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TECHNICAL ANNEX

Target Operating Model for the National Data Trust

WHAT IS THE NATIONAL DATA TRUST AND HOW DOES IT WORK?

This annex develops a high-level blueprint for a National Data Trust (NDT). It describes the functions of the NDT, its target operating model, the extent to which it addresses current challenges in data access and commercialisation, and the possible legal changes required to make it happen.

Overall Objective of the NDT

Access to high-quality health-care data has a broad set of benefits for patients, the NHS and the country.

For patients, it means better health outcomes from being treated in organisations that participate in research[1] and benefiting from the discovery of new treatments. In fact, NHS organisations involved in research were shown to have lower mortality rates.[2] Similarly, a high level of participation in hospital research improved colorectal cancer survival outcomes.[3] It is therefore vital to ensure that NHS patients have access to clinical research.

Better-curated data because of the existence of the NDT will also facilitate a wider set of use cases, including population health management, benefiting the NHS and its patients: use of data drives the quality of data. NHS trusts receive an average of £9,000 for every patient participating in clinical trials,[4] and this provides a strong incentive to ensure data are good quality, providing vital additional income at a time when most NHS organisations are fiscally challenged.

For the country, a dedicated and well-resourced concierge service for research will make the UK a more attractive place for life sciences, which generated a £94.2 billion turnover in

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[1] https://www.nihr.ac.uk/health-and-care-professionals

[2] https://pubmed.ncbi.nlm.nih.gov

[3] https://pubmed.ncbi.nlm.nih.gov

[4] https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/)

2021.[5] The O'Shaughnessy Review into clinical trials suggests that "the costs of the near halving of patients recruited to commercial research activity in the NHS over the last five years is in the region of £360 million, funding that has to be found from the taxpayer instead. Over this time period, an additional estimated £570 million could have been provided to the NHS to recover costs of running commercial trials".[6]

The wider benefits from clinical trials are significant. For example, the National Institute for Health and Care Research (NIHR) estimated that clinical research activity generated around £2.7 billion of gross value added to the UK economy and an estimated 47,500 full-time-equivalent jobs in 2018–19.[7]

The Scope and Remit of the NDT

The NDT will provide a central, easy-to-access and transparent concierge service to invest in and monetise health-care data in England. In short, it will provide a shared-services function to commercialise access to a range of different data sets on behalf of the NHS and other data controllers.

The NDT will not hold the actual data, which remains the prerogative of individual data controllers through a federated data-access model. It will therefore not create a central data lake but provide seamless access to a range of data assets similar to a physical library that enable access to books but prohibits those books from being removed from the premises.

The scope of the NDT will take several years to develop because of the infrastructure investments required.

In the short term, the scope of data includes all NHS data that are already available centrally, particularly through the NHS Research Secure Data Environment (SDE) Network and remaining Health Data Research UK (HDR UK) data-hub infrastructure. However, and to maximise the benefits from an NDT, its ultimate aim should be to provide a consolidated

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[5] https://www.gov.uk/government/statistics/bioscience

[6] https://www.gov.uk/government/publications

[7] https://www.gov.uk/government/publications

front door to all health-care data – discoverable via the HDR UK Health Data Gateway – which is already the medium-term intention of the NHS data-for-research-and-development (R&D) model. This would mean amalgamating commercial access to several currently separate data assets such as Clinical Practice Research Datalink (CPRD), Genomics England (GEL) and UK Biobank, many of which were not primarily set up to generate revenue, but rather to provide high-quality data for general research. The NDT will not take over the core business of organisations such as GEL and UK Biobank but will provide shared services on their behalf.

The NDT will also be able to connect meaningfully and effectively with the NIHR clinical-trial infrastructure, including the 12 local Research Delivery Networks (RDNs), Clinical Trial Acceleration Networks (CTANs) and the NHS App, as well as run digital trials, reflecting the vital importance of clinical trials to revenue generation.

The range of services provided by the NDT to third parties will therefore include:

- Data discovery via the HDR UK Health Data Gateway
- Direct access to health-care data for accredited third parties
- Basic descriptive and automated search functionality of data
- Feasibility studies for trials, for example to identify relevant cohorts using NHS DigiTrials
- Trials recruitment (through NHS DigiTrials, pre-consented cohorts and NHS-app functionality)
- Provision of data about individuals from a single, authoritative source for trials, locally recruited through the RDNs
- Health economics and wider analytical services including through a federated network of artificial-intelligence centres
- Ability to validate and develop machine-learning algorithms

These services will be regularly reviewed and developed according to market needs and be subject to annual business planning.

