

Imperial College
London

NHS data:
Maximising its impact for all

INSTITUTE OF
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INNOVATION



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Foreword

The UK is the best-placed large economy in the world to use its health data assets for transformative health, scientific and economic impact. Good progress is being made and all levels of society – including the government, the NHS, academia, charities, and industry – are committed to this agenda. **The COVID-19 pandemic highlighted the rapid translation of huge datasets to actionable treatments for millions of people around the world.**

Over the past five years, there has been a significant commitment from academics, policy makers, industry, NHS leaders and, most of all, the public to ensure that NHS data can be used in the most effective way possible. There have been significant changes at policy level to ensure a comprehensive strategy across the health and care system. However, more needs to be done to enable the UK to make the most of its advantages, with concomitant benefits for patients, the NHS, the research and development (R&D) community and the innovation economy.

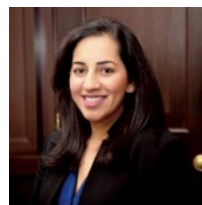
This report provides a broad overview of the UK's health data policy landscape. More specifically, it identifies strategic or technical recommendations to move towards developing a health data policy ecosystem designed so that value, either clinical, societal or financial, is more readily extracted from patient data. It provides a post COVID-19 update to the Institute of Global Health Innovation (IGHI) 2020 report *'NHS Data: Maximising its impact on the health and wealth of the UK'*.

Our vision is to provide the public with better, more efficient care, driven by responsible innovation that is underpinned by the UK's extensive health data. We have tried to answer some of the essential questions this enterprise poses but acknowledge that there

are many questions that need further research and inquiry. Our main message is this: the goal of any strategy must be to deliver benefits to people in the UK. Benefits to other parties will come as a corollary and are important considerations for the strategy.

We hope that this paper acts as a catalyst on how the UK's health data can be best used to improve the health and wealth of the entire nation. We hope that this work will not only resonate in the UK, but also help governments and health systems internationally to implement strategies to maximise the benefits of health data for their citizens.

We would like to thank the many outstanding contributors who have given their time and energy so generously to this work. We look forward to their continued contribution as we move forward.



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Introduction

For decades the NHS has collected routine data on millions of patients. In a world where big data has increasing value, the UK has an opportunity to truly leverage its health data assets to benefit people in the UK and across the world – both through better health and through the generation of more research and development and economic growth.

Achieving a step-change in the nation's health outcomes requires a broad range of measures. If healthcare data is used effectively and in a way which fosters public trust, the value it brings back to patients and the public is huge, with potential benefits including:

- **Improved patient care:** Increasing use of innovative treatments and technologies allows for better patient outcomes, personalisation of care, safety and efficacy of medications and devices and in particular novel technologies such as AI for advanced patient care.¹
- **Population health:** Health data helps better understand diseases and develop innovative treatments.² With larger population sets, trends are easier to observe and decode. In addition, with increasing machine learning methods, algorithms need to be trained on larger datasets.
- **Improved operational efficiency:** Better data can allow the NHS to develop more efficient services by understanding where increased resource allocation is required and what improvements can be implemented.³
- **Improved research and clinical trials:** Better access to data will allow more robust research and clinical trials to take place, resulting in better drugs and innovations for patients.
- **Economic growth:** Creating jobs and economic growth by enabling the life sciences and technology industries to develop data-driven solutions, technologies, and therapeutic interventions that directly benefit people in the UK.
- **Financial return:** Providing direct financial benefit for the NHS through appropriate licensing and value-sharing agreements with the right partners.

The UK is well placed to capture the opportunity of using healthcare data as an asset. We have a health

service that is the most trusted institution in the UK. There is a strong record of innovation in health and life sciences and a vibrant technology industry supported by world-leading universities.

This was seen first-hand in the response to the COVID-19 pandemic. Remarkable results were achieved as a result of bringing together government and multiple sectors of the economy resulting in real world impact in the form of a vaccine against the virus. Securely accessible data was used to accelerate the research process in the development of treatments. In the UK, the benefits of opting into the Randomised Evaluation of COVID-19 Therapy (RECOVERY) Trial, including the utility of using dexamethasone, which as saved an estimated one million lives globally, were rapidly implemented and visible to patients and the public. The NHS also relied on digital technologies, to ensure continuing access to healthcare throughout the pandemic, and saw significant and tangible benefits from being able to access and analyse vast amounts of healthcare data.

However, there is a changing healthcare landscape, with the NHS under more pressure than ever with increasing waiting lists, worsening outcomes and stretched finances. We are faced with an economic reality that we did not expect, and despite the additional funding allocated to the NHS, there are still significant challenges.⁴

Pressure on the NHS has been compounded by the significant backlog of care as a result of the COVID-19 pandemic. The waiting list for hospital-based elective care rose to a record of 7.2 million in January 2023.⁵

Over the past three years, political events, major public health events and NHS reorganisations have impacted the way health data is shared in the UK.

Acting together, they influence the policy landscape within this space, as well as public expectations concerning the use of personal health and social care data.

The public saw tangible benefits of the use of their data resulting in vaccines and treatments during the COVID-19 pandemic. To maintain these solid foundations, patients and the public must be consulted effectively at all stages of any process to maintain transparency and communication. Public benefit must also be central in all NHS data partnerships. A consistent call from citizens is

that public benefit must outweigh profit.⁶ Any lack of transparency fuels suspicion of the NHS and damages public trust as we have seen through the now indefinitely delayed roll out of the GP Data for Planning & Research (GPDPR) programme.

The UK's exit from the EU has created some uncertainty around data sharing across borders.⁷

The UK has absorbed the General Data Protection Regulation (GDPR) into UK law and passed two adequacy agreements to ensure data can flow freely between the UK and EU member states.⁸ The UK takes part in the EU Joint Action towards a health data ecosystem so data can be shared across future Trusted Research Environments (TREs) with shared data standards for research and innovation purposes.⁹

NHS Reorganisation

The NHS in England has undergone reorganisation at both national and local level. All areas in the English NHS are now part of one of 42 integrated care systems (ICS), replacing clinical commissioning groups (CCGs).

The Department of Health and Social Care (DHSC) has published the Hewitt Review - an assessment of the governance of integrated care systems.¹⁰ ICSs were made statutory in July 2022, with the aim of delivering better population health and joined up support for patients by bringing together health and care services provided by the NHS, local authorities and third sector organisations.¹¹ ICSs have been provided with a common vision for digital and data transformation, through the 'What Good Looks Like', 'Who Pays for What' and 'Who Does What' frameworks,¹²⁻¹⁴ to promote collaboration and standardisation at a system-wide level.

There has also been a significant shift in the NHS arm's length body landscape. NHS X, NHS Digital and Health Education England (HEE) have merged to become part of NHS England following recommendations from the Wade-Gery review.¹⁵

NHS X had set up the Centre for Improving Data Collaboration (CIDC) to act as a centre of expertise for frontline organisations when dealing with data driven collaborations. CIDC, along with the remaining functions of NHS X and NHS Digital are now part of the Transformation Directorate at NHS England. It is envisaged that the merger will improve and align digital transformation across the health and social care sector. However, the merger will result in a 30-

40% reduction in staff numbers by 2023/24, with concerns that this may impact the delivery of key areas of work.¹⁶

Several notable policy papers in the health data space have been published in the past two years. **The Goldacre review 'Better, Broader, Safer: Using Health Data for Research and Analysis'** addresses the safer use of patient data to drive forward innovation and lays focus on the infrastructure required for improved data resources for research, the need for secure and efficient platforms and the requirements for a skilled analytics workforce to support this work.¹⁷

'Data Saves Lives: reshaping health and social care with data'¹⁸ was published in full by the government in June 2022. The paper outlines a new strategy on supporting transformation across health and care using data and focuses on key commitments including funding for secure data environments and giving people better access to their own data.

Opportunities

The current data landscape across the NHS is extremely fragmented. This results in increasing costs, a lack of transparency around access and a reduction in analytic quality and efficiency. To fully maximise the use of health and care data, we need better infrastructure in place. **The move to Secure Data Environments (SDE) will help correct this and allow innovation to take place at a more rapid pace.** SDEs are data storage and access platforms upholding the highest levels of security and privacy. Analytics and research are done within the SDE; no raw data can be extracted and processed data which is extracted must go through strict review committees. **There is the aspiration that a move to SDEs will overcome issues of transparency, public mistrust and data privacy and security.** This is a once in a generation opportunity to improve the structure and quality of health and social care data in England and it is imperative to get this right.

To ensure that solid foundations are created in this complex arena of data infrastructure, patients and the public must be consulted effectively at all stages of any process to understand where the red lines are before embedding them into practice. Until now, too much consultation has been asking for forgiveness, not permission. Unless that changes, understandable public scepticism about who benefits from such health data sharing initiatives will potentially scupper one of the UK's most exciting health and economic opportunities.

Since 2020 there has been substantial national investment to improve health data quality and infrastructure. Investments have included £2.1 billion for NHS IT upgrades, £260 million to build NHS-led SDEs to develop advanced therapies, with £60 million ringfenced to expand the manufacturing arm of the life sciences sector [X[ON7]]¹³, and a £480 million tender to procure an NHS FDP. [X[ON8]]. These investments support the Life Sciences Vision (2021), a blueprint to develop an environment where industry can engage in, for the benefit of the NHS and patients, which proved vital during the COVID-19 pandemic.

The UK's life sciences sector is one of the dominant knowledge-based economic sectors in the UK.

The third iteration of the life sciences strategy, the ten-year Life Sciences Vision¹¹ puts forward a plan to allow the sector to prosper and tackle causes of death and illnesses. Building upon previous efforts to develop the life sciences strategy and subsequent deals, the current vision reframes the focus towards missions, in line with the future of UK government funded research based around mission-driven innovation.¹²

There has been a stocktake of the UK's R&D capabilities with a strong conclusion there has been chronic underinvestment in R&D.

