DAC BEACHCROFT

WHAT NEXT FOR NHS DATA?

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INTRODUCTION

The NHS holds patient records relating to over 55 million people, which if curated across primary, secondary and social care, could provide one of the most comprehensive patient data sets globally.

A recent review by one of the big four accounting firms estimated that the value to the NHS of such a data set could be as much as £5 billion per year, with the lion's share of that value deriving from operational savings and improved patient outcomes.

Those significant opportunities do, however, come with a number of potential challenges, not least in ensuring compliance with data protection and information law more generally, as well as maximising public trust and confidence in the use of their data.

This booklet sets out those opportunities in the context of the relevant legal framework.

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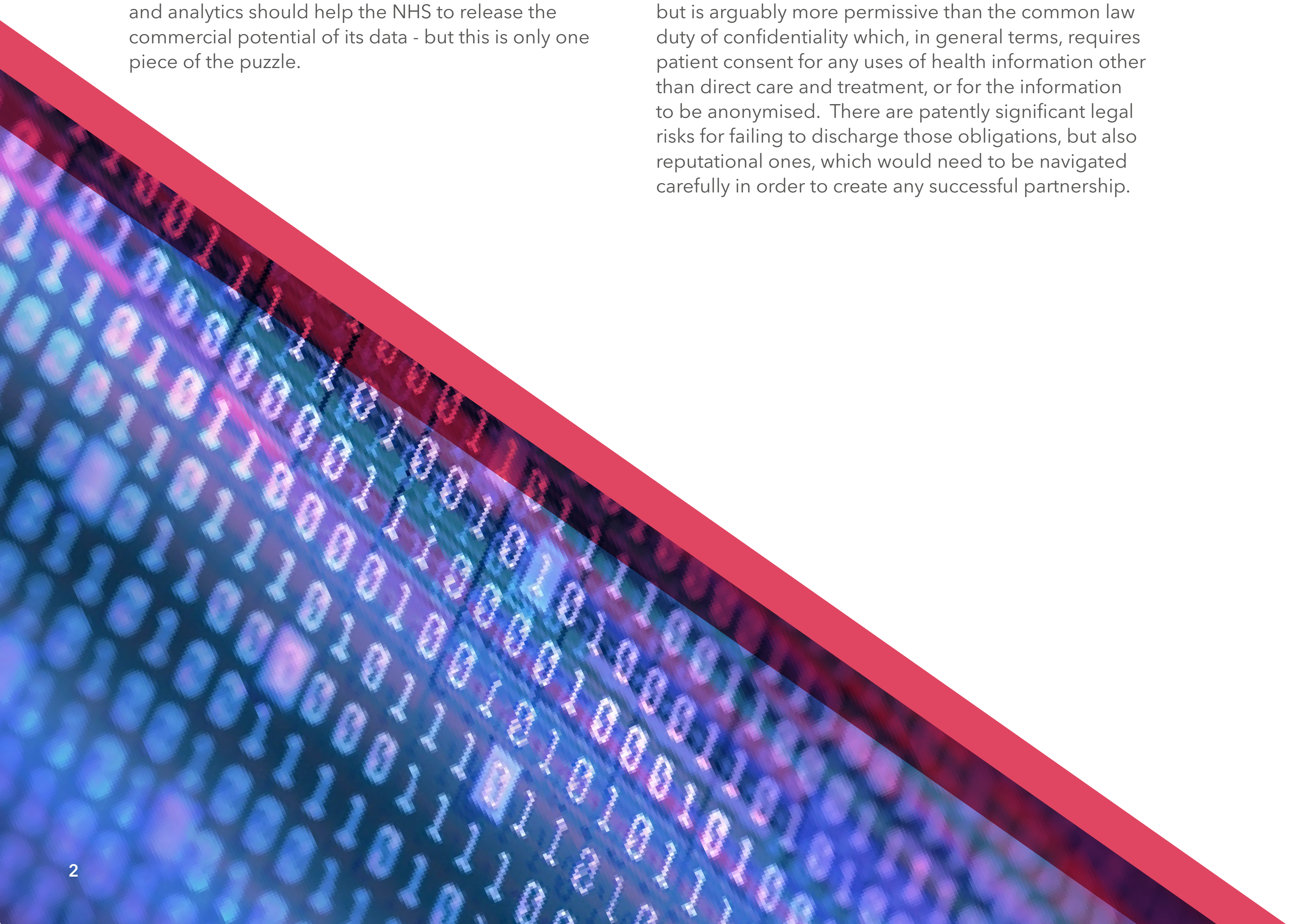
PARTNERING

