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Auditing demand for health and care data

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About Us

Future Care Capital is a charity which undertakes research to advance ideas that will help shape future health and social care policy and deliver better outcomes for individuals living in the UK.

Beginning life as the National Nursery Examination Board in 1945, the charity has evolved throughout its 70-year history and we continue to have Her Majesty the Queen as our Royal Patron.

More information:
http://www.futurecarecapital.org.uk

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Context

Our work to enable key stakeholders to harness the value of health and care data has involved extensive research, policy development and advocacy activity.

Related publications include: Intelligent Sharing, Facilitating Care Insight and our parliamentary briefing for the House of Lords.

Between November 2018 to April 2019, we undertook primary research with a view to auditing demand for data controlled by health and care organisations in England. We have also engaged broad-ranging stakeholders to generate a related Discussion Paper.

A summary of our research methodology and findings is provided here.

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Types of Health and Care Data

Three types of data are of interest and in scope for our purposes:

1. The data controlled/generated by publicly funded and accountable health and care organisations;

2. The data controlled/ generated by organisations who provide pertinent services to health and care commissioners;

3. The data controlled/generated by private entities whose core business might not be health or care related but which might, nonetheless, have the potential to generate useful insights about a population or individual's health and care.

Given the 'supply-side' complexities, we opted to focus on demand for data controlled/generated by one type of publicly funded and accountable health and care organisation: NHS Trusts.

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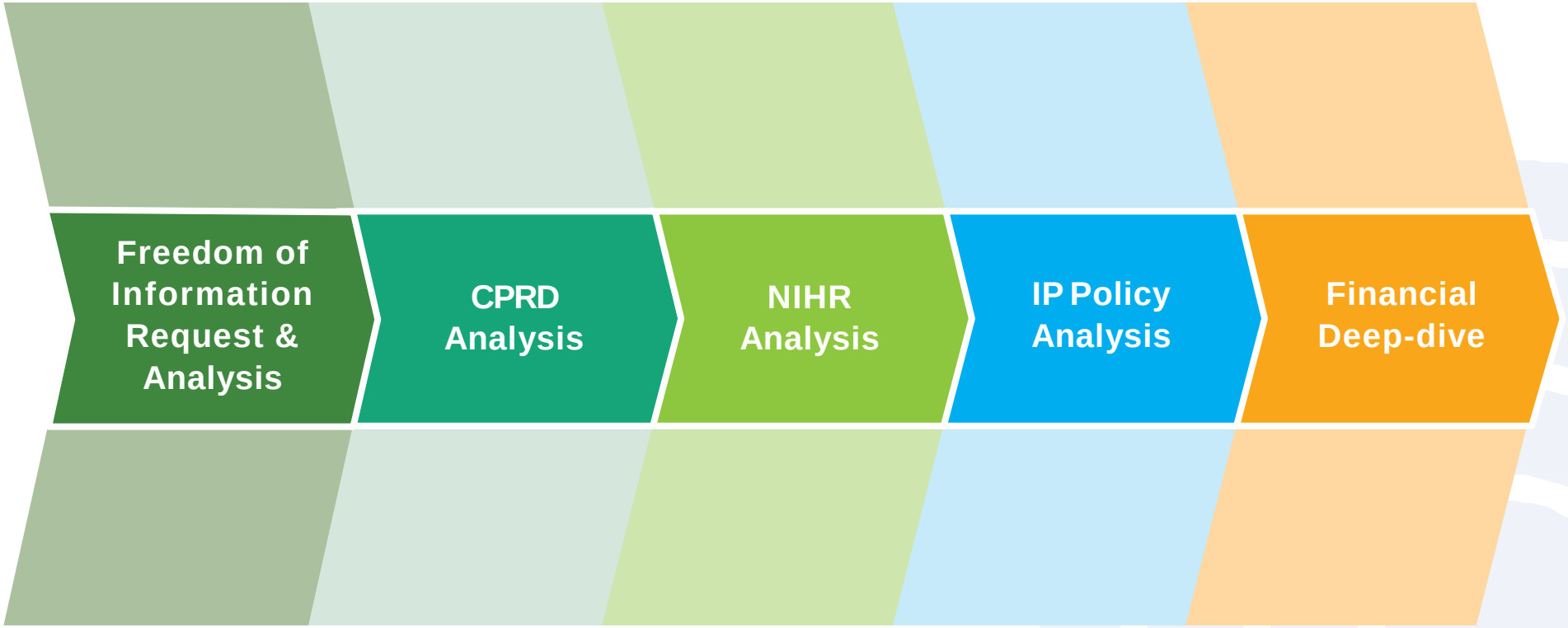
Auditing steps undertaken



