

A CATALYST FOR IN SILICO TECHNOLOGY IN
THE UNITED KINGDOM

The economic and health impact of UK CEiRSI: UK Centre of Excellence for In- Silico Regulatory Science and Innovation

GRANT-FUNDED
RESEARCH REPORT
October 2026

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ohe.org



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Please cite this report as:

Darrow, B., Oyalo, P., O'Neill, P., Napier, M., Hofer, M., Cole, A. and Cookson, G. 2026. The economic and health impact of UK CEiRSI: the UK Centre of Excellence for In-Silico Regulatory Science and Innovation, OHE Grant-Funded Research, London: Office of Health Economics. Available at: <https://www.ohe.org/publications/the-economic-and-health-impact-of-uk-ceirsi-the-uk-centre-of-excellence-for-in-silico-regulatory-science-and-innovation>

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Funding and Acknowledgements

This Grant Research Report was commissioned and funded by the UK Centre of Excellence for In-Silico Regulatory Science and Innovation. We would like to thank Professor Alex Frangi and Jonathan Pickstone in particular for their support and input.

We would like to thank all experts and steering groups for their valuable contribution and input. This study was guided by two steering groups, as outlined below. Steering group members were not responsible for the execution of the work or any errors within it. In addition, a draft of the report was shared with the UK CEIRSI Executive Committee for comment.

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Table of contents

About OHE Grant Research Reports	ii
Funding and Acknowledgements	ii
Table of contents	iv
Key Messages	v
Executive Summary	1
Introduction	3
1 The impact of ISTs	4
1.1 Health system impact	4
1.2 Patient welfare benefits	4
1.3 Industry benefits	5
1.4 Economic gains	5
1.5 Environmental and ethical considerations	6
1.6 UK government policy considerations	6
2 Barriers to ISTs' adoption	8
3 Economic impact of UK CEIRSI	9
3.1 Rationale	9
3.2 Approach	10
3.3 Input, activities and outputs	13
3.4 Outcomes and impact	13
4 Conclusion	18
References	19
Appendix A: Methodology	25
Appendix B: Expert Elicitation Survey	41
Appendix C: Survey results	49

The logo for UK CEiRSI is centered within a large white circle. This circle is partially overlapped by a light green circular shape on the left and a dark teal circular shape on the right. The text 'UK CEiRSI' is written in a dark blue, sans-serif font. The 'i' in 'CEiRSI' is stylized with a dot that forms a curved arrow pointing downwards and to the right.

UK CEiRSI

Key Messages

- In-silico technologies (ISTs) apply advanced computational and AI-based modelling to complement, refine, or replace traditional testing across the medical product lifecycle and health technology development. UK CEiRSI is an international centre of excellence established to accelerate the development of ISTs and to support their regulatory acceptance and adoption across the UK, and ultimately across the world.
- With adequate funding, UK CEiRSI can act as a powerful catalyst for IST uptake, delivering substantial benefits within its initial five-year implementation period. These include an estimated £21.9 billion contribution to the UK economy, £1.2 billion in NHS savings, £2.4 billion in population health gains, and £325 million in industry savings. These impacts are expected to generate further cumulative benefits well beyond the initial implementation phase.
- Beyond these quantifiable impacts, UK CEiRSI would accelerate wider IST benefits, including faster and more equitable access to treatments for more diverse patient populations, reductions in animal and clinical testing, and positive environmental and sustainability outcomes.

Executive Summary

In-silico technologies (ISTs) refer to a broad group of computer-based techniques that allow for computational modelling and simulation including the use of data sciences and AI for science, and other computational science and engineering techniques (e.g. more mechanistic numerical modelling). While these approaches have been used in other domains for some time, their timeliness in the life sciences is derived from triple advancement in vast digital data availability, increased agency in computational techniques/infrastructures for science, and greater mechanistic understandings of many fundamental processes and factors affecting disease and product performance. Combined, ISTs and this triple-agency offer the potential to transform pharmaceutical and medical device development by replacing traditional laboratory, animal, and human testing with advanced digital modelling.

The UK Centre of Excellence for In-Silico Regulatory Science and Innovation (UK CEiRSI) aims to further ISTs' development, regulation, and adoption in the life sciences sector in the UK and beyond. UK CEiRSI's vision and activities are intended to deliver global impact by providing leadership in international harmonisation, as well as driving the UK as a global leader in ISTs' regulation and adoption.

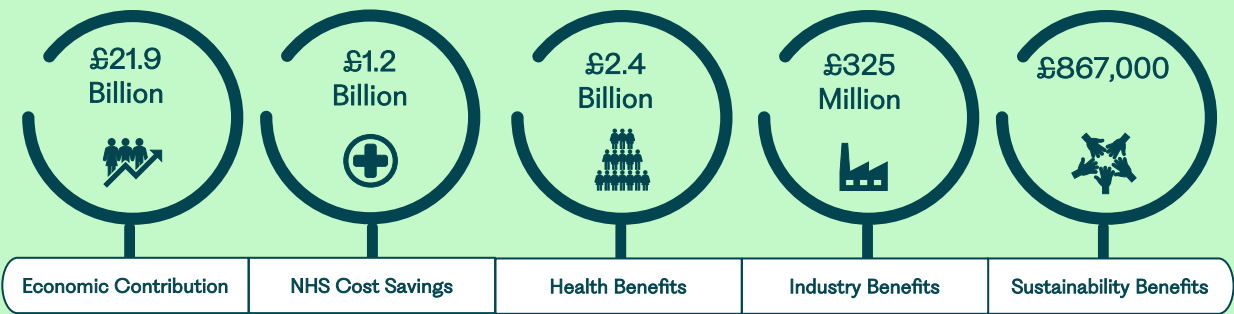
This report characterises the potential impact of ISTs on patients, health systems, and society as a whole. Furthermore, it identifies the key barriers to ISTs' adoption and assesses the role and economic impact of UK CEiRSI in leveraging its unique position to address these barriers and maximise the benefits within the UK context.

A narrative review of both academic and other relevant literature was conducted to better understand the full potential positive impact of ISTs. The literature review highlighted primary areas of ISTs' impact: the health system benefits, improved and new products and services and commercial benefits, patient welfare, economic efficiencies, and sustainability and ethical considerations. However, key barriers were identified that hinder adoption of ISTs, including their optimal integration in regulatory pathways, workforce skills gaps, legal and data access challenges, and social awareness and acceptance. UK CEiRSI is focused on overcoming these challenges.

On the basis of this literature review, an economic impact assessment of UK CEiRSI was performed, guided by the principles outlined in the UK Magenta and Green Books and informed by a social cost-benefit analysis. The assessment was based on the premise that UK CEiRSI is the only intervention in the UK specifically designed to address barriers to the adoption of ISTs and unlock their broader benefits for patients, the healthcare system, the associated industry sector, and the wider economy. A mixed-methods approach was applied combining evidence from existing literature with insights from an expert elicitation survey to estimate the potential value generated through its five-year implementation plan.

The economic analysis found that an adequately funded UK CEiRSI could act as a catalyst for ISTs' adoption and deliver substantial health, NHS, industry and macroeconomic returns within five years. These include an estimated £21.9 billion contribution to the UK economy, £1.2 billion in NHS savings, £2.4 billion in population health gains, £325 million in industry savings, and £867,000 in ethical and sustainability savings in the form of reduced animal testing. Beyond these quantifiable impacts, UK CEiRSI has the potential to accelerate wider IST benefits, including faster and more equitable access to treatments for more diverse patient populations, reductions in animal and clinical testing, and positive environmental and sustainability outcomes.

Return on investment within 5 years of UK CEiRSI implementation



Introduction

What are In-Silico Technologies?

In-Silico technologies (ISTs) are computer-based techniques like computational modelling, simulation and AI techniques.

In-silico technologies (ISTs) are widely used in sectors such as aerospace and automotive and have the potential to transform pharmaceutical and medical device development by complementing or replacing traditional laboratory, animal, and human testing with advanced digital modelling. The adoption of ISTs ultimately offers a promising path to achieve the objectives set forward by UK policymakers. ISTs could meaningfully contribute to fulfilling the goals of the NHS' 10-year plan, particularly its aim to utilise innovation—through the adoption of AI and personalised medicine—to drive healthcare reform (UK Government, 2025b). Additionally, with ISTs serving as an attractive alternative to animal testing, they could bring the UK closer to its commitment to phasing out animal testing (Department for Science, Innovation, and Technology et al., 2025).

In 2024, the UK Centre of Excellence for In-Silico Regulatory Science and Innovation (UK CEiRSI) secured funding from the Office of Life Sciences (OLS) and the Medicines and Healthcare products Regulatory Agency (MHRA), with Innovate UK (iUK) and the Medical Research Council (MRC) as the delivery partners, through a competitive process aimed at creating virtual regulatory science and innovation networks across the UK. This initiative seeks to build networks of expertise that generate research-based evidence and insights to inform regulatory decision-making throughout product lifecycles. The programme consists of an initial discovery phase, followed by a 12-month implementation phase, which is currently underway.

UK CEiRSI aims to further in silico research and support the development of a world-leading innovative research and development cluster in the UK life sciences sector, with a particular focus on tackling the logjam on the use of ISTs through a targeted five-year joint public-private programme targeting medical technology approvals.

This report characterises the potential impact of ISTs on patients, health systems, and society as a whole; identifies the key barriers to their adoption; and assesses the role and economic impact of UK CEiRSI in leveraging its unique position to address these barriers and maximise the benefits within the UK context.

1 The impact of ISTs

Before considering the value of UK CEiRSI in leveraging the untapped benefits of ISTs, it is necessary to first articulate what those benefits are. A narrative review of both academic and grey literature was conducted to better understand the full potential positive impact of ISTs. The literature supports five primary areas of impact for ISTs: the health system, patient welfare, industry benefits, economic gains, and ethical and sustainability considerations (Figure 1). This review aims to provide a qualitative assessment of the potential benefits afforded by ISTs; in Section 4 of this report, we provide a quantification of these benefits in the context of the UK and UK CEiRSI's role in accelerating IST adoption.

1.1 Health system impact

ISTs have the potential to generate value for healthcare systems by improving patient safety and enhancing product efficacy, specifically by reducing the costs associated with adverse events and less effective treatments.

In terms of patient safety, ISTs enable patient-specific modelling, which can improve our understanding and prevent side effects and adverse events associated with medicines and medical devices (Czypionka et al., 2022; KPMG, 2024; Roesler et al., 2024). Researchers can also use ISTs to simulate testing on populations who are generally not included in clinical trials, such as children and pregnant women, thereby increasing the safety of products used among these groups (Czypionka et al., 2022; Badano, 2021). A reduction in side effects and adverse events associated with the deployment of health technologies can result in cost savings to the health system (Frangi et al., 2023; Frangi, 2025b; KPMG, 2024).

ISTs can also facilitate improved product efficacy. Patient-specific modelling can help to determine varying degrees of product effectiveness across different patient populations, allowing researchers to understand who responds best to products (Czypionka et al., 2024; Badano, 2021; Frangi et al., 2023). Moreover, ISTs can enable the optimisation of the product and guidelines for its use, further enhancing product efficacy and safety (Czypionka et al., 2024, 2022). Taken together, these intermediate outcomes could have the effect of reducing healthcare system costs by preventing additional use of resources associated with less effective products and with adverse events (Frangi et al., 2023; Frangi, 2025b; KPMG, 2024).

1.2 Patient welfare benefits

Patients are some of the primary beneficiaries of ISTs' impacts, as the end users of products developed using ISTs. ISTs can reduce time-to-market, enabling patients to access innovative treatments earlier (Badano, 2021; Czypionka et al., 2022; Frangi, Denison and Lincoln, 2023; Frangi et al., 2023). Furthermore, ISTs' ability to streamline R&D processes can lead to more health-related technological innovation, resulting in improved health outcomes for patients (NHS England, 2024b).

1.3

Industry benefits

The literature indicates substantial benefits for the pharmaceutical and medtech industries from the adoption of ISTs, including reduced R&D costs, lower investment risk, increased development productivity, shorter time to revenue, and fewer product recalls, along with improved corporate reputation.

First, ISTs are expected to generate firm-level savings by decreasing the amount of time required throughout development processes. Specifically, by reducing clinical and nonclinical activity, ISTs are likely to yield time savings and a reduction in phase-specific costs (Badano, 2021; Czipionka et al., 2022; KPMG, 2024; DiMasi, 2002). Moreover, ISTs can enable earlier identification of products that will eventually fail, reducing the probability of products failing late in development timelines, when sunk costs are the highest (Frangi et al., 2023; Frangi, 2025a). Further, Czipionka et al. (2022) highlight that this earlier identification of product failures can have the effect of reducing the risk of investment in R&D, thus incentivising additional product development and ideation.

ISTs also present two primary opportunities for revenue growth. First, by accelerating time-to-market, ISTs could allow companies to capture earlier revenue streams, thereby extending the period that a product benefits from patent protection (Czipionka et al., 2022; Frangi, 2025a). Second, ISTs are predicted to increase the number of new innovations, which would enable companies to earn revenue from the commercialisation of additional products that would otherwise not have reached the market. Additionally, by reducing development costs, ISTs could allow firms to further reinvest in the R&D of future products (Badano, 2021; Frangi et al., 2023; Czipionka et al., 2022). With reduced risk of investment and additional resources for investing in R&D, firms are more likely to bring new products to the market and create new revenue streams from those products.

Beyond the financial gains, ISTs have the potential to improve firms' reputations. Czipionka et al. (2022) highlight that by facilitating more thorough investigations into rare effects and side effects, ISTs can help prevent adverse events, potential product recalls, and accompanying reputational damage. Moreover, by reducing preclinical activity, ISTs can decrease animal testing, thereby addressing growing ethical concerns and enhancing public perception of the industry (Czipionka et al., 2022).

1.4

Economic gains

For society more broadly, ISTs are expected to increase economic growth by creating productive jobs, increasing industry investment, and attracting inward investment into the life sciences industry (Frangi et al., 2023). Evidence from an analysis of the current IST landscape in the UK shows that the country has already secured substantial levels of such investment (Whorwood, Frangi and Wilkinson, 2023). This combination of investment and the wider adoption of ISTs has the potential to boost industrial competitiveness and increase exports from the sector (KPMG, 2024).

As ISTs can be applied across a variety of fields, they can create highly skilled jobs in a wide range of areas including R&D, modelling, and data science (Czipionka et al., 2022). Additionally, as ISTs proliferate, it is expected that investment into ISTs and the life sciences in general will increase because of the potential for revenue generation, leading to market expansion and enhanced profitability (KPMG, 2024; Frangi et al., 2023; Whorwood, Frangi and Wilkinson, 2023).

