Northern Ireland, where the complexity of divergence between UK and EU regulations, along with specific agreements in place like the Windsor framework, added to the challenges (see subsection 4.4).

> **“So it’s sort of acting as a gatekeeper. It’s, you know, not only at a site level, right, but actually trying to provide guidance to our sponsors of their studies and telling them can you just double check etc. So I mean that has delayed a huge number of studies and it has made staff on the ground weary, quite often asking lots of questions repeatedly before they actually get confidence that what they’ve got back is the right answer.”**
>
> Interview Participant, UK-based, Oct 2023

Multiple sources highlighted the burden placed on researchers during the period of uncertainty regarding access to Horizon Europe funding. This uncertainty led to missed opportunities to collaborate on joint projects with EU partners and forced researchers to make significant professional and personal decisions such as whether to relocate to another country [44, 49, 53, 56, 57, 61] or handover project leadership to a participating EU country [50] in order to secure ERC grant funding (see subsection 4.2). There were also ongoing concerns raised about the potential need to relocate in order to continue with certain research, should there be further regulatory divergence between the UK and EU. These concerns included the UK’s data protection regime and any potential impact on the EU’s future decisions on UK data adequacy (see subsection 4.4).

There was an overall sense of loss of autonomy and choice, as well as increased instability for UK-based researchers, related to earlier themes such as movement between countries, access to funding and future job opportunities [17, 44, 58, 63, 74, 82]. To mitigate these concerns and preserve mobility, some researchers sought to consolidate their right to live in their host country by applying for citizenship. Others perceived a lack of concern about how they, as individuals, were affected by the introduction of the UK-EU TCA, impacting both UK and EU-based researchers [82].

Finally, concerns about regulatory changes related to legal rights and working conditions [86] were also raised in the review. As described above, the loss of mutual recognition of medical qualifications could limit the ability of professionals to practice in the UK or EU, as well as a sense of identity and belonging to a certain nationality [76]. While the TCA did introduce new mutual recognition mechanisms, the requirement to demonstrate economic value hindered their development [15]. Additionally, there was ongoing uncertainty around any positive impact on the regulation of working hours for health and care workers in light of greater regulatory freedom since the UK’s departure [15, 36]. Furthermore, one source felt that the lack of EU access to data on fitness to practice of health professionals highlighted some inefficiencies stemming from the TCA. While the issue could be mitigated (in part) by information exchange by professional bodies, there is now less knowledge around activities in the EU [15].

4.3.3 Implications for people affected by cancer and the public

The sources perceived the challenges in the workforce, outlined above, as contributing to a knock-on effect on the public, patients, and those affected by cancer. These challenges were primarily seen as exacerbating exist-

ing staffing and capacity issues within the research and health and care systems [13, 15, 39, 80, 84, 85]. As described earlier, it was widely considered that the UK’s exit from the EU negatively impacted the ability to recruit and retain both cancer research and health and care workforce. This led to particular concerns about how changes to immigration policy could negatively impact the delivery of social care, which relies heavily on EU workers for many lower-paid care roles [32].

Furthermore, Lythgoe [87] suggested that workforce issues, together with existing care backlogs, could be detrimental to the NHS’s ability to conduct cancer research trials. Staffing issues and the ability to undertake research in hospital settings were also raised during the interviews, including references to front-line roles (e.g. Research Nurses) and other roles important to the set-up and delivery of research activity within health and care settings (e.g. Research and Innovation departments).

> **“The major issue we have in delivering trials is resources at site. They just don’t have the research staff and enough of the NHS. You need good NHS service, and you need good numbers of NHS staff plus your research staff to be able to deliver the trials, and without the people and all those Europeans that were moving around Europe, moving here and working here, we’ve lost so many staff.”**
>
> Workshop Participant, UK-based, Sep 2023

More generally, there were concerns that, in the long term, the loss of current and future talent from the UK (e.g. undergraduates and post-graduate students), changing roles, and added pressure on the existing workforce could reduce the UK’s ability to obtain funding and undertake innovative research. These, in turn, could directly impact those with cancer, their families and wider efforts to prevent cancer if less research is conducted (see subsection 4.5).

> **“[Interviewer: What’s your experience been?] Just reduced opportunities and having to work so much harder to do everything that we do and ultimately delaying progress for patients.”**
>
> Workshop Participant, UK-based, Sep 2023

Concerns and uncertainty were also raised if the UK is no longer a member of the European internal market for information sharing. This could potentially hinder knowledge exchange, particularly regarding fitness-to-practice alerts for individual healthcare workers. Such a change would have potential implications for the delivery of good-quality care and patient safety [36, 76].

Finally, the changes to free movement also effect access to healthcare for patients, particularly in Northern Ireland. This is described in more detail in subsection 4.4: Regulatory effects on research and the health and care environment.

4.3.4 Suggested ways forward

This final sub-theme draws together the variety of proposed suggestions from participants (workshops, interviews and surveys) and the review documents. These suggestions were proposed, from their perspective, to offer potential solutions to many of the identified workforce challenges. The majority of suggested solutions centred on overcoming the issues around the mobility of the research workforce and, to a lesser extent, the health and care workforce, as well as addressing factors felt to be influencing the movement of people. Examples included creating easier, faster and simpler immigration routes for researchers, the health and care workforce, and those in the manufacture of medicinal products, who are typically lower paid, to support mobility. Specific suggestions for achieving this included a Nursing Passport, mutual recognition of qualificati-

ons, and simpler processes [36, 50, 76]. In addition, reciprocal agreements that facilitate freedom of movement for researchers and health and care workers were also suggested [37, 70, 81] and were mentioned in the survey responses and interviews:

> **“An agreement for the mobility of talent, e.g. PhD students and postdocs in both directions between the UK and the EU ”**
>
> Survey Respondent, UK-based, Jun 2023

Greater financial and legal support from health and care providers for doctors applying for settlement was suggested [76]. Additionally, some sources proposed lowering the cost of visa fees and the IHS for those required to pay it [50] or allowing the cost to be spread over the duration of the visa rather than paying upfront:

> **“Nobody’s saying that they, you know, from students or workers, have to have free healthcare. But the thing of paying for it all upfront, particularly for PhD students, you know, to ask them to pay £4000 for a levy to cover their costs of health costs, is really difficult actually, you know? I mean, why can’t that be spread over the period of time? ”**
>
> Workshop Participant, UK-based, Sep 2023

The Global Talent Visa was generally considered to be reasonably effective for non-UK post PhD holders [28, 60, 63] and, therefore, should be continued. However, it was also noted that more proactive efforts, led by the Government and employers, are needed to reassure EU citizens that they are welcome and valued in the UK [76, 80]. To address the challenge of reduced inward mobility from the EU, some sources suggested increasing domestic recruitment and attracting talent from the rest of the world for healthcare and research roles [32, 35]. However, other sources indicated that while efforts to recruit domestically and outside the EU were already happening to help fill the gap left by EU workers since the UK’s withdrawal from the EU, these efforts were not considered sufficient to address the shortfall [39, 52]. Furthermore, ethical concerns were raised about the UK’s perceived increasing recruitment of health workers from ’red list’ low- and middle-income countries (LMICs) that are themselves experiencing workforce shortages [39].

Other suggestions included broad calls to address under-resourcing at the MHRA to increase capacity, although some sources [18] acknowledged that work in this area was already underway. There was also a suggestion for ongoing monitoring and transparency of the workforce situation to provide evidence of the impact of associated policy changes and support the best outcomes for health and care across the UK [15, 36, 41, 85]. Lastly, one source from the review indicated that the workforce challenges are likely to be short-term [28] and, therefore, require little mitigation.

4.4 Regulatory effects on research and the health and care system

This third theme explores the views and experiences of the CRUK research community and evidence review sources regarding the implications of regulation changes resulting from the UK’s withdrawal from the EU on both the research and health and care systems.

4.4.1 Sharing data, samples and products

In the interviews, researchers described how they collaborate with EU partners, which included sharing data and samples for analysis, concluding:

> **“Wider collaboration is always good, and data collaboration specifically is going to be really important moving forward.”**
>
> Interview Participant, UK-based, Oct 2023

All sources noted the importance of data adequacy, which enables the free flow of data, including for research, between jurisdictions with appropriate safeguards [69]. This was felt to be crucial to ensure effective collaborative research [15, 17, 34, 41, 88]. The granting of data adequacy is linked to the UK’s new data protection standards, which need to confirm compatibility with the EU General Data Protection Regulation (GDPR) [34, 50] but has also been considered in light of the politics of the wider EU- UK relationship. Specifically, it is believed that a loss of compatibility between the UK and EU’s data protection standards would significantly impact clinical trials and biomedical research. It would create an additional administrative burden, hindering robust decision-making and risk assessments, which would have wider impacts on patient safety [15, 34]. Indeed, the current frameworks and guidelines on data governance (and medical ethics) in some fields, such as digital pathology and AI, which were already challenging, were felt to be compounded by the UK’s withdrawal from the EU [89].

While the UK was first to grant EU data adequacy status [15], there was a period of uncertainty as the UK awaited the EU’s reciprocal decision [14, 36, 59, 64, 90]. The EU eventually granted the UK data adequacy status in June 2021 [58, 67] (see Stakeholder Group Statement on the UK Data Protection Regime) to the huge relief of the health research community:

> **“Let me tell you that at the beginning, when Brexit was announced, it was a big problem for us. You know, we had serious issues even in considering whether we could continue to hold this big worldwide database [...] So we were very concerned until there was the data adequacy decision in 2021.”**
>
> Interview Participant, UK-based, Sep 2023

The granting of data adequacy reflected the UK’s continued use of GDPR as retained law [69]. However, concern remains because this decision has a four-year sunset – for review in 2025 clause [69]. Without a common mechanism for data protection between the UK and EU [36], concerns were raised that regulatory divergence could affect whether the UK continues to be granted data adequacy [58]. This would have implications for cross-border trade in services and the research environment requiring the processing of personal data between the UK and the EU [36, 69].

While appreciating the importance of retaining data adequacy, researchers in both the surveys and interviews expressed their frustrations over how GDPR is understood. They emphasised the need for all countries to have a clear understanding of GDPR requirements to avoid unnecessary administrative burdens:

> **“I believe there is a misinterpretation of the GDPR... that is causing some extra massive administrative work from us because many [cancer] registries decided in many countries that they cannot submit full dates of birth, which are essential for our activity. And there is no way that these are forbidden in the GDPR. That actually was specifically written to facilitate public health research. I had to spend a lot of time with legal officers in the various countries that wanted a specific data sharing agreement that was not necessary in the past. And after understanding... they agree that it’s fine to submit the data.”**
>
> Interview Participant, UK-based, Sep 2023

> **“We all know that there are huge problems with GDPR particularly in the realms of research. Here’s an opportunity for the UK to look at that legislation and see if we can interpret it in a way that helps research, but we can’t go too far away from it because we [will] stop being trusted country for Europe. We do run a bit of a tightrope there, but I think there is an opportunity for some things because the problem with GDPR is it’s interpreted differently in every country.”**
>
> Interview Participant, UK-based, Aug 2023

Despite these frustrations, researchers made clear that any changes that would result in a lack of data adequacy were seen to be detrimental to collaborative research and may impact future access to Horizon Europe funding [37]:

> **“I’ve been challenged about what are you going to do if the adequacy decision is not going to be renewed? And I said, well, let’s see what’s gonna happen [...] I cannot say what I’m gonna do, but for sure, I cannot stop my research because I cannot do it in the UK. I would be forced to relocate.”**
>
> Interview Participant, UK-based, Sep 2023

New legal restrictions on goods (including medicinal products), which came into place as part of the UK’s withdrawal from the EU [81, 91], along with supply chain issues caused by COVID-19, have caused significant delays, costs and administrative burden in transporting laboratory samples, products, and goods to and from the EU [13, 17, 39, 63]. One source, however, acknowledged little disruption to the flow of medicines and related products in early 2021 due to the setup of protected shipping and freight routes [92]. Within the focus groups and interviews, researchers also reported mixed experiences regarding the impact this had had on their research. While some researchers reported no impact so far, others expressed concerns about the difficulties in shipping samples to their EU collaborators, which could deter future collaboration. This presented customs delays due to backlogs or because couriers were not using the right methods to ship samples:

