Title: Rare Cancers Private Members Bill Impact Assessment **IA No:** DHSCIA9681 **Lead department or agency:** Department of Health and Social Care **Other departments or agencies:** N/A	Impact Assessment (IA) **Date:** 07/07/2025 **Stage:** Development/Options **Source of intervention:** Domestic **Type of measure:** Primary legislation

Summary: Intervention and Options

Cost of Preferred (or more likely) Option (in 2024 prices)		
Total Net Present Social Value N/A	**Business Net Present Value** N/A	**Net cost to business per year** N/A

What is the problem under consideration? Why is government action or intervention necessary?

- Please note this is not considered a regulatory provision.
- Research into rare cancers can be less appealing for companies than research into common conditions because the smaller patient population can make it more challenging to develop a sufficiently robust evidence base to satisfy regulators, as well as limiting the available return on their investments. Research is crucial in tackling cancer, and rare conditions often have a severe patient impact and high unmet clinical need.

What are the policy objectives of the action or intervention and the intended effects?

- The overall aim of the Rare Cancers Bill is to incentivise research and investment into the treatment of rare cancers by introducing measures to streamline clinical trial recruitment and mandating a review of legislation that currently acts to incentivise the development of treatments for rare diseases.
- Indicators of success will include improved links between researchers and rare cancer patients leading to better access to innovative treatments for rare cancer patients and a published government review.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1. Do nothing. There would continue to be limited research into rare cancers, and patient clinical need would continue to be unmet.
2. Introduce primary legislation to incentivise research and investment into the treatment of rare cancers.

Option 2 is the preferred option, Department of Health and Social Care Ministers are keen to support this.

Will the policy be reviewed? It willbe reviewed. **If applicable, set review date:** TBC

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister Ashley Dalton Date: 07/07/2025

Summary: Analysis & Evidence

Policy Option 1

Description: Business as usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	PV Base Year 2025	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero by definition.

Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero by definition.

Other key non-monetised benefits by 'main affected groups'

N/A

Key assumptions/sensitivities/risks	Discount rate (%)
N/A	

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:		
Costs: **n/a**	**Benefits:** n/a	**Net:** n/a

Summary: Analysis & Evidence

Policy Option 2

Description: Introduce primary legislation to incentivise research and investment into the treatment of rare cancers amend the Health and Care Act 2012 and NHS Act 2006.

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	PV Base Year 2025	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

The main monetised costs are associated with the staff resource required for the orphan drug Regulations review, salary costs for a National Specialty Lead role for rare cancers in England, costs to share data between NHS England to NIHR and setting up a tailored registry. Refer to evidence base for further information.

Other key non-monetised costs by 'main affected groups'

To the extent that this policy fulfils its intention and increases research of rare diseases, and with other things equal, there will be the costs of funding and delivering that research, and then a cost of additional treatments. These are not assessed further here.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

n/a

Other key non-monetised benefits by 'main affected groups'

Improving access to patient populations for researchers aims to streamline recruitment, encourage the placement of clinical trials for rare cancer in England and ultimately lead to direct benefits for patients, the public and the life science sector.

Ultimately, the main benefits are expected to be in terms of increased research and improved treatment to rare cancer patients by improving access to treatment .

The NHS also benefits from additional revenues and cost savings from clinical research.

Key assumptions/sensitivities/risks **Discount rate (%)**

The main risks are related to data sharing. Allowing patients to be contacted about research, without their explicit consent, could be controversial. Some patients may not wish to be contacted about research or have their data shared with contact registries. Furthermore, as the disclosure of data can be shared in such a way as the Secretary of State for Health and Social Care may direct, this could pose a risk in the way rare cancer patient data is handled, outside of the policy intentions set out above. Refer to evidence base for further information on risks and associated mitigations.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:		
Costs: N/A	**Benefits:** N/A	**Net:** N/A

Evidence base

Problem under consideration and rationale

1. This Impact Assessment refers to a Private Members Bill (PMB) introduced by Dr Scott Arthur MP in the House of Commons on 16 October 2024, referred to in this document as the 'Rare Cancers Bill'[1].

2. Research into rare cancers can be less appealing for companies than research into common conditions because the smaller patient population can make it more challenging to develop a sufficiently robust evidence base to satisfy regulators, as well as limiting the available return on investment. For example, there is a relative paucity of clinical trials for brain cancer pharmaceuticals compared with other cancers[2].