Additionally, it is well established that an indirect effect of health gains associated with new health technologies is improved productivity for patient populations (PwC, 2022; Sampson, Subramanian and Napier, 2025). As a result, health technologies developed

through ISTs will not only generate additional health benefits but also yield broader productivity gains. Likewise, the improved health outcomes generated by reduced adverse events and improved product efficacy in terms of the health system gains could further result in decreased worklessness and improved productivity (Pinna Pintor, Fumagalli and Suhroke, 2024).

1.5

Environmental and ethical considerations

Another use case identified for ISTs is their potential to reduce both nonclinical and clinical trial activity, with the possibility of at least partially replacing traditional laboratory and animal testing and supplementing and reducing human clinical studies in pharmaceutical and medtech development (Viceconti, Henney and Morley-Fletcher, 2016; Frangi, Denison and Lincoln, 2023). Consequently, ISTs could help advance the 3R principles—replacement, reduction and refinement—of animal research by minimising or eliminating animal testing where feasible (Viceconti, Henney and Morley-Fletcher, 2016; Czypionka et al., 2022, 2024; KPMG, 2024; Judith C. Madden et al., 2020). Additionally, ISTs allow for a comprehensive exploration of product shortcomings and risks before physical testing begins, thereby promoting both human and animal safety when these experiments must occur (Frangi, 2024).

Furthermore, patient-specific modelling through ISTs allows for broader testing across diverse and potentially underserved populations, increasing the likelihood that innovations serve extended patient groups (Czypionka et al., 2022; Badano, 2021; KPMG, 2024). This could ultimately have the effect of enhancing equity, as underserved patient groups will be able to access more innovation (Czypionka et al., 2022, 2024; Viceconti, Henney and Morley-Fletcher, 2016; KPMG, 2024; Frangi, Denison and Lincoln, 2023).

Another potential benefit associated with reduced nonclinical and clinical activity is less environmental waste—ISTs can lower material consumption that might occur in other types of trials (Huanbutta et al., 2024; Leeds Institute for Data Analytics, 2023); however, it should be noted that, as with other forms of computational research, ISTs can require significant amounts of energy (Nature, 2023).

1.6

UK government policy considerations

Wider adoption of ISTs aligns closely with UK government and NHS policy priorities, supporting a more efficient, data-driven, and innovation-friendly life sciences ecosystem while enabling earlier patient access to effective health technologies (UK Government, 2025e, a, d; b).

The UK government's Life Sciences Sector Plan sets out a long-term industrial strategy structured around three interconnected objectives: enabling world-class R&D; making the UK an outstanding place to start, grow, scale, and invest; and driving health innovation and NHS reform (UK Government, 2025d). Adoption of ISTs can support these objectives by reducing clinical trial set-up times through modelling and simulation, strengthening evidence generation, and enabling more efficient regulatory and market access pathways. Greater recognition and adoption of ISTs could also enhance the UK's attractiveness as a destination for life sciences investment by lowering development costs and accelerating time to market.

Closely aligned with this, the AI for Science strategy highlights the transformative role of AI across the life sciences (UK Government, 2025a). Substantial public investment through UK Research and Innovation, the National Institute for Health and Care Research, and the development of the Health Data Research Service is intended to support

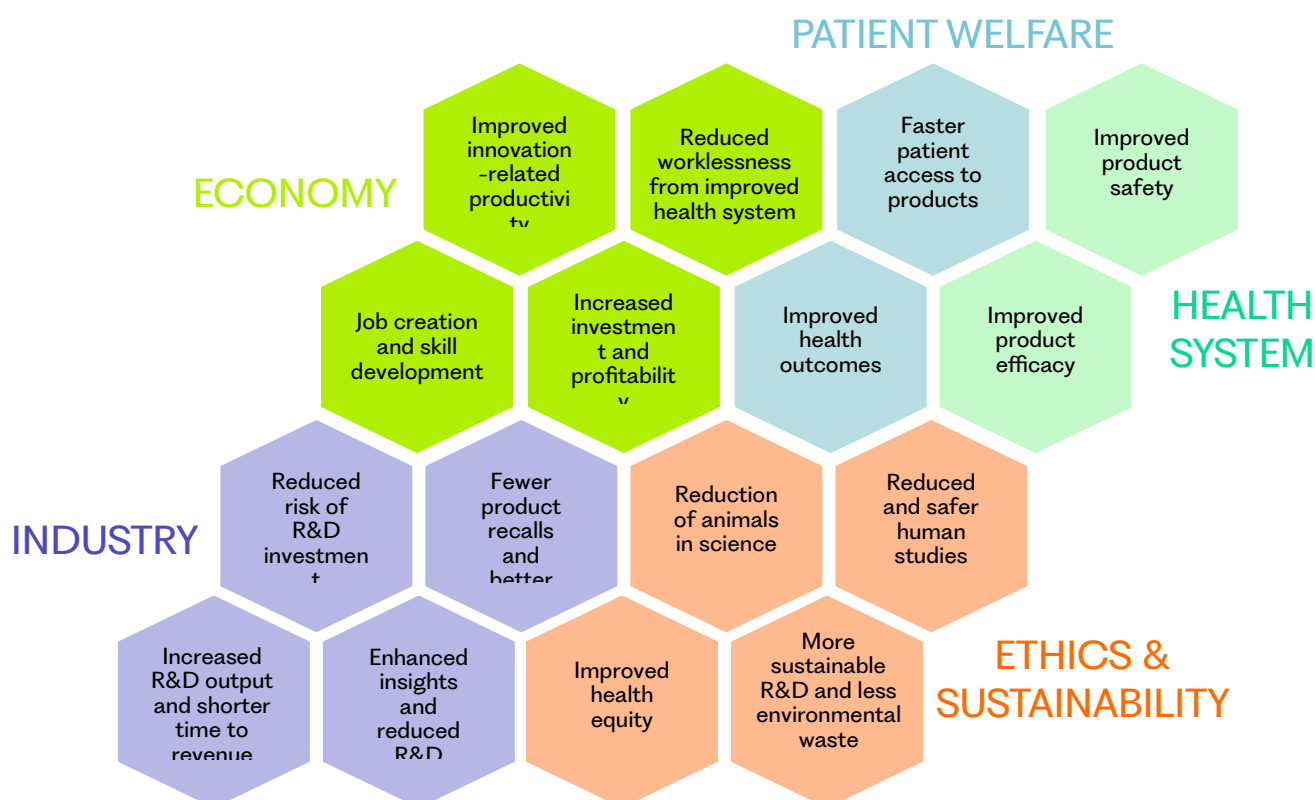
world-class, data-driven medical research. ISTs provide a mechanism to translate these investments into practical outputs that inform R&D decision-making, regulatory evaluation, and NHS adoption of new technologies.

The government's Replacing Animals in Science policy aims to minimise animal use by promoting alternative methods wherever possible (UK Government, 2025e). ISTs can directly support this ambition by accelerating the development, validation, and regulatory uptake of non-animal methods in discovery and preclinical research.

The NHS Long Term Plan sets out in Chapter 8 a vision for using innovation to drive healthcare reform (UK Government, 2025b). This includes a commitment to five key transformative technologies, among them the development of high-quality, interoperable data and the expanded use of artificial intelligence. The plan also emphasises accelerating clinical trials, supporting technology development, and advancing regulatory reform. ISTs offer a practical mechanism for bringing these elements together. By leveraging interoperable datasets, applying AI as an enabling technology, and supporting and accelerating R&D, ISTs help translate innovation into real benefits for patients and contribute to broader healthcare system reform.

Figure 1 Broader value framework

This figure summarises the key domains where ISTs have the potential to generate value for the health system, pharmaceutical and medtech industries, patients, the economy more broadly, and ethical and sustainability considerations. Each hexagon represents a value domain identified through a review of the literature and expert consultation, with colour-coded clusters corresponding to impact domains.



2

Barriers to ISTs' adoption

Despite the potential benefits that ISTs could yield, there are several barriers limiting their adoption in the UK. To understand these barriers, a narrative literature review was conducted and experts in the IST space were interviewed.

Likely the foremost barrier to full adoption of ISTs is regulatory acceptance, as there exists scepticism about the quality of evidence generated by ISTs that are not sufficiently certified. This is a global issue, with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) currently lacking clear pathways for approval for products with *in silico* evidence (Leo et al., 2022). Additionally, regulators might not fully possess the skills or capacity to effectively evaluate evidence generated using ISTs (KPMG, 2024). Full adoption of ISTs is ultimately unlikely without regulatory support for this type of evidence.

Alongside regulatory challenges are legal barriers, which could also limit ISTs' adoption in the UK. Namely, data protection and privacy is a concern due to ISTs' reliance on large volumes of personal data as inputs to build and validate underlying models (Frangi et al., 2023). Widespread resistance to share personal health data could limit the size and representativeness of the datasets available for model development and validation, which eventually could result in accuracy and generalisability concerns for the models. As such, developers will have to ensure that their practices align with the General Data Protection Regulation (GDPR) and build public confidence that personal health data will be handled appropriately and securely (Frangi et al., 2023).

In addition, the lack of people and companies equipped to effectively utilise ISTs is another barrier hindering their adoption in the UK. Indeed, only 35% of UK life sciences organisations report mature computer modelling capabilities, with only 15% fully integrating ISTs with real-world data (Frangi, 2025b). When looking at data skills more broadly, just under half of UK businesses reported struggling to recruit for roles requiring data skills (Frangi et al., 2023). A workforce with sufficient data skills is a necessary condition for the UK to fully capture the benefits of ISTs, suggesting that there is a need for training in in-silico methods.

Social and cultural resistance towards ISTs is also a relevant barrier. Beyond regulators, there can be a hesitancy among people to accept the reliability of simulated scenarios (Leo et al., 2022; Frangi et al., 2023; Viceconti, Henney and Morley-Fletcher, 2016; KPMG, 2024). From an equity standpoint, there are also concerns about models reflecting entrenched biases that disproportionately affect underserved groups (Leo et al., 2022). Thus, activities focused on proving ISTs' reliability, especially compared to in vivo and in vitro methods, are important to shift stakeholders' perceptions of the technology and the products it enables (Viceconti, Henney and Morley-Fletcher, 2016).

A current lack of industry investment in ISTs is yet another challenge to full adoption of the technologies. Indeed, while ISTs can afford industry benefits in terms of reduced R&D costs and time efficiencies—amongst others—they still present a financial risk. For instance, firms are required to develop costly in-house expertise, while regulatory ambiguity still exists (KPMG, 2024). Ultimately, industry investment in ISTs is a requirement for their adoption, and experts in the space must consider whether the case for ISTs is a strong enough incentive for firms to invest despite the financial risk.

Finally, NHS data availability and suitability is a barrier limiting growth in the UK life sciences sector more broadly (Office for Life Sciences, 2025). It likewise could limit the potential impact of ISTs, as the quality of data inputs is a critical determinant of IST models' efficacy (KPMG, 2024). Indeed, for research in general, NHS data has been highlighted as a critical barrier due to its variability in quality and accessibility (Office for

Life Sciences, 2025); this concern will need to be addressed for IST models' reliability and acceptability (KPMG, 2024).

3 Economic impact of UK CEiRSI

3.1 Rationale

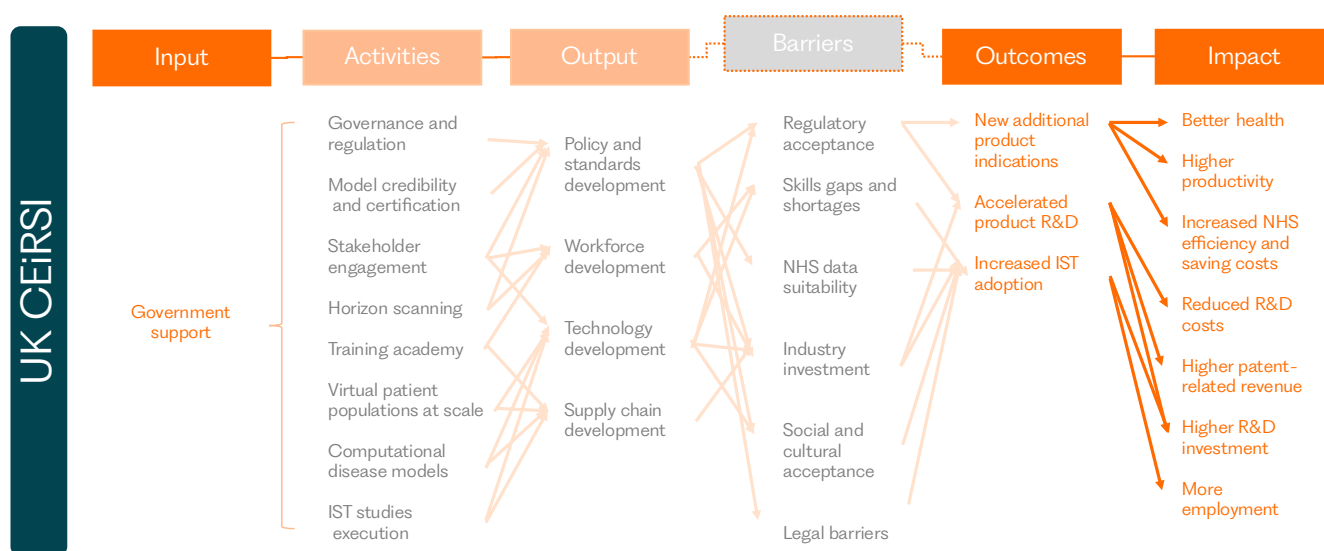
The vision of the UK CEiRSI is to support the overall transformation of the life sciences sector through the wider adoption of ISTs across different and innovative research specialisms. In turn, UK CEiRSI will also aim to unlock the commercial application of these approaches and actively contribute to the development of local supply chains to ensure the UK benefits from the significant health and economic benefits of ISTs.

UK CEiRSI's vision and activities are intended to deliver global impact by providing leadership in international harmonisation. This economic impact assessment will, however, focus on UK CEiRSI's role in positioning the UK as a global leader in regulatory science and innovation. It aims to quantify and monetise the benefits associated with UK CEiRSI, and to demonstrate the potential value generated through delivery of its five-year implementation plan.