> **“We are having to play twister when it comes to picking shippers to enter certain countries!”**
>
> Survey Respondent, UK-based, Jul 2023

> **“So that’s why you end up going to these more expensive companies that make sure that you have all the papers you need and you make sure that they will add the dry ice, that’s what you need to be sure that the box is gonna be frozen. Whereas [couriers] even if you pay extra to tell them [to] add dry ice, they just never do that. Well, they do that sometimes.”**
>
> Focus Group Participant, UK-based, Oct 2023

In addition, having the correct new paperwork to ship samples was identified as a challenge across sources [63]. For example, some researchers spoke of needing pre-paperwork from EU governments to permit sample customs clearance, which takes time. While Economic Operators Registration and Identification (EORI) numbers, used for customs clearance in the EU, existed prior to Brexit, they were not needed for trading within the EU when the UK was a member. However, since Brexit, any import or export of goods with the EU requires the use of EORI numbers [91]. These changes led to confusion among some of the research community around

which EORI number should be used - the research institute, sponsor or supplier:

> **“We have an EORI number, which is what you need to put on the customs declaration. But we have a very solid stance that we are not to use it for trials, and it should be the sponsor or the lab or whoever that uses their own EORI number, and that causes such a lot of drama. It’s very often that we have to sort of go back and forth and back and forth saying we need to use yours and they say well you need to use your own and that takes forever and that’s usually why samples get stuck.”**
>
> Interview Participant, UK-based, Oct 2023

Researchers within the interviews and focus groups reported that all of these changes resulted in increased shipping costs, more paperwork for shipping, needing to use customs brokers, lost research and delays to opening trials [17], which have been off-putting for collaboration:

> **“Everything we send to the European Union gets stuck in customs and that makes all collaborations very complicated because, you know, if you send something that you only have one sample of, then you just run into the risk of losing it, if it’s a frozen sample [...] so you think twice before collaborating with people if there are shipping of samples involved.”**
>
> Focus Group Participant, UK-based, Oct 2023

> **“...We have specific examples of trials [where] patient treatment has been delayed because we haven’t been able to ship samples out to get analysed or we’ve got samples backed up in the lab and freezers filling up because we can’t send them. We’ve also had trials delayed that it was supposed to open and couldn’t open on time because we couldn’t get everything we needed shipped over to us.”**
>
> Interview Participant, UK-based, Oct 2023

Despite these challenges, some researchers in the interviews and focus groups expressed optimism that the situation could potentially settle down in the future. They felt that improvements might occur, such as clearing backlogs which may have been impeded by other factors like the COVID-19 pandemic. However, others felt that this was the new norm that they just needed to adapt to. While some were hopeful that things could stabilise, concerns were felt that the right structures are not yet in place to help streamline processes:

> **“There have been problems with, you know, initial teething problems with getting drugs shipped in because they’re now, you know, there are now border controls. But to be honest I get everything else has been so slow. That’s probably not being the rate-limiting factor.”**
>
> Interview Participant, UK-based, Aug 2023

> **“I think it’s that problem that it’s something that’s recently been imposed, so there’s not the structures in place to sort of deal with it in a reasonably seamless way.”**
>
> Focus Group Participant, UK-based, Oct 2023

Yet, not all researchers were worried about the impact of the new good restrictions on the future of research. Indeed, some researchers felt that there were signs that could bring long-term positive change:

> **“I think we’re also seeing now that there are people that are moving operations to the UK to reduce some of these barriers. So things like central specimen reception, central specimen analysis, there are companies that are building labs in the UK to get around these issues and it’s quite an extreme way of avoiding any EORI number. But in the long run that could be a positive.”**
>
> Interview Participant, UK-based, Oct 2023

4.4.2 Regulatory changes affecting multi-national clinical trials

Changes to customs and border controls, as detailed in the above sub-theme (subsubsection 4.4.1), have also led to delays and increased costs for clinical trials [17]. Additionally, the UK’s exit from the EU meant immediate divergence in the regulatory governance of health products [41, 69]. The UK no longer came under the auspices of the European Medicines Agency (EMA), and the new EU Clinical Trials Regulation did not apply to the UK after the end of the Brexit transition period [14, 36, 69, 91, 93]. Furthermore, the EU no longer recognised UK sponsors of clinical trials or UK-based Notified-Bodies [64, 69, 91] (see subsubsection 4.4.4).

In September 2020, the UK’s medical regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), set out its requirements for clinical trials in Great Britain (with Northern Ireland remaining under the auspices of the EMA). This included changes to legal representation for imports of Investigational Medicinal Products (IMPs) and devices used in research [91]. The UK also had to adapt its processes for medicines approval [32, 59, 91] with the MHRA taking on more responsibility for approving medicines, such as those for cancer [69], since the MHRA used to be reliant on EU regulatory decision making in the case of novel medicinal products [94].

The previous UK Government and other bodies highlighted the benefits of regulatory divergence from the EU regarding medicines and devices, such as boosting competitiveness for the testing and release of drugs and streamlining processes to speed up access to drugs [91, 95]. Others, however, have noted that divergence has specific ramifications for UK biomedical research and clinical trials due to not being part of the larger EU clinical trials system processes as well as providing regulatory stability during a time of political uncertainty [94]. This includes reduced ability to access a large patient population, which is particularly important for research into rare diseases [36], as well drug safety monitoring (see subsubsection 4.4.4) linked theme of patient impact).

Sources within the evidence review predicted further divergence as the EU implemented new regulatory policies. In the context of medical devices and in-vitro diagnostics (IVDs), legislation which applied to Great Britain at the point of the UK’s EU withdrawal in 2020 reflected the Medical Devices and In-Vitro Diagnostics Directives that were aligned to the EU at that time [15, 69]. Since then, the EU has introduced the (new) Medical Devices Regulation (MDR) and IVD Regulation in 2021, which introduce further requirements on or- ganisations to report back on products that have been placed into the market to a central EU system [69, 95] (see Discussion section section 5 for further update). The UK plans to introduce its own new Medical Devices

Regulation in the future will need to consider the opportunities and costs of whether to converge or diverge from the EU [96].

In the interviews, researchers noted their institutions were sometimes not chosen as research sites because they are in the UK. Yet, a research study from the evidence review found that it is important to ensure UK sites are selected for pivotal clinical trials, such as large international trials, because of the correlation with NICE HTA decision-making [97].

Additionally, interviewed researchers expressed frustration with the delays in obtaining timely approvals or amendments for research from the newly structured MHRA, which had ramifications for study recruitment but also project partners and funders:

> **“We’re trying to get a study open. It has to go through MHRA, and it’s incredibly slow, whereas some of the other European countries can be much slicker through the EMA cause they’ve got approval and across Europe to proceed, whereas we’re stuck with the MHRA, who are being incredibly slow. So that’s been another factor that’s been quite negative for us.”**
>
> Interview Participant, UK-based, Oct 2023

The impact of MHRA delays on all clinical trials, the communication around those delays, and how the MHRA is prioritising cases were all recognised in the O’Shaughnessy Review, which included recommendations for remedial action [18] (see subsubsection 4.3.1 and subsubsection 4.5.3 for workforce implications on MHRA delays; and subsubsection 5.1.3 in the discussion for updates).

However, additional complexity and costs have been reported for UK-sponsored trials collaborating across Europe. Since the 1st January 2021, the clinical trial sponsor or its legal representative must be in the EU, which means that for UK-led multinational trials, there became a new requirement to hire a legal representative to act on their behalf in the EU [59, 70, 91]. In the interviews, researchers reported challenges, particularly with long-standing trials, in covering the costs of positioning a legal representative in the EU. At times, they have relied on the goodwill of their enduring collaborations:

> **“It was a massive thing that was just done out of the love and kindness of people. There was no money exchanged. It was just absolute dedication and amazingness [sic] of people just collaborating together and taking on these things. So if it wasn’t for that, I don’t know where we’d be right now. We wouldn’t have our EU sites open, so I think that was the biggest hurdle we had to overcome.”**
>
> Interview Participant, UK-based, Aug 2023

Regulatory changes around the importing of medicinal products had implications for clinical trials. Wholesalers importing medicinal products from the EU/EEA to GB now must apply for a wholesale dealer’s licence through the MHRA if they are UK-based. Alternatively, they can name a Responsible Person import (RPi) in their licence [69, 91, 93] to act on their behalf to ensure that the necessary import checks are completed [93]. Additionally, those importing must establish a system to confirm a Qualified Person (QP) in a listed country. The QP is responsible for certifying that each batch of medicinal products complies with the requirements of its marketing authorisation as well as Good Manufacturing Practice (GMP) [69, 91]. For clinical trial sponsors, this means ensuring that Investigational Medical Products (IMP) from the EU/EEA are batch-certified by a QP from a listed country before being sent to trial sites [91]. Researchers in the interviews reported that these changes brought about delays and added costs to opening trials sites in the UK:

> **“And we’ve got the trial up and running in the UK and it’s been recruiting but they started adding new arms since Brexit and we can’t open them in the UK. And the reason we can’t open them is that the European sponsor has to arrange an extra QP release of the drug in the UK. So the drug is QP released in Europe, but that’s not recognised in the UK because of the legislation that was put in place after Brexit. So now any imported drug has to go through a second QP release process in the UK and that adds time and cost.”**
>
> Interview Participant, UK-based, Aug 2023

Additional complexity and uncertainty in conducting clinical trials in Northern Ireland were identified across all sources. When the Northern Ireland Protocol was enacted on 31st December 2020, Northern Ireland remained aligned with EU standards and law, even though medicines are traditionally supplied through GB [71, 77, 93, 98]. Changes made in 2022 included EU regulations around batch testing to ease the movement of medicines between GB and Northern Ireland, provided those medicines did not enter the Republic of Ireland (and therefore the EU) [69]. In April 2023, the Windsor Framework [69, 98] sought to further realign Northern Ireland with GB regarding medicines, reducing checks and paperwork [69, 98]:

> **“Largely we were sort of left in this situation where we had clinical trials open in Belfast, but it wasn’t really clear as to what the arrangements were in terms of drug supply out there or whether there was a possibility we had to ship drugs into Europe and then from Europe to Ireland. Fortunately, I think the Windsor Agreement has resolved all those issues now, but it’s I think it’s still a theoretical barrier if you see what I mean.”**
>
> Focus Group Participant, UK-based, Oct 2023

However, medical products coming from GB to Northern Ireland must meet EU standards [15, 93], which were felt to be quite stringent.

> **“Actually, still to this day, it’s problematic in the fact that though the Windsor Framework it addressed a lot of things, but it failed to address the concerns we have in medical devices and in-vitro diagnostics.”**
>
> Interview Participant, UK-based, Oct 2023

Sponsors of clinical trials with sites in Northern Ireland need to ensure that medical devices meet EU standards as evidenced by a CE-mark. Since January 2021, the UK introduced a new system, the UKCA mark [93]. In the interviews, researchers spoke of increased complexity with regard to research involving medical devices and in-vitro/companion diagnostics, specifically when they are not CE-marked or when they are being used outside of their licensed indication (a common occurrence in cancer research). In such circumstances, there needs to be a separate notification to the UK’s MHRA. Consequently, setting up and conducting international trials in Northern Ireland was perceived as difficult, with some trials even being forced to halt, a factor that was picked up in the O’Shaughnessy Review [18] (see Discussion section 5 for updates regarding this live issue). Medical devices are mostly used in diagnostics for people with cancer. Access to a new diagnostic test can, for example, determine clinical trial eligibility. The reduction in opportunities to participate in clinical trials can have devastating effects on families if a patient lacks alternative treatment options (see subsubsection 4.4.4 and subsubsection 4.4.5):

> **“Because of the medical device/in-vitro diagnostics issue, it might be more attractive to do trials with the South of Ireland because they will meet those requirements without us having to go through this painful, painful sort of process.”**
>
> Interview Participant, UK-based, Oct 2023

In January 2022, the new EU Clinical Trial Regulation (CTR) came into force, replacing the previous EU Clinical Trial Directive 2001 to improve and harmonise clinical trial standards [15, 69, 87]. From 31st January 2023, all new EU trials need to use a new EU Clinical Trials Information System (CTIS) to improve efficiency and reduce the administrative burden of conducting trials across different EU countries [15, 69, 87]. Some interview participants viewed the UK’s exclusion from this regulatory umbrella as a barrier to collaborative research (see subsubsection 4.4.3 below).