This has been compounded by reduced productivity, regional inequities and poor infrastructure. The UK, and the NHS in particular, has a patchy record when it comes to innovation. As an economy we are very good at providing a platform for clinical trials and early-stage applications of technology, but much less good at taking successful interventions to scale. There is the strategic importance of long term R&D investment for the life sciences sector by the government to ensure the UK remains competitive globally. As a move towards this, the Department for Science, Innovation and Technology (DSIT) was created as part of a government reshuffle in February 2023.

To support this ambition of having a thriving life sciences sector there needs to be a more collaborative approach to working with commercial companies. Public benefit must be central in all NHS data partnerships and the NHS should receive fair value for the use of its data whether financial or in kind. A consistent call from citizens is that public benefit must outweigh profit.³⁵ This includes both direct and indirect impact such as new medicines and improved diagnostics, as well as increasing administrative efficiency respectively. Our

understanding of the public's opinion concerning what would constitute public benefit is growing, but more work needs to be done.

Areas of action

Based on the research conducted for the preceding [white paper](#),²⁴ six areas of action were identified as being key to maximise the impact of NHS data for the health and wealth of the nation:

1. Public Opinion and Engagement
2. Data Governance and Legal Frameworks
3. Data Quality and Infrastructure
4. Capabilities
5. Investment
6. Value Sharing

For each area, we have analysed policy updates since the previous white paper, interviewed a range of expert stakeholders in the field and held a roundtable discussion. All these activities have helped inform the contents of this paper and we have formulated recommendations for action.

UK or England?

Some of the legal and research landscape is shared across the nations of the UK. Responsibility for running the NHS is devolved, however, and we have focused on the situation in England.

1. Public Opinion and Engagement

Summary

- The NHS remains one of the most trusted public bodies in the UK, and when considering the sharing of patient data, care must be taken to avoid damaging this trust.
- The response to COVID-19 showed the benefits of data sharing and has created a more receptive public environment.
- However, the failed roll out of the GP Database for Planning and Research shows that clearer communication is still needed, along with genuine engagement with the public's concerns.
- Simplifying the opt-out process so that planning is not included and encouraging people to opt back in could significantly improve the quality of NHS Data.
- The public should remain central to the use of NHS Data as part of Data Advisory Boards for each ICS.

Data for research and innovation in healthcare is complex; one of the critical pillars of doing this properly is to uphold the trust that exists between the NHS and the public. Any data sharing agreements entered into by NHS organisations must primarily demonstrate real benefit for citizens and at the same time fully adhere to all applicable legal, regulatory, privacy and security obligations. Public trust is paramount in any partnership, and it is non-negotiable. Patient and public participation exercises demonstrate support from the public but there are red lines – people are broadly supportive of data-sharing when public benefit is clear and where the NHS is getting fair value for data.

There are existing structures in place providing safeguards to help maintain trust. The Government established the National Data Guardian (NDG) in 2014, as an independent voice raising the concerns and interests of the public to ensure patient data is only shared when appropriate.²⁵ A report published by the NDG last year created new guidance to aid organisations in conducting more consistent public benefit evaluations. It also featured public views on the uses of healthcare data, including the need for transparency in the decision-making process to uphold trust. The public expects transparency through the entire lifecycle of data sharing including secondary uses.²⁶ There should also be ongoing evaluation to ensure any unintended risks can be identified downstream and any learning shared.²⁶

The public benefits of NHS data sharing were demonstrated during the COVID-19 pandemic. For instance, the RECOVERY Trial,²⁷ using the NHS DigiTrials TRE, found that the steroid dexamethasone reduced deaths in hospitalised patients with COVID-19. As a result, COVID-19 has led to an increase in support for data sharing. This has been shown by both quantitative surveys and qualitative engagement. For instance, Citizens Juries on three COVID-19 data initiatives - OpenSAFELY, the NHS COVID-19 Data Store and Platform and Summary Care Record Additional Information all revealed net support for the data sharing.²⁸

The use of the NHS App to prove vaccination status helped drive a big expansion in users, with over 30 million people having signed up to access parts of their own medical record.²⁹ This is an extremely positive step forward for patients to have oversight and access to their own data. However, an evaluation of government progress on digitising the NHS states that the focus needs to move beyond the numbers using the NHS App to provide a compelling and

integrated service through the app.³⁰ It currently only displays a very limited amount of a person's medical record and links out to a highly fragmented landscape of GP-held records, shared care records and other patient portals. The Hewitt Review encourages the NHS App to be used as a platform for innovation and extending the open source approach to approved developers.¹⁰

Whilst the public have become more receptive to sharing data over the last three years, initiatives in this space need careful handling to avoid the risk of undermining, or even reversing these gains. The obvious example of this is the failed roll out of the GP Data for Planning & Research (GPDPR) programme/scheme.³¹ NHS Digital originally announced the launch of this data service in 2021. The aim of GPDPR was to give researchers and third-party organisations access to pseudonymised patient data to aid healthcare planning and research.³² However, significant concerns on the lack of public engagement and information led to this being pushed back and now delayed indefinitely. The collateral damage resulted in more than a million patients opting out of sharing their data and lack of trust in the system.³³

The lack of engagement and communication with the public around the roll out of GPDPR was acknowledged in the 'Data Saves Lives' white paper¹⁸ and a set of principles were set out to ensure that the health and care system would in future demonstrate its role as a trustworthy data guardian. These five principles include: securing data; transparency on how data is used; ensuring fair terms from data partnerships; listening to public opinion on how data is used and improving access for individuals to their own health data.¹⁸

There needs to be a considerable programme of public engagement to broaden understanding of views on a range of data sharing issues.¹⁸ Our understanding of the public's opinion concerning what would constitute public benefit is growing, but more work needs to be done. Public deliberation exercises have demonstrated that, to unpick what would constitute public benefit, end goals of data use are seen as crucial.³⁴ These include improved health outcomes, reduced health inequities and independent living. Less is understood about secondary benefits of health data use such as the development of new drugs and technologies and improved efficiency of services.

Despite most of the UK public being in support of the sharing of patient data, there is still mistrust

towards sharing with the commercial sector. The potential misuse or manipulation of data to benefit vested interests and agendas is seen as a threat with the potential to undermine trust. A particular concern for the public is commercial gain when perceived as counter to public benefit.³⁵ Public deliberation exercises repeatedly demonstrate that the public believe the bar to access data should be higher for commercial companies. This suggests industry should be trying to balance promoting the public benefit aspects of their work alongside commercial gains.³⁶

We still don't know what large segments of the UK population think about health data usage and sharing. Black and South Asian communities have demonstrated more complex concerns when it comes to the sharing of their personal health and care data.³⁷ Many inherently have low levels of trust in the NHS and are concerned about data privacy and low expectations concerning improved health outcomes for their communities with increased data sharing.³⁷ Some of the issues which have arisen are connected to their experiences with the health service as a whole, as many cite examples of racial discrimination and bias.

CASE STUDY: Imperial College Health Partners Public Deliberation

Imperial College Health Partners (IHP) hosts the Discover-NOW health data research hub for real world evidence.⁴⁰ It provides access to one of Europe's largest deidentified linked health and care datasets within a Trusted Research Environment (TRE). Alongside this, and in partnership with Ipsos UK, IHP has designed and delivered a number of public deliberation and engagement activities to understand public attitudes to health data sharing and use. This work started in 2020 with the OneLondon Citizens' Summit – a large scale deliberation with 100 Londoners on the uses of health and care data.³⁴ One of the topics explored in this four day deliberation was public expectations on how they should be involved on an ongoing basis in how their health and care data is used for a range of purposes. One of the recommendations was the formation of a Citizen Advisory Group (CAG), reflective of the broader population, that would form part of formal governance structures and aid future decision making. Discover-NOW since established a standing CAG to support the Hub's Board in ongoing decision making and policy formation. A series of 'mini' deliberative events were held with CAG members exploring topics such as access models and controls, commercial principles and value exchange, in particular how the value of linked data should be harnessed and distributed. Different value

exchange models (see Section 6) were presented to the participants and, although they did not reach a consensus over a single model, they formed a set of conditions which should be considered when future contractual agreements are made:

1. Access to data should be controlled and not be exclusive. Decisions about data access should be made by a independent group including (but not only) citizens.
2. Investment should be made in health and care organisations developing commercial skills so that the NHS gets a fair deal.
3. A range of benefits should be considered without limiting to financial benefits, though it is important that financial benefits are realised to (as a minimum) cover the costs of collecting and storing data.
4. The charging model for access should be tiered to ensure fairness and consistency, and importantly inclusiveness in research activities.

The deliberation demonstrated that any surplus should be allocated to the areas where there is potential for the greatest impact. In deciding where surplus should go (based on the principle of greatest impact), there must be a robust and transparent decision making process, which involves patients and the public. In allocating surplus, the driving factor for how the funds will be used should be the ability to address local issues (from where the data has derived).

It is critical to ensure wide-ranging public engagement considers public benefit cases, the role of the commercial sector, and the experience of minority groups. The NHS should strive to ensure engagement activities are genuine co-production and may follow successful models pioneered by IGHI such as the Data Can of Worms public outreach project.³⁸ Alongside this two-way engagement, there is a strong case for a campaign on the benefits of data sharing. This would require a clear narrative and explanation for how and why patient data is used. Such a narrative could draw on COVID-19 case studies to make the case for data sharing. The aim would be to encourage some of the 3.3 million people (5.36% of those registered with a GP practice)³⁹ with a national data opt-out to opt back in once they are reassured by the information presented to them. In the longer term, given that public concern centres on commercial companies accessing NHS data, it would make sense to limit the opt-out to research activities, rather than the current situation of research *and* planning. Unnecessary planning opt-outs hamper the ability of ICSs to do population health management, for instance. This is a longer-term solution as it will require legislative change and public deliberation.