The assessment is based on the premise that while many organisations are advancing the use of ISTs, UK CEiRSI is the only institution in the UK specifically designed to address barriers to the adoption of ISTs and unlock their broader benefits for patients, the healthcare system, industry, and the wider economy. The UK CEiRSI logic model illustrates how targeted inputs and activities are structured to overcome key barriers and deliver measurable impact (Figure 2). UK CEiRSI focuses on a wide range of activities that support policy and standards, the development, workforce training, technology advancement, and supply chain coordination, and directly address regulatory, technical, operational, financial, and cultural obstacles to ISTs' adoption (UK CEiRSI, 2025). Through the enablement and adoption of ISTs that these activities engender, UK CEiRSI is expected to enable outcomes such as new product indications and accelerated R&D. In turn, these outcomes are expected to drive long-term impacts, including improved health, higher productivity, greater NHS efficiency and cost savings, reduced R&D costs, additional revenue, increased investment, and higher employment.

This logic model focuses on impacts that can currently be quantified within an economic modelling framework. Importantly, UK CEiRSI can also enable a range of wider benefits that are not fully captured by the economic model. These broader impacts, discussed in earlier sections, include faster and more equitable access to treatments for more diverse patient populations, reductions in animal use and clinical testing, and positive environmental and sustainability outcomes. In addition, UK CEiRSI activities can directly support UK government and NHS policy objectives across research, regulation, and patient access to innovation by accelerating the adoption and effective use of IST.

Figure 2 UK CEiRSI logic model underpinning the economic impact assessment



3.2 Approach

The economic impact analysis was guided by the principles outlined in the UK Magenta and Green Books and followed a structured approach (HM Treasury, 2022, 2020). All methodological details on the approach can be found in Appendix A. However, Figure 3 provides a brief visual overview of the methods.

First, a UK CEiRSI-specific logic model was developed to map the pathways through which ISTs' adoption could generate benefits for patients, health systems, industry, and the wider UK economy (Figure 2). This model was informed by the literature review on potential impacts and barriers described in the previous chapters (Appendix A.1 & A.3).

Building on this, an economic model was constructed to reflect the logic model and estimate the potential economic impact of UK CEiRSI in leveraging ISTs' benefits within the UK context guided by social cost-benefit analysis methodology (Appendix A.4). To capture and quantify outcomes and impacts, a mixed-methods approach was applied combining evidence from existing literature (Appendix A.4 – A.10) with insights from an expert elicitation survey (Appendices A.2, B, and C).

Our analysis adopts principles of the Green Book. However, this report does not describe a full cost-benefit analysis. This analysis is partial in several ways:

- Outcomes were measured and valued in a disaggregated way, permitting and reflecting the different levels and perspectives through which value is accrued.
- The model incorporates two time horizons: a five-year implementation phase (~until 2030) and a 15-year long-term phase (until ~2040) for sustained benefits beyond implementation. Benefit accrual was scaled according to expected gradual uptake of ISTs and experts' beliefs on how UK CEiRSI would translate that enhanced uptake of IST into impact value. This may not fully

capture the staged nature of the UK CEiRSI activities themselves (and their impact) over the initial five-year period.

- The analysis does not include the costs of UK CEiRSI adoption or other intended or unintended cost implications amid significant knowledge gaps and uncertainties. Consequently, these cost factors were not incorporated into the calculation of net value or return on investment. For example, the costs associated with adopting UK CEiRSI itself and any government contribution remain unknown. The analysis also excludes the potential costs of procuring additional product indications, given the lack of clarity regarding the nature of these indications and the differing pricing and procurement practices that may apply. An additional example of an unintended consequence is the potential revenue loss to the health system associated with changes in research and development activity; this was not included due to the absence of a clear understanding of its scale or of potential alternative revenue-generation mechanisms.

Expert elicitation was used to capture insights on the expected scale of outcomes and impacts of UK CEiRSI (Appendix A.2). For the outcomes, experts provided input on how ISTs are expected to be utilised in the pharmaceutical and medical technology sectors and their anticipated impact on R&D output (e.g. number of new additional indications and speed of development). In addition, experts provided input on the expected impact of UK CEiRSI by selecting pre-specified impact scenarios. Expert elicitation was facilitated through interviews with NHS experts and an online survey, which was open for participation from 27 October to 10 December 2025 (Appendix B). The survey was open to all and promoted through key stakeholder networks, the UK CEiRSI mailing list, and via LinkedIn and other social media channels. In total, 46 experts participated. Most respondents were from the medical device sector, followed by supporting sectors and the pharmaceutical industry. In terms of work type, the majority were engaged in R&D activities, regulatory functions, and manufacturing. Respondents represented a mix of organisations, including research institutions, SMEs, and large industry players. Geographically, most participants were based in the UK, with additional representation from the US, Australia, Taiwan, and Switzerland (Appendix C).

Two sets of pre-specified scenarios were developed for expert elicitation: counterfactual scenarios estimating outcomes if UK CEiRSI were not implemented; and impact scenarios assuming UK CEiRSI mitigates key barriers and reinforces enablers to varying degrees (Table 1). These scenarios were structured across three levels of impact and linked to weighted indicators. This enabled the quantification of the acceleration and magnitude of impact associated with UK CEiRSI relative to any gains that will likely still be made from ISTs in the absence of UK CEiRSI.

Results are presented in accordance with Green Book recommendations, reporting all impact scenarios in absolute terms relative to the counterfactual “business-as-usual” scenario. Additionally, 90% confidence intervals are included to capture a distribution of results derived from expert elicitation. This approach ensures full transparency and illustrates the sensitivity of results in relation to all provided expert input regarding ISTs’ adoption, parameter assumptions, and the estimated level of impact. Consistent with Green Book guidance, all costs and health gains were discounted using rates of 3.5% and 1.5%, respectively (HM Treasury, 2026).

Figure 3 Overview of report methods

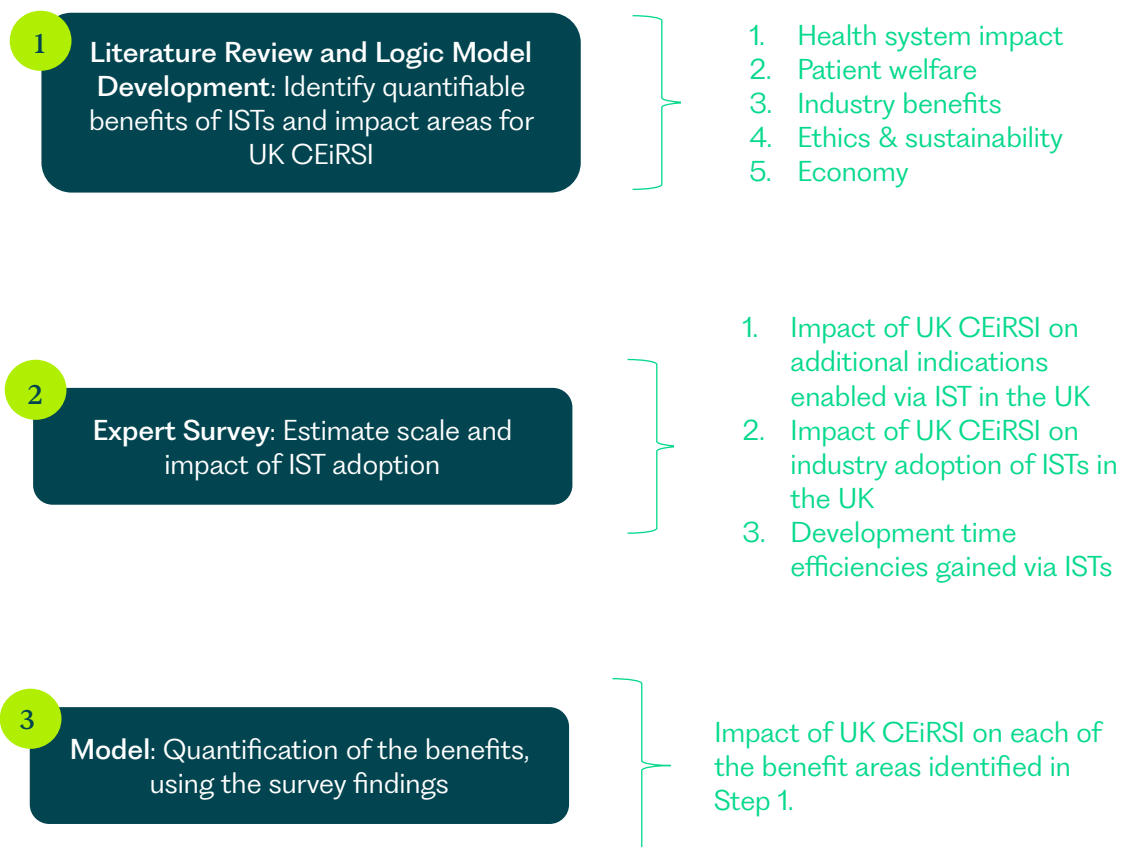


Table 1 Scenarios for impact assessment

	COUNTERFACTUAL SCENARIOS	IMPACT SCENARIOS
LEVEL 1/ MINOR	Without UK regulatory acceptance of ISTs, innovation benefits are minimal, global spillovers are limited, and declining competitiveness leads to reduced investment and job losses.	Regulators cautiously acknowledge ISTs through pilot initiatives, but limited UK prioritisation by developers results in only marginal gains in R&D investment and employment.
LEVEL 2/ MEDIUM	The UK captures modest spillover benefits from global adoption of ISTs, but fragmented capability development leaves R&D investment and jobs largely stagnant.	Clear validation standards enable wider uptake of ISTs, encouraging developers to seek UK approvals and delivering moderate growth in investment and workforce capacity.
LEVEL 3/ SIGNIFICANT	Despite improved global acceptance of ISTs, the absence of a UK-led strategy confines benefits to baseline economic growth, leaving the UK a follower.	UK regulators and UK CEiRSI establish global leadership in ISTs, embedding qualified models in decision-making and driving strong growth in investment, innovation, and jobs.

3.3 Input, activities and outputs

UK CEiRSI has so far been supported by the CERSI partners (MHRA, OLS, and UKRI) and is currently seeking financing for a full five-year implementation programme. In addition to public funding, UK CEiRSI will seek in-kind contributions from stakeholders, including industry partners, as it develops a range of business services (data, research, model certification, and training) to drive commercial revenue. UK CEiRSI will also work with government, foundations, and trusts to attract grants and sponsorship to advance agendas that form part of its benefits suite, including reducing animal harm and adopting AI in science.

Planned activities of UK CEiRSI initiative span the full ecosystem needed to enable safe and effective adoption of ISTs. These include strengthening governance and regulatory frameworks, establishing processes for model credibility assessment and certification, and engaging stakeholders across industry, academia, regulators, and the NHS. Forward-looking activities such as horizon scanning and a training academy support long-term capability and workforce building. More technical activities involve advancing computational disease models, developing virtual patient populations at scale, and supporting the execution of IST studies.

Collectively, these activities aim to generate outputs such as policy and standards development, technology maturation, workforce readiness, and supply-chain growth. By focusing on activities that address key IST adoption barriers, such as regulatory and social acceptance, legal constraints, skills shortages, NHS data suitability, and limited industry investment, UK CEiRSI plays a critical role in enabling ISTs' adoption. It also helps place the UK as a leader in the use of ISTs, with most research anecdotally thought to be carried out in the USA currently.

3.4 Outcomes and impact

In this section, the results from the economic impact assessment are reported in summary impact tables together with the business-as-usual counterfactual scenario

without UK CEiRSI implementation. For illustrative purposes, all three UK CEiRSI impact-level scenarios (minor, medium, significant) are provided (Table 2 and Table 3).

For the counterfactual scenarios, most experts agreed that without UK CEiRSI, the UK would only achieve modest benefits from global IST spillover (level 2). Regarding economic development, survey participants did not reach a clear consensus, with views ranging from decline to modest improvement (level 1 — level 3). To address this uncertainty, an adjusted scenario informed by complementary interviews was created. This resulted in a projection of an inflation-adjusted steady-state baseline for R&D investment and jobs over time, combined with a gradual decline aligned with ISTs' adoption in other countries.

Most experts across sectors agreed that UK CEiRSI could deliver a medium-level impact (level 2). Under this scenario, regulators establish clear validation standards for specific IST tools and models, allowing qualified models to be accepted as supportive evidence across multiple therapeutic areas. This would encourage developers to actively seek UK approvals, with UK CEiRSI facilitating broader IST adoption, driving moderate growth in both investment and workforce capacity.

Short-term outcomes and impact

Throughout the UK implementation period (assumed to be 2026-2030), UK CEiRSI initiatives are expected to enable the adoption of 14 new and additional product indications (2 medicines and 12 medical devices) leveraging ISTs.

For patients, these innovations would generate an estimated 37,282 additional quality-adjusted life years (QALYs), valued at £2.4 billion.

For the NHS, IST-enabled product indications would allow for more effective treatment thereby reducing adoption costs, which could save £9.3 million. Furthermore, safer product indications would reduce safety-related costs, for example averting drug-related hospitalisations to the value of around £1.17 billion. In total, this represents around £1.2 billion in possible NHS savings that could be redirected to NHS health improvement activities. When applying UK government's Department of Health and Social Care methodology (UK Government, 2025c), an NHS investment of this scale could be associated with an estimated 80,000 QALYs, with a corresponding valuation of £5.6 billion.¹

Greater utilisation of ISTs can replace the need for animal research in R&D, resulting in estimated savings of £867,000.

UK CEiRSI initiatives are projected to drive £4.6 billion in additional R&D investment, creating around 111,000 new jobs and contributing £14.6 billion in gross value added to the UK economy. In addition, patients are likely to benefit from productivity gains resulting from their improved health, adding a further £2.7 billion to economic output. It should be noted that the estimated productivity benefits are linked to QALY improvements from new innovations (valued above). As a result, the monetised health gains and productivity gains may overlap, potentially leading to a degree of double counting.

¹ This quantification is provided to offer additional context on the broader value associated with the estimated NHS cost savings. The UK government's Impact Assessment of the Statutory Scheme for Branded Medicines Pricing (2025) sets out in Annex 4 a methodology that applies an estimate of the cost per QALY "at the margin" of £15,000 per QALY to value NHS cost savings in terms of the potential health benefit that could be generated by re-investing those savings. In addition, the Assessment notes that QALY gains can subsequently be valued from a societal perspective, in line with Green Book guidance, using a value of £70,000 per QALY.

For industry, IST-driven efficiencies in R&D processes could cut development costs by £58.5 million, while accelerated timelines may unlock £267.4 million in extra revenue through extended patent protection. These figures reflect global industry impacts, as the international nature of R&D makes it impractical to isolate the UK-specific share attributable to UK CEiRSI and ISTs.