3. The Rare Cancers Bill is intended to support research and development for rare cancers. There are different definitions for what is defined as a rare cancer, e.g. some charities including Cancer Research UK define this as prevalence of less than 6 in 100,000. However, for the purposes of the Rare Cancers Bill, Dr Scott Arthur MP has defined a rare cancer as equivalent to the definition for a rare disease i.e. defined as a condition which affects less than 1 in 2,000 people, as per the UK Rare Diseases Framework[3].

Policy Background

4. DHSC will publish a National Cancer Plan, following the NHS 10 Year Health Plan, which will consider all tumour types, including brain tumours.

DHSC/NIHR Research Funding

5. The Department of Health and Social Care invests over £1.6 billion per year in research through the National Institute for Health and Care Research (NIHR). NIHR research expenditure for all cancers was £133 million in 2023/24, reflecting its high priority.

6. DHSC also funds NIHR infrastructure, which provides world-class research expertise, specialist facilities, a research delivery workforce and support services, which all help to support and deliver research across the NHS and wider health and care system. The NIHR Research Delivery Network (RDN) launched in 2024. Building on the success of the NIHR Clinical Research Network (CRN), its mission is to enable the health and care system to attract, optimise and deliver research across England.

7. In England, the NIHR currently has National Specialty Leads for research delivery within the Research Delivery Network (RDN). Their role is primarily to support research delivery in their discipline within health and care settings, with knowledge and experience of the full scope of the NIHR and the wider health and care delivery infrastructure in England. Working with patients, public, health and care professionals (including research and development communities within the NHS and wider care system), academics and life sciences partners, the National Specialty Leads aim to ensure strategic oversight and a focus on continuous improvement of the research delivery portfolio.

1 Commons Order Paper for Wednesday 16 October 2024, Hansard, Last accessed 13/02/2025 [https://commonsbusiness.parliament.uk/Document/89015/Html?subType=Standard#_idTextAnchor005]

2 The Brain Tumour Charity, Clinical trials for brain tumours, Last Accessed 11/02/2025 [Brain tumour clinical trials | The Brain Tumour Charity]

3 The UK Rare Diseases Framework, Department of Health and Social Care, Published 9 January 2021 [https://assets.publishing.service.gov.uk/media/5ff781138fa8f5640335254e/the-UK-rare-diseases-framework.pdf]

8. In September 2024, DHSC, through the NIHR, announced new investment in brain cancer research through a series of targeted calls designed specifically to help stimulate the research community, working with partners such as the Tessa Jowell Brain Cancer Mission to reach the broader community. The most significant element in this approach is the Brain Tumour Research Consortium, a transformative new funding call to bring together the research community to evaluate novel therapies and treatments. Early interest in being part of this new initiative has been extremely strong.

Disease and contact registries

9. A disease registry is a collection of data about individuals who have a specific disease or condition. In England, the National Disease Registration Service collects and manages data on individuals diagnosed with cancer, which is shared with NHS England through an opt out process via a Secretary of State Direction.

10. A contact registry is a database that collects and stores information about individuals who are interested in participating in research. Unlike a disease registry, a contact registry helps researchers connect with potential study participants. The Be Part of Research Registry is provided by the NIHR in England. It allows individuals across the UK who are interested in taking part in research to find studies – including clinical trials - that are relevant to them and sign up. Research teams are also able to recruit to studies via Be Part of Research.

Orphan drugs and designation

11. An orphan drug is a pharmaceutical developed for a rare disease. The Medicines and Healthcare products Regulatory Agency (MHRA) published guidance on Orphan medicinal products 31 December 2020.

12. The MHRA is responsible for reviewing applications from companies for orphan designation at the time of a marketing authorisation application (MAA). There is no orphan designation step prior to application for a marketing authorisation in the UK.

13. To qualify for orphan designation in an orphan condition, a medicine must meet the following criteria:
    a. it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating
    b. the prevalence of the condition in UK must not be more than 5 in 10,000, or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development
    c. no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists in UK or, if such a method exists, the medicine must be of significant benefit to those affected by the condition
    d. Satisfactory methods may include authorised medicinal products, medical devices or other methods of diagnosis, prevention or treatment which are used in the UK.