To ensure trust and transparency, oversight and good governance are required. A final way of ensuring public engagement in the use of NHS Data would be to have a data advisory board for each ICS. This advisory board could be made up of the public, frontline staff and charities. They would provide advice on data sharing and usage within the ICS to make it easier for the public to understand.

Recommendations

Public Engagement and Deliberation

- 1.1** NHS England and DHSC need to make progress on the principles and commitments that were set out in *Data Saves Lives*. The best way to do this would be extensive, two-way, public engagement to fill gaps in our knowledge on what the public views as acceptable data sharing. This should happen during 2023.
- 1.2** Any public deliberation exercises should be done both at national level and regionally. National level exercises will allow to provide clarification on the appropriate use of data across the UK. A more local approach will allow a nuanced understanding of variation in thought across the population and ensure better representation.
- 1.3** NHS England and the DHSC need to ensure that an effective budget is in place to ensure that public deliberation can take place across the country and that any programme launch needs to be facilitated with clear communications for better patient and public understanding.

Reducing Opt-Outs

- 1.4** A clear narrative of why and how patient data is being used should be developed. This narrative could then be used in public awareness campaigns to outline benefits as well as risks of data sharing, with the goal of people opting back into sharing for research and planning purposes.
- 1.5** In the longer-term, when there is an opportunity to amend legislation, there should be further public deliberation exercises to review the opt-out process and if this should be limited to opting out of research and not for planning purposes.

Public Involvement in Governance

- 1.6** Data advisory boards should be established in each ICS to provide a sense check on the appropriate use of data within ICSs, and ensure the public remain central to how NHS data is used.

2.

Data Governance and Legal Frameworks

Summary

- The main policy changes since the 2020 report have been changes in legal frameworks as a result of Brexit and the COVID-19 pandemic.
- GDPR has been incorporated into UK domestic law so UK GDPR now sits alongside the Data Protection Act 2018.
- Two adequacy decisions have been passed which determine UK data protection regulations to be similar enough to standards set in the EU, so data can continue to flow across borders.
- Due to the COVID-19 pandemic, the UK government released the Control of Patient Information (COPI) notice, which allowed UK patient data to be accessible to researchers for its use to find an appropriate response to mitigate the spread of the disease.

As a result of Brexit, GDPR has been incorporated into UK domestic law so UK GDPR now forms part of the Data Protection Act 2018.⁴¹ Data transfers to and from EU member states have been the subject of two ‘adequacy decisions’. Adequacy decisions are a vehicle through which the EU decides whether a country outside the European Economic Area (EEA) has adequate data protection laws to permit the sharing of data across borders without additional safeguards. Post-Brexit, the EU GDPR has been incorporated into UK domestic law so that now UK GDPR forms part of the Data Protection Act 2018. Given that the Data Protection Act 2018 is based on the EU GDPR and the Law Enforcement Directive (LED), they are similar enough to EU law that a data adequacy agreement has been formally recognised.⁴²

The result is that personal data can continue to be transferred between Europe and the UK without additional safeguards. This is useful for public health monitoring as well as being less burdensome for the sharing of data more generally, which can be material for the operations of many multinational technology and biopharmaceutical companies. For the first time, however, a ‘sunset clause’ has been included which allows the EU to review its decision every four years,⁴³ recognising that the EU and UK data protection laws may diverge over time. The UK’s commitment to remain party to the European Convention of Human Rights⁴⁴ and to Convention 108, meaning the UK remains a member of the European ‘privacy family’, has assisted with these adequacy decisions.

The UK legal framework governing the use of personal confidential data in healthcare has been under scrutiny due to the EU withdrawal agreement. This legal framework is being reviewed to ensure UK data protection laws are still adequate. Where previously the European Data Protection Board (EDPB), a body with a mandate to ensure consistent application of data protection laws, and the European Data Protection Supervisor (EDPS), a body charged with investigating and administering sanctions in cases of complaints concerning data usage, held legal standing in the UK, this has now been discontinued.⁴⁵

In the longer-term, divergence between datasets may cause issues for pan-European data analysis. The UK will not remain integrated within the Eurostat system, the EU’s statistical office, which may lead to reduced ability to collect and share comparable UK/EU data over time.⁴⁶ The COVID-19 pandemic illustrates the

importance of comparable data; the European Centre for Disease Prevention and Control was able to share data to aid monitoring the spread of the disease and its variants.⁴⁷ Divergence in the metrics for datasets makes their interaction and comparison more difficult. Should the UK dataset differ in its standards too widely from international partners, its value may diminish.

Integrated care systems

New ICSs have legal duties related to research, including data as part of research, at both Integrated Care Board and provider levels. In March 2023, NHS England set out guidance for integrated care systems focused on legal duties, including how these duties are relevant when engaging with industry in commercial research.⁴⁸ Legal duties include facilitating and promoting research and using evidence generated in the health service. Statutory guidance is also available to aid ICSs and their partner providers to meet the legal duty to work with people and communities to reduce health inequalities.

The UK Department for Culture, Media and Sport ran a consultation ‘Data: a new direction’ on suggested reforms of the data protection policy landscape with lessons learnt from the COVID-19 pandemic.⁵² Post-Brexit, the UK is able to redraw its data regulation framework recognising some changes may cause an issue. Signalling the start of the second mission within the National Data Strategy,⁵² the aim is for policies to become pro-growth and friendly to innovation. Industry has been responsive to developing trustworthiness in this regard. For example, the Association of the British Pharmaceutical Industry developed a new set of principles for members to follow when using NHS data for research purposes.⁵³

The provision of open access data was at the forefront of the effort to innovate and drive research through the COVID-19 pandemic, enabling the scientific community greater access to data to advance knowledge.⁵⁴ Using this experience as a catalyst, the government hopes it will use the learnings to help form a basis for future data adequacy agreements with other trading partners.

There is an industry ask for the development of standardised documentation and guidelines to use

as part of data value agreements, including how to navigate GDPR, medical confidentiality, and how to streamline approval from the Confidentiality Advisory Group (CAG). This will further reduce barriers to responsible data sharing between the NHS and industry.

CASE STUDY: Control of patient information (COPI)

The COVID-19 pandemic led to changes in data governance previously unseen, due to the release of the COPI notice. As the pandemic was declared a national emergency, restrictions on the processing of Confidential Patient Information without patient consent were temporarily lifted from March 2020 till June 2022, and extended throughout this period.⁴⁹

The UK government decided to allow patient data to be used for COVID-19 related research, accelerating the research process to understand how people were contracting the virus, as well as to explore effective treatments. Key research projects have emerged because of the release of the COPI notice, including mega-clinical trials such as the RECOVERY Trial, the world's largest clinical trial into treatments for COVID-19. Public opinion was overwhelmingly positive, with a large number of patients agreeing to take part. By December 2020 this figure stood at 21,000⁵⁰ but by December 2021 this had increased to 45,700 across 189 hospital sites.

During the pandemic, the use of COPI notices also benefited direct patient care through access

to summary care records for patients and the single national data sharing agreement between GP practices so that they could share patient record info with each other (and with urgent care) via the GP-Connect APIs, whereas pre-Covid, a bilateral data sharing agreement needed to be in place.⁵¹

The benefits arising from the COPI notice approach have led to some commentators arguing for their continued use to aid researchers working in both the public and commercial sectors, and for patients and the NHS. During the pandemic, the COPI mechanism was used as the most efficient way to communicate the changes to GP Connect and Summary Care Record Additional Information, and given the benefits to patients and healthcare professionals, changes have continued beyond the end of the COPI notice.⁵¹

In contrast, others wish to revert to patient data use as it was prior to the pandemic. Given the opposing viewpoints, undertaking public consultation on the topic of whether COPI could be applied to the great healthcare challenges outlined in the life sciences strategy (e.g., cancer, cardiovascular disease, respiratory disease),²¹ offers an opportunity to determine if there is public support for use in a non-emergency situation.

Recommendations

Global data regulations

2.1 The UK's exit from the European Union requires evidence of better delivery of new data protection regulations as well as clarity. More guidance and resources for businesses on new legal requirements should be developed to aid the navigation of regulations and adherence to them.

2.2 Brexit has created layers of increasingly complex regulation which is becoming difficult to understand in the global context. The set-up of an entity which connects all data regulations globally, with knowledge of how they differ to UK law, would add value in providing clarity and increasing confidence across stakeholder groups including the NHS and industry.

Data use for research

2.3 The use of COPI notices resulted in positive gains during the COVID-19 pandemic and should be used again in future pandemic/emergency situations with public support. Issuing the COPI notice showed the potential benefits that data can deliver, which could be extended beyond pandemics. Public deliberation exercises should be considered nationally to review if there is significant backing to extend the use of COPI notices to other disease areas such as dementia or whether there should be reform of CAG section 251 on uses of data.

2.4 NHS England (CIDC) should work towards the development of standardised documentation and guidelines to use as part of data value agreements, including on how to navigate GDPR, medical confidentiality, and how to streamline approval from the Confidentiality Advisory Group.

3.

Data Quality and Infrastructure

Summary

- The NHS has gone through a period of reorganisation centrally with NHS Digital, NHS X and Health Education England being merged with NHS England. There has also been the creation of 42 Integrated Care Systems (ICSs), replacing Clinical Commissioning Groups.
- Secure Data Environments (SDEs) are a key part of the NHS's data strategy and have been championed by several recent policy reports including 'Data Saves Lives', the Goldacre Review and the life sciences strategy.
- SDEs address the safer use of patient data to drive forward innovation in the NHS and improve health and social care services.
- NHS England has opened a tender process to procure a federated data platform (FDP) to be announced later this year.