Table 2 **Summary table of impact: 5-year time horizon**

Figures in £ million or £ thousands (reduced animal testing and employment) with 90% confidence intervals in brackets, representing the distribution of expert elicitation responses, and represent cumulative 5-year values

		BUSINESS AS USUAL	UK CEiRSI IMPLEMENTATION			INCREMENTAL IMPACT
		No CEiRSI counter- factual	Minor impact	Medium impact	Significant impact	Counterfactual vs medium impact
PATIENTS	Health gains	£6,100 [£3,007 - £9,194]	£7,321 [£3,609 - £11,032]	£8,540 [£4,210 - £12,871]	£9,150 [£4,511 - £13,790]	£2,440 [£1,203 - £3,677]
NHS	Adoption savings	£23 [£15 - £31]	£28 [£18 - £38]	£33 [£21 - £44]	£35 [£23 - £47]	£9 [£6 - £13]
	Safety-related gains	£2,357 [£1,112 - £3,982]	£2,939 [£1,380 - £4,982]	£3,527 [£1,652 - £5,993]	£3,832 [£1,793 - £6,518]	£1,170 [£540 - £2,012]
INDUSTRY*	R&D savings	£7,707 [£4,147 - £12,421]	£7,736 [£4,156 - £12,488]	£7,765 [£4,165 - £12,555]	£7,780 [£4,169 - £12,588]	£58 [£18 - £134]
	Additional on-patent revenue	£47,816 [£26,660 - £75,440]	£47,949 [£26,690 - £75,770]	£48,083 [£26,719 - £76,111]	£48,150 [£26,734 - £76,279]	£267 [£59 - £671]
ETHICAL	Reduced animal testing savings	£155,117 [£122,685 - £188,080]	£155,551 [£122,822 - £188,917]	£155,984 [£122,959 - £189,753]	£156,201 [£123,027 - £190,172]	£867 [£273 - £1,674]
ECONOMY **	R&D investment	£14,488 [£14,675 - £14,302]	£18,292 [£18,245 - £18,338]	£19,052 [£18,969 - £19,145]	£19,813 [£19,673 - £19,953]	£4,564 [£4,284 - £4,844]
	Employment	222 [241 - 203]	315 [310 - 319]	333 [324 - 343]	352 [337 - 366]	111 [82 - 140]
	Employment value added	£29,274 [£31,784 - £26,765]	£31,182 [£30,710 - £31,653]	£43,911 [£42,657 - £45,166]	£46,351 [£44,469 - £48,233]	£14,637 [£10,872 - £18,402]
	Productivity gains ***	£6,663 [£3,285 - £10,042]	£7,996 [£3,941 - £12,050]	£9,328 [£4,598 - £14,059]	£9,995 [£4,927 - £15,063]	£2,665 [£1,314 - £4,017]

* Figures represent global industry impacts;

** Because the baseline scenario assumes a failure to adopt IST and associated declines in investment and competitiveness, confidence interval bounds may occasionally appear reversed, with upper-bound values lower than lower-bound values. This reflects the direction of the estimated impact relative to the baseline.

*** Monetised health gains and productivity gains may overlap, leading to potential double counting.

Long-term outcomes and impact

Looking beyond the initial five-year period, the adoption of ISTs through UK CEiRSI is expected to deliver transformative benefits for healthcare, industry, and the economy when comparing it to the business-as-usual scenario.

Table 3 **Summary table of impact: 15-year time horizon**

Figures in £ million or £ thousands (reduced animal testing and employment) with 90% confidence intervals in brackets, representing the distribution of expert elicitation responses.

		BUSINESS AS USUAL	UK CEiRSI IMPLEMENTATION			INCREMENTAL IMPACT
		No CEiRSI counter-factual	Minor impact	Medium impact	Significant impact	Counterfactual vs medium impact
PATIENTS	Health gains	£35,145 [£23,425 - £46,179]	£42,174 [£28,111 - £55,415]	£49,203 [£32,796 - £64,651]	£52,718 [£35,138 - £69,269]	£14,058 [£9,370 - £18,472]
NHS	Adoption savings	£109 [£77 - £142]	£131 [£92 - £170]	£153 [£107 - £199]	£164 [£115 - £213]	£44 [£31 - £57]
	Safety-related gains	£17,012 [£9,794 - £26,025]	£21,229 [£12,172 - £32,585]	£25,474 [£14,548 - £39,232]	£27,672 [£15,773 - £42,687]	£8,462 [£4,754 - £13,208]
INDUSTRY*	R&D savings	£57,585 [£38,789 - £80,928]	£58,141 [£39,066 - £81,890]	£58,697 [£39,344 - £82,853]	£58,975 [£39,484 - £83,334]	£1,112 [£557 - £1,925]
	Additional on- patent revenue	£351,480 [£238,884 - £485,427]	£354,760 [£240,524 - £491,001]	£358,040 [£242,164 - £496,575]	£359,680 [£242,983 - £499,362]	£6,560 [£3,279 - £11,148]
ETHICAL	Reduced animal testing savings	£769,377 [£650,492 - £890,011]	£776,197 [£654,653 - £899,840]	£783,016 [£658,813 - £909,668]	£786,426 [£660,894 - £914,582]	£13,639 [£8,321 - £19,657]
ECONOMY**	R&D investment	£9,171 [£9,830 - £8,513]	£19,621 [£19,456 - £19,785]	£21,711 [£21,381 - £22,040]	£23,801 [£23,306 - £24,295]	£12,539 [£11,551- £13,527]
	Employment	118 [139 - 98]	341 [335 - 346]	385 [375 - 395]	429 [414 - 445]	267 [236 - 297]
	Employment value added	£18,933 [£22,195 - 15,672]	£40,927 [£40,314- £41,540]	£61,533 [£59,903- £63,164]	£68,633 [£66,187 - £71,079]	£42,600 [£37,708- £47,492]
	Productivity gains ***	£38,388 [£25,587 - £50,440]	£46,066 [£30,704 - £60,528]	£53,743 [£35,822 - £70,616]	£57,582 [£38,380 - £75,660]	£15,355 [£10,235 - £20,176]

* Figures represent global industry impacts;

** Because the baseline scenario assumes a failure to adopt IST and associated declines in investment and competitiveness, confidence interval bounds may occasionally appear reversed, with upper-bound values lower than lower-bound values. This reflects the direction of the estimated impact relative to the baseline.

*** Monetised health gains and productivity gains may overlap, leading to potential double counting.

Over a 15-year scenario (10 years after CEiRSI implementation, assumed to be 2030–2040), cumulative health gains could multiply significantly as more product indications and advanced therapies enter the market through accelerated innovation cycles and deeper integration of IST-enabled processes, driving global competitiveness for UK-based R&D.

After 15 years, UK CEiRSI initiatives could enable 77 new product indications (17 medicines and 60 medical devices), delivering £14 billion in patient health gains. For the NHS, adoption of ISTs is expected to save £8.5 billion through improved safety and £44 million by reducing low-value care. Assuming NHS reinvestment in accordance with UK government's Department of Health and Social Care methodology (UK Government, 2025c), this could unlock an estimated 566,667 QALYs, with a corresponding valuation of £39.7 billion.² Furthermore, replacing animal research in R&D can generate savings of £13.6 million. Overall, UK CEiRSI initiatives are projected to drive £12.5 billion in new R&D investment, create 267,000 jobs thereby adding £42.6 billion in gross value to the UK economy by 2040, alongside £15.4 billion in productivity benefits from patients who are treated by the extra innovation. Finally, industry stands to gain £1.1 billion in R&D cost savings and £6.6 billion globally in additional revenue from extended patent protection.

² This quantification is provided to offer additional context on the broader value associated with the estimated NHS cost savings. The UK government's Impact Assessment of the Statutory Scheme for Branded Medicines Pricing (2025) sets out in Annex 4 a methodology that applies a marginal cost-effectiveness threshold of £15,000 per QALY to value NHS cost savings. In addition, the Assessment notes that QALY gains can subsequently be valued from a societal perspective, in line with Green Book guidance, using a value of £70,000 per QALY.

4

Conclusion

This report characterised, through a literature review and expert elicitation, how ISTs can continue to transform R&D in the pharmaceutical and medtech sectors, generating wide-ranging benefits for patients, the healthcare system, industry, and the broader economy and society.

This transformation presents a timely opportunity to invest in the national adoption of ISTs to fully leverage these benefits. UK CEiRSI is uniquely positioned to drive this transition in the UK, delivering national impact and shaping global progress by leading international harmonisation and establishing the UK's position as a global leader in regulatory science and innovation.

This report demonstrated how UK CEiRSI can act as a catalyst for the regulation and adoption of ISTs in the UK. By addressing key barriers to adoption, UK CEiRSI could accelerate ISTs' uptake and unlock significant health and economic gains.

Our economic impact assessment shows that investing in UK CEiRSI could deliver substantial returns within its ambitious five-year implementation plan, including:

- UK economy: £21.9 billion through increased R&D investment, productivity gains, and GVA.
- NHS: £1.2 billion in savings from improved safety and adoption of more efficacious products, which can be reinvested to advance patient health.
- Patients: £2.4 billion in health gains.
- Global innovative health technology industry: £325 million through R&D efficiencies and additional revenue.
- Ethical and sustainability: £867,000 savings from reduced animal research.

We also estimate that UK CEiRSI has the potential to further reshape the regulatory landscape and deliver cumulative, long-lasting economic benefits. Beyond these quantifiable impacts, UK CEiRSI has the potential to accelerate wider IST benefits that we documented in this report including more equitable access to treatments for more diverse patient populations, reductions in risk of R&D and clinical testing, and positive environmental and sustainability outcomes.

In conclusion, our analysis supports the view that an adequately funded UK CEiRSI can act as a catalyst, transforming the potential of IST for health technology development and regulation into tangible health improvements, NHS cost savings, and significant economic gains for the United Kingdom.

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Appendix A: Methodology

1. Narrative literature review on the impact of ISTs

We conducted a narrative review of both academic and grey literature to better understand the full potential positive impact of ISTs. The literature review was loosely structured around the existing literature reports of the impact of ISTs in the UK (Frangi, Denison and Lincoln, 2023; Whorwood, Frangi and Wilkinson, 2023; PwC, 2022) and used forward and backward snowballing techniques. The literature review was used to establish the broader value framework of ISTs (Figure 1).

2. Expert elicitation on the impact of ISTs

The literature did not provide sufficiently robust or quantitative estimates of the current or future impact of ISTs' adoption in the pharmaceutical and medtech industries, which were required to parameterise the economic model.

To address this gap, we conducted an expert elicitation exercise using a structured survey (survey instrument and results provided in Appendices B and C). We relied on a survey, rather than other forms of expert elicitation, because we believed that a survey would allow us to capture the perspectives of a wider range of stakeholders than we could through interviews or group discussions. The survey asked experts to estimate the potential scale and impact of ISTs' adoption within globally operating pharmaceutical and medtech R&D processes, under the assumption that existing barriers to implementation could be fully mitigated.

For the purposes of this study, "adoption" was defined as the potential for ISTs to refine, reduce, or replace existing R&D processes and technologies. Examples include the refinement of clinical study protocols; the supplementation of the evidence base to reduce the need for additional studies; and the replacement of in vivo animal testing with validated alternative methods. Experts were also asked to provide estimates regarding the impact of ISTs' adoption on the number of additional clinical indications and on achievable efficiencies in R&D timelines.

3. UK CEiRSI logic model

The UK CEiRSI logic model (see Figure 2) shows how government support can enable a set of UK CEiRSI activities aimed at strengthening the UK innovation ecosystem for the adoption of ISTs. These activities include developing governance and regulation, ensuring model credibility and certification, engaging stakeholders, horizon scanning, running a training academy, scaling virtual patient populations, advancing computational disease models, and executing IST studies. Together, these activities generate four core outputs: (1) policy and standards development, (2) workforce development, (3) technology development, and (4) supply-chain development. Progress from outputs to outcomes must navigate several barriers, including regulatory acceptance, skills gaps, NHS data suitability, variable industry investment, social and cultural acceptance, and legal constraints. When these barriers are addressed through UK CEiRSI activities and outputs, the system delivers key outcomes, such as generating new additional product indications, enabling accelerated R&D, and leveraging greater IST adoption in the UK. Ultimately, these outcomes drive wider impacts, including improved health, higher productivity, improved NHS efficiency and cost savings, reduced R&D costs, increased patent-related revenue, higher R&D investment, and greater employment.

4. Overview of the economic model

We developed an economic model based on the logic model to estimate UK CEiRSI's outcomes and impact. The logic model uses inputs derived from expert elicitation to

estimate three main outcomes of UK CEiRSI and capture a pathway to impacts, where UK CEiRSI can add value by leveraging the benefits of ISTs in the UK specifically. Impact is estimated across the five areas of impact identified in the broader value framework (see Figure 1): the health system, patient welfare, industry benefits, economic gains, and ethical sustainability considerations.

Model inputs were derived combining the results from the expert elicitation (see Appendix B and C):

- Global IST impact: the level of adoption of ISTs in industry R&D over time (2030, 2035, 2040), the additional new indications as a result of ISTs' adoption over time (2030, 2035, 2040), the time savings in R&D as a result of the ISTs' adoption (2030, 2035, 2040). These estimates by experts were used as input into impact scenarios.
- UK CEiRSI impact: the level of impact that UK CEiRSI would be able to achieve and how this compares to a counterfactual projection. Survey respondents specifically indicated how they anticipated ISTs would affect the number of approved indications in pharmaceuticals and medical devices, as well as the proportion of indications developed using ISTs in a baseline scenario, where UK CEiRSI hypothetically did not exist. They selected scenarios reflecting UK CEiRSI's impact, and we used these scenarios to scale the baseline inputs. For further details on the survey, refer to Appendix B, which includes the full questionnaire. The tables below describe each scenario and indicate the scaling factor we used for each.

Table 4: Full description of scenarios and associated scaling factors

	BASELINE SCENARIOS	IMPACT SCENARIOS
LEVEL 1	ISTs will lack regulatory acceptance or guidance, preventing progress in the UK. This would result in minimal innovation benefits and only limited spillover from global IST adoption. UK pharma and medtech industries would fail to adapt to global R&D trends, leading to declining investment and job losses. As global IST adoption accelerates, the UK's competitiveness would erode significantly. Apply a scaling factor of 10% to global values	Regulators begin acknowledging ISTs' applications and promote their use through "regulatory sandbox" initiatives. While developers test these systems, they do not prioritise the UK market. UK CEiRSI facilitates limited IST adoption, resulting in only small increases in R&D investment and job creation. Apply a scaling factor 110% to baseline values.
LEVEL 2	Some innovation benefits are realised through global IST adoption and spillover. UK industry R&D investment and jobs stagnate, with no significant growth opportunities as ISTs become embedded in global R&D processes. Workforce development and investment in IST remain fragmented, with minimal UK-led initiatives. Apply a scaling factor of 20% to global values.	Regulators establish clear validation standards for specific ISTs, enabling qualified models to be accepted as supportive evidence across multiple therapeutic areas. Developers actively pursue UK approvals, and UK CEiRSI drives broader IST adoption, resulting in moderate growth in investment and workforce capacity. Apply a scaling factor 140% to baseline values.