Description of Options Considered

Option 1 – Business as Usual

14. Under this option, no changes would be made. As a result, there would be no benefits to research and development of new treatments for rare cancers.

Option 2 - Introduce primary legislation to incentivise research and investment into the treatment of rare cancers, amend the Health and Care Act 2012 and NHS Act 2006

15. Under this option, legislation would be introduced with the aim to incentivise research and investment into the treatment of rare cancers.

16. Option 2 is our preferred option. Committing to further support research and innovation for rare cancers.

Policy Objectives

17. The overall aim of the Rare Cancers Bill is to incentivise research and investment into the treatment of rare cancers by introducing measures to streamline clinical trial recruitment and mandating a review of legislation that currently acts to incentivise the development of treatments for rare diseases. The Bill aims to achieve this through the four legislative measures listed below:

A. Mandating a Government review of the orphan drug regulations.

- This will place a duty on the Government to publish a review which will be a comparison of orphan drug Regulations (specifically Part 5 of the Human Medicines Regulations 2012) and international regulatory approaches to supporting the research and development of orphan medicinal products that are for the diagnosis, prevention or treatment of cancers. Since the review is concerned with orphan drug regulations it is by default covering rare cancers.
- The findings should be published within 3 years.

B. Mandating that the 'Be Part of Research' registry must establish a tailored service for rare cancers.

- Practically the Bill places a duty on the Secretary of State to facilitate rare cancer patients being contacted more easily about research. This will be implemented through the development of a tailored registry service for individuals with rare cancers, via the Be Part of Research Registry.

C. Legislate to appoint a National Specialty Lead for rare cancers in England, to oversee research delivery.

- This aims to ensure there is adequate oversight of research delivery for rare cancers, by appointing a named person in England to provide leadership and advice for the delivery of rare cancer research. It is envisaged this individual would be employed by the NIHR. See Policy Background for more information on NIHR Specialty Leads.

D. Legislating to ensure patient data from the National Disease Registration service is shared with the 'Be Part of Research' Registry.

- By amending the Health and Social Care Act 2012 Section 261(5), which is the part of the Health and Social Care Act 2012 that includes a power of NHS England to disclose information obtained in connection with information systems. This provision aims to make it easier for patients with rare cancers to be contacted about relevant research and clinical trials, aiding recruitment of participants.
- This intention of this amendment is to allow patient data – held in information systems at NHS England – to be shared for the purpose of facilitating the carrying out of relevant clinical trials by enabling potential participants in those trials to be identified and contacted. Specifically, the provision allows the Secretary of State for Health and Social care to direct NHS England to allow for this to happen. The policy intention is to allow information from the National Disease Registration Service to be shared with the NIHR Be Part of Research contact registry, to allow rare cancer patients to be identified and contacted.

Cost summary

Financial costs

18. There are no cost implications for businesses or trade incurred directly as a result of the Bill (although of course the Bill aims to stimulate additional research into rare cancers, to the benefit of patients). However, the Bill is expected to have some direct financial implications for central Government, but these are not expected to be significant.

19. Quantified costs are below. We do not expect the requirements to come into force until the next Spending Review period (post spring 2025). These figures may rise with inflation over time, it is important to note that these figures may therefore be subject to change.

    a. It is difficult to estimate the resourcing costs required for the orphan drug review, since the exact scope remains to be agreed. However, we estimate the cost to the Department of Health and Social Care to produce and publish a report on orphan drug Regulations to incur costs of approximately £0.14m in relation to staff resource. This reflects the cost of 0.3 x SCS staff, 1 x FTE Grade 6 or Grade 7 staff, 0.3 x Grade 7 staff and 0.5 x SEO staff for one year.

    b. This Bill is expected to have an annual cost of approximately £16,000 per year for a National Specialty Lead role for rare cancers in England, to be funded through the NIHR.

    c. The Bill is estimated to have a one-off cost of £0.25m for development to ensure that that potential clinical trials participants may be identified and contacted, by developing a tailored registry support service via Be Part of Research.

    d. The financial implications of further data sharing by NHS England, per Clause 3, are dependent on a Secretary of State direction being produced to provide the specifics of how the data should be shared, so the financial costs are variable. To achieve the specific policy aims of the Bill, it is estimated this would cost approximately £175,000 every three years. This is the cost of Data Access Request Service (DARS) charges.