While the previous UK Government stated the UK would remain closely aligned with the EU Clinical Trials Regulation, there are concerns this alignment could change in the future [99]. While researchers were content that the UK would align with the EU’s clinical trials framework, the fact the UK will not have access to the EU clinical trial registry or form part of the new EU CTIS (which provides a central place for regulatory reporting and protocol approval) was a cause for concern, as highlighted in the evidence review and the interviews [87]. Researchers worry that despite the best intentions, UK (MHRA) alignment with EU-approved protocols may not work well in practice:

> **“We won’t be able to get that amended by something that’s already been approved by half a dozen Member States. And so we’ll be on the outside, and if we keep coming back to our European sponsors going, oh, we can only participate in the UK if you completely amend this approved protocol. They’re going to say we can’t work with you.”**
>
> Interview Participant, UK-based, Aug 2023

However, the introduction of the new EU CTIS has not always been viewed positively, particularly against the backdrop of wider legal and regulatory changes affecting multi-national research. Some researchers leading new multi-national trials that include EU countries noted that, prior to CTIS, each member country handled their own regulatory reporting. With the new system, they now faced the additional burden of centrally coordinating regulatory reporting from each EU country involved into a single submission to meet the new CTIS requirements. This process was felt to be particularly burdensome due to the need to access the system, understand the submission process and gather the necessary documentation from across the member states, all of which would incur further costs:

> **“We have to do it if you want to go out to the EU sites, you’d have to cost that in. You’d have to cost the CTIS stuff in. You’d have to cost the legal rep in, and then any other requirements for drug shipment [...] the regulatory rollout of CTIS is a big worry for me at the moment.”**
>
> Interview Participant, UK-based, Aug 2023

4.4.3 Opportunities for regulatory innovation to improve access

Sources from the evidence review, interviews and focus groups identified some opportunities arising from regulatory divergence from the EU, as well as chances to streamline and improve existing processes and from

the UK to make its own choices now that the UK is unrestricted from EU membership [15]. Indeed, the last UK Government aimed for an innovative and flexible approach to AI and medical devices [96]. However, many have warned that to capitalise on these opportunities, the UK needs to work in collaboration and ensure the right level of scrutiny [15]. This collaboration was seen to be important for regulatory innovation, improving UK regulatory systems, and achieving regulatory harmonisation with other countries [95, 100].

To establish the UK as a priority country for new medicine approval, the UK has joined two international collaborations - the Access Consortium and Project Orbis. Both initiatives aim to accelerate access to medicines for all participating countries by evaluating new drugs concurrently [87]. The Access Consortium is a network of regulatory authorities across Australia, Canada, Singapore and Switzerland [94] and has already supported the regulatory approval of cancer medicines, although most of these were before the UK joined [87].

Project Orbis, launched in 2019 by the FDA Oncology Center of Excellence (OCE), aims to speed up access to cancer medicines and involves seven project partners [91, 94, 101, 102]. A study looking at the approvals through Project Orbis found that 11 new cancer drugs and indications have been approved since the UK participation in the partnership. These drugs were given UK approval just before EU approval (c. 3 months) but after FDA approval (c. 5 months) [87]. This suggests that working in international partnerships can accelerate access to vital cancer medicines for people with cancer.

> **“One of the unintended consequences of not being linked to the EMA is the UK’s part of Project Orbis, which means they get the approval once the drugs finished clinical trials...whether they do it quicker, but they do actually get the regulatory package sooner or have an option to... So it does mean that we potentially can see things earlier.”**
>
> Interview Participant, UK-based, Aug 2023

While the regulatory approval and market authorisation process appears to have been accelerated, sources within the evidence review have highlighted areas for further consideration. For example, drugs approved through an accelerated process may later fail to demonstrate clinical benefit in post-approval confirmatory trials; rescinding market authorisation is complex and takes time [87]. However, the UK has a potential safeguard for timely withdrawal, as such approvals involve the Competition and Markets Authority (CMA) framework, which has a fixed approval expiry of one year and requires annual renewal [87]. Additionally, the legal requirements for Paediatric Investigation Plans (PIPs) aim to ensure that there is sufficient evidence to support the safe use of medical interventions in children [91].

Another consideration highlighted through the evidence review is that drug approval through an accelerated access scheme does not guarantee its use in clinical practice. In England, the National Institute for Health and Care Excellence (NICE), establishes clinical and economic benefits to make its recommendations. Drug and other treatments receiving positive recommendations allow access and reimbursement through NHS England [91]. Health and Social Care in Northern Ireland (HSC) also relies on NICE decisions about which medicines are available to patients in Northern Ireland [93].

While NICE aims to complete assessments within 90 days of regulatory approval, the accelerated approval process has sometimes prevented this timeline from being met [77, 87]. Additionally, opportunities to link drug licencing with Health Technology Assessment (HTAs), such as those undertaken by NICE, have also been raised. This could enable faster access to promising new technologies, including those developed through genomics, AI and big data, which are typically challenging to get evaluated [92]

A survey of stakeholders interested in UK healthcare regulatory science identified a need for the UK’s regulatory science to be flexible, co-developed, responsive and speedy [100]. Some of these requirements are being addressed. For example, in 2021, the UK set up the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate the development and access to promising drugs, building on lessons learnt from

COVID-19. ILAP involves UK regulators, HTA bodies, the NHS, and patient advocacy groups and has already provided an accelerated pathway for a new cancer drug in the UK [69, 87, 91, 94]. Furthermore, new frameworks such as the Early Access to Medicines Scheme (EAMS), which provides access to unlicensed promising medicines for patients with rare or life-threatening diseases [87, 91, 94], may also help to supplement new processes once established.

Within the field of medical devices, stakeholders were reported to be exploring ways to ’relax’ regulatory pathways while still ensuring patient safety [95]. Regarding data sharing, some researchers felt that there was excessive ’red tape’, particularly with data sharing agreements. However, there was a general consensus that alignment in data sharing is important, especially for pharmacovigilance [36, 91, 93], which is crucial for patient safety.

> **“Obviously, the pharmacovigilance is slightly different now as well. So if patients get SAEs [Serious Adverse Events] on trials, instead of just reporting it into the MHRA system, we now have got dual reporting. We’ve gotta make sure that the [EU’s] EudraVigilance guidelines are also followed. So that’s just been an additional thing we’ve had to look at.”**
>
> Interview Participant, UK-Based, Aug 2023

4.4.4 Implications for people affected by cancer

As noted above (see subsubsection 4.4.2), regulatory changes following the UK’s withdrawal from the EU have created challenges in accessing medicines, medical devices, and equipment [15, 69, 71]. While one source suggested that Brexit-related regulatory changes are unlikely to have a detrimental impact on drug access as the UK’s population density still makes it an attractive market for pharmaceutical launches [103], other sources highlight challenges arising from changes in import and export regulations [47, 71] and stemming from global product supply issues influenced by the broader political environment (e.g. Ukraine war) [15, 38, 81]. Additionally, medical device manufacturers may be less incentivised to enter the UK market if new UK regulatory requirements diverge significantly from EU regulations, particularly due to the increased costs for smaller device manufacturers [95]. As a consequence of this regulatory divergence, interview participants explained that it can be difficult to gain access to experimental drugs:

> **“If, you know, countries are under different umbrellas, sometimes it’s more difficult, obviously, to get agreements to have access to experimental drugs that are being supplied from pharma companies, if you will, to two different environments.”**
>
> Interview Participant, UK-based, Sep 2023

All of this has been associated with both delays and rising costs around the access to the most innovative medicines to UK patients [36, 39, 76, 91] as well as patients in mainland Europe [14, 41, 90], which in the context of cancer has significant implications. Paediatric and rare cancers appear to have been particularly adversely affected due to the small population of people affected with these cancers, and therefore, international collaboration to recruit patients into studies is essential (see subsubsection 4.4.3). Researchers in both interviews and focus groups spoke of their frustration with how new regulations affect drug imports and the need for a second (i.e. duplicative) QP release in the UK. The price of this second QP release was felt to be outside of what could be covered by academic and charity sponsors:

> **“[T]hat adds time and cost and it’s something that… the complexity of it is that our collaborators have just not been able to do it. We’ve said that we can go to Cancer Research UK to ask for funding to try and cover it”**
>
> Interview Participant, UK-based, Sep 2023

> **“[H]ere in Northern Ireland, on a per batch basis of every investigational medicinal product that was being brought in from GB, via GB, a quality person [sic] being available for that did not exist within the health service here in Northern Ireland. All of a sudden, I find myself in a position that in order to continue on with our trials where that QP release and drug was coming in that route, I was going need to find an alternative.... huge time resource for myself and then ultimately was horrified at the cost”**
>
> Interview Participant, UK-based, Oct 2023

This makes getting access to innovative drugs as part of trials difficult and costly, ultimately impacting poorly on patients:

> **“So you have active drugs for paediatric patients with relapsed refractory poor prognosis cancers who cannot get access to drugs on the trials that we’ve written, and that’s an absolute scandal.”**
>
> Focus Group Participant, UK-based, Oct 2023

Concerns remain about the access and supply of medicines (and medicinal products) to Northern Ireland for both research and health services [15, 93]. This issue is compounded by the fact that the supply chain to Northern Ireland primarily came from GB prior to Brexit [77, 93]. Although the Windsor Framework aimed to facilitate easier access to medicines between GB and Northern Ireland, there are questions about its practical implementation. Specifically, concerns have been raised when a drug has divergent licensing and a lack of communication to support decision-making.

Some sources in the evidence review have argued that it is essential to include the patient voice in legislation around access to drugs [98]. Additionally, commercial decisions by industry, driven by increased costs to import medicines into Northern Ireland, have affected access to certain drugs in clinical trials and with hospitals. Furthermore, as noted above, issues regarding medical devices and IVDs persist. Since Northern Ireland typically recognises NICE recommendations, any regulatory divergence between the UK and EU could prove a challenge [93, 104]:

> **“When the companies looked at the cost of what was going to be required to bring in a drug into Northern Ireland, they made a commercial decision based on population basis and demand that they were no longer going to supply certain drugs and that actually resulted in a number of studies where we couldn’t do it with certain arms of this study because they were these were to be hospital supplies and that commercial supply no longer being available here in Northern Ireland.”**
>
> Interview Participant, UK-based, Oct 2023

The interviews and focus groups revealed mixed opinions on whether reduced patient access to clinical research within the EU would impact UK cancer patients. On one hand, it was felt that most patients would continue to access trials and medicines within the UK as they always have. However, all agreed that patient choice for access to treatments and clinical trials for patients in NI was reduced. Previously, patients could easily travel between Northern and Southern Ireland for care. Now, the provision for cross-border care came through as unclear. Some sources in the evidence review and focus groups suggest a lack of provision [36], while others noted that the Southern Irish Government had paid for Northern Irish residence to benefit from the previously named European Health Insurance Card [13]:

> **“Prior to the Brexit deal, people could go from Northern Ireland to Southern Ireland. They can’t now because if the patient from Southern Ireland has treatments in Belfast and they need intensive care on a clinical trial [...] then they can’t get it. So they can’t have intensive care. So even if Belfast is closer to them than Dublin, which in some parts of the borders it is, or more accessible, they can’t receive treatment in Belfast.”**
>
> Focus Group Participant, UK-based, Oct 2023

Sources from the evidence review highlighted how legal and regulatory changes need to ensure patient safety. Accelerated access, including changes to the NICE review process, to new medicines has the potential to benefit people affected by cancer (and rare diseases) by providing timely access to new treatments [92]. However, as the number of new cancer drugs available through accelerated approval increases, some have raised concerns, particularly regarding the USA, about the therapeutic value of all these approved drugs. Delays in obtaining evidence through confirmatory studies have raised concerns about both the clinical benefits and patient safety of using such medicines before their efficacy is confirmed [87]. To address these concerns within the context of cancer medicines, some sources suggested the incorporation of patient-reported outcomes, value-based frameworks and socioeconomic analysis to ensure they truly benefit patients [87].