LEVEL 3

Regulatory acceptance of ISTs improves through global collaboration, allowing the UK to benefit from worldwide IST adoption and introduce new indications.

The UK realises modest IST-related benefits, with R&D investment and jobs growing only in line with general economic trends. Workforce capabilities and investment improve somewhat through international initiatives, but without a UK-led strategy, the UK remains a follower rather than a leader in innovation of ISTs.

UK regulators emerge as global leaders in ISTs' adoption, establishing a clear regulatory framework and streamlined approval pathways. Qualified ISTs are systematically integrated into decision-making, and developers prioritise UK submissions.

UK CEiRSI positions the UK as a frontrunner in IST innovation, fully leveraging NHS data and creating strong incentives for investment and job growth.

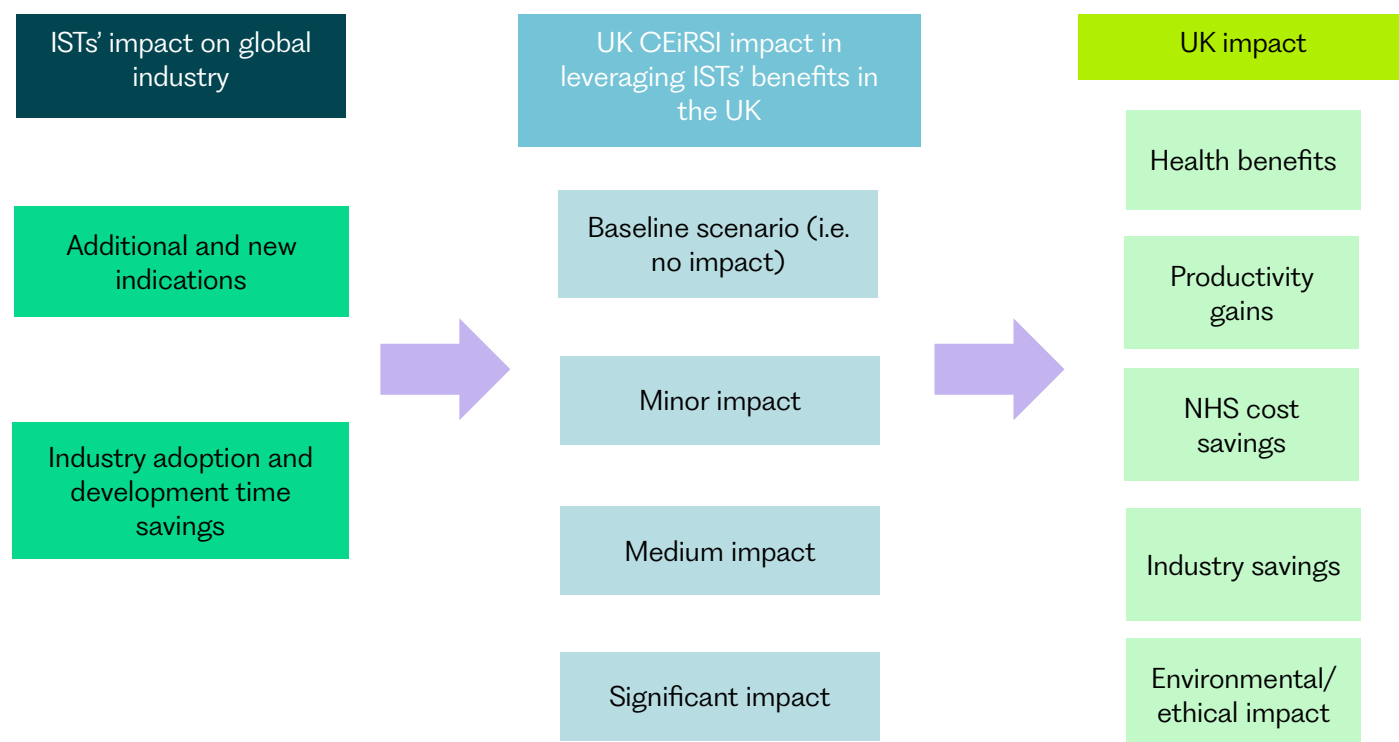
Apply a scaling factor of 30% to global values.

Apply a scaling factor 150% to baseline values.

Model inputs capture UK CEiRSI impacts:

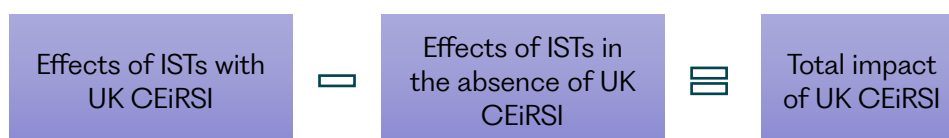
- 1) **New IST-enabled indications in the UK:** UK CEiRSI drives the regulatory acceptance of additional and new indications for pharmaceutical and medical devices in the UK. These generate health benefits and patient productivity gains for the UK population and yield NHS cost savings via two routes: improved efficacy and safety.
- 2) **Accelerated R&D in industry:** UK CEiRSI will support and leverage ISTs' adoption in in the life science industry. This drives time efficiencies and cost savings in R&D processes, as pharmaceutical and medical device companies refine, reduce, and replace existing R&D methods. These efficiencies translate into lower R&D expenditure for industry, which in turn can improve returns on investment and free up resources for reinvestment into innovation and broader economic growth.
- 3) **ISTs' adoption in industry leveraged in the UK:** UK CEiRSI will strengthen the UK's competitiveness in the global life sciences sector by fostering an ecosystem that actively supports and enables the adoption of ISTs. By creating a favourable environment for innovation, the initiative can help attract and retain R&D investment and high-value jobs in the UK, particularly relative to regions where ISTs' adoption is less advanced or less supported.

Figure 4 Overview of model inputs and outputs



To quantify UK CEiRSI's impact, we modelled two scenarios: one using the inputs derived from the baseline scenario, which projected ISTs' impact across the four categories we considered in the absence of UK CEiRSI; and one using the scaled inputs reflecting ISTs' amplified impact in the UK as a result of UK CEiRSI. We took the difference between these values to be the overall effect of UK CEiRSI across our four areas of impact.

Figure 5 Calculating UK CEiRSI's impact using survey scenarios



5. Health system cost savings

The health system cost savings generated by ISTs are obtained through two value streams:

Efficacy value stream (deployment-related efficiency effects)

This stream captures the NHS efficiency savings associated with ISTs' adoption, driven by improved effectiveness and more targeted use of healthcare technologies developed through ISTs. Accordingly, we apply this estimated reduction to the deployment costs of new health technologies introduced into the NHS in the economic model. These deployment cost estimates were derived from NHS England (2016).

Deployment-related savings were estimated by applying an evidence-based proportional reduction to baseline deployment costs.

- Baseline deployment costs: applied in the early rollout period, using a programme implementation cost proxy (NHS England, 2016).
- IST-linked proportional reduction: proxied using the median relative reduction reported across de-implementation trials (Heus et al., 2023).

$$\begin{aligned} \text{Deployment – related saving (year } t) \\ &= \text{baseline deployment cost (year } t) \times \text{proportional reduction factor} \\ &\times \text{IST adoption level (year } t) \end{aligned}$$

Safety value stream (reduced adverse events leading to lower hospital utilisation)

This stream captures NHS cost savings generated by deploying safer health technologies developed through ISTs. These savings arise from reductions in adverse events associated with health technologies, which in turn lower subsequent hospital utilisation.

Safety outcomes were estimated by translating baseline NHS-admitted activity into expected adverse-event-related utilisation, applying an IST-attributable relative reduction, and monetising avoided events using available cost evidence.

It is split into:

- 1) Pharmaceuticals: adverse drug reaction (ADR)-related hospital admissions.
- 2) Medtech: adverse medical device events (AMDEs) generating hospital activity, restricted to Class III (high-risk) devices, which we considered to be the device class most likely to make use of IST.

Pharmaceuticals: ADR-related admissions and cost savings

Step 1: Baseline ADR admissions

$$\text{Baseline ADR admissions (year } t) = \text{total admissions (year } t) \times \text{ADR admission rate}$$

Step 2: Avoided ADR admissions

$$\begin{aligned} \text{Avoided ADR admissions (year } t) \\ &= \text{baseline ADR admissions (year } t) \times \text{IST relative reduction factor} \\ &\times \text{IST adoption level (year } t) \end{aligned}$$

The relative reduction factor was anchored to IST-enabled modelling-and-simulation evidence comparing model-informed dosing with standard dosing and showing a reduction in Grade ≥ 2 neuropathy incidence (Centanni et al., 2024).

Step 3: Monetisation

$$\begin{aligned} \text{ADR cost savings (year } t) \\ &= \text{avoided ADR admissions (year } t) \times \text{unit cost per ADR admission} \end{aligned}$$

Medtech: Class III device-related adverse events and cost savings

The medtech component was restricted to Class III (high-risk) devices.

Step 1: Baseline AMDEs

Baseline AMDE incidence was informed by Samore et al. (2004) and applied to admitted activity levels as a proportional incidence measure.

Step 2: Avoided AMDEs

Avoided events were estimated using the same relative reduction framework as pharmaceuticals:

$$\begin{aligned} \text{Avoided AMDEs (year } t) &= \text{baseline AMDEs (year } t) \times \text{IST relative reduction factor} \\ &\quad \times \text{IST adoption level (year } t) \end{aligned}$$

Step 3: Monetisation

Avoided AMDEs were monetised using an NHS unit cost proxy ADR admission cost input to maintain internal consistency across safety components

Handling of non-UK evidence

Some of the inputs such as the AMDE incidence rate were drawn from international literature (NHS England, 2016; Samore et al., 2004). In such cases, where evidence was not UK-specific, values were treated as proxies and preference was given to unitless proportional parameters (e.g., relative reductions, incidence per admission) to improve transferability.

Assumptions and limitations

Several assumptions were incorporated in the health system costs savings calculations:

- The ADR reduction factor was anchored to an IST-enabled modelling-and-simulation study in paediatric vincristine dosing (Centanni et al., 2024) and extrapolating this effect to all serious ADRs that generate hospital admissions is a strong assumption and a key limitation.
- The baseline ADR admission proportion was informed by NICE Clinical Knowledge Summaries (NICE, 2025) and historic UK evidence (Pirmohamed et al., 2004), but true rates vary by setting, case-mix, and coding or attribution methods.
- Adverse medical device event incidence was informed by a US hospital surveillance study and may not reflect current NHS incidence or reporting; in addition, the medtech scope was limited to Class III devices which improves clinical plausibility for high-harm events but may under-represent total device-related harm across all device classes.
- Programme implementation costs were proxied using NHS Diabetes Prevention Programme impact assessment implementation cost estimates, which may not reflect the resource profile for IST deployment in practice, including informatics, governance, clinical adoption, and supplier costs.
- Hospital activity inputs were anchored to a single observed year of admitted activity and, unless separately adjusted, implicitly assume stability over the analytic horizon.

6. Patient welfare

Existing literature on ISTs and their benefits suggests that it will result in new indications being approved for pharmaceuticals and medical devices. We consider two ways by which population health will be impacted by new indications:

- 1) **Monetised health gains:** measured as Quality-Adjusted Life Years (QALYs) gained by patients from new products, and monetised using the UK Green Book's valuation of a QALY of £70,000 (HM Treasury, 2022)
- 2) **Productivity gains:** measured as increased output from healthier individuals who can work more or work more effectively

Although productivity gains are described in this section because of their link to QALY gains from new innovations, they may be more appropriately categorised as part of ISTs' broader economic impact. For this reason, we ultimately report them under that impact category. It is also important to note that the Green Book's £70,000 value per QALY represents the societal value of an additional year of life in perfect health (HM Treasury, 2022; Cubi-Molla et al., 2023). This value implicitly captures improvements in individuals' ability to participate in productive activities. As such, monetised health gains and productivity gains may overlap, leading to some degree of double counting.

To estimate the impact of ISTs on monetised health gains, we leaned on a Naci et al. (2025) paper, which estimated that new medicines appraised by NICE between 2000 and 2020 resulted in 3.75 million new QALYs. We first annualised this value, assuming a uniform distribution of QALYs across years, and we then scaled this value up by the ratio of the average annual number of indications recommended by NICE in the past six years to that of the period under study by Naci et al (2025). We took this value to be the current baseline of QALYs gained at the population level by new pharmaceutical indications recommended by NICE.

To quantify how ISTs and UK CEIRSI would change these values, we scaled these annual QALY gains further by the predicted increase in indications each year from expert elicitation. Given that this result was specific to pharmaceuticals, we also generated a ratio of the median incremental QALY gained from new medical devices compared to that of pharmaceuticals. We then multiplied this value by the annualised estimate of population QALY gains from new pharmaceuticals each year, thereby estimating the yearly population QALY gains owed to medical devices. These QALY gains were converted to monetary values using the UK Treasury's valuation of a QALY (HM Treasury, 2022). Specific parameters are presented in Table 6.