The NDT will also hold and manage the ongoing investment in the data infrastructure and be the banker on behalf of its investors – public and private – including the distribution of any surplus. It owns the digital infrastructure it is investing in to make available de-identified data for research purposes. It will not, however, own or invest in core health IT infrastructure such as electronic patient records for wider use cases such as population health management.

The NDT will be the contracting body for third parties on behalf of the UK and hold the commercial risk. In this context, it will seek to innovate the commercial models, drawing on a number of potential value-sharing frameworks such as shared intellectual property or equity.[8]

Strategic Fit of the NDT

A key question for the NDT is if and how it can help overcome some of the challenges that currently hold the UK back from reaching its potential in the commercialisation of data.

Many of the challenges set out above, such as faster information governance processes, better data quality, and a comprehensive end-to-end single front door and service function are not automatically fixed by moving operations to an external company, even if a more centralised model is desirable. They need addressing in any case and are necessary conditions regardless of the structural and legal form of a commercial function.

However, there are at least four specific benefits that an external NDT would bring compared with the status quo or a centralised in-house model.

First, and most importantly, it helps ensure longevity of intent and funding. Government is not able to make credible medium-term funding commitments, which in turn makes it difficult to create lasting data infrastructure on the ground. In addition, government structures are subject to frequent change; for example, NHSX and NHS Digital were both absorbed into NHS England. These structural changes have high opportunity costs and are hugely disruptive to delivery.

Establishing the NDT outside government enables more long-term funding and institutional stability. Given the vital role reliable and long-term funding plays, this is a significant advantage, as is evidenced by the global success of UK Biobank, which has been operating successfully for 23 years. The process of establishing the NDT outside government can be undertaken in stages over two or three years, with the NDT initially being incubated by an existing suitable external national or local body before becoming a separate legal entity.

Secondly, government cannot easily carry forward funding from one year to the next. This makes any commercial venture difficult as all funding must be spent within a year,

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[8] https://spiral.imperial.ac.uk/bitstream

preventing revenue being carried forward into investment. The NDT model would help avoid the clawback of funding.

Thirdly, having the NDT as a private entity with greater fiscal flexibility will help to raise funds from industry and other sources. At a time of limited fiscal headroom, this helps shift investments off the public balance sheet.

Finally, the proposed model will make it easier to attract talent, given the greater flexibility in employment terms and conditions.

The Target Operating Model of the NDT

The target operating model of the NDT describes the structural, legal and commercial form required to discharge its functions.

Legal Form

The NDT's governance structure will depend on its chosen legal form, which should be determined through a systematic review of existing models used by organisations such as Our Future Health, UK Biobank, GEL and local data hubs. This review must consider factors such as commercialisation, external funding, tax, governance and public acceptability.

Currently, UK health-data entities take a variety of public and private legal forms (see Figure 1), with most being government-owned and controlled. The choice of organisational form significantly impacts fiscal autonomy and agility, which are crucial for improving health-data access for research and innovation. To circumvent the constraints and short-term thinking that often hamper public-sector initiatives, the NDT could follow the BBC’s model of combining public service with commercial success. The broadcaster provides a public service while also operating BBC Studios, a revenue-generating subsidiary that upholds public trust.

Figure 1 – Examples of data assets in the UK and internationally

	Legal form	Revenue	Access model	Central/local	Service offer
GEL	Private limited company owned by the Secretary of State for Health and Social Care	£140 million, of which £3.8 million is commercial	Independently reviewed by the Access Review Committee against the National Genomic Research Library Protocol – involves experts, clinicians, and a Participants Panel representing individuals whose data is in the project	Central	Access to data in the GEL research environment, with tools embedded to support analysis
Discover-Now	Company limited by guarantee (non-profit organisation)	£2 million	Local-access committee; meets every two weeks	One ICB; 2.6m patients	Feasibility studies, health economics, implementation support, AI and patient recruitment
DigiTrials	NHS England	Cost-recovery basis	Health Research Authority (HRA) approval (research-ethics committee – 7–18 members of experts and non-experts – and HRA assessment) and Data Access Request Service approval (a case officer will assess)	Central	Feasibility service, recruitment service, communications and outcomes
Biobank	Charitable company	£7.6 million income, with £2 million from data access	Trained reviewers, scientists; if there are concerns, goes to expert access committee	Central	Research Analytics Platform (RAP);