Changes in regulations can have unintended consequences affecting patients with cancer, as seen with the EURATOM withdrawal, which impacts nuclear science and related areas like cancer screenings [37].

4.4.5 Public health and cancer prevention

Most evidence for this sub-theme came from the evidence review. The review sources identified several considerations for public health that could have implications for cancer prevention stemming from legal and regulatory changes due to the UK’s withdrawal from the EU. Indeed, some sources felt the changes being implemented by the UK were risking a health crisis due to a lack of protection from the effects of the cost-of-living crisis [68], or raised concerns around how future trade deals could, if lowers current standards, may pose a risk to public health [76]. Some of the changes brought about by Brexit were envisioned to have potential positive effects on public health regulation, but sources argue they need to be monitored [15].

Some of the early sources from the evidence review highlighted the implications to public health collaboration and comparative data resulting from reduced agency-level cooperation. Notable examples included the lack of access or formal agreements with the European statistical system coordinated by EUROSTAT, the European Centre for Disease Prevention and Control (ECDC), and the EU’s Early Warning and Response System (EWRS), which is used for sharing information and coordinating responses to public health threats [13, 36]. Some of these may have implications for cancer prevention.

Tobacco regulation emerged as a key public health concern within the evidence review, given that it is the biggest cause of preventable cancer. As noted by [105], the EU played a significant role in the supply and regulation of tobacco products in the UK through directives such as the EU Tobacco Products Directive, EU Tobacco Advertising Directive and the EU Tobacco Tax Directive (revisions of which were a key part of the EU Beating Cancer Plan but have been delayed). The UK is now trialling its own track-and-trace system, which tracks tobacco products in the UK [105]. While Brexit presents an opportunity for the UK to diverge from EU tobacco control regulations (including those for e-cigarettes) to potentially improve public health [36, 106] and position itself as a world leader in tobacco harm reduction [106], future UK- EU agreements could still have an influence in this area. Ultimately, political decisions within the UK are the most important factor [105].

Changes in the regulatory landscape regarding food were another area of concern identified in the evidence review. Concerns about the impact of Brexit on food shortages, the UK’s reliance on imported foods, and potential trade agreements suggest that people on low incomes, and the UK population more generally, are more likely to spend a larger portion of their money on ultra-processed food and red-meat while consuming fewer fruit and vegetables [107]. This dietary shift is linked to rising levels of obesity and diet-related diseases, such as cancer [40, 81, 107, 108]. What could have been an opportunity to bring about further regulation was seen to be hampered by industry pressures due to COVID-19 and Brexit [40]. An analysis of Brexit-related policy approaches and their potential impact on the food system and dietary health found that Brexit could have a detrimental impact on UK dietary and public health [107]. To mitigate these potential impacts, the community is calling on the government to ensure that all future trade deals are health-sensitive [108].

A third area of concern picked up in the evidence review was cancer-causing chemicals. There is a recognised need to reduce Occupational Exposure Limits (OELs) in certain areas. These limits are administered through the EU and often serve as a benchmark for employers. Although UK employers are not legally required to meet these benchmarks, the risk of liability for cancer-related health issues may well encourage them to meet the OELs. However, in light of new scientific evidence, the EU is considering adopting new OELs relating to substances which are linked to a range of cancers, the legal implications for which may not take effect in the UK because of Brexit [86] and the UK could fall behind.

4.4.6 Suggested ways forward

This final sub-theme draws together the variety of suggestions from participants (workshops, interviews and surveys) and the evidence review documents. These suggestions were proposed, at the time, from their perspective, to offer potential solutions to the regulatory issues and challenges as identified throughout theme three.

Communication was a key area that came up across multiple sources that warranted attention. Participants in the interviews and survey expressed the need for clear communication, guidelines and support from the UK Government, regulatory bodies and research funders to explain the practical implications of regulatory changes for the research community, research sponsors and those undertaking cancer research in the UK, with particular attention to the specific requirements in Northern Ireland. Additionally, clear guidance from both the UK and the EU regarding GDPR was felt to be important to reduce misunderstandings and different interpretations across countries which can impact international research:

> **“Guidance documents that will make it clear to the sponsors what is required for any participants in Northern Ireland to be recruited onto their trials.”**
>
> Interview Participant, UK-based, Oct 2023

> **“If CRUK had a basic website or a guideline, or an SOP or something about it, that would be brilliant. You know, because then they could say themselves. Look, you know, we’re not happy if you use unlicensed product or we don’t allow you to do this in our trials and it would be as clear as day or you know we don’t want you to delegate CTIS applications to anyone. We want you to do it yourself. Then you’re like 100% clear instead of having to go around and, you know, ask 100 people and stuff. So yeah, I think if the if the sponsors or the funders had guidelines, that would also be very helpful.”**
>
> Interview Participant, UK-based, Aug 2023

> **“[We need] clear, consistent rules on data sharing aligned between countries.”**
>
> Survey Respondent, UK-based, Jul 2023

An early source from the evidence review emphasised the need for the UK Government to enhance communication with the public and people with cancer to help alleviate any fears around the future of cancer research post-Brexit [41].

After communication, one source highlighted that in order to take advantage of post-Brexit opportunities, there is a need to increase the capacity of the MHRA and HRA to support a more integrated system for rapid clinical trial approvals [18]. Additionally, Oximio, which provides logistics services for clinical trials, recommends that to mitigate high costs and unnecessary delays, trial organisers should plan for extra time when coordinating collaborative trials between UK and EU partners [17].

Regarding public health, one source in the evidence review felt that the UK Government should commit to maintaining the same level of food safety protection as the EU [81]. This commitment could help ensure continued high standards and alleviate concerns about food safety post-Brexit. All future trade agreements need to ensure health sensitivity [108].

It will be important to balance regulatory alignment while ensuring there is freedom for regulatory innovation, particularly for emerging technologies [37, 69, 96]. Close alignment with Project FDA’s Project Optimus was felt to be important for cancer drug development, and particularly given the UK’s involvement in Project Orbis [102]. Moreover, any developments in regulation need to consider how they can be practically implemented by both manufacturers and regulators [96], leverage our existing assets, involve collaboration and partnership, and have the right level of scrutiny and be monitored to understand the impacts on health and UK healthcare systems [15, 77, 90, 95].

A report, “Building a Strong Future for European Science: Brexit and Beyond” (2008) as cited in [37] highlighted that the UK should continue cooperating on pre-competitive research regulation and agree with the EU on maintaining the free flow of personal data for research, particularly for clinical trials, where identifiable data is sometimes necessary; the UK plays a significant role in European clinical trials, and a research and innovation agreement should enable the UK to participate in the EU’s harmonised clinical trials system similarly

to Member States [37].

4.5 UK environment for research, innovation and health and care

This theme covers the wider challenges and opportunities facing UK research, innovation and health and care sectors following the introduction of the UK-EU TCA and, more broadly, the UK’s exit from the EU within the global context. It was recognised that for many of the opportunities discussed, it is still too early to determine whether they will be realised or if the challenges identified will have a lasting impact.

4.5.1 UK position and reputation as a science leader and global collaborator

Across the sources, there is continued respect for the quality of UK science and expertise, and the UK continues to be an important partner and contributor to science internationally [17, 77, 109].

> **“There is still an interest from colleagues in other countries to engage with UK scientists and a continued respect for the quality of research we do.”**
>
> Survey Respondent, UK-based, Jun 2023

The importance of maintaining UK leadership in science for economic, political and security advantages has been emphasised along with the previous UK Government’s stated ambitions to make the UK a ’science superpower’ [27, 51, 87]. However, many within the sources considered this goal to have been made more difficult since Brexit [34, 36, 52, 100].

> **“It’s unrealistic to expect the UK and its research community to continue to keep up with the best of the research community internationally with an isolationist attitude.”**
>
> Survey Respondent, UK-based, Jun 2023

There is much uncertainty about the potential long-term damage to the UK’s reputation and position as a leading nation for science and innovation outside of the EU [13, 16, 18, 27, 37, 47, 60, 62, 95]. Furthermore, it is also considered to extend beyond the UK, with potentially harmful implications for the reputation and position of European Science generally [33, 49, 54, 56, 57, 63].

Much of this concern hinged on the decision about the UK’s associate status in Horizon Europe and regaining access to this funding source and opportunity for global collaboration [28, 34, 41, 44, 47, 50, 58, 73]. A resolution to the UK’s membership to Horizon Europe was achieved during the period of data collection for this research; see subsection 4.2 for further detail. However, some believe that the damage to the UK’s reputation had already occurred, regardless of the outcome, due to the period of uncertainty about the UK’s membership status to Horizon Europe. This uncertainty led to a reduction of UK involvement in research collaborations and European networks and associations, as well as the UK no longer having an influencing role in the strategic direction of Horizon Europe [27, 53, 69] (see subsection 4.2).

Concerns were also raised about the UK’s loss of influence not just on Horizon Europe but within Europe and internationally more generally on matters of science, research, regulation and healthcare innovation. This perceived loss of influence was attributed to a lack of representation from UK organisations now that the UK is no longer part of the EU [42].

> **“If the UK does not associate with Horizon it will be another very serious blow to UK science.”**
>
> Survey Respondent, UK-based, Jun 2023

The workforce challenges described in subsection 4.3 are also felt to have implications on the wider UK environment for research and innovation. If the UK is unable to attract the best talent to its workforce, there are concerns about the long-term damage this could have on the UK’s reputation as a globally important research leader and collaborator [61, 63]. In turn, this may contribute to the UK being less successful in securing international research funding and collaborative opportunities, further compounding the detrimental impact on the UK’s global position [53].

> **“The personnel things, those are the long-term sort of insidious damage that if we lose a lot of scientific talent that would have come to the UK from the EU but hasn’t, then, you know, you’ll start to see that impacting on the quality of UK science in the next 10 years or so.”**
>
> Workshop Participant, UK-based, Oct 2023

> **“Scientifically, we punch above our weight. A lot of that is because we recruit excellent people from elsewhere. [...] And the worry is that we start to turn those taps off, particularly the PhD level. We will ultimately lose a cohort of truly outstanding scientists who would have contributed to our excellence, our [UK] punching above our weight right.”**
>
> Interview Participant, UK-based, Aug 2023

4.5.2 Changing Research Landscape

This sub-theme encompasses changes and proposed reforms impacting the way in which research is funded and undertaken in the UK.

There were concerns about the UK Government’s ongoing commitment to research and innovation funding, both what this could look like going forward [28, 33, 41, 42, 44, 74] and being subject to change due to changing political influences and reliance on charity funding. These included uncertainty about how participation in Horizon Europe would be paid for and if that would come at the cost of the amount of other research funding available domestically [15, 46, 60, 75]. The ending of existing funding schemes such as the Global Challenges Research Fund also caused concern amongst the research community [45, 57], as well as there being less funding potentially available for research in general.

The last UK Government announced commitments to increasing spending on research and development [50, 75] along with new funding initiatives (see subsubsection 4.2.1), but it is not yet clear if and how this will support funding for cancer research specifically and is considered to be less investment compared to other European countries [50].

Alternative UK funding and collaborative opportunities that continue to be available or have been introduced since the UK’s withdrawal from the EU were mentioned across the sources. Examples include the Cancer Grand Challenges programme, co-founded by CRUK and the US National Cancer Institute (now with other inte-

rnational funding partners), which supports a global research community to come together in multinational teams to address the most difficult cancer challenges. Additionally, small university-led grants have been established to support collaborations between UK and EU-based universities.