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Freedom of Information Request and Analysis

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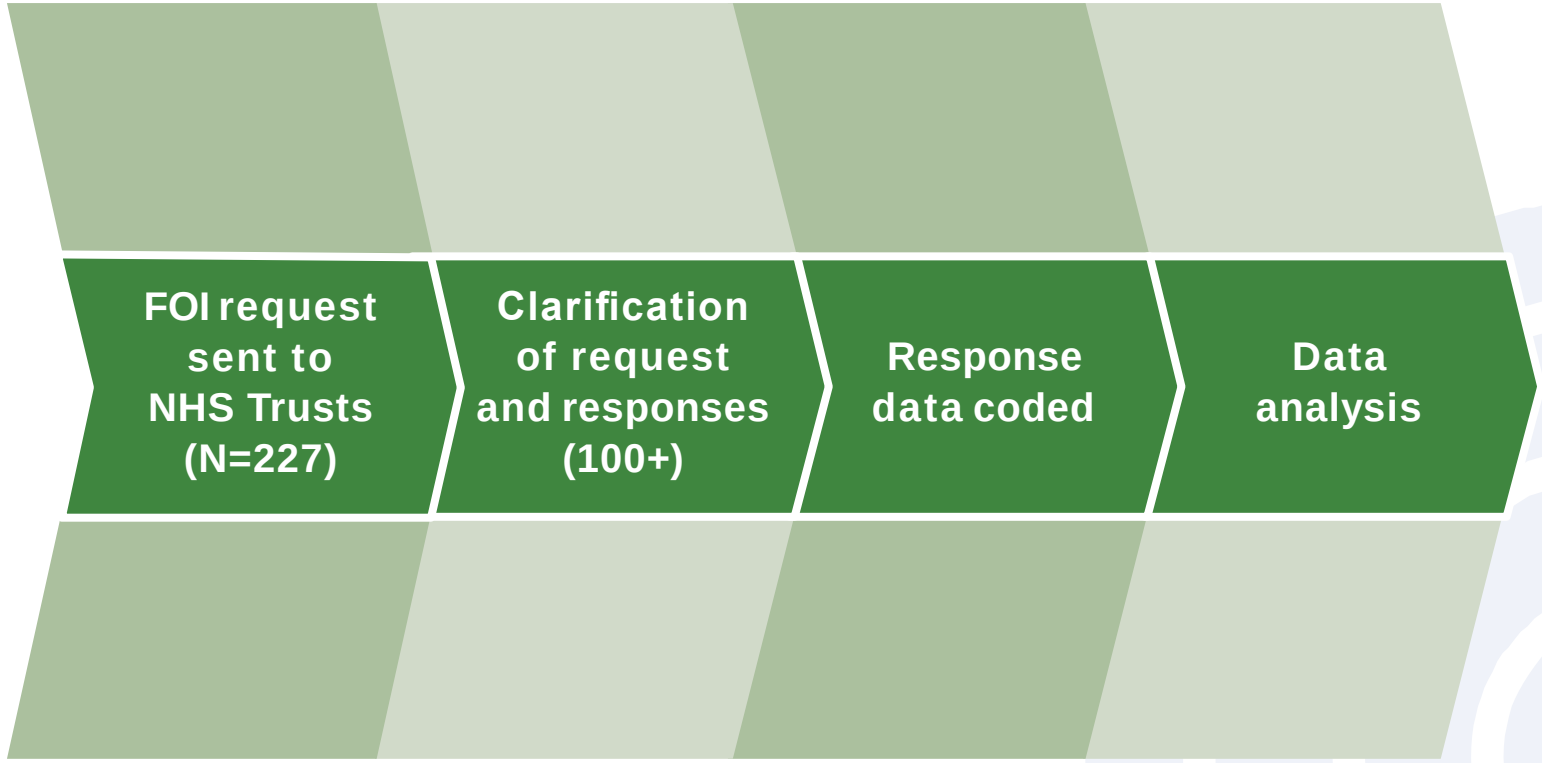
Methodology