National infrastructure and landscape

The NHS in England is currently going through another period of reorganisation. NHS Digital, NHS X and Health Education England have now merged to become part of NHS England. The functions of NHS Digital and NHS X (including the Centre of Improving Data Collaboration) are under the umbrella of the transformation directorate at NHS England. Concurrently in July 2022, the Health and Care Act formalised 42 ICSs across England as legal entities. ICSs bring together NHS organisations, local authorities and others to collectively plan services with the aim of improving health and reducing inequalities across geographical areas.^{55,56} ICSs population coverage varies, with the smallest (Shropshire, Telford and Wrekin) ICS covering 542,000 people, and the largest (North East and North Cumbria) covering 3.51 million people.⁵⁷

It is envisaged that these changes across the NHS in England will deliver a more streamlined and aligned approach to the delivery of patient care and drive efficiency and reduce bureaucracy. ICSs have been provided with a common vision for digital and data transformation, through the ‘What Good Looks Like’ framework,¹⁴ to promote collaboration and standardisation at a system-wide level. Currently both NHS England and ICSs across the country are cutting staff numbers across the board by up to a third to allow new ways of working. However, there are concerns that this will stymie planned changes and the delivery of key commitments. A 2023 Public Accounts Committee report has also found that short-term challenges faced by the NHS, such as the elective care backlog and A&E waiting times, mean that ICSs will struggle to progress on their longer-term objectives, including to reduce health inequalities.⁵⁸

The recently published Hewitt Review has recommended shifting the focus of health upstream towards prevention. The review states that there should be an earned autonomy model for ICSs to operate more independently with fewer targets and a shake-up of funding rules enabling long term planning and exploration of new types of reimbursement. There is also a focus for ICSs to connect data from multiple sources to allow for better care both at individual and population level and increased productivity of the health and care system.¹⁰

Data infrastructure

The current health and social care data landscape across the NHS is extremely fragmented. SDEs are a key part of NHS England’s data strategy as a significant step forward to ameliorate this. This is in a bid to develop research platforms which the public deem trustworthy.⁵⁹ The data can only be used for specified purposes and access to the environment is only given to authenticated users for an agreed purpose and is monitored. Post-analysed data leaving the environment is audited to ensure patients cannot be reidentified and that no pure data leaves the environment.

Secure Data Environment⁶⁰ is now the umbrella term for data platforms to access NHS health and social care data (previously included trusted research environments) and incorporates both:

- 1. SDEs for planning and population health management,** such as the NHS COVID-19 Data Platform and the federated data platform. The primary use for these platforms is to improve internal planning and operational management across NHS organisations.⁶⁰
- 2. SDEs to support research by academia and industry,** this includes platforms created by NHS Digital and OpenSAFELY⁶¹. These platforms will be the preferred route to support medical research and innovation. Some of these environments are geographically limited in scope, others have national reach.⁶⁰

NHS England created an SDE service, software provided by Palantir during the COVID-19 pandemic to allow researchers access to de-identified patient data, accelerating the research process in a time of national emergency.⁶² Other SDE examples in the UK include the Scotland Data Safe Haven programme,⁶³ UK Secure eResearch Platform in Wales,⁶⁴ Genomics England Research Environment,⁶⁵ UK Data Service Secure Lab,⁶⁶ and OpenSAFELY.⁶¹

The Goldacre Review, published in 2022, focused on the infrastructure required for secure and efficient data platforms, as well as the need for a skilled workforce to enable this to happen.¹⁷ It places a focus on the need for transparency using SDEs where researchers can access, process, and analyse data without leaving this secure environment.

A shift towards the increasing use of SDEs employing patient data for secondary purposes

has led to the need for greater data uniformity.

SDEs store de-identified patient data securely and are virtual platforms through which researchers and NHS analysts can request access and conduct analysis within this safe space. Only analysed data can leave the environment after review by a data access committee to ensure no identifiable data is present^{67,68} - though there are concerns about the scalability of this approach. For service delivery purposes, it is envisaged that data teams will be located within ICSs (responsible for datasets for local services) but can feed into higher level policy at national level for planning and monitoring of population health.

There is the aspiration that future NHS SDEs will overcome issues of data and code uniformity, and base themselves on the open working methodology currently employed by the OpenSAFELY analytics platform.⁶¹ The OpenSAFELY route to standardisation allows for compatibility across datasets. It promotes the use of 'Reproducible Analytical Pipelines' (RAPs),⁶⁹ open-source standardised software analytics methods and tools as the minimum standard for academic and NHS analysts to ensure all code for data curation paid through public means is shared openly. This creates an online library for NHS data curation code,⁶¹ reducing duplication of effort and ensuring resources are used more efficiently and effectively.¹³

Much of the progress on SDEs has been developed based on balancing the needs of the research and analyst community alongside ensuring public trust in the handling of patient data. The UK Health Data Research Alliance has been running a project looking at how SDEs can be designed in such a way that the technical and functional needs of researchers are met, whilst also using the **Five Safes Model**⁵⁹ as the foundation to develop public trust, which has the aim of protecting the privacy of patients by design:

- **Safe People** – Researchers must be appropriately trained and approved
- **Safe Projects** – Projects involving data must be ethical and approved
- **Safe Settings** – Secure technology ensure that data never leaves the safe location, i.e., the SDE
- **Safe Data** – Data used by researchers must be de-identified

- **Safe Outputs** – Outputs must be checked to be sure they cannot be used to identify an individual

Commercial Partnerships with NHS Trusted Research Environments

SDEs are seen as a way to overcome the ethical concerns the public have with granting commercial entities access to patient data. Historically, the issue of privacy risks to patients has been conducted within the same discussion as commercial access. The Goldacre review¹⁷ attempted to address this by identifying the need to separate these two issues but did not go into detail on how commercial innovators would work with SDEs. The review outlines that open logs and resulting auditing processes overcome concerns around allowing access to data from industry. It suggests that through deliberation with the public, consensus over the important role of commercial innovators can be sought.

SDEs are resource intensive. Funding for infrastructure needs to go beyond the current capital committed to ensure that there is enough resource to achieve the full potential from SDEs in the longer term in view of the significant investment. There is a need to ensure that funding brings in return on investment for patients and the public and enough funding needs to be committed to have enough capacity and capability within the system to deliver this programme and national and local level.

Federated data platform

More recently in January 2023, NHS England opened a tender process to procure a federated data platform (FDP) for the NHS.⁷⁰ The purpose of the FDP is a data analytics platform to improve data quality for planning services and improve data standards and linkage. It is anticipated the contract value will be £360 million for five years, with an option for two 12-month extensions worth £120 million.²⁰ The aim is that the FDP will bring together siloed data from the 42 ICSs, reduce regional variation and enable easier connections between them as well as centrally.¹⁰ The FDP will provide ICSs with some common functionality as well as national solutions. Initially the national solutions will focus on five key NHS priorities: population health and person insight, care coordination, supply chain, vaccination and immunisation and elective recovery.⁷¹

NHS England must be very clear in their communication surrounding the framework used to select the provider of the FDP and the process taken to reach this decision. This is critical to maintain public trust. Concerns include that there will be a single provider that will have access to data across the NHS in England and the NHS will be dependent on one organisation. NHS England have stated that the privacy enhancing part of the contract will be kept separate to the data processing contract in a bid to safeguard the service.⁷² The NHS and the successful provider need to demonstrate its trustworthiness and transparency in all aspects of the platform and how it will be used. Knowledge of how data will and is being used, by which organisations and for what end goals or purposes is essential.

CASE STUDY: 100,000 Genomes Project and NHS Genomic Medicine Service

The UK Government has invested heavily in trusted research environments (TREs) through the 100,000 Genomes Project, set up in 2012 as a part of the UK life sciences strategy and hosted by Genomics England.⁷³ 18.5% of data collected within the project has thus far translated into actionable findings, with more than 100,000 genomes sequenced.⁷³ Allowing whole genome sequencing to become routine in clinical practice, it paved the way for the development of personalised genomic medicine.

Access is provided to researchers via a secure research environment to better understand diseases and develop treatments.⁶⁵ NHS clinicians are granted access to the data held

within the TRE free of charge,⁷⁴ as well as any academic researchers participating in Genomics England Clinical Interpretation Partnership.⁷⁵ Access for industrial partners within the life sciences sector is provided through the Discovery Forum, which is approved once an Access Review Committee confirms organisations take part in legitimate research that supports the interests of participants and communities who have donated their data.⁷⁶

The legacy of the 100,000 Genomes Project is now being built upon through the UK Government's wider Whole Genome Sequencing work. Seven hubs which make up a Genomic Laboratory Network are now conducting genomic testing for the NHS, with the eventual aim of creating a longitudinal dataset of the UK population's genome sequences.⁷⁷ Research and Innovation will be embedded within clinical care through this service so that healthcare can be transformed to be centred around genomics.⁷⁸ A secondary use of the dataset is to develop new ways to analyse large datasets and for medical innovation.

Recommendations

Secure Data Environments

3.1 Shared data structuring and data standards should exist across SDEs to ensure consistency across SDEs in their quality and usefulness for administrative and research purposes. More needs to be done on common standards and ensure there is less variation regionally.

3.2 There needs to be a move to improved interoperability and comparison of data across SDEs, including ensuring a single patient's data is not present in more than one SDE. It is hoped that the Federated Data Platform will support this.

3.3 The Goldacre review focused on SDEs for research use. There needs to be clearer guidance on more commercial uses of SDEs - NHS England need to put this out by the end of 2023.

3.4 In view of the proposed staff cuts announced by NHS England, there needs to be assurance that there is enough capacity and capability within the system to deliver this programme.

Investment in data infrastructure

3.5 NHS England needs to ensure that there is adequate funding to train analysts at ICS level as part of the roll out process, to ensure maximal output from this very resource intensive set of platforms.