					500,000 population
Our Future Health	Private Limited Company by guarantee without share capital; use of “Limited” exemption	Currently piloting data access for free	Access Board: experts, public, participants; accreditation assessed by Dionach Ltd	Central	Analytics tools within the TRE
Findata	–	€1.7 million income for secondary-access fees	Permits have to be approved by the data controller	Data remains with the data controllers of various national datasets	Data permits, combining and pre-processing of data, SDE
Singapore (WIP)	National initiative by government	TRUST will support public-private data sharing and projects – commencing second half of 2024	Data-access committee: members are selected on the basis that they have relevant knowledge in health care, science, technology, law, ethics; plus senior representatives from TRUST partner institutions	Data contributor owns the data – fused data sets will be owned by TRUST	Data concierge service; bring own code, subject to approval
Mayo Clinic platform	Private not-for-profit company	Data access generates $5 million	Mayo Clinic Institutional Review Board (IRB) and the Mayo Clinic Biobank Access Committee	Central	Solutions studio– curation

European Health Data Space (work in progress)	EU	€11 billion expected to be saved for the EU over around ten years, with these savings gained from better access and exchange of health data; and from better use of health data for research, innovation and policy making	Legislation pending – in new platform HealthData@EU	Local	Reviews requests for access to data; issues data permits
Denmark	Government	–	Requires multiple permits based on what data you want access to from a number of different authorities (though they call this a single gateway) https://www.enindgangtilsundhedsdata.dk/en/services/ansoegningsportalen	Federated	"Metadata" map

Source: TBI

Any design of the governance structure will need to balance the public interest with that of investors and other key stakeholders. This could be done through the creation of appropriate sub-boards, as is the case with Our Future Health.[9] Although the NDT's objectives could theoretically be achieved within the public sector, it would require a comprehensive overhaul of practices, from funding cycles to operational methods. This is an unrealistic undertaking given the immense scale of change required.

The board of the NDT would need to have the necessary autonomy to pursue the organisation's commercial and wider interests set out above. Operational independence is of vital importance to the success of the NDT to avoid the bureaucratic constraints and short-term political considerations that have often hindered the agility and effectiveness of

[9] https://ourfuturehealth.org.uk/about-us/how-were-governed/

public-sector data initiatives. The design of the NDT must foster rather than hinder data access and avoid becoming a single point of failure. Organisational design and structure both serve to mitigate this risk – both compelling reasons for establishing an external body.

Access to Data

Data access will be non-exclusive and independent of financial interests in the NDT itself; in other words, investors may be given preferential rates for data access but will not be able to stop others from accessing the NDT's assets. Health data remain a public good.

Access to the data will be governed by a pre-accreditation licensing system that, once approved, allows third parties basic access to the data (mainly to search it for feasibility studies similar to the current NHS DigiTrials self-service tool). Any substantial use of patient-level de-identified data, including for clinical trials, will go through a data-access committee process.

While there will eventually be a single sign-off process for all data, initially – and due to current legal constraints – sign-off will have to go through a federated system of access committees – for example, 11 sub-national secure data environments (SNSDEs) groups with delegated authority similar to the Integrated Research Application System – depending on which data are being accessed.

As timely sign-off is a key success factor for commercialisation, legislative changes which are currently being worked up should be prioritised, so that central sign-off and access to projects is possible within weeks not months (see below).

The NDT process will be the only way to gain access to health-care data within the SDE family (and eventually to all other publicly funded data for research purposes) to ensure a transparent and consistent approach that is professionally run.

Establishing a coherent approach to opt-out rules (including making it easier to opt back in) and adequate legal safeguards should be an urgent priority. Learning lessons from Covid-19 and striking the right balance between not stifling access to data and legitimate concerns about privacy and transparency will be essential and require strong public engagement.

Opt-out rates increased by 80 per cent following the General Practice Data for Planning and Research programme and stands currently at around 5.4 per cent on average.[10] However, rates have not significantly increased following the award of the Federated Data Platform programme. There is limited public understanding of different opt-out routes and what citizens can and cannot opt out from. This creates a difficult space for any data-sharing project, whether commercial or otherwise, and needs a resolution which itself should be co-created with the public.

Commercial Model

The NDT will be tasked with generating revenue on behalf of the taxpayer to increase the fiscal headspace of the health sector, while not compromising on the wider purpose of fostering knowledge generation and benefits to patients as set out above.