> **“I put together another grand challenge bid. [...] We weren’t shortlisted, so that’s fine. But you know that stretched from Korea and Singapore through Africa, Europe, UK and America and South America actually and you know. So I think particularly when you’re thinking about clinical problems and this particular problem with early onset cancers, we really need to think about this, not just from a, you know, what happens because we’re no longer part of the EU, but how can we create relationships on a very global perspective.”**
>
> Interview Participant, UK-based, Aug 2023

> **“My university has created initiatives to generate collaborations with other countries. [...] And so you could go and look for partners within those places and then write an application and get small pots of money. I mean like £20,000 - £30,000 to generate preliminary data together, and so actually those have worked really, really well.”**
>
> Interview Participant, UK-based, Aug 2023

As outlined in subsubsection 4.4.2, several regulatory changes have impacted the delivery of multinational clinical trials. In addition, further changes and reforms are being considered to how UK clinical trials may be carried out in the future [18].

A government policy paper, ’Saving and improving Lives: the future of UK clinical research delivery’ summarised by Lythgoe [77] describes the vision for clinical research delivery from 2022 to 2025. This vision builds on lessons learned from COVID-19 and focuses on faster clinical trial authorisation. In 2022, the MHRA proposed a number of reforms to the clinical trials system, largely to realign with changes to the EU system but also to boost UK competitiveness to attract commercial clinical trials [69].

More recently, the O’Shaughnessy government review ’Commercial Clinical Trials in the UK’ [18], published in May 2023, sets out 27 recommendations to advance UK commercial clinical trials in the short and long term. This represents an opportunity for the UK, which some are optimistic about [69]. However, there is also scepticism about the feasibility of implementing further reforms without first addressing the existing delays and issues associated with the MHRA (see subsection 4.4 and subsubsection 4.3.1) and the capacity of the UK health system [18, 87] (see subsection 4.3).

> **“There’s a lot of noises there trying to use the opportunity of not being part of the EMA to do things differently, but at the moment they [MHRA] can’t even do the basic things it seems.”**
>
> Workshop Participant, UK-based, Sep 2023

4.5.3 Industry Investment in the UK

Strong concerns were reported across a number of sources that the associated challenges, particularly around the delays at MHRA, customs issues, and possible divergence away from EU regulations in the future (see subsection 4.4) could make it more difficult to trade and work with the EU. Many felt that this could deter industry investment in the UK, including decisions to use the UK as a commercial clinical trial location [18, 50, 52, 71, 91, 95]. Combined with the UK now representing a much smaller market, concerns were that this could reduce industry interest in the UK as a place to do research and launch medicinal products, having implications for research, patients and the UK economy [15, 28, 33, 53, 69, 87, 110].

> **“We’ve always been quite an expensive environment to do clinical trials, but now we’re expensive and we’re slow [describes issues regarding responsiveness of MHRA] we’re losing a lot of momentum. There is quite a lot of data, you know, you can look for it online on the fact that drug companies are not perceiving the UK as being an optimal environment to do clinical trials anymore and that is a real problem.”**
>
> Interview Participant, UK-based, Aug 2023

The Association of the British Pharmaceutical Industry (ABPI) reported a decline in the overall number of commercial clinical trials in the UK between 2017 and 2020 [17]. More specifically, this decline has impacted the supply of certain drugs and the ability to run certain clinical trials due to industry withdrawing commercial supplies of drugs to Northern Ireland [93]. This decline was also observed by survey and interview respondents working in clinical trials research:

> **“So I have a study, but it’s co-funded by CRUK and [Pharmaceutical company] and, you know, drug companies want research to be done fast and at the moment all these delays are causing a lot of issues with [Pharmaceutical company] and I think that the UK in general, not just for this study, but in general is perceived to be not the most favourable environment to conduct these drug studies because it’s taking so long.”**
>
> Interview Participant, UK-based, Aug 2023

> **“We’re hearing, and it is anecdotal, that the drug companies are saying, ‘well, we’ll collaborate with you, but not if you open it in the UK because that’s just too difficult’.”**
>
> Interview Participant, UK-based, Aug 2023

However, sources from the review also report evidence to suggest that the UK continues to be important to industry both for research [109] and investment generally, such as for life sciences [17, 41, 47] and the biopharmaceutical industry [77]. The work of the Office for Life Sciences on cancer vaccines was highlighted in one of the workshops as an example of where government-backed initiatives can effectively encourage industry investment:

> **“I must say that the one real big sort of jewel that is shining nice and brightly at the moment is obviously in the cancer vaccine space where, you know, I think the UK Government and the Office for Life Sciences does extremely well to get [Industry partners] engaged in such an immensely profitable way.”**
>
> Workshop Participant, UK-based, Oct 2023

Those working within clinical trial centres and study sites also report continued interest from industry partners investing in the UK:

> **“So one of the big fears around Brexit was if companies would stop coming to the UK to do their clinical trials. And, my sense was that did not happen. I think Industry continued to come to the UK because they know we can deliver and the expertise and the patient populations.”**
>
> Interview Participant, UK-based, Oct 2023

Greater regulatory freedom and potential future changes to regulation were also identified as potential opportunities for the UK. Rather than detracting from investment, these changes could increase investment from industry, particularly if regulatory innovations can support research for more innovative treatments and rapid market authorisation processes, as was the case in the rollout of the two main COVID-19 vaccines launched by Pfizer and Astrazeneca [92]. For further details on regulatory opportunities, see subsubsection 4.4.3. However, much uncertainty remains, and the success of these opportunities was considered to be largely dependent on addressing other related challenges described in subsection 4.4; such as the delays to regulatory approvals, supply chain issues and processes for market authorisation and recognition of Good Manufacturing Practice (GMP).

Encouraging industry investment in the manufacture of medical devices, drug development and digital technologies within the UK was also seen to be an opportunity to further enhance the UK’s ability to drive innovation and commercialise scientific research [92], as well as secure the supply of essential medicines [38] and resources for medical device production [99].

There were also opportunities identified to provide greater support to UK science industry, both domestically and internationally, particularly around start-ups and fostering links between academia and industry [50, 52]. UK Catapult centres were mentioned as having a role in supporting this, but they were considered to have been impeded by ad-hoc reviews and limited funding [50, 52]. Others were also sceptical about the UK’s effectiveness at translating scientific research into innovation and commercialisation, particularly in light of the challenges of attracting the best talent (research and enterprise see subsection 4.3) and the relative size of the UK market now it is no longer in the EU [50].

For some, it was considered that it may still be too soon to fully assess the impact the UK’s exit from the EU had on UK industry [91, 94] and continues to be an area under active monitoring:

> **“I am monitoring closely the uptake and our ability to retain and attract clinical trials. You know, again it’ll probably be another year or two before I really get data through that I can be confident that there is no carry-over from just a downturn in research activity [as a result of COVID].”**
>
> Interview Participant, UK-based, Oct 2023

4.5.4 Concerns about the impact on UK Higher Education Institutions

There were significant concerns about challenges such as access to EU funding (see subsection 4.2) and the recruitment of talent (see subsection 4.3), including undergraduate and PhD level students from the EU. The concerns raised were that these challenges might impact UK universities and Higher Education Institutions (HEIs) financially and their ability to conduct research, collaborate and support innovation in cancer treatments, prevention and science more broadly as well as contribute to the UK economy [28, 34, 37, 50, 52, 53, 60, 82]. As described in sub-theme subsubsection 4.2.1 (changing research landscape), the loss of access to European Structural Funds also raised concerns about the impact on UK HEIs, particularly those in poorer regions [28].

A further knock-on effect on HEIs, noted in the evidence review and survey, was the decision of the previous UK Government’s decision to withdraw from the ERASMUS+ scheme, which supported student exchange between UK and EU institutions, on the basis that it was too costly and benefited the EU more than the UK [27, 34, 41, 45, 59, 60, 61, 70].

The Turing Scheme, established to provide a global offer post-ERASMUS+ for UK students, is felt to include several attractive elements, such as supporting the last UK Government’s ’levelling up’ agenda, skills development, unemployment, and targeting students from disadvantaged backgrounds [27, 60]. However, sources in the scoping review highlighted issues with the Turing Scheme’s support for British students wanting to study abroad. Furthermore, it was suggested that, in practice, money that would have been earmarked for British universities to fund EU students studying in the UK is no longer available [34]. In addition, the timing of the funding cycle, uncertainty about tuition fee coverage, and who would be administrating the scheme have also been scrutinised, making many believe that it is more limited than its predecessor [13, 27, 28, 34, 60].

Beyond the Turing Scheme, some sources emphasised the mutually reinforcing connection between higher education and research [28]. A loss of inbound mobility through ERASMUS+ has been argued to be a risk to future research collaboration and the UK’s international research enterprise [34, 61, 63]. This could contribute to a lack of EU talent to support private and public sectors in the UK, as well as intercultural competencies, all of which would negatively impact the UK economy [27, 61].

> **“PhD students now forced to pay exorbitant fees. Loss of ERASMUS has meant many great EU students now unable to visit (and often remain/return for PhD).”**
>
> Survey Respondent, UK-based, Jun 2023

There were also concerns raised about how the loss of freedom of movement could impact the delivery of Transnational Education (TNE), where UK institutions deliver higher education level awards in a country or to students other than where the awarding provider is based. This was considered to be an important source of income for UK HEIs [28].

4.5.5 UK Competitiveness within the global market

An overarching consequence of the concerns and challenges identified from the sources in each of the themes and sub-themes in this report is the implications to the UK’s overall competitiveness and attractiveness. These concerns and challenges were felt to affect the UK’s ability to attract research trials, research funding, industry investment and workforce talent to the UK within the global context [18, 36, 50, 62, 69, 95].

> **“I guess it’s just, you know, it’s a whole ecosystem, isn’t it? So you know the delay with the trials is, we’re saying, makes it less attractive from an industry perspective. So less investment from industry impacts from an academic perspective, you know, not being able to access EU funding impacts from an academic through; I guess the concern is, more broadly, how the UK manages to maintain its position as a key location from a science perspective. And that then, therefore, impacts in terms of our ability to attract partners.”**
>
> Workshop Participant, UK-based, Sep 2023

Beyond the UK, the global competitor landscape for research and investment was also felt to be changing. Examples of this change include the rise of high-quality clinical research and significant investment in countries such as China and Japan [42]. These developments, combined with the current challenges being faced in the UK (e.g. delays at MHRA and lack of capacity in the health and care system), raised concerns about the UK’s ability to remain internationally competitive and attractive to industry.

> **“Increasingly South Asia and Southeast Asia are playing an incredibly big role in the drug development space, particularly at late phase.”**
>
> Workshop Participant, UK-based, Oct 2023

> **“So all of those coming together again is that going to make us less of an attractive location for industry to be running their trials. Um, so again it will impact our ability to be kind of be within that innovative space and being able to kind of compete with what’s going on in the international sphere.”**
>
> Workshop Participant, UK-based, Sep 2023

Furthermore, concerns were raised that the very nature of leaving the EU makes the UK look insular and impacts the global significance of UK research [73] and UK competitiveness within the research and innovation space.

> **“We’ve got to put ourselves back into a position where we work, optimize the collaboration and the ability to collaborate. [...] We’ve really gotta break the little Johnny England [mentality].”**
>
> Workshop Participant, UK-based, Oct 2023

Nonetheless, there was also optimism that the UK will remain a key player in internationally relevant research and collaborations [17], including industry [77], and become more competitive in clinical trials [41]. This is further explored in subsection 4.2.

> **“Well, I think you know, despite all I have said, we do still get approached to collaborate on studies. So it’s not that UK’s not being considered at all. I think there’s a lot of very good expertise in the UK in lots of different areas of Cancer Research. And I think that is recognised around Europe and globally, and therefore, people want to continue to work with the UK for those reasons, to access the expertise. ”**
>
> Interview Participant, UK-based, Oct 2023

4.5.6 Implications for the UK health and care system

Concerns were raised across the review, survey and interviews about how the challenges described could impact funding for and the capacity of UK Health and care services in the future, such as through reduced opportunities:

> **“All the international studies I have worked on ceased, and nothing new regards commercial studies have been opened in the hospital where I work. ”**
>
> Survey Respondent, UK-based, Jun 2023

There were also concerns raised about broader negative impacts on the UK economy as a whole and what this could mean for patients and the public if it were to reduce the capacity to fund the health and care system and provide access to innovative treatments and medicines. This could cause further knock-on effects on delivering health and care services, including cancer care [15, 36, 76].