The desire is clear within the NHS to enable the development of tools which can improve patient care and provide solutions to the healthcare challenges that the UK faces. Most would agree that the NHS does not, at present, have the capacity and capability to realise maximum value from the data that it holds.

The NHS Digital Academy has already been set up to develop digital leaders who can drive health IT transformation, and it will shortly welcome its third cohort of delegates from across the system in England. Creating a larger internal resource with a deeper understanding of data collection, quality management and analytics should help the NHS to release the commercial potential of its data - but this is only one piece of the puzzle.



The skills and know-how to develop data-driven products and services will come from private sector partners operating in the medtech sector. NHS data can prove invaluable to these partners, but the NHS must of course ensure that it realises fair value from any data which it shares with those developing healthcare technologies.

In addition, development and adoption of data driven technology inevitably entails the use of health data, often in significant quantities, in collaboration with those potential partners. The GDPR establishes a number of clear parameters in respect of the use of such data, but is arguably more permissive than the common law duty of confidentiality which, in general terms, requires patient consent for any uses of health information other than direct care and treatment, or for the information to be anonymised. There are patently significant legal risks for failing to discharge those obligations, but also reputational ones, which would need to be navigated carefully in order to create any successful partnership.

POLICY AND REGULATORY FRAMEWORK

DHSC has established a policy framework in this area through the publication of guidance to NHS organisations on the exploitation of data. The framework sets out some broad, guiding principles to help the NHS realise benefits for patients and the public where data is shared. DHSC stresses that NHS organisations should not undermine, inhibit or impact the ability of the NHS, at national level, to maximise the value or use of NHS data.

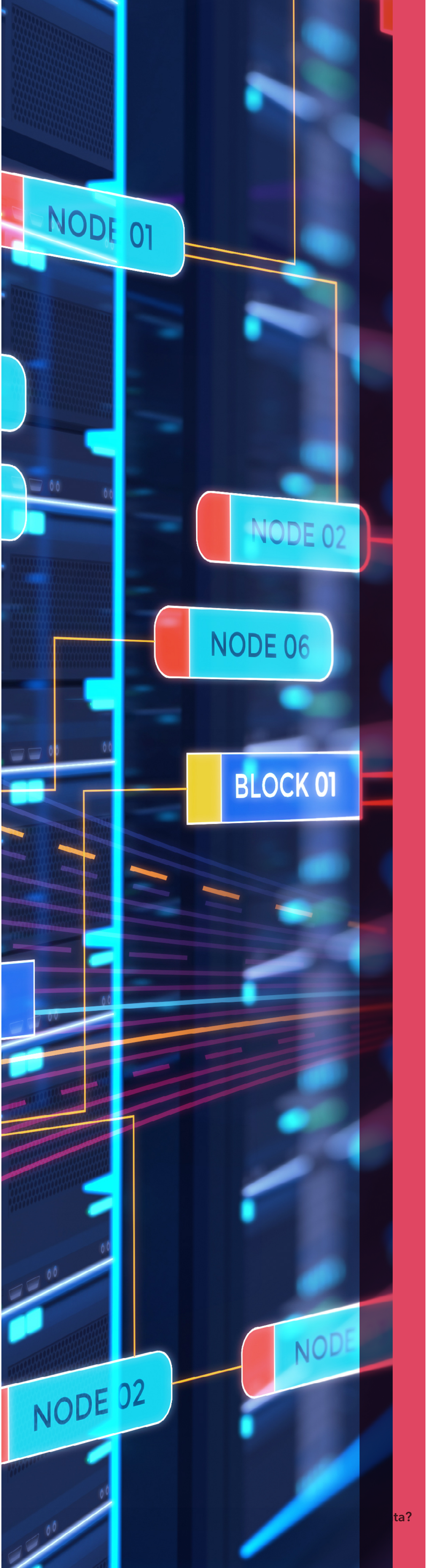
In particular, the guidance takes the line that NHS organisations should not enter into exclusive arrangements with researchers for raw data, and are not to include conditions limiting any benefits from being applied at a national level, nor undermine the free flow of data within the wider NHS digital architecture.