- Freedom of Information request sent to 227 NHS trusts on 12 Dec 2018
- 35 trusts (18%) cited an exemption under section 12 (s12) of the Freedom of Information Act (2000) - indicating that the cost of complying with the request would exceed the limit the Act provides for
- 192 responses received (85%)

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Freedom of Information Request

We asked NHS Trusts in England about any requests to use or access data for commercial or research purposes where the Trust is/has been a controller, joint controller or controller in common as follows:

- the number of requests made in each of the financial years 2015-16, 2016-17 and 2017-18;
- the percentage of requests that have been accepted, rejected or held pending in each of the financial years 2015-16, 2016-17 and 2017-18;
- a breakdown of the form, size and sector type of the entities that made the requests in each of the financial years 2015-16, 2016-17 and 2017-18; and
- a breakdown of the form, size and sector type of the entities whose requests were successful in each of the financial years 2015-16, 2016-17 and 2017-18; and
- the percentage of those successful requests which resulted in the trust, or its constituent hospitals, entering into a commercial or financial relationship with the requestor or its affiliates in each of the financial years 2015-16, 2016-17 and 2017-18.

We also asked:

Can the Trust confirm whether it, or one of its constituent hospitals, has entered into a commercial or financial relationship with any of the following entities as a result of the requests made in each of the financial years 2015-16, 2016-17 and 2017-18? Google; DeepMind; Sensyne Health; Benevolent AI; Orion Health and/or IBM.

Can the Trust supply a copy of its intellectual property policy document/s, if any, covering the period 2015-present?

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Clarifications and Caveats

We were asked to provide clarification by 100+ Trusts because:

- they tended to interpret our enquiry as being limited to requests to access/use patient-identifiable data.
- the Health Research Authority (HRA) and National Institute for Health Research (NIHR) have clear definitions of the term 'research' and associated processes – where they are concerned with patient identifiable data – and Trusts rightly sought to exclude reference to NIHR coordinated clinical studies in which they were/are participating because, technically, they did not receive a request from a third party to access data controlled by the Trust but, instead, were invited to participate in a study with a view to generating new data.
- there is currently no standard or accepted definition of what is meant by the term 'commercial' and, therefore, few (if any) trusts maintain records which differentiate between requests made by/for research as distinct from commercial purposes.
- only a minority of Trusts retain complete records of requests to access/use data they control, such that most are only able to provide confirmation of the numbers that were approved (i.e. it is not possible to obtain a comprehensive picture of demand for data controlled by NHS Trusts from third parties at this time).
- Trusts which were not used to being approached by third parties did not, in a number of instances, appear to think that the data they control might be of interest/value to others.

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Data Analysis

NHS trusts are not currently required to record data about requests to access/use the data they control for research/ commercial purposes in a consistent manner for the purposes of reporting.

1/5 Trusts that responded to our audit reported not holding **any** information regarding the number of requests received for research or commercial purposes.

Of the trusts that **had** received requests, 1/5 ***only kept records of accepted requests*** – i.e. they do not hold records of requests that were rejected.

Among Trusts that reported having received requests for data:

- Acute and Mental Health trusts received x10 as many requests to access/use the data they control for research and/or commercial purposes each year as Ambulance and Care trusts.
- Foundation Trusts received x2-x3 as many requests as non-Foundation Trusts.