3.6 There is the need to ensure that this investment brings in return on investment (ROI) for patients and the public in terms of better clinical outcomes, more efficient services and population health. There also needs to be demonstrable value to UK taxpayers. We recommend an annual report be published on ROI from SDEs by 2024/25 financial year.

Public trust

3.7 NHS England must be very clear in their communication about the decision-making process used to select the provider of the Federated Data Platform and the process taken to reach this decision. This is critical to maintain public trust.

4.

Capabilities

Summary

- HEE has merged with NHS England which may impact on how workforce planning and digital education and training is conducted.
- HEE has launched several programmes through the Digital Academy focused on developing clinician-informaticists within the NHS including: the Digital Health Leadership programme and the Topol Digital Fellowship.
- Cross-government initiatives for professionalisation and accreditation of Data, Digital and Technology (DDaT) roles have been established.
- There is a growing focus on the workforce transformation efforts that will be required to support digital capability development. Recruitment, retention and remuneration challenges for informatics professionals require particular attention.
- Collaboration opportunities with industry have been proposed including pooled talent models and industry placements within training programmes.

HEE has recently merged with NHS England/ Improvement and NHS Digital in April 2023⁷⁹ with a restructure and planned approximate reduction in 30-40% of roles in the newly merged organisation.⁸⁰ The rationale behind the merger is to ensure workforce, service and financial planning are incorporated within a single process. Potential implications include the loss of a ringfenced education budget, loss of posts focused on developing digital and data education, and loss of an independent HEE voice in raising issues in workforce planning.⁸¹

Strategic plans, recommendations and frameworks for developing digital capabilities within the NHS workforce have been outlined in several recent policy reports. **Health Education England (HEE) has published an ‘Artificial Intelligence (AI) and Digital Healthcare Technologies Capability Framework’ with the University of Manchester,⁸² and HEE and the NHS AI lab have published two joint reports exploring confidence in the workforce in relation to AI technology.**⁸³

The ‘Data Saves Lives’ report¹⁸ outlines plans to build analytical and data science capabilities within the NHS, including developing competency frameworks, training, career opportunities and the work of the Developing Data and Analysis as a Profession Board. ‘A plan for digital health and social care’, published in June 2022, sets out a roadmap for the digital transformation of health and social care. Proposed efforts include supporting HEE programmes through the Digital Academy, adding digital skills development to academic curricula and developing future digital leaders through graduate and apprenticeship schemes.⁸⁴ The Hewitt Review acknowledges the lack of trained personnel to deliver digital transformation and has recommended that NHS England develops an in-house skilled team that can be embedded in provider systems and can help train front line staff to deliver change.¹⁰

The Goldacre Review,¹⁷ made several recommendations for NHS workforce transformation and educational needs. These include a call to expand the workforce of data analysts and promote shared learning across sites. It also recommends that open training programmes be shared online to all within the NHS. The Wade-Gery report ‘Putting data, digital and tech at the heart of transforming the NHS’ published in November 2021,¹⁵ sets out recommendations for a shift in culture, operating

model, skills, capabilities and processes to put data, digital and technology at the heart of how the NHS transforms health services.

Established educational opportunities

Several education programmes have been launched focused on digital capability development in the healthcare workforce.^{85,86} The Topol fellowship has now been extended to non-clinical and social care staff. HEE has commissioned the University of Manchester to develop a Clinical Data Science programme.⁸⁷ Flexible portfolio training (FPT) is a pilot training initiative within higher specialty training programmes offered by HEE and the Royal College of Physicians that offers protected time to develop additional skills alongside clinical training. Clinical informatics is one of four pathways offered within FPT.⁸⁸ Health Data Research UK (HDR UK) has developed a talent and training strategy outlining hybrid master’s programmes, as well as PhD training, to encourage the development of new career pathways that cross traditional boundaries of academia, industry and government.⁸⁹

Professionalisation of the data and informatics workforce

The NHS England Transformation directorate’s the ‘Year of the Digital Profession’⁹⁰ includes a five-year strategy and roadmap to build a sustainable digital and data workforce aligned with the ‘NHS Long Term Plan’⁹¹ and the ‘What Good Looks Like’ framework.¹⁴ One of the top priorities for the programme is professionalisation of the informatics workforce through core competency frameworks. The Digital, Data and Technology (DDaT) Profession Capability Framework has been launched across government⁹² and can promote the development of formal qualifications in data and informatics.

Some digital and data professionals within the NHS are already regulated. For example, NHS clinical scientists who specialise in bioinformatics are trained through the National School of Healthcare Science (NSHCS) and are regulated by the Health and Care Professions Council (HCPC).⁹³ **Although there is no formal professional body for data and informatics staff within the NHS, several organisations have been supporting professionalisation efforts, including the Faculty of Clinical Informatics (FCI).** As an example, the FCI has published a standardised

job description for Chief Clinical Informatics Officers with the plan to expand this work to staff at other levels working within healthcare informatics in the NHS.⁹⁴

Workforce transformation

Several recent reports have highlighted the significant workforce transformation that will be required to support education, training and professionalisation efforts. Findings from ‘NHS Informatics Workforce in England’, a report commissioned by HEE in 2019, predicted a 69% increased requirement for digitally skilled staff by 2030.⁹⁵ This was followed by the ‘Data Driven Healthcare in 2030’ report⁹⁶ in March 2021, which projected the need for an additional 32,000 whole-time equivalents (WTEs) within the NHS digital workforce to reach a forecasted size of 78,000 WTEs in 2030.

Recruitment and retention

Recruitment and retention of DDaT and informatics professionals in the NHS represents a particular challenge, and remuneration is likely to be limiting recruitment. The NHS Agenda for Change pay scale framework⁹⁷ limits the salaries of data science professionals as they are classified as ‘administrative/clerical’ staff. Data scientists and data analysts can expect to earn more than twice the salary of equivalent NHS roles in the private sector.¹⁷ The call to reconsider the Agenda for Change pay scale was echoed in the Goldacre Review, recommending that ‘competitive remuneration packages’ be introduced for technical skills that ‘reflects market value’. It argues that “the NHS must stop expecting to pay highly skilled technical staff in data science and software development on salary scales devised for low and intermediate level IT technical support.”¹⁷

Collaboration with industry

HEE has established the Health Innovation Placement (HIP) pilot⁹⁸ as part of the Digital Academy. It provides healthcare professionals with an opportunity to work with start-ups / small to medium sized enterprises (SMEs) on the development of a technological solution to a specific NHS problem. Informatics Skills Development Networks (ISDNs) offer opportunities for collaborative

training with industry. HEE has supported the establishment of eight regional ISDNs across England which provide learning, sharing, and networking opportunities to health and care staff interested in informatics, as well as an accreditation scheme.⁹⁹

Recommendations

Training and skills development

4.1 Ensure the momentum for digital skills development within HEE is not lost with the merger of HEE and NHS England. A dedicated budget needs to be ring fenced to support this.

4.2 Significantly increase training numbers for specialist digital and informatics training programmes, including the Scientist Training Programme. Additional training pathways should be established including joint clinical/digital training programmes for clinicians.

Professionalisation of the DDaT and informatics workforce

4.3 A singular governing body needs to be established for the professionalisation and regulation of the DDaT and clinical informatics workforce within healthcare and develop competency frameworks for clearly defined and universally recognised data and informatics job roles.

Workforce transformation

4.4 Provide significant financial investment to support the recruitment, reimbursement and retention of data and informatics professionals in the NHS, including an urgent review of the Agenda for Change pay scale

4.5 Establish collaborative training opportunities with industry to promote cross-sector data and analytics expertise and strengthen the skills development of clinical digital specialists.

5.

Investment

Summary

- Data-driven health is a government priority, with clear dedication to investing resources towards realising long-term ambitions to develop data quality, infrastructure, and capabilities.
- Brexit and the COVID-19 pandemic have changed the UK investment landscape making it pertinent for the UK and the NHS to keep pace with other nations, ensuring levels of investment do not lag behind.
- A Knowledge Assets team sitting within the UK Government's Department for Business Environment and Industrial Strategy has been set up with the aim of tapping into previously neglected sources of intangible capital assets such as knowledge and innovation within the public sector.
- The Office for Artificial Intelligence and the Office for Technology Transfer have been set up to aid in harnessing AI as a growth area and the better use of public sector assets respectively.

There has been a step-change in investment to develop health data quality, infrastructure, and capabilities. Data-driven innovation is a government priority, with the Department for Science, Innovation and Technology (DSIT) created as part of a government reshuffle in February 2023.²³ The Science and Technology Framework has set out the government's approach to make the UK a science and technology superpower by 2030.²³ Health sector innovation is recognised as essential to the economy in creating jobs and making the UK an attractive investment to big businesses as well as generating support for spin off companies and SMEs.

The UK's life sciences have an £88 billion annual turnover, raising £1.8 billion in finance in 2022 alone, and are in a strong position to drive world-class innovation.¹⁰⁰ A fully implemented and supported data for research and development programme, as outlined in 'Data Saves Lives'¹⁸, could generate up to £1.7 billion over 10 years, including £380 million direct patient benefits through improved diagnosis and treatment.³⁰ To ensure that the UK is at the forefront of clinical research and innovation and can deliver a return on investment, there needs to be an assurance that the SDE programme is adequately funded over the coming years.