There was also concern about the interplay between the workforce challenges described in subsection 4.3 and how this might contribute to the UK being a less favourable environment for undertaking clinical cancer research within the UK health and care setting due to a reduced research and health and care workforce.

> **“So even if the study is set up, if you have very busy clinics full of patients waiting to be seen, it’s not that straightforward to include patients in clinical trials because they do take a lot of time. ”**
>
> Interview Participant, UK-based, Aug 2023

A loss of industry investment in the UK and de-prioritising it as a market to launch and offer medicinal products could impact the UK health and care system’s ability to buy certain goods and services, thus reducing patient access to healthcare through loss of medicine supplies [39, 76, 91, 95]. This is particularly concerning for Northern Ireland [93] in light of current regulatory changes impacting the movement of goods here (see subsection 4.4: ’Regulatory effects on research and health and care’ above for more detail). However, there was also evidence to suggest that the UK remains an attractive ’early medicines launch’ destination [103, 109], meaning patients across the UK could be amongst the first in the world to access innovative new treatments, which could benefit those affected by cancer. As declared by Milmo [92], the last UK Government also hoped to use its reputation as one of Europe’s biggest research centres to help unlock opportunities that would speed up UK access to innovative treatments for UK health services and patients. Furthermore, if future regulatory changes facilitate faster development and approval processes, this was considered to have the potential to speed up the availability of new and innovative treatments within health and care settings [95].

The UK no longer being bound by EU procurement requirements (with a few exceptions set out in the UK- EU TCA [15]) was suggested to potentially facilitate greater competition, at least domestically [15]. Still, there was

was also a concern that outside of the EU, UK health and care could become a much smaller market, and the potential for trade barriers and a downturn in the UK economy could weaken its bargaining power and make medical procurement more expensive and complex [36, 69, 76].

Finally, it remains to be seen what the impact could be on the role of health within future trade deals with the EU and beyond [32] and its implications to cross-border care [15, 36]. There were concerns about whether trade agreements sufficiently safeguard the NHS and the prices it pays for medicines and uncertainty about whether such commitments effectively address the provisions that might negatively impact the health service [71]. However, it was felt that an opportunity existed to have ”better trade agreements” and greater recognition of health and specifically aspects impacting public health such as food [81, 107, 108], obesity [40] and tobacco within future trade deals [36, 105] (see subsubsection 4.4.5 for further detail). One article in the scoping review called for renegotiations on aspects of the UK-EU TCA to minimise trade barriers that are considered to be damaging to health and the supply of medicine [81].

4.5.7 Suggested ways forward

This final sub-theme presents a synthesis of suggestions posed by participants (workshops, interviews and surveys) and in the scoping review documents as possible mitigation or potential solutions that could help to overcome the challenges to the UK environment for research, innovation and health and care, and/or realise the potential opportunities described. The majority of suggestions focused on the role of the UK Government in facilitating change to support the UK environment for research and innovation, touching on many of the preceding themes relating to collaboration and funding, workforce, and regulation.

Suggestions included fostering more collaborations between industry and academia to support innovation and commercialisation of basic research [37, 50, 52], as well as between UK and EU scientists to ensure the UK remains open to opportunities. It was also highlighted that the UK Government should ensure that the UK’s approach to risk mitigation around research collaboration is proportionate [54] and to maintain or enhance the UK’s role in international networks, like its previous position within the EMA, to stay competitive and drive healthcare innovation [100].

Increased funding and government-backed initiatives were also emphasised to support UK industry growth and investment, particularly for start-ups [50, 52] and the UK’s medical device sector [95]. This included capitalising on opportunities linked to the last UK Government’s ’levelling-up’ agenda and applying learning from other nations, such as the California stem cell initiative at UCLA, in order to drive investment in the life sciences industry in the North of England [110]. Additionally, there was a call for increased infrastructure to support domestic production of materials required for drug and device development, such as cell production for human trials [110].

Addressing the workforce challenges raised in subsection 4.3 and skills shortage—particularly in roles such as Clinical Academics and the ability to attract skilled entrepreneurs to support innovation and commercialisation [50]—was considered a critical enabler [53]. Springford [52] suggests this could be achieved through long-term reforms to the UK education system and, in the short term, through a simpler immigration system. Additionally, supporting lower-skilled positions in manufacturing [50] was highlighted.

> **“The other thing that is also gonna undermine translation and innovation over the next 10 years in the UK is the big, big shortfall in clinical academics that is coming right around the corner across all medicine.”**
>
> Workshop Participant, UK-based, Oct 2023

Regarding regulation, the careful introduction of new legislation and regulation to boost competitiveness and attractiveness to international industry investment [52, 69, 81, 95], as well as ensuring these changes benefit health and the NHS across the UK’s four devolved health systems [15] was recommended. For example, simpl-

er processes for setting up clinical trials in the UK could be beneficial:

> **“UK should use the opportunities arising from Brexit to make trial setup and running simpler to make the UK more attractive as a collaborator and participant in research. ”**
>
> Survey Respondent, UK-based, Jun 2023

Cutting across all sub-themes was the sense of uncertainty and desire for greater clarity, collaboration, communication and engagement between government, regulators, the scientific community and patients. This includes, for example, the design and availability of future UK research and innovation funding [41, 57, 75] amidst mixed signals from the government [60], future changes to the regulatory and research landscape, and the implementation of new regulations to advance in emerging fields [92] (also see subsubsection 4.2.6):

> **“[T]here has been a few stumbling blocks, and since the trade agreement and work will continue to undoubtedly fall into more potholes with it over the time, but there does seem to be a way out and it’s just all about, you know, being transparent and good communication. ”**
>
> Interview Participant, UK-based, Oct 2023

Re-entering the single market or ”Reversing Brexit” was identified as a possible solution in some of the sources. However, for most, this was recognised as being unrealistic and unlikely [50, 52]. There was, however, a suggestion of negotiating a revised agreement to rejoin the European Economic Area (EEA).

> **“I do think that we could attempt to go back into the EEA and that would go on to European regulations, go back into the European markets on to European regulations again, which is probably the most that we’ll be allowed to do in the near future. ”**
>
> Workshop Participant, UK-based, Oct 2023

5. Discussion

The themes identified in this research signal a multitude of challenges and opportunities perceived and experienced by the science, research and health and care community in the UK since the introduction of the UK- EU TCA. These are highly interconnected and are being influenced further by factors beyond the UK’s relationship with the EU, e.g., the COVID-19 pandemic, the global economy and geopolitical events such as wars and national elections, along with others. Here, we discuss the overarching features and considerations based on the findings from this thematic analysis and possible next steps.

5.1 Complex and rapidly changing

This complex and rapidly changing environment means that aspects of the landscape, and thus the associated challenges and opportunities, have evolved throughout this project. We highlight some specific areas where ongoing change during our data collection, analysis and write-up could further impact cancer research, prevention, and cancer care delivery.

5.1.1 Changing landscape throughout this project

This project aimed to understand what, if any, implications resulted from the UK-EU TCA. It is clear that the UK’s exit from the EU and the implementation of the UK- EU TCA continue to have ramifications on all research. However, the consensus from this research is that there is a particular impact on clinical research. This has led to increased costs, time and resources required for research, which, in some cases, continues to prevent patients from accessing cancer treatment through clinical trials.

The period during which the UK withdrew from the EU, coupled with ongoing negotiations, occurred during a uniquely complex landscape, notably the COVID-19 pandemic. Consequently, it was often challenging to disentangle one effect from the other. This could suggest that some of the negative effects on research, and health and care during this period will be mitigated over time. However, the current economic climate, along with international policies and conflicts overseas (e.g., Israel’s war on the Gaza Strip), continue to exacerbate the already challenging landscape [111].

Recent figures have shown a modest improvement in the number of commercial clinical trials and recruitment between 2021 and 2022 [112]. ABPI data suggests that “for every patient recruited onto an industry clinical trial between 2016 and 2018, the NHS in England received more than £10,000 in revenue and cost savings from life sciences companies”. After the Government commissioned the O’Shaughnessy review [18] into industry trials, it introduced several measures to improve the environment [113]. Additionally, the National Contract Value Review, introduced in October 2022 as a standardised approach to costing commercial contract research, appears to be having some positive impact on trial set-up time [112, 114]. While these developments have been welcomed by the community, there is caution that any improvements benefiting commercial research must not come to the detriment of academic studies [18]. Maintaining a balanced portfolio of non-commercial and commercial research is critical for industry. For example, the Experimental Cancer Medicine Centres, funded by Cancer Research UK, the Little Princess Trust and UK Government health research funders, support early phase trials that are vital to industry funding for later phase trials.

Data collection during this project coincided with the announcement of the UK’s associate membership to Horizon Europe and Copernicus. This was very welcome news, leading to a reported ”bounce back” in Horizon Europe applications from the UK [115]. Association to Horizon Europe has provided UK researchers access to an enormous funding stream and major collaboration opportunities. The UK could only associate to EU framework programme(s) beyond 2027 with UK Government support. As an associate member, however, the UK is limited in its contribution to the shaping of these funding programmes and it is not the same as our previous full membership.

Our findings show that the experience of joining Horizon Europe has generated continued concerns and a lack of trust within the scientific community towards political actors due to the use of science as a political bargaining tool. The UK Government may wish to consider these concerns in any future negotiations regarding EU funding programmes, including the next EU Framework Programme for Research and Innovation, currently known as ”FP10” [116].

At the time of writing this report, the UK General Election has been called. How the UK Government’s foreign policy from 2024 will support health and science will be clarified in due course. In particular, opportunities to improve UK-EU relationships will enable (i) research collaboration and (ii) UK participation in the EU’s cancer plan initiatives that could benefit patients across the European region. The EU’s flagship cancer projects, for example, the European Network of Comprehensive Cancer Centres (UK partners contributed to previous iterations of this project [117]) and the EU Cancer Inequalities Registry, continue to develop.

It is also important to acknowledge the evolving landscape within the cancer research community. During the course of this project, for example, CRUK’s innovation engine, Cancer Research Horizons, continued to develop new industry and charity partners. Five new Cancer Grand Challenge teams were announced with £100m in funding.

5.1.2 UK Immigration Policy

Our findings highlighted ongoing concerns within the cancer research community regarding the impact on the mobility of the research, health, and care workforce between the UK and EU following the UK’s exit from the EU. This is consistent with the quantitative results from the CRUK Global Collaboration Survey, where 76% of respondents reported difficulties in recruitment and retention of research talent, despite these being in the top three factors crucial for their research success [118, p. 38].

During 2023-24, after data collection for this research, the then-UK Government implemented a series of restrictions and cost increases to the immigration system aimed at reducing net migration (See: Reducing Net Migration Factsheet for a summary). These changes have likely exacerbated uncertainty and concern within the research community about the impact on the recruitment and retention of international scientific talent within the UK.

For instance, in 2022, CRUK explored the implications of changes to the immigration system for the UK’s cancer research community in the blog post: Why the Government needs to do more to attract international researchers. The blog highlighted particular concerns about visa costs. These were reflected in 2023 in the CRUK Global Collaboration Survey findings [118] and have since been reinforced by the Royal Society’s visa costs analysis update 2024.

The Royal Society analysis shows that UK visa costs are 17 times higher than the average for other leading research nations [119, p. 1]. The Immigration Health Surcharge (IHS) is highlighted as a significant factor, but UK visa costs remain higher, even without the IHS. The IHS makes the Global Talent visa for science leaders or potential leaders the most expensive visa compared with other leading science nations – 1,583% higher than the average [119, p. 7]. The cost of a Skilled Worker visa, which supports many people in scientific careers, is also significantly higher than the comparable international average and has increased by 9% in real terms between 2021 and 2024 [119, p. 4].

Given the global nature of scientific careers, visa costs will likely continue to be a major concern for organisations aiming to develop and sustain a world-class scientific workforce. Cancer Research UK called for reductions in visa costs in their Programme for Government, Longer, Better Lives [118].