While helpful in confirming the overarching aims of commercialisation – improving operation of the NHS and the health of patients - and emphasising the need for the NHS to secure fair value from any data sharing, the guiding principles do not propose a national strategy on commercialisation of data across the NHS. There is no nationally-mandated model(s) for NHS organisations to adopt when commercialising their data.

It is therefore encouraging to note the work of the Office for Life Sciences, firstly by working to establish a framework to realise the benefits for patients and the NHS where data underpins innovation. The aim is to strike the right balance between the NHS and private sector, to enable patients to understand the benefits of health technology. Secondly, the establishment of the National Centre of Expertise, by NHSX, to oversee the policy framework, and provide specialist commercial and legal advice to NHS organisations which should help to provide consistency in approach. Inevitably, the efficacy or otherwise of these initiatives, particularly in terms of filling the vacuum outlined above, can only be judged in due course.

There is also a lack of consensus as to crucial aspects of the legal and regulatory framework. In particular, although there is broad agreement on the key obligations, there are ongoing disagreements on the parameters of confidentiality and the requirements for obtaining valid consents which can hamper the adoption of new technology. This is a prominent theme in the Institute of Global Health Innovation’s report, published earlier this year, on maximising the benefit of NHS data for patients. That report set out a number of recommendations, including for the ICO to issue NHS-specific guidance about data sharing, and for there to be a transparent public debate about clear rules for data access by private sector organisations.

There is also important work being undertaken in this space by the National Data Guardian, a statutory body with the power to issue guidance relating to the use of NHS data, which may help in relation to this legal uncertainty. In particular, it is championing the development of an additional Caldicott principle based on the concept of ‘reasonable expectations’. The precise parameters of this are still under consideration and subject to consultation, but would essentially require anyone using NHS data to consider whether the proposed use is something which patients would be surprised by, or if they would reasonably expect their data to be used in that manner.



COMMERCIAL MODELS

NHS organisations will therefore need to continue to develop their own partnerships at the local level, agreeing their own commercial models, to ensure that they obtain an appropriate financial return for use of their data by private sector partners.

There are various options that NHS organisations could explore when considering how to collaborate with a private sector partner, each with its own potential advantages and downsides. Every partnership will have its own objectives and specific terms but, at a high-level, it is often helpful to think of commercial models in three broad categories:

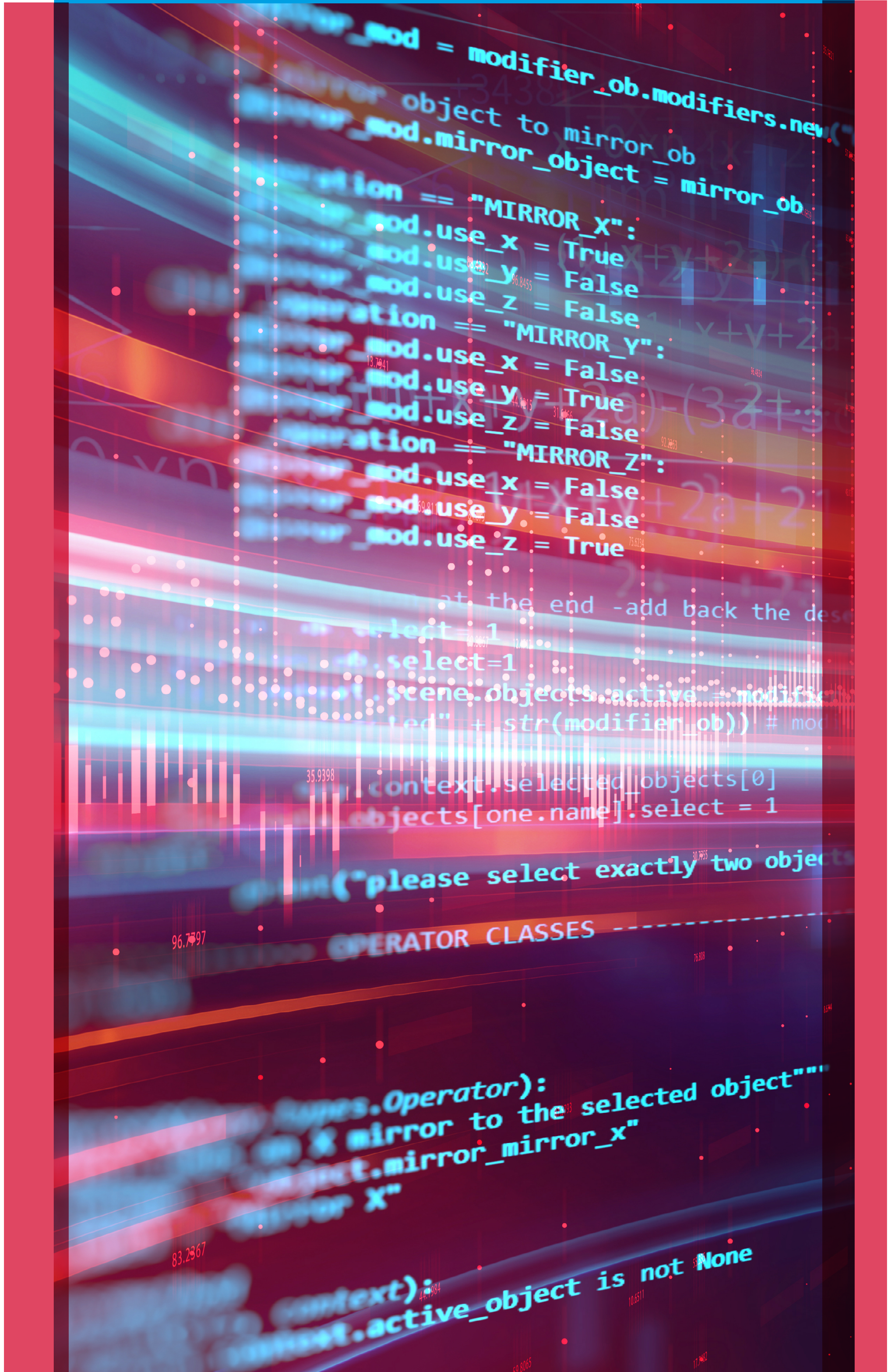
Model	Data Licensing	Collaboration/Consortium	Joint Venture
Legal form	NHS organisation licences private sector partner to use data to develop data-driven products or services. Parties enter into a data licensing agreement.	Contractual joint venture between NHS organisation and one or more partners (private sector and potentially also academic institution) to develop data-driven products or services. Partners enter into a collaboration/consortium agreement, including licences to use data.	Corporate joint venture between NHS organisation and one or more partners (private sector and potentially also academic institution) to develop data-driven products or services. Partners form a company, in which they each hold shares. The company is licensed to use data.
Advantages	Upfront fee and/or continuing licence fees payable to the NHS organisation. NHS organisation secures commercial return irrespective of success of the private sector partner's products or services.	NHS organisation receives a proportion of the profits from the products or services developed using data. Free/discounted products or services for NHS organisation (or the NHS as a whole)? Potential for NHS organisation to jointly own any IP in the products or services? Private sector partner may require additional NHS contribution in terms of funding or background IP/know-how, over and above making data available.	NHS organisation receives a proportion of the profits from the products or services developed using data, through the payment of dividends by the company. Possible increase in the value of NHS organisation's shares in the company over medium/long term. Potential for NHS organisation to hold "golden share" in the company i.e. either 51% of shares or veto over certain decisions. However may be commercially unattractive for private sector (or other) partners (and would depend on NHS contribution in terms of funding or IP/know-how, over and above making data available)
Downsides	NHS organisation does not receive a proportion of the private sector partner's profits from products or services developed using data.	NHS organisation less likely to get upfront fee from private sector partner. NHS organisation's commercial return dependent on success of the private partner's products or services Involves more NHS time and management resources, to engage with and play its role in managing the collaboration/consortium.	Private sector partner may require initial investment from NHS organisation, in terms of working capital or loans for the company. Value of NHS organisation's shares only crystallise on sale of the company/shares. Involves more NHS time and management resources, in terms of being a shareholder in the company and ensuring appropriate standards of corporate governance.
Example	NHS Digital's Data Access Request Service (DARS) products and services.	Moorfields and Google Health research partnership.	Sensyne Health strategic research agreements with a number of NHS foundation trusts.