The economic climate in the UK has changed drastically in the past three years with implications for health sector spending and investment. Economic uncertainty following Brexit and the COVID-19 pandemic has led to concerns the UK is heading for a recession, while Brexit has had a substantial impact on investment.¹⁰¹ There has been underinvestment in direct public R&D investment relative to competitor nations.¹⁰⁰ UK R&D government funding was around 0.46% of GDP in 2019, below the OECD country average of 0.6%.¹⁰² Going forward the UK's strong public R&D infrastructure base can be leveraged with sustained investment to maintain global excellence in this field. The NHS Transformation Directorate has invested in NHS DigiTrials service to support large-scale clinical trials, including aiding trial organisers to recruit over 140,000 participants into the world's largest trial of a blood test that can detect more than 50 types of cancer.¹⁰³

Since 2020 there has been substantial national investment to improve health data quality and infrastructure. Investments have included £2.1 billion for NHS IT upgrades and digital health technology as part of a wider £5.9 billion capital funding to clear

the backlog of NHS patients awaiting treatment,¹⁰⁴ £790 million to support breakthroughs in new treatments, diagnostics and medical technology.¹⁰⁵ On data infrastructure, investments have included £200 million through the Data for Research and Development programme, including £100 million to develop regional SDEs.¹⁰⁶ Other investments include £260 million to build NHS-led SDEs to develop advanced therapies, with £60 million ringfenced to expand the manufacturing arm of the life sciences sector,¹⁹ and in January 2023, a £480 million tender to procure a NHS FDP.^{20,107} These investments support the Life Sciences vision,²¹ a blueprint to develop an environment that industry can engage in for the benefit of the public, which proved vital during the COVID-19 pandemic.¹⁰⁸

Intangible (knowledge) assets, including intellectual property, skills and abilities and general knowledge, are a key source of capital within the public sector.

The government has started building upon the recommendations of the Mackintosh Report¹⁰⁹ with an increasing emphasis on the knowledge economy and innovation in the public sector. This has led to the set-up of a new Knowledge Assets team, who has launched guidance on knowledge asset management in government.¹¹⁰

The Government Office for Technology Transfer will aid in the better management of public sector knowledge assets by providing guidance on how UK knowledge assets can be managed and commercialised. These knowledge assets are estimated at £104 billion.¹¹⁰ Technology transfer is the broad term used to describe the transfer of assets, such as intellectual property, technology, or new knowledge, from one organisation to another. For example, University of Leeds and the Leeds Teaching Hospitals NHS Trust developed the Leeds Virtual Microscope (LVM) and licenced the product and intellectual property to healthcare company Roche.¹¹¹ The functions, activities and governance of university technology transfer offices can provide useful learnings for the NHS.

Advances in artificial intelligence (AI) have the potential to make great changes in health and care through AI's ability to analyse large quantities of data. The Office for AI has been set up to oversee the National AI Strategy and supporting the transition towards an AI-enabled economy. The UK is ranked third globally for private venture capital investment into AI companies, with a total of £22.7 billion

invested into UK technology firms by global investors in 2022 (though investment dipped in Q4).^{112,113} The government has also invested £2.3 billion into AI since 2014 and the NHS AI Lab was created in 2019 to bring together government, NHS, academics and technology companies.¹¹⁴ The UK is leveraging significant private investment with a commitment to building AI capabilities in the UK, as seen in the AI Action Plan¹¹⁵. **Falling behind in AI innovation risks the UK's national security and economic competitiveness becoming a service industry economy dependent on external providers from global competitors.**^{100,116}

CASE STUDY: Our future health, secure data environments as part of investing in data

Our Future Health (OFH) is the UK's largest ever health research programme, building a community of five million volunteers across the country. The programme will enable researchers to use OFH data to identify more effective ways of tackling diseases,¹¹⁷ including cancer, dementia, diabetes, heart disease and stroke.

OFH is a collaboration between the public, charity and private sectors. The programme was developed in close partnership with the NHS, who provide significant support in inviting people across the UK to join the programme.¹¹⁸ The UK's leading health research charities help deliver the programme, providing expertise on methods of prevention, early detection and treatment of diseases and health conditions.¹¹⁹

The OFH Secure Data Environment (SDE) will be the default route for researchers accessing the data and aims to speed up research and maximise the potential impact of discoveries.¹²⁰

The SDE allows researchers to securely access and analyse data using a variety of bioinformatics and biomedical research tools, including genomic analysis. SDE and cloud platform providers will not have access to any of the data in the programme and the information will be de-identified, encrypted, stored and managed securely in the UK.¹²¹ Such measures are in line with public consultations run by OFH which informed how the programme provides access to the SDE.¹²²

OFH was set up with £160 million funding from leading life sciences companies who invested in and provided expertise in the design and successful delivery of the programme, including the building of SDEs to host the data. In exchange, during the early years of the programme, industry partners are the only large commercial organisations eligible to apply to use OFH resources for research (researchers from SMEs or non-commercial organisations can apply to use the resources).¹²³ OFH industry partners can profit from discoveries made using resources but have agreed to make reasonable efforts to ensure subsequent innovations are made available in the UK to benefit NHS patients.



Recommendations

Investment

5.1 The UK should commit to a multi-year funding settlement to ensure sustainable resourcing of the necessary data quality infrastructure and capability programmes. The post-COVID step change in investment requires a focus on long-term financing comparable to other high-income nations to achieve impactful innovation of quality, infrastructure and capability to increase the value and use of data in the NHS.

5.2 By continuing to prioritise data quality, infrastructure and capabilities, the UK government and NHS can drive innovation and look to attract and leverage greater private sector investment.

Monitoring progress and impact

5.3 All stakeholders should ensure that spending commitments are reviewed on a regular basis and barriers to delivering on spending commitments are addressed.

6.

Value-sharing

Summary

- Data sharing agreements can provide health, social and financial value for patients and the NHS as well as economic and societal value for the UK.
- NHS organisations should be clear that developing data through the value chain is essential to remain competitive in the global market.
- The Centre for Improving Data Collaboration (CIDC) was set up to support the health and care sector to enter into data-sharing partnerships that benefit the NHS, patients and the public. Now part of the Transformation Directorate at NHS England, there is an opportunity to consolidate expertise to develop guidance for NHS organisations.
- In entering into data sharing agreements, NHS organisations should consider utilising different structures based on various deal-specific factors, acknowledging the short- and long-term implications of agreements.
- We have provided a framework describing core value-sharing agreements that can be considered by NHS organisations.

The NHS should receive fair value for the use of its data, whether financial or in kind. Theoretically, the UK is well poised to benefit from NHS data as it is comprehensive and longitudinal with a single patient identifier. Fair value needs to be defined for all parties when entering into a value-sharing agreement and such a definition should be derived in consultation with patients and the public. **First and foremost - any value should always be prioritised for patients through better clinical outcomes, better medications and services, improved public health and NHS services.**

Improved understanding of the value of NHS data is fundamental to maximise the benefit of value-sharing agreements. As highlighted in the 2020 report,²⁴ there are three primary “types” of value, including:

- 1. Health and social value:** Provide benefits to patients and to the public by using data to improve preventative care, have access to new medicines and devices and enable more accessible and cost-effective provision of care.
- 2. Financial value:** Provide income streams for the NHS through appropriate licensing and value-sharing agreements with the right partners.
- 3. Economic and societal value:** Create jobs and economic growth by enabling the life sciences and technology industries to develop data-driven solutions, technologies and therapeutic interventions that directly benefit people in the UK.

The NHS must be more strategic in its approach to working with commercial organisations interested in accessing health data. The provision of NHS data without (or for a limited) charge has a long history of assisting in research and development with the aim of advancing health research. Engagement with interested research and commercial organisations must be supported through a robust set of principles set out in the 2018 Life Sciences’ Sector Deal:¹²⁴

- data use must have the explicit aim to improve the health, welfare and/or care of NHS patients;
- organisations entering agreements should ensure fair terms for their organisation and the NHS;

- agreements should not undermine or impact the ability to maximise value or use of NHS data at the national level;
- agreements should be transparent and clearly communicated to the public;
- agreements should adhere to applicable legal, regulatory, privacy and security obligations.

There are limited best practice examples of how NHS organisations should respond to proposed data- and value-sharing agreements to ensure they make decisions in line with public values. The ‘Data Saves Lives’ report reiterates the importance of agreements never undermining the ability of the NHS to use NHS data to benefit patients.¹⁸ Boards of NHS organisations should consider themselves responsible for ensuring agreements are “fair, including recognising and safeguarding the value of the data that is accessed and the resources that are generated as a result of the arrangement.”¹⁸

Since 2020, efforts within the NHS to develop guidance for NHS organisations on the use of health data have expanded.¹³⁰ CIDC are planning to launch a value-sharing framework that has been designed to accelerate agreements on fair terms. It is hoped that by applying the framework to new data partnerships, at the same time as the NHS shifts to granting access to data for R&D only via an SDE, should rapidly expand the scale and scope of NHS data partnerships and the patient benefits they deliver.

A capability gap across the NHS has led some NHS organisations to have greater expertise, enabling them to negotiate better terms (and potential or realised benefits) in agreements with commercial companies. The move to develop ICSs should be viewed as an opportunity to up-skill NHS Trusts to negotiate and manage commercial transactions as a mechanism to unlock expertise and value at regional level. However, there are still concerns that not all ICSs have developed or aligned their digital strategies,¹³¹ which is further challenged by their varied size, and complexity, as well as a lack of clarity on lines of accountability.^{132,133} An experienced and engaged central team within the NHS (currently not the function of CIDC) could be set up to oversee and advise on all data partnership agreements providing clearer visibility of which data sets are being used, by whom and for what, and who is accountable.

There are several common types of agreements for health data access:

- 1. Transactional data-sharing agreements** (either bilateral or multilateral) involve the one-time sharing of data or a data set between healthcare organisation(s) and a research or commercial organisation.
- 2. Master services agreements** are rolling transactional data-sharing agreements, which facilitate the provision of access to several different datasets over a set time period. This type of agreement sets out the key terms between parties regarding all activities, supplemented by additional 'statements of work' or 'work orders' which are entered into (in a pre-agreed form) from time-to-time to give effect to the performance of specific activities.

- 3. Research and collaboration agreements or hybrid data sharing/fee for service agreements** whereby healthcare organisation(s) provide both data and clinical (or other expertise) to a research or commercial organisation.