There has also been an incremental increase to the minimum salary a ’skilled worker visa’ holder must earn up to the cap of £38.700 [120]. While health and care workers are exempt from the salary threshold [121], this is likely to present additional barriers to lower-paid workers such as ECRs and those in roles supporting the research industry, such as the manufacture of medical devices.

Whilst only covering data for NHS England, a 2023 House of Commons report, NHS staff from overseas: Statistics, suggests that although the proportion of joiners reporting an EU/EEA nationality has fallen from 10.9% since 2015/16 to 6%, the overall number of NHS staff with an EU/EEA nationality has increased over- all [122, p. 12]. Furthermore, non-EU/EEA nationality joiners have risen sharply from 9.9% in 2017/18 to 25.3% in 2022/23 [122, p. 12]. However, as noted in the report, improved data quality and coverage of NHS workforce nationality data may partly explain the changes over time. Therefore, any comparisons should be treated with caution.

Factors such as the COVID-19 pandemic and conflicts like the war in Ukraine are likely contributing to any changes, not just Brexit. This suggests that some concerns raised in our findings about the impact of the UK’s withdrawal on the mobility of the health and care workforce may not be as stark as some of the sources perceived them to be.

Regardless, our findings highlighted that there are ethical concerns about recruiting from certain LMICs [39]. Therefore, it’s important that the UK Government and recruiting organisations, especially into health and care roles, take steps to ensure that immigration and recruitment practices in the UK are sustainable not only for the UK health system but also for the countries from which the workforce is migrating. The UK Government published guidance in August 2023 regarding best practices in the international recruitment of health and social care personnel in England.

In the long term, addressing the shortage of domestic health and care workers should continue to be a priority, such as meeting the goals set out in the NHS Long Term Plan.

5.1.3 Changing regulatory landscape

Regulatory changes are complex and have ramifications for various parts of the UK research and care ecosystem. Our findings indicate that legal and regulatory changes brought about by Brexit and UK- EU TCA have impacted both research and care delivery in similar ways. These changes have important implications for people affected by cancer and for public health.

The UK’s new Clinical Trials Regulation is expected to come into force in October 2025, following a 12-month grace period (to be confirmed). Alongside updates to existing legislation, it aims to ‘build international interoperability’ to attract multinational trials to the UK. While the UK-EU TCA means that barriers to cross-border trials will still exist, reducing the remaining uncertainty about the level of compatibility of the new UK legislation with the EU’s Clinical Trials Regulation is expected to be beneficial.

It is important to acknowledge that Brexit was not the only reason for MHRA workforce challenges [123, p. 8]. Moreover, as shown in the MHRA Annual Report and Accounts 23-24, significant improvements have been reported since Autumn 2023, with a notable increase in clinical trial application assessment within 30 days from 25.9% in 2022/2023 to 40% in 2023/2024 [124, p. 41]. Monitoring future MHRA capacity and workforce planning will be crucial, given its vital role for people with cancer and the significant impact of delays, as our findings show.

For success, it is essential that legal regulations, real-life processes, and regulatory bodies are designed for both safety and speed, communicate effectively with stakeholders, and are well coordinated with global counterparts and processes. CRUK makes recommendations on securing approval for the use of innovations, including for the MHRA, in Longer, Better Lives: A Programme for Government [118, p. 63].

The MHRA has developed the new International Recognition Procedure, which aims to enable the swiftest possible safe access to new medicines for patients by relying on the regulatory decisions made by trusted partners, which include Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States.

Further amendments to the Windsor Framework changes will also allow decisions to be made for the whole of the UK, ensuring that medicines are available to patients simultaneously across the UK (Project Orbis applies to Great Britain only). This will help to reduce the treatment inequity seen in Northern Ireland since the UK’s withdrawal and Northern Ireland protocol. Furthermore, all medicines that have been approved by the UK’s regulatory authority will be available for purchase, and the Regulation of all medicines available for purchase in Northern Ireland will now be carried out by the UK’s MHRA rather than the EU’s EMA.

In terms of medical devices, the UK responded to the new EU regulations (EU MDR 2017/745) with its own transitional arrangements for GB, including amendments to The Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR), and separate rules for Northern Ireland where the EU regulations apply. People in Northern Ireland should be able to benefit from devices approved either by the EMA or the MHRA. A new GB framework is anticipated (at least for ‘core elements’) in 2025 for medical devices that prioritise patient safety. The new regulation affecting GB will bring further compliance with EU legislation regarding CE marking. However, once implemented, this will need to be monitored to ensure equal access across the UK.

Going forward, it will be interesting to see how Northern Ireland-Republic of Ireland research activity (e.g. through the All-Island Cancer Institute), including trials, continues to adapt and grow.

Given the lack of new treatments for children and young people (CYP) with cancer and the biological differences in CYP cancers, specific innovations are needed. There is an especially strong global impetus in the CYP research community to drive international collaboration (e.g., the ACCELERATE platform), to include researchers, patient and parent involvement, clinicians, industry, and regulatory support as part of the process for establishing new treatments and medicines on the market. Our findings highlighted that researchers in the UK continue to inform policy activity in both the UK and the EU, including the reform of the EU pharmaceutical legislation. It is not yet clear how the proposed new EU regulations within the pharmaceutical package, such as the revised EU Paediatric and Orphan Medicines Regulations [125], will impact countries beyond the EU, including the effect on industry decision-making across the whole European region (see this post on the key challenges and unresolved questions).

For the NHS workforce, recognition of professional qualifications remains an area for potential change. The EU Standstill Provisions (updated in 2023) already mean that all EEA-qualified healthcare professionals are able to work in the NHS without needing to sit additional exams or assessments. These professionals can continue to register with the relevant professional regulator without the need to sit for additional professional exams, mitigating delays to registration and employment in the NHS. These provisions are in place until 2028, when a further review is expected. In the meantime, the Labour Party 2024 manifesto committed to seeking to negotiate a mutual recognition agreement for professional qualifications with the EU [126, p. 118].

What is clear is that there are two potentially opposing aspects within the regulatory arena. On one hand, many researchers expressed a need for regulatory alignment to facilitate multinational research, particularly within the EU context. On the other hand, some aspects of the alignment were felt to be clunky (for example, GDPR, given the different interpretations of its implementation), or others highlighted the potential opportunities for UK science and health through regulatory divergence. It appears that alignment and divergence are seen to be important going forward, but the question remains whether this ’sweet spot’ can truly be achieved. Can the UK be regulatory aligned and different?

5.1.4 Ongoing Monitoring

The UK and EU continue to legislate and set policy direction, with the potential for significant divergence over time in various policy areas that affect cancer research and care. Due to the changing landscape, it is vital that ongoing monitoring of the situation is undertaken by the government, scientific community, researchers, regulatory bodies, industry, and health service providers.

The Nuffield Trust’s ‘Health and International Relations Monitor project’, supported by the Health Foundation, will continue to be a beneficial resource, including its report published in April 2024 *The future for health after*

Brexit [127]. In addition, UK in a Changing Europe (UKiCE) has developed a ‘UK-EU divergence tracker’ [128], which is an important resource to identify and analyse significant divergence in regulatory standards between the UK and EU since the TCA. However, it is less clear about the implications at a more granular level, such as for cancer research and care delivery, or in areas important for common global interests where the EU contributes to global norms, such as Artificial Intelligence, climate change and digital care. It would also be helpful to understand divergence in terms of processes, which is crucial for understanding the real-world experience of the UK-EU relationship.

Periods of uncertainty over UK-based researcher access to Horizon Europe presented a range of challenges to the research community. While access has now been granted it will be necessary for the UK to monitor the effect – in the longer term and on UK participation rates until 2027 – to which these periods of uncertainty have had on collaborative research and the UK’s ability to be a significant beneficiary of Horizon funding, as it was before Brexit.

In terms of cancer care, patients in the UK might expect similar access to supplies of items such as medicines as if the UK had remained in the EU. It will be essential to monitor, for example, the length of time it takes for patients to access new cancer medicines compared with leading nations. An analysis of the European Access Hurdles Portal data conducted by IQVIA on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) shows the EMA is slower than regulators in the USA and Japan for medicines approval and that “in the UK, MHRA approval comes, on average, 91 days later than EMA approval” [129, p. 10] (based on data from 2021 - 2023 an average for all innovative medicines, including oncology and orphan drugs).

However, this analysis did not take into consideration early access schemes for innovative oncology medicines, such as the UK’s Early Access to Medicines Scheme (EAMS), and MHRA delays are improving [124]. Therefore, the full pathway should be compared where possible, including health technology assessment and pricing/reimbursement processes, to understand any disparities in patient access.

It will also be important to monitor the impact of global medicine shortages on the UK (the EU maintains a public list of shortage medicines, unlike the UK) and the development of the UK’s radionuclide supply chain. The latter has a known capability gap, which means the UK relies on imports of nuclear materials (UK House of Commons Oct 2024) that support cancer diagnosis and treatment (see UKNNL website for details). Euratom also supports the supply of nuclear medicines. Therefore, it would be useful to understand the impact of leaving Euratom on care as well as research in the medium term and whether there might be pressure in future to rejoin the programme.

One aspect of the last UK Government’s strategy to respond to the opportunities of leaving the EU was greater regulatory freedom to transform the UK’s approach to clinical trials and faster access to medical treatments, as outlined in the Government report *Benefits of Brexit* [130]. It will be important to independently monitor the impact of new initiatives and changes to understand their impact and if such benefits have been realised.

For example, a new Health Impact Assessment (HIA) has been used to analyse the Comprehensive and Progressive Trans-Pacific Partnership trade agreement (CPTPP) and found both positive and negative aspects to different population groups in Wales. Such HIAs could be useful in assessing the public health impacts of future UK trade agreements.

In support of the UK’s ambitions to be a science and technology superpower by 2030, the UK science and technology sector (including UK Government, academia and industry) need to undertake active monitoring of the global environment and changing international landscape. It is also important to recognise the unique mix of research funders in the UK and the role of the charity sector. This should all be used to inform and respond to changes in the global competitor landscape of commercial trials and new medicinal products to maximise UK competitiveness.

5.1.5 Effective and clear communication

Communication and effective guidance from the government, regulatory bodies, sponsors of research and research funders were identified as key areas for improvement by the research community, particularly during this period of change. Enhanced communication, guidance and involvement of the scientific community and industry would help research sponsors, including those funded by or collaborating with the charity sector and industry, to better co-develop and navigate new legal and regulatory frameworks affecting research, commercial industry and healthcare. This would ensure that the UK remains seen to be open for business. Clear communication was an apparent concern for Northern Ireland, given its position within the EU and GB regulatory spheres. For example, medical devices, including IVDs, are areas where the MHRA is aware and taking steps to mitigate risk to patient access. MHRA’s capacity to address all such issues arising from the UK’s EU exit depends significantly on sustained UK Government funding.

In the examples we heard regarding logistical problems affecting research, leading to delays or even lost research, a better understanding of the new regulations, systems and processes is likely to solve at least some of the problems and reduce delays for projects across the research spectrum, from discovery to trans- lation to clinical research. However, this is unlikely to reduce the time those who support research now need to spend on additional post-Brexit paperwork, which is ’baked in’ to the kind of relationship the UK now has with the EU.

5.2 Implications for cancer research

Through our analysis of the interviews, focus groups, survey data, and evidence review, we identified challenges and concerns arising from all these changes and periods of uncertainty. These included access to EU funding and initiatives, the impact on collaborative research as well as specific implications for multinational clinical trials.