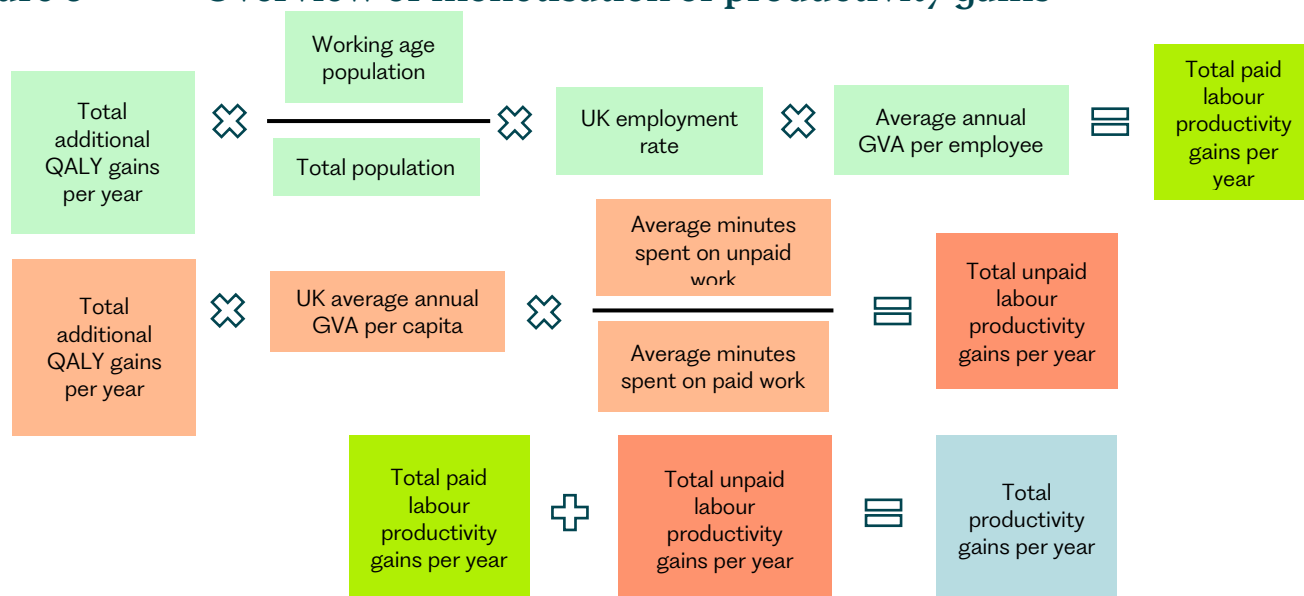
Overall, our approach has two main limitations. First, we assumed that Naci et al.'s (2025) figure on total additional QALYs over a 20-year period was uniformly distributed. In reality, QALY distributions over time are dependent on the specific medicines and indications that are approved each year and the time required to achieve the anticipated health gains. However, since we ultimately aggregated the QALY gains over a time horizon, we felt our assumptions were not unreasonable. Second, by applying the ratio of incremental QALYs for medical devices and pharmaceuticals to the annualised population QALY gains, we implicitly assumed that the same number of patients each year use new pharmaceuticals and new medical devices in their approved indications. Ultimately, we made this assumption due to the paucity of information that exists on new medical devices and their utilisation in the UK.

We used the same QALY estimates as inputs to a productivity framework developed by PricewaterhouseCoopers (2022), which translates health improvements into economic productivity gains. This adapted framework is illustrated in Figure 6. Productivity benefits

are linked to the QALY improvements valued above. Monetised health gains and productivity gains may therefore overlap, leading to potential double counting.

Figure 6

Overview of monetisation of productivity gains



7. Industry savings

We consider two routes by which industry might yield gains from ISTs:

- 1) **Time savings:** ISTs enable more efficient progression through R&D phases, reducing development timelines and the costs accumulated in each phase of development.
- 2) **Extended patent revenue:** faster time-to-market allows products to generate revenue under patent protection for a longer period before generic entry.

We monetised time savings using the approach of Di Masi (2002), which estimates capitalised cost reductions associated with time reductions in each phase of pharmaceutical R&D. Table 5 presents the phase-specific cost savings parameters derived from this paper (DiMasi, 2002).

Our expert elicitation indicated that ISTs would yield time savings of 40% in the preclinical and clinical phases for medicines, and 40% in the nonclinical phase and 30% in the clinical phase for medical devices. We applied the corresponding percentage cost reductions to the expected capitalised costs for each R&D phase, assuming clinical time savings applied uniformly across Phases I, II, and III (i.e., a 40% reduction in clinical time meant a 40% reduction in time in all three phases). Phase-specific costs are presented in Table 6 .

Below we present the equation used to estimate the cost reduction associated with the expert-informed time savings for medicines. We followed the same approach for medical devices but using the device-specific expert-elicited time savings.

$$\text{Time Savings} = (3.80\%) * (\text{Preclinical Cost}) + (2.20\%) * (\text{Phase I Cost}) + (6.10\%) * (\text{Phase II Cost}) + (9.00\%) * (\text{Phase III Cost})$$

To provide an annual industry-wide value of time savings, we multiplied the per-indication cost reduction by the number of indications adopting ISTs in each phase.

A limitation of this approach is that we applied the same cost reductions to medicines as we did medical devices. This was ultimately due to limited data on time savings in the medical device space.

Table 5 **Cost reduction (%) resulting from decreases in phase time (DiMasi, 2002)**

REDUCTION IN PHASE LENGTH (%)	PRECLINICAL COST REDUCTION	PHASE I COST REDUCTION	PHASE II COST REDUCTION	PHASE III COST REDUCTION
5%	0.50%	0.30%	0.80%	1.20%
10%	1%	0.60%	1.60%	2.30%
15%	1.50%	0.80%	2.30%	3.50%
20%	2%	1.10%	3.10%	4.60%
25%	2.40%	1.40%	3.90%	5.80%
30%	2.90%	1.70%	4.60%	6.90%
35%	3.40%	1.90%	5.30%	8%
40%	3.80%	2.20%	6.10%	9%
45%	4.30%	2.50%	6.80%	10.10%
50%	4.70%	2.70%	7.50%	11.20%

Time reductions attributable to ISTs enable products to reach market earlier, thereby extending the period of patent-protected revenue generation prior to generic or biosimilar entry. We estimated this benefit using the expert-elicited reduction in R&D development time from our survey.

For each phase where ISTs generate time savings, we calculated additional revenue as follows: If ISTs reduced time in a given phase by 40%, we added 40% of that phase's duration to the baseline period between market entry and generic/biosimilar entry (approximately 13 years). We then calculated the present value of revenue under this extended period and compared it to the present value under the baseline period.

Formally, we represented this as

$$\begin{aligned} \text{Added Revenue} = & PV(\text{Discount Rate}, \text{Time to Generic Entry} \\ & + \text{Time Savings}, \text{Annual Revenue on Patent}) \\ & - PV(\text{Discount Rate}, \text{Time to Generic Entry}, \text{Annual Revenue on Patent}) \end{aligned}$$

We estimated the global annual on-patent revenue of branded medicines using estimates from a 2024 paper, which found that the median sales per new therapeutic agent was \$6.7 billion over a median follow-up period of 13.2 years (Wouters et al., 2024). We annualised this figure by dividing the sales estimate by the follow-up period length. After

inflating this figure and applying a USD-GBP exchange rate, we took this value forward as an approximation of the annual global sales currently earned by on-patent medicines

Since indications may adopt ISTs in one or both development phases after patent filing (that is, preclinical and clinical), we calculated revenue gains for two categories. For indications adopting ISTs in both phases, we calculated the combined time savings from both phases. We assumed the number of indications using ISTs in both phases equals the minimum of the phase-specific adoption estimates from our expert survey, with the remainder (i.e. the difference between the minimum and maximum number of indications adopting ISTs in the clinical or preclinical phase) adopting ISTs in only one phase. We then multiplied each per-indication revenue gain by the corresponding number of indications in each adoption category (i.e., in both phases or a single phase) and summed across categories to obtain the aggregate industry revenue gain.

Crucially, we only calculated additional revenue due to faster time-to-market for pharmaceuticals—not medical devices. This is because the nature of patents in the medical device industry is quite different from that of pharmaceuticals. Competition tends to follow very quickly after medical devices enter the market, as it is possible to design medical devices for specific uses in different ways (Kahn, 1991; Lietzan, Aciri and Weidner, 2023).

Moreover, it is also important to note that for the category of industry benefits, we present global values. That is, for the other categories, we indicated the added value of ISTs and UK CEiRSI within the UK, as those benefits can be more clearly attributed to the UK. However, the multinational structure of pharmaceutical and medical device companies and the global nature of research and sales make it impractical to isolate the UK-specific portion of R&D savings and future revenues generated as a result of UK CEiRSI and ISTs.

8. Environmental or ethical impact

To quantify UK CEiRSI's environmental and ethical impact, we considered how ISTs might reduce animal testing and the consequent industry savings that this reduction would produce.

We estimated these benefits using expert survey projections of ISTs' adoption rates in clinical-stage R&D for 2030, 2035, and 2040. For each indication using ISTs in the clinical stage, we assumed full replacement of animal testing, meaning these values should be taken as an overestimate of UK CEiRSI's potential for impact in this space, as it is more likely that ISTs would simply reduce—rather than entirely replace—animal testing. Below we express the equation we used to calculate savings due to reduced animal testing:

$$\begin{aligned} \text{Annual Savings} = & (\text{Annual animal testing procedures}) * (\% \text{ increase in new indications}) \\ & * (\% \text{ of indications using IST in clinical phase}) \\ & * (\text{Cost of animal tests per indication}) \end{aligned}$$

We calculated this value only for pharmaceuticals, given that animal testing is more commonplace in the pharmaceutical industry than in the medical device industry. Indeed, the Home Office's Annual Statistics of Scientific Procedures on Living Animals indicates that while there were 148,694 experimental procedures performed on animals in 2024 in accordance with legislation on medicinal products for human use, only 23 were performed on animals per medical devices legislation (Home Office, 2025).

9. Parameter values for calculations

Table 6

Parameter values for impact assessment calculations

	PARAMETER	VALUE	REFERENCES / NOTES
KEY SPECIFICATIONS AFFECTING MULTIPLE OUTCOMES	Baseline number of new indications approved by NICE each year	70	NICE has approved 500 indications over six years, with 84% of decisions being positive (NICE, 2025; Darrow et al., 2025)
	Number of new Class III medical devices in 2014	500	Assuming that the number of Class III devices receiving CE marking in Europe would equal the number being approved for use in the UK (MedTech Europe, 2015)
	Average annual growth rate of the medical device industry	5.4%	(MedTech Europe, 2024)
	Estimated number of new Class III medical devices	846	Calculation, applying compounded annual growth rate to the number of Class III medical devices in 2014
	Proportion of medical devices registered with the MHRA that are used by the NHS	0.25	(DHSC, 2024)
	Estimated number of new Class III medical devices that will be adopted for use by the NHS each year	212	Calculation, applying the proportion of medical devices registered with the MHRA that are used by the NHS to the estimated number of new Class III medical devices
HEALTH SYSTEM COST SAVINGS	IST Cost Reduction	17%	Median reduction in low value care following targeted de-implementation (Heus et al., 2023)
	Baseline NHS Deployment Cost (Annualised for Years 1 to 3))	£2,783,333.33	(Roll-out implementation cost is £8.35m over 3 years. We convert this to an annual Year 1—3 cost by dividing by 3 (NHS England, 2016)
	Number of Hospital Admissions/year	17,600,000	(NHS England, 2024a)
	Baseline ADR hospitalisation rate	6%	(NICE, 2025)
	Number of hospital admission due to ADRs	1,056,000	(Calculation, applying the baseline ADR hospitalisation rate to the annual number of Finished Admission Episodes)
	In Silico Impact on ADR	13.0%	(Relative reduction in ADRs calculated as (baseline-post-IST)/baseline. ADRs fall from 62.1% to 53.9%, giving a ~13% relative reduction. Centanni et al., 2024)
	Avoided annual ADR(under full ISTs adoption)	137,280	(Calculation, applying ISTs driven ADR reduction to annual number ADR hospitalisations)
	ADR avoided per IST-enabled medicine (under full in silico adoption)	92	(Calculation, dividing the number of avoided annual ADRs by the number of distinct medicines used in UK as per the BNF)
	Cost of ADR	£2,293	(Osanlou et al., 2022)

% of adverse medical device events	8.37%	(Samore et al., 2004)
Baseline device-related events per year	6965.01	(Calculation: Calculated by applying the AMDE incidence per admission to annual NHS admissions to estimate total AMDEs per year, then dividing by the expected annual number of Class III devices to obtain baseline ADR events per device per year.)
Device events avoided per device per year (under full ISTs adoption)	905.45	(Calculation: Calculated by multiplying the baseline device-related events per year by the in-silico impact on ADR reduction (Centanni et al., 2024))

HEALTH BENEFITS

Average annual population QALY gains from new medicines between 2000-2020	187,500	This value is generated by dividing the 3.75 million QALYs that were gained between 2000-2020 by 20 years (Naci et al., 2025)
Average annual number of recommended pharmaceutical indications 2000-2020	14.35	(Naci et al., 2025)
Estimated annual population QALY gains from new pharmaceutical indications in 2024	915,000	Calculated by scaling up 187,500 by the ratio of the baseline number of new pharmaceutical indications approved by NICE in the past six years (70) to the annual number approved by NICE from 2000-2020
Median incremental QALY gains from novel pharmaceuticals	0.49	(Naci et al., 2025)
Median incremental QALY gains from medical devices	0.13	(Chambers et al., 2022)
Estimated annual population QALY gains from new medical devices in 2024	243,000	Calculated by scaling down 915,000 QALYs by the ratio of median incremental QALY gains from medical devices to pharmaceuticals
Monetary valuation of a QALY	£70,000	(HM Treasury, 2022)
Working age population in the UK	43,266,000	(Office for National Statistics, 2025d)
Total population	68,265,209	(Office for National Statistics, 2024b)
UK employment rate	75.30%	(Office for National Statistics, 2025c)
Average annual GVA per employee	£76,401.91	(Office for National Statistics, 2025e)
Average annual GVA per capita	£37,622.43	(Office for National Statistics, 2025e)
Average minutes spent on unpaid work in the UK	187	(Office for National Statistics, 2023)
Average minutes spent on paid work in the UK	175.9	(Office for National Statistics, 2023)

INDUSTRY SAVINGS

Mean capitalised pre-clinical cost	£1,132,000,000	(DiMasi, Grabowski and Hansen, 2016)
Capitalised cost per approved drug — Phase I	£432,000,000	(DiMasi, Grabowski and Hansen, 2016)
Capitalised cost per approved drug — Phase II	£494,000,000	(DiMasi, Grabowski and Hansen, 2016)
Capitalised cost per approved drug — Phase III	£579,000,000	(DiMasi, Grabowski and Hansen, 2016)
Capitalised cost of medical devices — Nonclinical phase	£423,000,000	(Sertkaya et al., 2022)
Capitalised cost of medical devices — Clinical phase	£73,000,000	(Sertkaya et al., 2022)
Mean months spent in preclinical phase — Medicines	52	(DiMasi, 2002)
Mean months spent in Phase I — Medicines	12.3	(DiMasi, 2002)
Mean months spent in Phase II — Medicines	26	(DiMasi, 2002)
Mean months spent in Phase III — Medicines	33.8	(DiMasi, 2002)
Mean months spent in regulatory review — Medicines	18.2	(DiMasi, 2002)
Mean months spent in nonclinical phase — Devices	60	(Sertkaya et al., 2022)
Mean months spent in clinical phase — Devices	84.9	(Sertkaya et al., 2022)
Estimated annual revenue from marketing approval to generic entry (global earnings)	£476,823,519	The median sales for new therapeutic agents is \$6.7 billion over a median follow-up period of 13.2 years (Wouters et al., 2024). We calculated annual values using these figures, and we inflated the price to 2024 values and applied a US-GBP conversion.
Mean time from marketing approval to generic entry (years)	13.00	(Tu et al., 2025)

ENVIRONMENTAL & ETHICAL

Cost of animal testing per product	£2,340,000	The approximate cost required for rodent testing in cancer therapeutics (Van Norman, 2019)
Experimental procedures performed on animals in 2024 per legislation on medicinal products for human use	148,694	(Home Office, 2025)

1. All costs are inflated to and reported in 2024 GBP

10. Macroeconomic impact

We separately modelled UK CEIRSI's impact on the broader UK economy. This assumes that CEIRSI will have a significant role in facilitating, and attracting, investment in IST research into the UK over the period to 2040.