Based on a review of the most up-to-date legal and regulatory considerations and lessons from a larger pool of use cases, we have updated the framework outlining potential value-sharing options first published in the 2020 report. Depending on the nature of the organisation(s) entering into agreements with the NHS, the quality of the data set, the potential return on use of the data, certain of the value-sharing options presented may be considered feasible or acceptable.

There is an associated risk profile associated with each type of agreement. For example, while

CASE STUDY: Sensyne Health, a cautionary tale in seeking equity

Sensyne Health, previously Drayson Health, was set up to use AI to analyse NHS patient data to drive clinical insights that can be utilised commercially.¹²⁵ In July 2017, Sensyne Health, a healthcare technology company, established its first major partnership with University of Oxford and the Oxford University Hospitals NHS Foundation Trust.¹²⁶

Sensyne is a unique example of a commercial organisation which utilised an equity model primarily as part of the strategic research agreements with NHS Trusts. The equity model was unusual for data agreements as the majority of commercial organisations will not be willing to offer equity, in exchange for data, in part due to the nature of the commercial organisation, the legal challenges of such agreements, and the simple fact that often interested parties can get data from elsewhere without the need to negotiate over equity.

In 2022, NHS Trusts owned 16.2% of Sensyne Health, which was offered in exchange for anonymised patient data provided by the

Trusts.¹²⁷ These agreements in part provided the company with 25,500,000 unique patient records.

In April 2022, Sensyne Health was delisted from the alternative investment market (AIM) after share prices dropped 98% from its initial public offering price.¹²⁸ In October 2022, Sensyne, renamed Arcturis, began a process of operational and financial restructuring by raising £12.5m from existing investors.¹²⁹ The uncertainty around the future of the company highlights the risks of seeking long term returns (including via equity) from data agreements. In the case of equity shares, NHS Trusts may ultimately be fighting for a share of nothing should the commercial organisation become defunct.

In this regard, pragmatism is key. NHS Trusts should negotiate and secure at least some initial value return in the first instance, building out from there recognising that future contingent revenue (whether through equity, royalty, milestones or otherwise) may not accrue. In some cases, long term value-add may be possible (e.g., through discounted products) and using a combination of revenue structures will reduce the risk of NHS organisations failing to recoup value from data access agreements.

a bigger sum may ultimately, after many years, be obtained via a royalty payment, there is no guarantee of this. As such, the NHS may prefer to receive less money overall but with the guarantee of receipt. This is one of the drivers for utilising a combination of revenue structures in NHS data- and value-sharing agreements. We have further outlined the potential legal challenges associated with some of the options in the framework presented.

There are several vehicles through which the NHS might enter into licensing arrangements with any of the value-sharing options included in the table. In particular, the NHS might consider setting up a spin out company or an IP holding company (IPCO). Establishing a spinout company, where the NHS or Department of Health (DH) sets up a wholly owned business to hold the relevant data asset (and related IP). Similarly, establishing an IPCO which owns the data sets and related IP rights which it licences to collaboration partners, would allow the NHS to ring fence liability with respect to the IP assets. But, in both cases, the board of the spin out company or IPCO would be required to work in the best interests of those companies rather than the NHS. Should the NHS/DH consider using these vehicles, it will be important to undertake thorough public consultation as these might be perceived by the public as an effort to commercialise data with the potential misuse or manipulation to benefit vested interests and agendas.

The industry experts we consulted echoed the view that most commercial organisations will not be willing to offer IP rights in exchange for data, not least because of the complexities this introduces for a commercial IP strategy and the substantial contribution of the organisation in developing any such IP. **It is important to clarify that the linking, curation, and cleaning of data has the potential to result in IP, not the data itself.** The investment in SDEs and the FDP is a step in the right direction for the NHS in ensuring this crucial step is not missed. It should also be remembered that such parties can get data from elsewhere without the need to negotiate over IP.

Recommendations

Guidance and stakeholder management

6.1 Provide NHS organisations with a clear framework for entering into value-sharing agreements when licensing data. This should come from NHS England by the end of 2023 and can build on our framework below.

6.2 Provide guidance to industry and academic institutions regarding what the NHS wants from value-sharing agreements. All parties must understand what the expectations are from each other in order to make informed decisions and ensure compliance with policy objectives.

Governance

6.3 There needs to be greater consideration of how data partnerships are negotiated which could be by a central team or whether the responsibility should be through ICSs. In either scenario expertise should be consolidated to ensure any duplication of efforts is avoided.

6.4 SDEs, and ICSs, will need to lead these conversations as part of their development plans and will need to engage through public engagement activities to guide what they think is appropriate for their region.

Value-sharing framework for the NHS

AGREEMENT	DESCRIPTION	MAIN BENEFITS FOR THE NHS	POTENTIAL ISSUES
No value sharing	The NHS shares data for free	<ul style="list-style-type: none"> No direct financial benefit for the NHS, but stimulates innovation that may benefit patients and the health system 	<ul style="list-style-type: none"> No financial return on any products developed using the data
Free or discounted products / prioritisation of products	The product developed using NHS data is provided to the contributing NHS organisation (or wider NHS) for free, at a discount or a defined or unlimited period, or product is launched in the UK prior to release elsewhere	<ul style="list-style-type: none"> NHS contracting organisation (or even as a whole) gets access to cutting-edge products at no or reduced cost /patients in the UK get first access to a novel product 	<ul style="list-style-type: none"> Risk that no useful product is developed such that no benefit is received for the data NHS as a whole may not get free or discounted product The provision of product free of charge or discounted (particularly to other, non-contracting NHS organisations) would need to be carefully considered to ensure no breach of applicable laws or regulations
Return of data	The NHS provides raw data to a licensee who invests significant time and effort in cleaning and curating the dataset for use before returning to the NHS	<ul style="list-style-type: none"> NHS obtains curated data for free, which can be used to develop innovation internally by offering patient and system value NHS can potentially obtain a higher return on the licensing of such curated data in future 	<ul style="list-style-type: none"> No immediate direct financial return Potential financial return is dependent on the NHS agreeing financial terms for the future licensing of the improved curated data
Equity share	The NHS receives a share of the equity of the company developing solutions from the data	<ul style="list-style-type: none"> NHS receives the capital appreciation value of its shares on sale of the shares NHS receives a dividend of the profits of the company unless/ until it sells its shares 	<ul style="list-style-type: none"> Difficult to decide what a fair share of the equity for the NHS would be Difficult to predict the amount of any dividends paid to the NHS It may be sometime before any dividend is received as the company may take time to become profit making The NHS may be contractually obligated not to sell its shares for a period time or be subject to contractual ‘drag along’ rights (i.e., NHS required to sell its shares to a third party)

AGREEMENT	DESCRIPTION	MAIN BENEFITS FOR THE NHS	POTENTIAL ISSUES
Equity share (continued)			<p>in certain circumstances when all or a majority of the shares in the company are being sold)</p> <ul style="list-style-type: none"> • Ability to sell the shares and, receive financial value for them, may be limited unless/ until the licensee company is listed or if the company becomes defunct
Royalty/revenue share	The NHS receives a royalty on revenue generated from products or services developed using or relying on its data	<ul style="list-style-type: none"> • Potential long-term source of income • Risk is shared between the parties such that the NHS receives a financial return if the data generates value (i.e., when a resulting product is commercialised) 	<ul style="list-style-type: none"> • Risk that no revenue-generating product or service is successfully developed • Potential conflict of interests if the NHS receives a royalty on the purchase or use of a particular product when it has buying power in respect of such a product or service • Revenues may not be significant if, for example, the resulting product is not successful, is quickly replaced, or sales reduced due to competitor products • The NHS would need resources to monitor royalty payments
One-off upfront payment	NHS receives a one-off payment in exchange for access to the data	<ul style="list-style-type: none"> • Quick and certain access to funds with no risk or ongoing relationship 	<ul style="list-style-type: none"> • Depending on the pricing, the NHS could generate less revenue than if it had pursued other revenue sharing options • Depending on the fee, this may create a financial barrier to initial access to data, potentially penalising smaller companies
Annual/periodic licensing fee	NHS licenses data on a subscription model (or annual licensing fee model)	<ul style="list-style-type: none"> • Quick and certain access to funds with no risk or ongoing relationship (aside from the performance of the contractual obligations under the data sharing agreement) 	<ul style="list-style-type: none"> • Depending on the pricing, the NHS could generate limited value or less revenue than if it had pursued other revenue sharing options

AGREEMENT	DESCRIPTION	MAIN BENEFITS FOR THE NHS	POTENTIAL ISSUES
Annual/periodic licensing fee (continued)		<ul style="list-style-type: none"> • Relatively straight forward to administer • Repeat renewal of the licence is a medium to long term revenue stream 	<ul style="list-style-type: none"> • NHS may need to build in costs for maintenance of the dataset (e.g., providers of Trusted Research Environments)
Milestone payments / Multiple one-off fees linked to product development and/or sales	<p>NHS receives payments of fixed amounts triggered by the licensee achieving certain development and product milestones (e.g., start of a clinical trial, regulatory approval, volume of sales, in each case of a product relying on the relevant data)</p>	<ul style="list-style-type: none"> • NHS able to generate increased revenue compared to an upfront fee alone • No risk or ongoing relationship (aside from the performance of the contractual obligations under the data sharing agreement) • Risk is shared between the parties such that the NHS receives a financial return if the data is generating value (e.g. it results in a product which is ready for clinical assessment and which then goes on to be authorised for use etc.) • Less complex to administer than a royalty 	<ul style="list-style-type: none"> • Risk that no successful product is developed • NHS would need to manage the payment of such milestones (e.g. conducting audits if needed etc.)

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Appendix

Public Opinion and Engagement Recommendations

Public Engagement and Deliberation

1.1 NHS England and DHSC need to make progress on the principles and commitments that were set out in Data Saves Lives. The best way to do this would be extensive, two-way, public engagement to fill gaps in our knowledge on what the public views as acceptable data sharing. This should happen during 2023.