GRANT FUNDING

Grant funding is often mentioned in the context of potential models for data commercialisation.

However grant funding is not a commercial model in itself but rather a means of securing investment which may be used by NHS organisations (and, in some cases, their private sector partners) in the implementation of one of the models summarised above. A good example of this is the funding awarded by Health Data Research UK to the various Health Data Research Hubs, which are collaborations between the NHS, academic institutions and industry.

Where any commercialisation of NHS data is backed by grant funding, it is, of course, necessary to ensure that the terms of the partnership are in compliance with the conditions attached to the grant, for example, in relation to ownership of intellectual property, IP licences back to the funder and sharing the revenue arising from commercialisation.



WHAT'S THE HOLD-UP?

At present, the commercialisation of NHS data could reasonably be described as a 'slow burner', even though the models summarised above are well-established in other contexts, and have already been used in this space.

This may, in part, be due to reluctance on the part of some NHS organisations to press ahead with partnerships in the absence of a nationally-mandated model, given the obligation on those organisations to ensure that their use of a particular model in any given partnership will not have a negative impact at system level. It may not always be easy for individual NHS organisations to assess the likelihood of local arrangements having an adverse effect nationally. The blurred lines around data governance also cause NHS organisations to think twice before pressing ahead with collaborations which rely on using significant quantities of NHS data.

Sections of the private sector have also indicated that the lack of a national strategy on appropriate commercial models is a factor affecting their ability to develop and deploy certain data-driven products and services, such as artificial intelligence technologies.

The policy framework also requires individual NHS organisations to agree "fair" terms for their organisation but also for the NHS as a whole. It has been highlighted that if all partnerships operate at local level only, some NHS organisations may see varying commercial returns dependent on the comparative quality of their data, or may not realise significant commercial benefits at all. This brings with it the risk of increasing or creating inequalities in the system.

WHAT NEXT?

For these reasons, and as recommended by Reform's "Making NHS data work for everyone", it is hoped that DHSC will provide an indication of those commercial models which it considers will allow individual NHS organisations to unlock the potential of patient data without a negative impact system-wide. The work of the Office for Life Sciences and NHSX, as mentioned above, also provides some potential impetus to progress.

Even with a steer from the centre, it is clear that individual NHS organisations will need to consider a range of models, and forge their own partnerships, in order to release the commercial value stored within the data which they hold. By the nature of the NHS, and different approaches in different organisations, the data that each organisation holds may be unstructured, and part of the collaboration may well include assistance in that regard. A central steer on acceptable models should, however, provide confidence both to the NHS and its partners as the fundamentals from which such partnerships should be approached.

With the right support in place, NHS organisations have the opportunity to develop partnerships with private sector partners that help to improve outcomes for patients and provide a commercial return that can be reinvested in the NHS, in the process.

Should you wish to discuss any of the themes in this article, please contact:

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FURTHER READING

[NHS Digital Academy](#)

Department of Health and Social Care Guidance: Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation

Institute of Global Health Innovation: NHS data: Maximising its impact on the health and wealth of the United Kingdom

Reform: Making NHS data work for everyone

Department of Health and Social Care Guidance: Code of conduct for data-driven health and care technology

Department for Digital, Culture, Media & Sport Guidance: Data Ethics Framework dacbeachcroft.com

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