Other non-quantified costs

20. As mentioned above, the Bill will incur other non-quantified costs to achieve its anticipated benefits. For example, the cost of funding and delivering research and clinical trials for rare cancers and the cost of treatments, which is variable and not possible to estimate at this stage – this should be considered when reviewing the benefits below.

21. Additionally, if changes to the orphan drug regulations are identified and recommended following the mandated review, there may be further financial and operational costs implicated. These broader costs cannot be estimated or assessed for impact until any changes are identified.

Benefits

22. The Bill's provisions aim to introduce multiple long-term benefits to streamline and incentivise research into rare cancers, that would benefit patients through better outcomes in the long term.

23. Clinical research is considered beneficial since this has direct benefits for patients, the public and the life science sector. It is well documented that high quality clinical research improves patient outcomes, creates jobs and drives economic growth. The NHS also benefits from additional

revenues and cost savings from clinical research, particularly from large late phase interventional studies. Based on data shared by the NIHR, the average per-patient payment NHS income in 2022/23 across commercial studies sponsored by the NIHR Clinical Research Network (CRN) was £26,311 (£28,808 once adjusted for inflation to 2024 prices)[4].

24. A government review of regulation surrounding orphan drug designation is considered beneficial to ensure these regulations are continuing to deliver for patients.

25. The recommended option (2) could act to encourage the placement of clinical trials for rare cancer in England, by ensuring the patient population can be easily contacted by researchers, streamlining recruitment processes.

26. There are multiple benefits to making it easier for rare cancer patients to be contacted about research:
    - Improved access to innovative and potentially life-saving treatments for rare cancer patients, enhancing quality of life for patients and families.
    - Improved access to patient populations for researchers, resulting in accelerated recruitment, trial completion and hence accelerated progress in this disease area for patients.
    - Innovation and breakthroughs from the results of research could lead to long term NHS savings.

27. There are benefits to ensuring that there is additional oversight of research delivery for rare cancers. For example, additional oversight would ensure that the overall portfolio of research studies – including clinical trials – is being delivered effectively to meet the needs of patients.

Risks

28. The provisions in the Bill allow patients to be contacted about research, without their explicit consent, which may be controversial. Some patients may not wish to be contacted about research or have their data shared with contact registries – this could risk opt-outs from existing NHS England information systems i.e. the National Disease Registration Service.

29. Furthermore, as the disclosure of data can be shared in such a way as the Secretary of State for Health and Social Care may direct, this could pose a risk in the way rare cancer patient data is handled, outside of the policy intentions set out above. For example, the Bill does not specify to what entity the data transfer should be made, just that it is data from 'rare cancer patients', though the intention currently is for this to be made to the Be Part of Research contact registry. This means in practice a direction could be produced to share data with other entities.

30. The risks are considered low given the following factors:
    - A secondary opt-out procedure i.e. from the point at which data is shared from NHS England information systems should be built in during implementation, to avoid the risk of mass opt-outs from national databases. For example, by the organisation seeking approval from the Health Research Authority Confidential Advisory Group.
    - A direction from the Secretary of State must be approved following robust analysis and advice from Civil Servants, on the impact to patients and the public. Therefore, there are necessary mitigations in place to prevent improper sharing of patient data through a direction.
    - Data sharing would still be subject to protection under the Common Law Duty of Confidentiality, which is not overridden in the Bill.

[4] The value of industry clinical trials to the UK, Extended report, The Association of the British Pharmaceutical Industry, Published December 2024 [https://www.abpi.org.uk/media/5evd0zcl/the-value-of-industry-clinical-trials-to-the-uk-extended-report.pdf]

31. Additionally, the benefits of research outlined above should be considered. The Government's broad position concerning patient data is that any improvements to make it easier to contact patients about research, particularly if considered as part of their treatment plan, are beneficial for patient outcomes. This is also in line with commitments made by the Government to join up clinical trial registries and the Government's Health and Growth missions by encouraging investment in clinical trials and ensuring that fewer people die from the big killers.

32. We have engaged with the Office of the Data Protection Officer and Information Commissioners Office regarding the elements of the Bill that would have an impact on data policy.

A summary of potential trade implications of the measure

33. This Bill is not considered a regulatory provision. There are no direct impacts on trade, however by improving access to rare cancer patient populations to researchers, this may result in companies selecting the UK as a preferred location to carry out research, including clinical trials.