The analysis focused on two dimensions of economic activity:

- 1) Total expenditure on UK research and development
- 2) UK employment and UK value added associated with employment.

For each dimension, a three-step approach was used to calculate the future impact of UK CEiRSI in the context of the evolution of ISTs' adoption.

- Using UK official statistics establish a baseline to 2023, measuring economic impact of pharmaceutical and medical technology research in the UK
- Extrapolate the value of economic activity, to 2040 using Office for Budget Responsibility data
- Calculate the impact of UK CEiRSI to 2030 and 2040 by adjusting extrapolated values, based on survey responses.

Step 1. Calculate baseline activity

To establish the baseline values, various Office for National Statistics datasets were used. These were: "Research and Development by UK Business", "Annual Business Survey" and "Employee Jobs By Industry" (Office for National Statistics, 2025a, 2024a, 2025b). This is in line with previous exercises benchmarking the economic footprint of the sector, such as the Office for Life Sciences' "Life sciences competitiveness indicator" (Office for Life Sciences, 2024).

The pharmaceutical industry is clearly delimited in official statistics, associated with either a defined category in the research and development data or a specific classification in the industrial statistics. Specifically, it is referred to using the Standard Industrial Classification (SIC) two-digit division code: "21. Manufacture of basic pharmaceutical products and pharmaceutical preparations." There is no direct SIC code for the medical technology industries in official statistics. We used a combination of SIC codes: "26.6 Manufacture of irradiation, electromedical and electrotherapeutic equipment" and "32.5 Manufacture of medical and dental instruments and supplies." For medical technology research, we used "72.11 Research and experimental development on biotechnology" and "72.19 Other research and experimental development on natural sciences and engineering." These will include an element of pharmaceutical industry activity, but this is not readily disaggregated.

One consideration was the differential impact of the adoption of ISTs on each phase of the development of medicines. For pharmaceutical R&D, the reported statistics disaggregate investment into basic, applied and experimental development. These categories use OECD Frascati Manual definitions and, although not a direct match, we have mapped these to phase 1, 2 and 3 respectively (OECD, 2015).

In the absence of official statistics, the baseline medical technology employment figure used the joint life sciences trade association 2025 report, which utilised a mix of official and commercial sources and estimated a total of 59 thousand employees (Lightcast, 2025). This report also estimated 154 thousand jobs in supporting industries in 2022, and these have been incorporated into the modelling.

Step 2. Trending baseline and counterfactual to 2040

For the counterfactual scenarios, experts did not reach a clear consensus, with views ranging from decline to modest improvement (level 1- level 3). To address this uncertainty, we created an adjusted scenario informed by complementary interviews that projected an inflation-adjusted trending baseline adjusted with a gradual decline aligned with ISTs' adoption in other countries.

- The recent trend data enabled a baseline to 2023 to be established. These values were inflated to 2030 using actual and estimated deflators published by the Office for Budget Responsibility published for each year to 2030 and then trended to 2040 at an estimated 1.95% per year. This is a conservative estimate and in line with longer term inflation trends (HM Treasury, 2025). This steady state scenario calculates what investment would be required to retain investment in the life sciences at current levels. Relative to this baseline four scenarios were modelled.
- The trending baseline was adjusted downward in line with expert estimates of ISTs' adoption. This models a scenario in which increased R&D investment-driven by ISTs' uptake flows into markets outside the UK in the absence of UK CEiRSI activities. In other words, it reflects the counterfactual situation where the UK does not capture the additional investment associated with ISTs' adoption because the enabling ecosystem is developed elsewhere.

Step 3. Assessing the impact of UK CEiRSI

To assess the impact of UK CEiRSI, we modelled the ability of the UK to retain a share of research investment in ISTs.

The survey results on global trends in ISTs' adoption were applied to the UK counterfactual to 2040. This enabled a calculation of ISTs' evolving share, by phase, of economic activity for the UK across the three dimensions: research investment, employment and employment value added. We defined these values as the "ISTs' adoption effect". The effectiveness of UK CEiRSI was calculated by associating different levels of impact with the share retained of the UK "ISTs' adoption effect". These were defined as followed (with results in Figures 7 and 8):

1. No impact — UK CEiRSI activities will have no effect. Assumption: UK captures 0% of the global IST adoption effect.
2. Minor impact — UK CEiRSI enables limited IST adoption, driving small increases in R&D investment and jobs. Assumption: UK captures 25% of the global IST adoption effect.
3. Medium impact — UK CEiRSI drives broader IST adoption, attracting moderate investment and workforce growth. Assumption: UK captures 50% of the global IST adoption effect.
4. Significant impact — UK CEiRSI positions the UK as a leader in IST adoption, fully leveraging NHS data and creating strong incentives for investment and jobs. Assumption: UK captures 75% of the global IST adoption effect.

Figure 7 Impact of scenarios on R&D investment £M

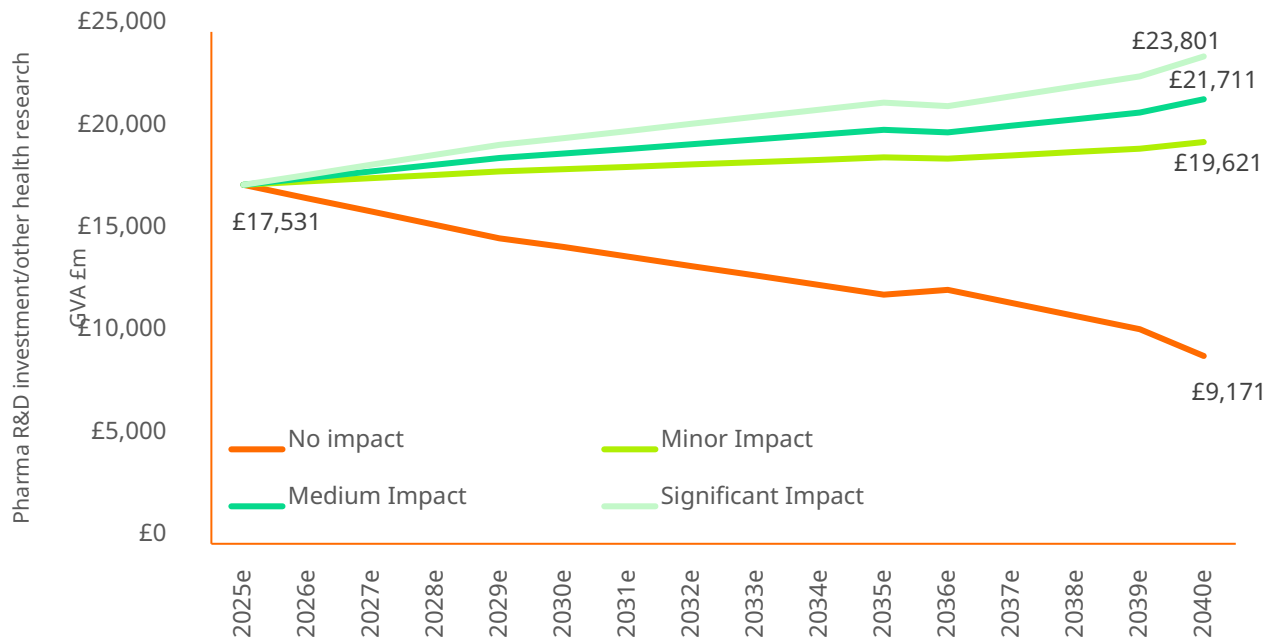
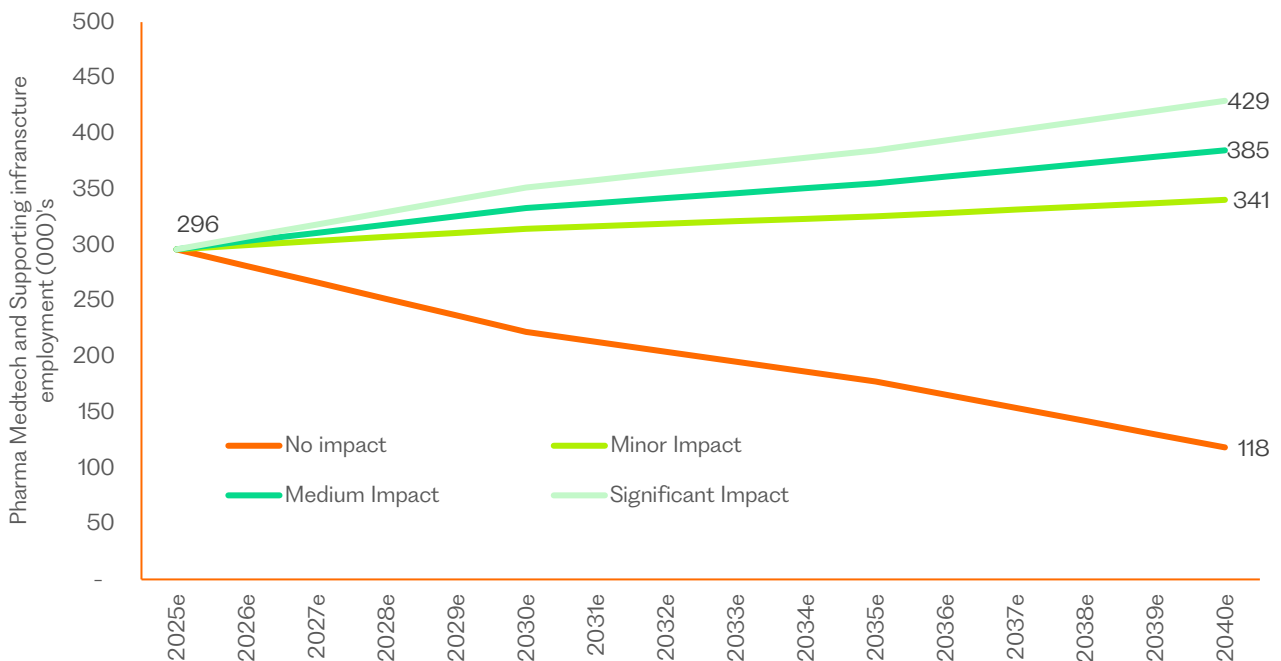


Figure 8 Impact of scenarios on employment (000's)



Appendix B: Expert Elicitation Survey

Introduction

In Silico technologies (ISTs) are computer-based techniques like computational modelling and simulation and AI techniques. They could transform pharmaceutical and medtech/device development by replacing traditional animal and human testing with digital modelling.

This survey aims to gather expert insights on the global adoption of IST in pharmaceutical and medtech/device R&D, and the expected impact of UK CEiRSI in enabling IST benefits in the UK.

It consists of four parts:

1. IST adoption in pharmaceutical R&D
2. IST adoption in medtech/device R&D
3. Impact of UK CEiRSI
4. Your professional background

The survey takes about 15 minutes to complete.

All questions are mandatory, but you to skip any questions you prefer not to answer. It is fully anonymous, but we would like you to tell us your professional background.

The results will be used for an economic impact assessment of UK CEiRSI.

Part 1: IST adoption in pharmaceutical R&D

Objective: Estimate the potential scale and impact of IST adoption in R&D processes in the (global) *pharmaceutical* industry [note: we will ask about the medtech industry in the next question]

Definitions and clarifications: We define adoption as the potential for IST to refine, reduce, and replace existing R&D processes and technologies in the industry. For example, the refinement of clinical study protocols; the supplementation of the existing evidence base to reduce the need for further studies; or the replacement of in vivo animal testing.

For this part of the survey, we ask that you consider the potential for IST to be adopted in R&D processes in the innovative pharmaceutical industry that operates **globally** (i.e. not UK-specific), **assuming that any prevailing barriers to adoption and implementation can be overcome**.

When we ask about clinical indications — we mean additional and new treatment populations reached, by the adoption of IST technology as outlined above, including in development of new technology or expansion in use of an existing technology.

1.1 IST Adoption by Phase and Year

How do you envisage the trajectory of adoption as the potential for IST to refine, reduce, and replace existing R&D processes and technologies in the industry? For example, an

answer of 50% would imply that IST would be used to refine, reduce and replace 50% of R&D activity across phases and time.

Please estimate the percentage of IST adoption:

DEVELOPMENT PHASE	BY 2030	BY 2035	BY 2040
DISCOVERY	_____ % adoption	_____ % adoption	_____ % adoption
PRECLINICAL	_____ % adoption	_____ % adoption	_____ % adoption

☐ Cannot / Prefer not to answer

1.2 Additional Clinical Indications Enabled

How do you envisage the trajectory of new clinical indications being altered by IST? Please estimate how many **additional** clinical indications you expect to be enabled because of IST. For example, an answer of 50% would imply that IST would enable 50% more indications to be developed on top of current development trajectories that do not encompass IST.

Please estimate the additional clinical indications enabled by IST over time.

Year	Estimated [%]
By 2030	%
By 2035	%
By 2040	%

☐ Cannot / Prefer not to answer

1.3 Time Efficiencies Expected

How do you envisage the R&D process to be shortened by IST? Please estimate the potential time savings for each development phase attributable to IST. For example, a response of 50% would imply that IST would reduce the duration of that development phase by half through increased efficiency.

What time efficiency gains do you expect from IST in each phase?

Development Phase	Estimated [%]
Discovery	
Preclinical	
Clinical	

☐ Cannot / Prefer not to answer

Part 2: IST adoption in medtech/device R&D

Objective: Estimate the potential scale and impact of IST adoption in R&D processes in the (global) **medtech** industry.

Definitions and clarifications: We define adoption as the potential for IST to refine, reduce, and replace existing R&D processes and technologies in the industry. For example, the refinement of clinical study protocols; the supplementation of the existing evidence base to reduce the need for further studies; or the replacement of in vivo animal testing.