1.2 Any public deliberation exercises should be done both at national level and regionally. National level exercises will allow to provide clarification on the appropriate use of data across the UK. A more local approach will allow a nuanced understanding of variation in thought across the population and ensure better representation.

1.3 NHS England and the DHSC need to ensure that an effective budget is in place to ensure that public deliberation can take place across the country and that any programme launch needs to be facilitated with clear communications for better patient and public understanding.

Reducing Opt-Outs

1.4 A clear narrative of why and how patient data is being used should be developed. This narrative could then be used in public awareness campaigns to outline benefits as well as risks of data sharing, with the goal of people opting back into sharing for research and planning purposes.

1.5 In the longer-term, when there is an opportunity to amend legislation, there should be further public deliberation exercises to review the opt-out process and if this should be limited to opting out of research and not for planning purposes.

Public Involvement in Governance

1.6 Data advisory boards should be established in each ICS to provide a sense check on the appropriate use of data within ICSs, and ensure the public remain central to how NHS data is used.

Data Governance and Legal Frameworks Recommendations

Global data regulations

2.1 The UK's exit from the European Union requires evidence of better delivery of new data protection regulations as well as clarity. More guidance and resources for businesses on new legal requirements should be developed to aid the navigation of regulations and adherence to them.

2.2 Brexit has created layers of increasingly complex regulation which is becoming difficult to understand in the global context. The set-up of an entity which connects all data regulations globally, with knowledge of how they differ to UK law, would add value in providing clarity and increasing confidence across stakeholder groups including the NHS and industry.

Data use for research

2.3 The use of COPI notices resulted in positive gains during the COVID-19 pandemic and should be used again in future pandemic/emergency situations with public support. Issuing the COPI notice showed the potential benefits that data can deliver, which could be extended beyond pandemics. Public deliberation exercises should be considered nationally to review if there is significant backing to extend the use of COPI notices to other disease areas such as dementia or whether there should be reform of CAG section 251 on uses of data.

2.4 NHS England (CICD) should work towards the development of standardised documentation and guidelines to use as part of data value agreements, including on how to navigate GDPR, medical confidentiality, and how to streamline approval from the Confidentiality Advisory Group.

Data Quality and Infrastructure Recommendations

Secure Data Environments

3.1 Shared data structuring and data standards should exist across SDEs to ensure consistency across SDEs in their quality and usefulness for administrative and research purposes. More needs to be done on common standards and ensure there is less variation regionally.

3.2 There needs to be a move to improved interoperability and comparison of data across SDEs, including ensuring a single patient's data is not present in more than one SDE. It is hoped that the Federated Data Platform will support this.

3.3 The Goldacre review focused on SDEs for research use. There needs to be clearer guidance on more commercial uses of SDEs - NHS England need to put this out by the end of 2023.

3.4 In view of the proposed staff cuts announced by NHS England, there needs to be assurance that there is enough capacity and capability within the system to deliver this programme.

Investment in data infrastructure

3.5 NHS England needs to ensure that there is adequate funding to train analysts at ICS level as part of the roll out process, to ensure maximal output from this very resource intensive set of platforms.

3.6 There is the need to ensure that this investment brings in return on investment (ROI) for patients and the public in terms of better clinical outcomes, more efficient services and population health. There also needs to be demonstrable value to UK taxpayers. We recommend an annual report be published on ROI from SDEs by 2024/25 financial year.

Public trust

3.7 NHS England must be very clear in their communication about the decision-making process used to select the provider of the Federated Data Platform and the process taken to reach this decision. This is critical to maintain public trust.

Capabilities Recommendations

Training and skills development

4.1 Ensure the momentum for digital skills development within HEE is not lost with the merger of HEE and NHS England. A dedicated budget needs to be ring fenced to support this.

4.2 Significantly increase training numbers for specialist digital and informatics training programmes, including the Scientist Training Programme. Additional training pathways should be established including joint clinical/digital training programmes for clinicians.

Professionalisation of the DDaT and informatics workforce

4.3 A singular governing body needs to be established for the professionalisation and regulation of the DDaT and clinical informatics workforce within healthcare and develop competency frameworks for clearly defined and universally recognised data and informatics job roles.

Workforce transformation

4.4 Provide significant financial investment to support the recruitment, reimbursement and retention of data and informatics professionals in the NHS, including an urgent review of the Agenda for Change pay scale

4.5 Establish collaborative training opportunities with industry to promote cross-sector data and analytics expertise and strengthen the skills development of clinical digital specialists.

Investment Recommendations

Investment

5.1 The UK should commit to a multi-year funding settlement to ensure sustainable resourcing of the necessary data quality infrastructure and capability programmes. The post-COVID step change in investment requires a focus on long-term financing comparable to other high-income nations to achieve impactful innovation of quality, infrastructure, and capability to increase the value and use of data in the NHS.

5.2 By continuing to prioritise data quality, infrastructure and capabilities, the UK government and NHS can drive innovation and look to attract and leverage greater private sector investment.

Monitoring progress and impact

5.3 All stakeholders should ensure that spending commitments are reviewed on a regular basis and barriers to delivering on spending commitments are addressed.

Value-sharing Recommendations

Guidance and stakeholder management

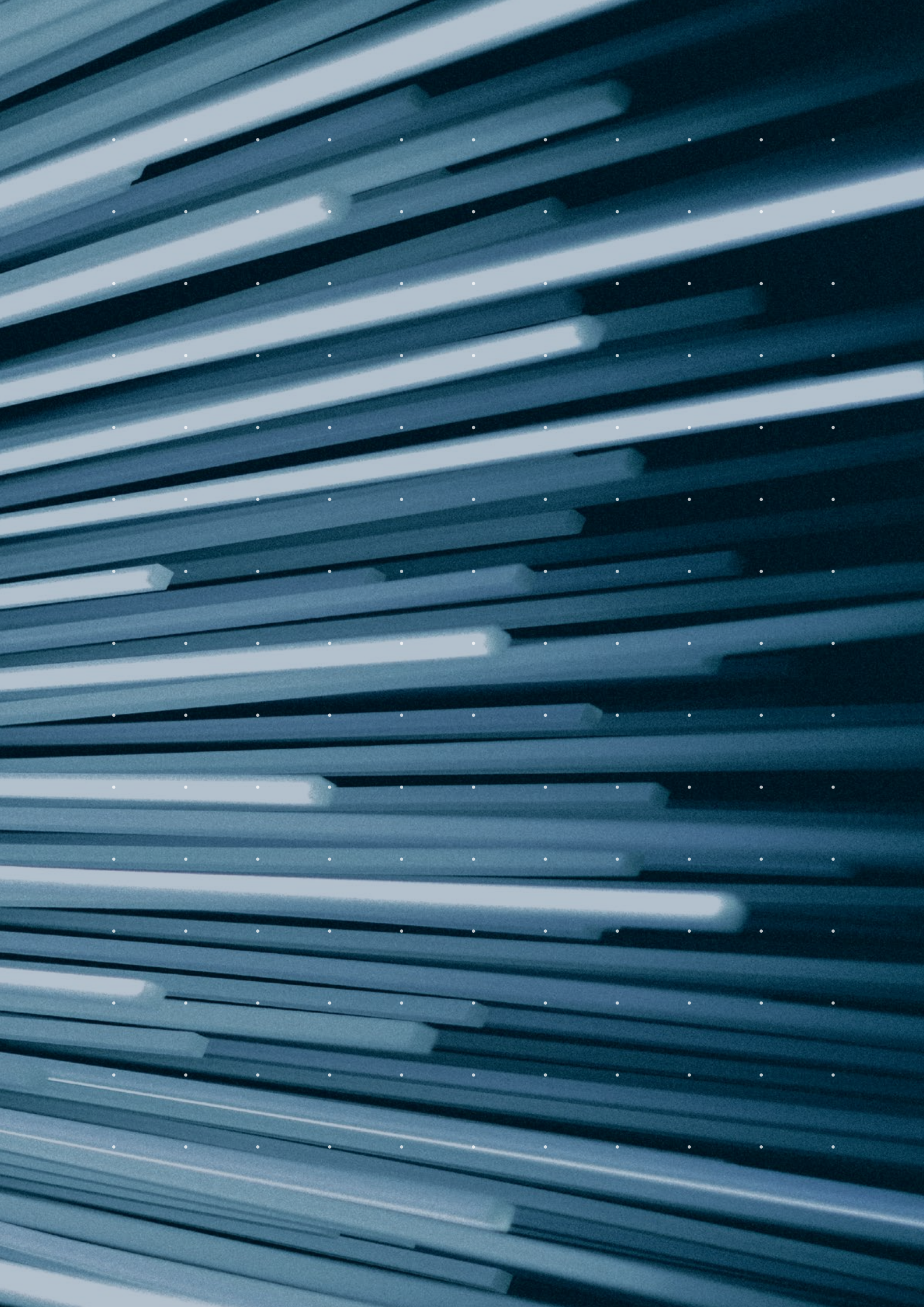
6.1 Provide NHS organisations with a clear framework for entering into value-sharing agreements when licensing data. This should come from NHS England by the end of 2023 and can build on our framework below.

6.2 Provide guidance to industry and academic institutions regarding what the NHS wants from value-sharing agreements. All parties must understand what the expectations are from each other in order to make informed decisions and ensure compliance with policy objectives.

Governance

6.3 There needs to be greater consideration of how data partnerships are negotiated which could be by a central team or whether the responsibility should be through ICSs. In either scenario expertise should be consolidated to ensure any duplication of efforts is avoided.

6.4 SDEs, and ICSs, will need to lead these conversations as part of their development plans and will need to engage through public engagement activities to guide what they think is appropriate for their region.



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