Other locally developed and funded data assets (for example, in universities or other tertiary institutions) would be invited to use the NDT so that they can benefit from the scale and expertise on a non-exclusive and fee-for-service basis. It is hoped that the service offer of the NDT is compelling enough that it has the broadest possible appeal. However, anyone using the NDT will have to adhere to the general service and data-quality standards set out below.

Any surplus (revenue after costs) that the NDT generates is either reinvested into its services and infrastructure or distributed among its owners and those contributing data assets. Redistribution will be governed by a set of clear principles to be co-designed with the public, investors and data controllers.

Those principles will be guided by four core objectives:

1. To crowd-in investment from external sources
2. To incentivise a stronger focus on research by the NHS locally
3. To incentivise higher data quality
4. To free up resources to be invested in core health-care infrastructure.

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[10] https://digital.nhs.uk/dashboards/national-data-opt-out-open-data

At its heart, a redistribution model will need to take into consideration the relative risk those contributing to the NDT are taking (financially, and in terms of data governance and public trust) as well the right balance between achieving a return on the initial investment while simultaneously ensuring the company invests sufficiently into the future development of its services. Revenue should be tied to clients' actual use and not just the availability of data, to incentivise the provision of high-quality data in the first place.

Consideration should also be given to the practical and fiscal implications of distributing revenue to a potentially large number of individual data controllers. This might be overcome by focusing on larger federated entities such as the SNSDEs and other contributors of data, such as GEL or UK Biobank, rather than individual data controllers. It will be paramount for continued public support that revenue does not simply flow to investors but benefits the NHS in visible and direct ways.

This also offers an opportunity to be creative about the use of any revenue. Government could commit to ringfencing any surplus for specific purposes such as prevention, public health or the overall research budget. This could provide incentives for the NHS and R&D community to invest time and effort in making the commercialisation of data a priority (see final section on strategic fit).

However, such an approach would require flexibility in the fiscal architecture to allow for a degree of hypothecation of revenue, carefully balancing the benefits and risks.[11] This might be easier to address if the source of additional revenue (health-care data) is the same as the intended use of that revenue (i.e. the health service).

It is likely to take significant time before a surplus can be realised, given the upfront investment in infrastructure required.

The NDT will have a clear and transparent pricing model informed by public engagement and market intelligence as well as the experience of existing organisations operating in this space, such as GEL, NHS Research SDE Network and CPRD).

We already know from existing public engagement (for example, in London) that citizens are supportive of the commercialisation of their health-care data, particularly where there is strong public benefit from the use of those data. For example, the public favours a tiered

[11] https://researchbriefings.files.parliament.uk

pricing model depending on ability to pay and location (favouring UK-based organisations). Such model is already operationalised in parts of the SDE.[12]

Public engagement has also signalled that citizens are not looking for financial returns to be remitted to them individually but instead want them reinvested in health services. However, there may be scope to explore whether people pre-consenting to clinical trials, through the NHS app or otherwise, should be given more explicit recognition through concepts such as a data-donor card and be kept informed about when their data have been used.

Team and Capabilities

The NDT will employ a core team to ensure that it can operate in an efficient and professional way, providing a first-class user experience. The core team will include an executive team, business development and marketing departments, together with investment expertise. Most importantly, the NDT requires analytical and trial-design proficiency.

While it will most certainly want to employ an appropriately sized core team, it may also wish to consider a more federated model of employment that is able to link into other existing local data services to maximise the breadth and depth of expertise. This might operate under a franchise arrangement that allows local data assets to use the NDT infrastructure if they adhere to an agreed set of standards under service-level agreements.

Other models, such as partnerships with third-party providers (for example, for analytics) or a secondment model (from public or private entities) should be considered. All of this will help make the NDT more competitive in an increasingly tight labour market for data and analytical talent.

Federation

The NDT will centralise where necessary but federalise wherever possible. This means building on the current NHS Research SDE Network approach (and previously HDR UK) which is investing in local or disease-specific data assets locally, which are deeper than national data can be, while also creating a national data asset at scale but with less depth through a central SDE. The NDT will initially focus on data that are already centrally

[12] https://www.onelondon.online/empowering-citizens-99-1-my-journey-of-the-onelondon-citizens-summit-from-2020-to-2023/

available such as the central SDE or GEL. Over time, this will expand to other locally held sources.