For this part of the survey, we ask that you consider the potential for IST to be adopted in R&D processes in the innovative medtech industry that operates **globally** (i.e. not UK-specific), **assuming that any prevailing barriers to adoption and implementation can be overcome.**

When we ask about clinical indications — we mean additional and new treatment populations reached, by the adoption of IST technology as outlined above, including in development of new technology or expansion in use of an existing technology.

2.1 IST Adoption by Phase and Year

How do you envisage the trajectory of adoption as the potential for IST to refine, reduce, and replace existing R&D processes and technologies in the industry? For example, an answer of 50% would imply that IST be used to refine, reduce, and replace 50% of R&D activity across phases and time.

Please estimate the percentage of IST adoption:

DEVELOPMENT PHASE	BY 2030	BY 2035	BY 2040
DISCOVERY	_____ % adoption	_____ % adoption	_____ % adoption
PRECLINICAL	_____ % adoption	_____ % adoption	_____ % adoption

☐ Cannot / Prefer not to answer

2.2 Additional Clinical Indications Enabled

How do you envisage the trajectory of new clinical indications being altered by IST? Please estimate how many **additional** clinical indications you expect to be enabled because of IST. For example, an answer of 50% would imply that IST would enable 50% more indications to be developed on top of development trajectories that do not encompass IST.

Please estimate the additional clinical indications enabled by IST over time.

Year	Estimated [%]
By 2030	
By 2035	
By 2040	

☐ Cannot / Prefer not to answer

2.3 Time Efficiencies Expected

How do you envisage the R&D process to be shortened by IST? Please estimate the potential time savings for each development phase attributable to IST. For example, a response of 50% would imply that IST would reduce the duration of that development phase by half through increased efficiency.

What time efficiency gains do you expect from IST in each phase?

Development Phase	Estimated [%]
Discovery	
Preclinical	
Clinical	

☐ Cannot / Prefer not to answer

Part 3: Expected Impact of UK CEiRSI

Objective: Assess the expected impact of UK CEiRSI activities in mitigating barriers and leveraging potential IST benefits within the UK specifically.

UK CEiRSI will work on these activities **over the next 5 years**:

- Demonstrating IST's value in delivering safer, more effective, and equitable products.
- Orchestrating and bridging industry and regulation to overcome regulatory and legal hurdles.
- Driving development of a connected digital infrastructure to improve data availability and interoperability.
- Advancing in partnership the certification of in silico models including those developed by UK CEiRSI.
- Training and futureproofing the in-silico regulatory workforce in the UK to close critical skills gaps.
- Providing thought leadership for UK policy and global standards to foster acceptance and attract investment.

In the impact assessment, we assume that UK CEiRSI is positioned to mitigate four key barriers:

1. Regulatory acceptance — uncertainty around how regulators and certifiers will evaluate and approve IST-based evidence and models.
2. Skills gaps and workforce shortages — lack of trained professionals in modelling, simulation, and regulatory science.

3. NHS data availability and suitability — limited access to high-quality, interoperable health data for IST validation.
4. Industry investment — insufficient funding and incentives for companies to adopt IST at scale.

3.1 Regulatory Impact for pharmaceuticals and medtech

Focus: Policy and standards development to bridge industry and regulation and provide UK/global thought leadership.

3.1.1 If UK CEiRSI is NOT implemented, what do you believe will happen?

Please select the scenario that best reflects your view:

- ☐ **No meaningful regulatory change** — Regulatory acceptance or guidance on IST will not progress. The UK will fail to benefit from additional innovation in the UK with low-level spillover effects from global IST adoption.
- ☐ **Spillover benefits** — Regulatory acceptance or guidance on IST will not progress significantly in the UK. The UK will fail to benefit from additional innovation in the UK with **medium-level spillover effects** from global IST adoption and adopt some new indications.
- ☐ **International harmonisation benefits** — Regulatory acceptance or guidance on IST will improve through **international collaboration and harmonisation**, enabling the UK to benefit from global IST adoption and adopt new indications.

	NO MEANINGFUL CHANGE	SPILOVER BENEFITS	INTERNATIONAL HARMONISATION BENEFITS	CANNOT / PREFER NOT TO ANSWER
PHARMACEUTICAL INDICATIONS	☐	☐	☐	☐
MEDTECH INDICATIONS	☐	☐	☐	☐

3.1.2. What level of impact do you expect UK CEiRSI's activities to have on the regulatory environment and the number of new additional pharmaceutical and medtech indications being approved for use in the UK market as a result of IST?

- ☐ **No impact** — UK CEiRSI activities will have no effect
- ☐ **Minor impact** — Regulators acknowledge IST applications and promote use in “regulatory sandbox” initiatives. Developers test the system but do not prioritise the UK.
- ☐ **Medium impact** — Regulators establish clear validation standards for certain IST tools/models. Qualified models accepted as supportive evidence across multiple therapeutic areas. Developers actively seek UK approval.
- ☐ **Significant impact** — UK regulators become global leaders in IST acceptance, providing a clear regulatory framework and streamlined approval pathways. Qualified IST models systematically used in decision-making; developers prioritise UK submissions.

	NO IMPACT	MINOR IMPACT	MEDIUM IMPACT	SIGNIFICANT IMPACT	CANNOT / PREFER NOT TO ANSWER
PHARMACEUTICAL INDICATIONS	☐	☐	☐	☐	☐
MEDTECH INDICATIONS	☐	☐	☐	☐	☐

3.2 R&D investment and workforce development in pharmaceutical and medtech sectors

Focus: Contributing to an environment where the UK is able to attract investment in IST by the pharmaceutical and medtech industries. Ensuring that the UK pharma and medtech sectors are able to leverage the opportunities offered by IST and expand the workforce as a result.

3.2.1. If UK CEiRSI is NOT implemented, what do you believe will happen?

Please select the scenario that best reflects your view:

☐ **Decline in UK competitiveness:** The UK pharma and medtech industries fail to adapt to global R&D trends and IST adoption. UK industry R&D investment and jobs decline while global IST-adoption rises, leading to a significant erosion of UK competitiveness.

	DECLINE	STEADY STATE	MODEST IST BENEFITS REALISED THROUGH GLOBAL HARMONISATION	CANNOT / PREFER NOT TO ANSWER
PHARMACEUTICAL SECTOR	☐	☐	☐	☐
MEDTECH SECTOR	☐	☐	☐	☐

☐ **Steady state with limited spillover:** UK industry R&D investment and jobs stagnate, with no significant growth opportunities as IST becomes embedded in global R&D processes. Workforce development and investment in IST remain fragmented, with minimal UK-led initiatives. Some benefits are realised through global IST adoption.

☐ **Modest IST benefits realised through global harmonisation:** UK industry R&D investment and jobs grow in line with general UK economic trends. Workforce capabilities and investment improve modestly through international initiatives and harmonisation, but without a UK-led strategy, UK remains a follower rather than a leader.

3.2.2. What level of impact do you expect UK CEiRSI's activities to have on the R&D investment and number of employees of the pharmaceutical and medtech industries as a result of IST?

☐ **No impact** — UK CEiRSI activities will have no effect.

☐ **Minor impact** — UK CEiRSI enables limited IST adoption, driving small increases in R&D investment and jobs.

☐ **Medium impact** — UK CEiRSI drives broader IST adoption, attracting moderate investment and workforce growth.

☐ **Significant impact** — UK CEiRSI positions the UK as a leader in IST adoption, fully leveraging NHS data and creating strong incentives for investment and jobs.

	NO IMPACT	MINOR IMPACT	MEDIUM IMPACT	SIGNIFICANT IMPACT	CANNOT / PREFER NOT TO ANSWER
PHARMACEUTICAL SECTOR	☐	☐	☐	☐	☐
MEDTECH	☐	☐	☐	☐	☐

Part 4: About You

4.1. What sector do you most closely associate with (select all that apply)

- ☐ Medtech /device sector
- ☐ Pharmaceuticals sector
- ☐ Supporting sector: supply chain, enabling re-search, technologies, and services (e.g., simulation and modelling, software, computer and storage infrastructure, data, hubs and providers, contract research organisations, etc.)
- ☐ Other (specify)

4.2. What type of work do you do?

- ☐ Research & Development
- ☐ Manufacturing
- ☐ Regulatory
- ☐ Supply and distribution
- ☐ Access & Sales
- ☐ Other (specify)

4.3. What type of organisation do you work for?

- ☐ Healthcare providers (e.g., health and care professionals as defined by HCPC)
- ☐ Research organisation (e.g., High-er education institutions, independent research organisations, public sector research establishments, UKRI-funded Institutes/Units)
- ☐ Industry (Large, >250 employees)

- ☐ Industry (SME, <250 employees)
- ☐ Regulatory and notified bodies,
- ☐ Compliance Testing
- ☐ Government
- ☐ Foundations and funding bodies, re-search charities
- ☐ Trade association or other related sector body
- ☐ Patients and Public
- ☐ Other (describe)

4.4. What country are you based in?

- UK
- Other (free text):

4.5. Any further comments on the survey or the economic impact of in-silico trials (free text):

Appendix C: Survey results

Table 7 summarises the expert survey results on the expected percentage of new indications arising from IST and the proportion of indications anticipated to use IST in development.

Table 7 **Survey results: IST adoption and additional indications**

	PHARMA	MEDTECH
Additional indications expected by 2030	10% [3.95% - 16.05%]	20% [13.55% - 26.45%]
Additional indications expected by 2035	23% [15.32% - 29.68%]	25% [17.44% - 32.56%]
Additional indications expected by 2040	43% [33.96% - 51.04%]	40% [30.64% - 49.36%]
Proportion of indications adopting IST in discovery in 2030	35% [28.57% - 41.43%]	28% [19.76% - 35.24%]
Proportion of indications adopting IST in discovery in 2035	50% [43.57% - 56.43%]	50% [42.05% - 57.95%]
Proportion of indications adopting IST in discovery in 2040	70% [63.11% - 76.89%]	68% [59.35% - 75.65%]
Proportion of indications adopting IST in the preclinical phase in 2030	30% [23.93% - 36.07%]	23% [15.79% - 29.21%]
Proportion of indications adopting IST in the preclinical phase in 2035	40% [33.49% - 46.51%]	40% [33.09% - 46.91%]
Proportion of indications adopting IST in the preclinical phase in 2040	60% [53.15% - 66.85%]	50% [42.48% - 57.52%]
Proportion of indications adopting IST in the clinical phase in 2030	10% [3.16% - 16.84%]	15% [8.45% - 21.55%]

Proportion of indications adopting IST in the clinical phase in 2035	25% [17.85% - 32.15%]	23% [15.40% - 29.60%]
Proportion of indications adopting IST in the clinical phase in 2040	40% [32.14% - 47.86%]	38% [29.48% - 45.52%]
Predicted time efficiencies in discovery	50% [42.36% - 57.64%]	30% [21.72% - 37.61%]
Predicted time efficiencies in the preclinical phase	40% [33.20% - 46.80%]	40% [33.16% - 46.84%]
Predicted time efficiencies in the clinical phase	40% [32.05% - 47.95%]	30% [21.64% - 38.36%]

Table 8 indicates the distribution of respondents selecting each hypothetical baseline scenario — i.e. what would happen to the UK if UK CEIRSI did not exist.

Table 8

Survey results: Baseline scenarios

AREA OF IMPACT	BASELINE SCENARIOS (I.E., PREDICTED OUTCOME IF UK CEIRSI DID NOT EXIST)	PROPORTION OF RESPONDENTS CHOOSING EACH BASELINE SCENARIO	
		Pharma	MedTech
Regulatory impact	No meaningful regulatory change	24%	31%
	Spillover benefits	40%	41%
	International harmonisation benefits	36%	28%
	N	25	32
R&D investment and	Decline	37%	28%
	Steady state	22%	28%

workforce impact	Modest IST benefits realised through global harmonisation	41%	44%
	N	27	32

Table 9 indicates the distribution of respondents selecting each hypothetical impact scenario for UK CEiRSI, where each scenario describes the impact that UK CEiRSI would have, relative to the baseline indicated in Table 8.

Table 9

Survey results: UK CEiRSI impact scenarios

AREA OF IMPACT	IMPACT SCENARIOS (I.E., PREDICTED OUTCOME AS A RESULT OF UK CEiRSI)	PROPORTION OF RESPONDENTS CHOOSING EACH IMPACT SCENARIO	
		Pharma	MedTech
Regulatory impact	No impact	0%	3%
	Minor impact	22%	12%
	Medium impact	44%	41%
	Significant impact	33%	44%
	N	27	34
R&D investment and workforce impact	No impact	8%	12%
	Minor impact	23%	12%
	Medium impact	31%	42%
	Significant impact	38%	33%
	N	26	33

Generally, the scenario selected by the majority of respondents was used as the model input for both the baseline and impact scenarios. Where no clear majority emerged, we selected the scenario most frequently chosen across both sectors. For example, in the regulatory impact for medtech, responses were split between a “significant” and a “medium” impact of UK CEiRSI; in this case, we applied the “medium” impact, as it was favoured by respondents when aggregating answers across both sectors.

Moreover, it should be noted that, while 46 individuals participated in the survey, the number of responses varies by question ($N < 46$) because respondents were able to skip questions. All available responses were used, and respondents' answers were included wherever provided.

Table 10 **Survey respondent demographic information**

What sector do you most closely associate with?	Sector	Percentage of total respondents selecting each sector
	Medical device sector	52%
	Pharmaceutical sector	15%
	Supporting sector: supply chain, enabling research, technologies and services	17%
	Other	7%
What type of work do you do?	Work type	Percentage of total respondents selecting each type of work
	Research and development	48%
	Manufacturing	9%
	Regulatory	28%
	Supply and distribution	0%
	Access and sales	7%
	Other	13%
What type of organisation do you work for?	Organisation type	Percentage of total respondents selecting each type of organisation
	Healthcare providers (e.g., health and care professionals as defined by HCPC)	7%
	Research organisation (e.g., High-er education institutions, independent research organisations, public sector research establishments, UKRI-funded Institutes/Units)	30%
	Industry (Large, >250 employees)	17%
	Industry (SME, <250 employees)	24%
	Regulatory and notified bodies	4%
	Compliance Testing	0%
	Government	4%
	Foundations and funding bodies, research charities	4%
	Trade association or other related sector body	4%
	Patients and Public	0%
	Other (please specify)	7%
What country are you based in?	Country	Percentage of total respondents selecting each country

UK	48%
USA	15%
Australia	2%
Taiwan	2%
Switzerland	2%
Netherlands	2%

*Note that the percentages do not sum to 100% because not all respondents answered each question, and respondents could select multiple answers.

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