5.2.1 Sources of funding for cancer research

The main research funding mentioned throughout all sources was around the EU’s Horizon Europe programme and ensuring that the UK remains able to access funding through this mechanism, which happened. However, there are other EU funding programmes that provide significant funding to cancer research that were not raised in any of the sources we reviewed as part of this research. For example, the EU4Health Programme has been set up to tackle cross-border threats and has aligned with the EU Beating Cancer Plan, and the DIGITAL Europe programme funds the European Cancer Imaging Initiative. The Euratom programme, which was mentioned briefly during the review and interviews, funds research and training that applies to the use of radiation in cancer care. However, the last UK Government decided not to participate. Therefore, UK organisations may be able to participate in calls under these programmes, but there are caveats. They will normally be associate partners, meaning they will not receive EU funding, and can only participate as long as the ”programme’s legal basis allows”. Currently, there is no UK funding mechanism to support associated partnerships in these programmes, except Euroatom (See UK Research Office Brussels (UKRO) website). In the case of Euratom, the Government is pursuing its own fusion energy strategy, but it is not clear whether it intends to replicate the cancer research element of Euratom [131, 132]. However, UK Parliament scrutiny around the Government’s decision not to participate in some of these programmes, e.g. EU4Health, which was felt to mean missing out on working with the EU to improve health outcomes in the UK, could mean that could change in the future.

Other UK-based funding initiatives not identified during the data collection but that also have the potential to support international cancer research collaborations include the International Science Partnerships Fund (ISPF) being managed by the Department for Science, Innovation and Technology (DSIT). The ISPF is designed to support collaborations between UK-based researchers and others from around the world and is currently one of three funders supporting The Cancer Research Transatlantic Development and Skills Enhancement (DSE) Award, a cancer collaboration between the UK and USA to support future cancer research leaders.

5.2.2 The future of collaborative cancer research

The European Health Data Space provides crucial opportunities for health research, including research that supports cancer prevention and care, and will support some of the ambitions of the EU Beating Cancer Plan. Clarity is needed on how the UK might be further involved and could benefit from this going forward. The EU adequacy decision the UK currently has in place is considered an important enabler for potential future participation [133]. It is possible that the House of Lords European Affairs Committee inquiry into UK- EU Data Adequacy and its implications for the UK- EU relationship might provide a user steer to the UK Government, should the Committee publish a report as expected in 2024–25.

With fewer opportunities for collaboration following Brexit, the next generation of leading cancer researchers in the UK faces challenges in building and expanding their networking opportunities with peers and collaborators in the EU. The struggles described in our findings have indeed impacted cancer research, but the question remains: What will the long-term impact be? In recent years, UK cancer researchers have had to depend on goodwill from peers in the EU, benefiting from their pre-existing relationships with the EU research community. How will the future generation of researchers generate the kind of goodwill the current generation has been forced to rely on? This reliance on goodwill underscores the esteemed reputation of the UK research community among EU partners. However, it also highlights a concerning trend where collaborator goodwill is becoming integral to the system, which may not be sustainable in the long run. This reliance on goodwill may compromise the overall desirability of working with UK-based researchers, both in terms of financial and non-financial costs. We heard from the research community how reliance on goodwill provided the necessary coordination support to ensure the recruitment and retention of patients within trials. Struggles with recruitment may also hinder the formation of high-quality collaborator relationships in the future. As time progresses, relying on continued goodwill from collaborators might become increasingly challenging.

A CRUK online survey of people affected by cancer in 2023 showed that 99% of survey respondents believe it should be easy for CRUK scientists to collaborate globally and with EU researchers [118, pg. 45]. An analysis of the closed questions from the CRUK’s Global Collaboration survey (the open questions from which were included in this research) found that 78% of research community participants said they engage in multinational collaborations. Among them, 58% intend to collaborate with US-based scientists in the immediate future, while 92% plan to do so with EU-based scientists. Although 98% of respondents stress the importance of collaborating with EU-based scientists, 79% find it more challenging to initiate new collaborations post-Brexit [118, pg. 45].

5.2.3 The clinical trial environment

In May 2023, the last UK Government published the O’Shaughnessy review [18] with recommendations that could lead to further changes to how clinical trials are undertaken in the UK and, thus, the potential for greater divergence from the EU. The recommendations are meant to enhance the quantity and variety of clinical trials conducted in the UK, creating a favourable environment for the industry to host clinical trials and make the UK a competitive and appealing destination, with the hope of resulting in an overall improvement and benefit. However, the report lacks references to the operation of multinational clinical trials beyond general set-up times, and it is unclear how the recommendations will further support UK-EU trials - a potentially missed opportunity to generate political support for further progress, particularly for people with rare diseases, including children with cancer.

Moreover, an independent review of UKRI in 2022 undertaken by Sir Paul Nurse and Professor Adam Tickell had specific recommendations for UKRI to improve its process, which could result in changes in the UK Government funding landscape in the near future [134]

An ongoing concern is that non-commercial cancer research is primarily funded by the charity sector. An analysis of the distribution of health research by the public and charity sector showed that 68% of cancer funding comes from the charity sector [135, p. 44]. Overall government funding for cancer research in the UK

is significantly less compared with other countries such as the US, Norway, Canada, and France [136]. COVID-19 has had an impact on the total funding of the health research charity sector [135], which, in the context of cancer, is a cause for concern. CRUK estimate a shortfall of more than £1bn in cancer research investment over the next decade [136].

Therefore, there is a need to ensure that there is continued investment and long-term funding solutions in cancer research. This not only has treatment benefits for people living with cancer (and their families) but also for the UK economy in terms of employment within cancer research and the UK industry associated with the supply chain. Indeed, a CRUK report on the economic value of cancer research and its impact on the industry, Understanding the economic value of cancer research, found that in 2020/2021, £1.8 billion in investments in cancer research generated more than £5 billion in economic impact [137, p. 8].

5.3 Implications for cancer care delivery

Our findings suggest that the UK’s withdrawal from the EU (and the UK-EU TCA) has increased research costs across multiple areas, although we could not quantify this for this project. This raises a question: if research is more expensive, will research funders have the ability to support fewer projects? If not, this will likely lead to slower progress in cancer research and fewer people able to access treatment through research.

Our findings also showed that the UK’s exit from the EU has reduced UK patients’ options in terms of access to clinical trials, with some trials not opening or being heavily delayed in the UK. This includes reduced access to a patient population for trials in Northern Ireland, where pre-Brexit recruitment would sometimes occur across the border. For example, individuals living much closer to Belfast than Dublin could access care in Northern Ireland as part of a trial, and vice versa for UK individuals living closer to Dublin. This means that some EU and UK (Northern Ireland) citizens are no longer able to travel for innovative cancer treatments, with the results of the trial available to support innovative treatment across the UK and beyond.

It is clear that there is a need for more flexibility to enable travel and healthcare access for patient benefit and to support the research environment in Northern Ireland. Researchers already collaborate through the All Island Cancer Research Institute, and there is significant interest in understanding what might be possible for patients in future through a more focused “all-island” approach, such as the potential creation of an All-Island Oncology Innovation Cluster [138].

5.4 Implications for public health and cancer prevention

Our findings indicate that changes following the UK’s exit from the EU present both opportunities and challenges to public health. A report by the Faculty of Public Health [139] made several recommendations to ensure that future trade agreements are health-sensitive. These include the involvement of the health community in the development of negotiations, ensuring ”A duty to regulate” and ”Health in All Policies Approach”, and embedding the Government’s commitment to do no harm and uphold the right to health [139].

UK Governments will need to decide whether to leverage opportunities for the increased freedom to regulate public health. The UK could become a world leader in various public health matters with different political choices. For example, with the legislative consent of all four UK nations, the UK could be the first country in the world to create a ‘smokefree generation’ through tobacco age of sale legislation. The Irish Government, however, has indicated that an EU country could not follow to the same extent due to the existing EU regulatory environment.

There is much interest across Europe in the UK’s ‘sugar tax’ and the work of coalitions such as the Obesity Health Alliance and Obesity Alliance Cymru. The UK Government could implement 2022 legislation aimed at combatting childhood obesity and seek to go further (see House of Commons Research Briefing on Obesity Policy in England).

Any changes to UK tobacco regulation will also need to consider illicit trade. A report by Public Health Wales [140] highlights that the UK’s loss of access to EU criminal databases and the creation of Freeports (which set to reduce checks and regulation in areas to boost investment) may present further opportunities for the illicit trade of tobacco (alcohol and drugs) unless the right strategies are put in place to control them [140, p. 4, 13, 15].

It will continue to be vital that the UK takes part in global knowledge-sharing across public health matters, particularly to understand and share experiences of industry tactics. Monitoring EU public health progress is also crucial so that the UK does not fall behind, for example, in terms of clean air.

The sources we analysed highlighted public health concerns and opportunities concerning tobacco, food and occupational exposure limits for carcinogens. However, our search of the literature did not identify sources with a broader discussion on the impact of regulatory reforms and future trade agreements on wider determinants of health [141]. For instance, in response to an EFRA Select Committee inquiry into UK trade policy, The Sustain Alliance raised concerns around potential changes which would increase pesticide residues and the risk of antimicrobial resistance (AMR). Additionally, if the EU sets further targets in the future, the UK could fall behind its EU neighbours unless the UK were to align.

Finally, this research included a scoping review. We did not seek to assess the quality of the articles and documents included, given the need to understand the perceptions and experiences of the UK research community. However, we are aware that one of the articles referenced in this report, the author of which has been subject to scrutiny for their relationships with the tobacco industry.

5.5 Areas for future work

- This research sought to collate and summarise the challenges and opportunities expressed by the scientific, healthcare and policy communities, with a specific focus on UK cancer research and care delivery following the introduction of the UK-EU TCA. However, it is likely that the challenges and opportunities identified here are also applicable to other disease areas and types of research.
- Further work could be done to engage directly with and understand broader perspectives, such as those from industry, regulation, clinicians and patient and public involvement in cancer research and lived experience, to understand the impact of the introduction of the UK-EU TCA and associated changes in more detail.
- Future research could look to:
  - quantify the impact, particularly around the associated costs and delays to the delivery of cancer research.
  - more fully understand and quantify the impact of EU Exit on cancer prevention, including the impact of the UK’s new global trade deals with recommendations for future trade policy.
  - create a “divergence tracker” to map in detail the UK and EU legislative and policy changes that impact specifically on cancer research and care.
  - understand the opportunities and challenges for collaboration beyond Europe, focusing on priority countries in the Americas and the Asia Pacific region

5.6 Conclusion

This research has highlighted significant challenges arising from the UK and EU’s changing relationship. These challenges impact cancer research and have consequences for those affected by cancer. However, there is al-

so optimism and potential opportunities for greater EU collaboration and global collaboration that could be realised if managed effectively. There remains significant uncertainty and concern about whether these opportunities can and will be realised. Some in the research community, see rejoining the EU as the solution to address these challenges. For most, rejoining the EU is thought to be unrealistic, at least in the short term.

The UK rejoining Horizon Europe offers hope for addressing further challenges related to funding, regulation, movement of people and the UK’s position as a leader in global research. This holds great potential for cancer prevention and new treatments that stand to benefit the global effort against cancer.

Moving forward, policy reforms and calls for more transparency and better communication are needed to support the delivery of cancer research and care. While Horizon Europe was a key focus within the sources we analysed, UK researchers may also benefit from access to other EU programmes which provide significant funding for cancer research, such as, for example, EU4Health, to which the UK is not associated [19]. If leveraged, the CRUK research community can continue to be a competitive international player for cancer research, attract industry investment, and draw the best global talent to the UK.

5.7 Considerations and limitations of this work

- This research included the use of a scoping review. We did not assess the quality of the articles and documents included given the nature of the research questions.
- Due to the rapidly changing nature of the situation, the project findings here represent a snapshot of perceptions and experiences in 2023. They may no longer be relevant in the medium term.
- The findings in this research reflect the experiences and perspectives of those we spoke to. Therefore, they may have expressed misunderstandings around some of the technical aspects of the UK’s withdrawal and the UK-EU TCA, which is not surprising given the complexities around this and the fact that it keeps changing.
- The authors of this report have no technical background in trade agreements or regulatory frameworks/science. The findings presented here reflect their understanding and interpretation of the data presented.
- It was often difficult to understand how new initiatives would be implemented and have an impact across the UK. In particular, complexities around Northern Ireland added to the uncertainty around whether initiatives would or could be UK. In most instances, we have referred to initiatives in the way they are stated, i.e. UK or GB.
- The primary data collection only captured perspectives from the CRUK cancer research community. This might not fully reflect the views of the wider cancer community as well as those from industry, regulation, government and people affected by cancer.

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