For this to work and respond to industry calls for scale, in order to cover, for example, research into rare diseases, the technical linkage of the federated SNSDEs will be critical. This must mean not only that the data are discoverable (which they already are through the HDR UK gateway), but also centrally accessible through one front door. The NDT will therefore continue to invest in local SNSDEs and the remaining HDR UK network to link and curate data and make them available through a federated cloud environment. Technical models successfully deployed by organisations such as the Francis Crick Institute should be considered, but it needs to be recognised that this will take several years to be fully functional.

However, beyond a transition period of 24 months, local SNSDEs will not provide data access directly to third parties. Similarly, CPRD, GEL and UK Biobank should cease to trade commercially within two years of the establishment of the NDT, recognising that GEL and UK Biobank were not primarily set up and optimised to generate commercial income. However, this will only impact access to the data of these organisations, not their wider functions and core purposes.

The federation model will operate through an accreditation process that is already being developed for SDEs and will be made available to other locally or nationally operated and owned data assets. This franchise model will set out the respective expectations between the NDT and data assets through a series of service-level agreements. These will stipulate the data standards, sign-off times for access (the SDE will require less than a month), and revenue sharing.

There are many important use cases from better data linkage. The biggest tangible financial gain is likely to arise from increasing the number of commercial clinical trials in the UK, which would likely reverse the current downward trend.

A significant strategic requirement is therefore for the NDT to work seamlessly with the clinical-trials ecosystem.

In practice, the NDT will provide a data platform on top of which the NIHR and NHS England trials applications can sit. The specific trials-related functions provided will include:

- Running feasibility studies utilising and developing the NHS DigiTrials platform
- Recruiting patients for trials using a number of routes including Section 251, existing pre-consented local and national cohorts, and a new feature on the NHS app that allows patients to pre-consent and/or sign up for trials directly
- Providing real-time and authoritative data for patients recruited through the newly created 12 regional NIHR RDNs[13]
- Providing data access to the newly established CTANs (and focusing initially on, for example, the Vaccine Innovation Pathway and the Dementia Mission) following the O'Shaughnessy report

To make this happen, further investment in linking the currently separate parts of the trials ecosystem is required. However, and more importantly, this will also need to break down the historical policy silos between NIHR and NHS England.

Funding

The medium-term aim of the NDT is to become financially self-sustained so that funds currently invested in creating research capacity and capability can instead be redirected to frontline service provision and other initiatives. However, sustainability will take some years and require further initial investment by government and external sources. Government funding should come from a broader economic growth agenda, rather than relying solely on the health department's budget to reflect the wider spill-over effects of a globally leading data asset.

One of the core purposes of the NDT will be to hold funding to invest in the data for research infrastructure. Funding will come from a number of sources including government and the private sector.

Government has already invested around £60 million in the 12 SDEs in 2023–24, including SNSDEs and the NHS England SDE (around £120 million over three years). The annual contribution to GEL is around £140 million as well as £80 million for Our Future Health, which received a further £160 million from industry for exclusive access to its data. The UK Biobank had cumulative investment of around £500 million over 23 years, mainly from the

[13] https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm

Wellcome Trust and the Medical Research Council. HDR UK has invested £38 million into seven digital innovation hubs and industry contributed through further match funding.

The fundamental challenge of the UK data ecosystem remains the fragmentation and lack of longevity of these investments as well as the size of available funds. To be useful, the NDT will therefore need to address this problem by aggregating existing funding as well as raising additional external funding to provide scale and longevity.

Today's level of SDE funding is likely to fall short of being able to afford the development of comprehensive multimodal and unstructured data sources. The current funding period, linked to the Spending Review, is set to end in 2024–25 and there is currently no forward commitment to maintain the infrastructure that is being built. There is also no funding available to link multiple federated data assets in such a way to provide meaningful central access. Finally, there is no funding for a service team to facilitate access to the data, although there are small teams locally in some SNSDEs.

The current situation suggests that over the next two-to-three years, another £200 million is likely to be required to develop the full functionality of the SDE data asset, including multimodal and unstructured data sources across the 11 localities, as well as to make the data fully operationalised. Subject to the development of a full business plan, the probable annual business-as-usual cost of the SDE network will be at least £20 million thereafter. Finally, the core annual operating costs of the NDT will need pump-priming before revenue is sufficient to be self-sustained and are likely to be between £5 million and £10 million.

The NDT would therefore initially aim to raise between £200 million and £300 million and, assuming government would want to retain a majority stake in the NDT, would mean raising between £100 million and £150 million externally, which is comparable with what Our Future Health has achieved. To help meet this funding goal, the government should consider utilising part of the £400 million investment programme of the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG).[14]

To maintain the NDT as a public good, no exclusive access to data should be granted in return for investment. Instead, external investors might be offered reasonable preferential access and service fees.

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[14] https://assets.publishing.service.gov.uk/media/657b2977095987001295e139/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth.pdf

The revenue of the NDT would be a mix of data-access fees and the facilitation of clinical trials and wider services set out above.

Spending data by industry on clinical trials are patchy. The available data suggest that between 2016–17 and 2018–19 the NHS received on average £9,000 per patient recruited to a commercial clinical trial.[15] In 2022, the UK recruited around 28,000 patients into clinical trials, down from 50,000 in 2017–18.[16] Facilitating a share of these trials directly (for example, through NHS DigiTrial) or in partnership with mcontract research organisations would constitute a core part of the NDT's revenue.

In addition to trials income, the NDT is set to generate between £10 million and £20 million in annual data-access fees.[17]

Generating the meaningful revenue would therefore rely on the significant growth of clinical trials and data-access activity.

An important rate-limiting factor is the capacity of the NHS to absorb significantly more funding to deliver the technical changes required. This is already a challenge at current rates of investment.

A full business case that works through the detail of the economic model (investment required, potential market size, available resources) and the operational and delivery challenges is an important next step to calibrate the scale of the NDT.

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[15] https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/22489#:~:text=For%20each%20patient%20recruited%20onto,drugs%20replaced%20the%20standard%20treatment)

[16] https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review

[17] Extrapolation from local experience of existing services such as Discover-Now. GEL is generating around £3.8 million and Discover-Now between £1 million and £2 million annually from data-access services.

Risks

Most notably, it may be more challenging to address public concerns about a private company with industry investment commercialising sensitive health data. It is therefore crucial that such a model has strong and meaningful public engagement from the start.

The second significant risk is the separation of services and investment from delivery capacity inherent in setting up the NDT as an external body. Currently, the Department of Health and Social Care, DSIT and NHS England as funders have the financial and managerial levers to direct delivery capacity locally. However, this is already challenging, given how stretched the NHS is overall, and research is not always seen as a priority on which to focus scarce resources. Moving the NDT outside government and separating it further from technical delivery capacity locally and general performance management, may make this even harder.

The lack of focus on research within the NHS is therefore a fundamental risk that cannot be mitigated by the choice of a particular legal structure. It will require more fundamental levers. NHS England will need to hold integrated care boards (ICBs) to account for supporting research as set out in the Health and Care Act 2022. This is not currently the case.

Third, the benefits from commercialising data need to be felt by the NHS frontline and data controllers. This is partly about a financial return (see above) and partly about better data infrastructure that can be used across a range of use cases such as population health management.

The final risk is that centralising access to services may lead to a single point of failure. Unless the NDT provides an efficient, user-centric service, customers have nowhere else to go in the UK and, rather than strengthen the UK's position, it will weaken it. Again, this is less about the organisational form and more a function of centralisation. One might argue that spinning out the NDT by running it as a private entity in a globally competitive market and sharing risk may mitigate this issue. However, it is paramount that the NDT has sufficient autonomy and distance from public-sector bureaucracy.

Legal and Policy Changes Required

The government already has the necessary powers to set up external companies and allow for external investment and there is precedent (for example, the Behavioural Insights Team and Fera Science Limited). There are also already existing mechanisms for the public to

invest in public infrastructure, such as community impact bonds in local authorities, should this be desirable.

For the NDT to work (though this also applies to any other central function whether in-house or not), there are two urgent legal changes that should be prioritised.

The first is to enable a single sign-off process for access to all de-identified data. This is currently not possible unless it is for pre-consented data (GEL and UK Biobank). For all other data, local data-access committees usually consider and sign off data-access requests. Practice and process vary across the country, not least among the UK's 42 ICBs, and this delays access to data and prevents a meaningful single front-door approach. Government is currently developing the necessary legislative change to bring multiple ICBs under a single data-access-committee process and this should be prioritised.

The second issue is control of data. Currently, there are thousands of data controllers across the country, including general practitioners and hospital trusts. Unlike in Scotland, there is no joint controllership between NHS England and individual data controllers.

A clear roadmap should be developed across all current public health-care data investments to consolidate commercial access and functions. This may require a transition period of between 12 and 18 months.