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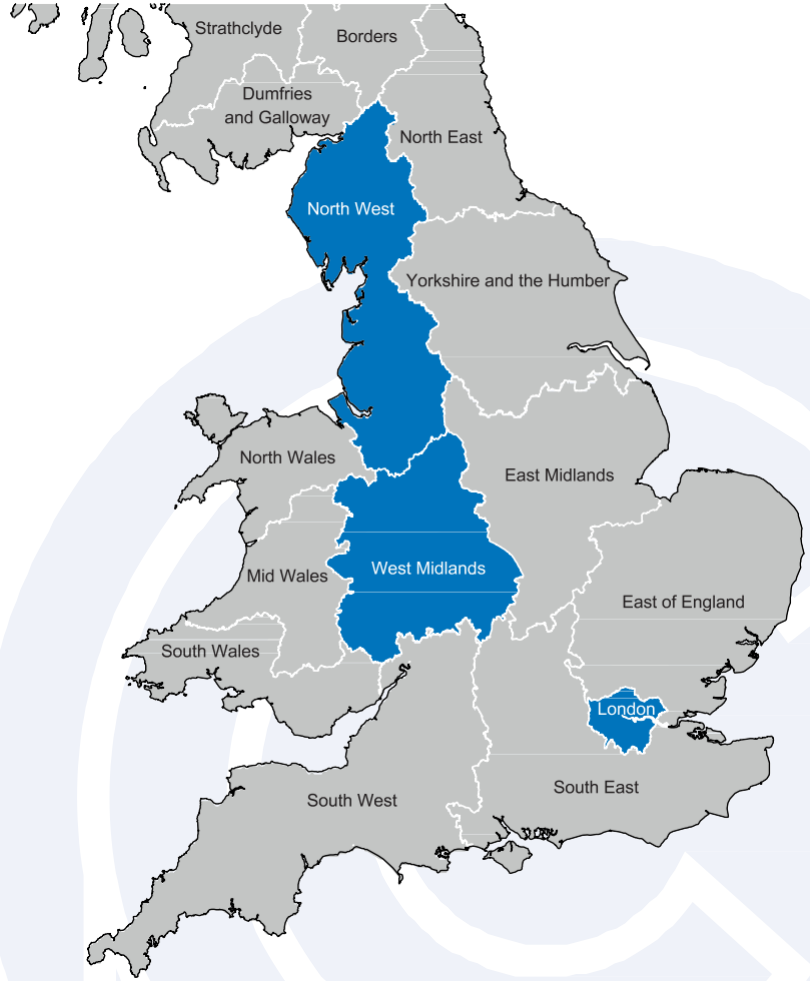
Data Analysis

Trusts in the West Midlands (WM), London and the North West (NW) received more requests than other regions in the three financial years we asked about and demand, generally, mapped to the proximity to a Russell Group university.

Of the Trusts that responded to our audit, 27% said they had not received any requests for data for the purposes outlined in our request. However, among those Trusts that did receive requests, the vast majority (87%) were accepted.

The majority of respondents were unable to provide a breakdown by sector of parties interested in the data they control, but were able to say more about the types of organisations which approached them. The majority of recorded requests were reported as having come from Higher Education Institutions (HEIs).



NB: we are unable to confirm the extent to which requests from HEIs led to activity funded by and/or involving commercial entities.

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Data Analysis

31% of requests resulted in a financial or commercial relationship between the Trust and the requester.

Trusts from London, the West Midlands and the North West were most likely to enter into such relationships.

This, perhaps, provides some indication as to the urban/rural/coastal split in associated revenues - although this is not something we are able to verify from our FOI Request.

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Comparison with other Data Sources

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Additional Data Sources Used

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Complexities and Further Steps

FCC's audit of demand for data **controlled** by NHS Trusts is, we think, unique and our Freedom of Information request returned a response rate of 85% but

- use of the Freedom of Information Act limited the utility of the responses we received; and
- larger trusts, in particular those belonging to the Shelford Group, are under-represented in our sample.

As a result, we opted to cross-reference our findings with information about the demand for primary care data **controlled** by the Clinical Practice Research Datalink (CPRD) in an attempt to better understand the scale, scope and geography of third party interest.

Crucially, however, mapping 'demand' for data which is or could be **generated** by the NHS is not the same as mapping demand for data that is already **controlled** by the NHS.

Interest in **generating new data**, **working with the NHS** is helpfully captured by the National Institute for Health Research (NIHR) in its clinical research study league table - but only with regards to patient identifiable data. Interest in **non-patient data generated by activities commissioned from third parties** – or the potential for the same - remains something of an unknown quantity at this time.

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Auditing Demand: CPRD

The Clinical Practice Research Datalink (CPRD) provides a portal for access to national, de-identified patient data derived from GP records.

A public register of **approved** studies which make use of the data is available via the CPRD website: https://cprd.com/protocol-list

We analysed demand for access to/usage of CPRD data – in particular, we considered the institution of the principal investigator listed in respect of each approved study.

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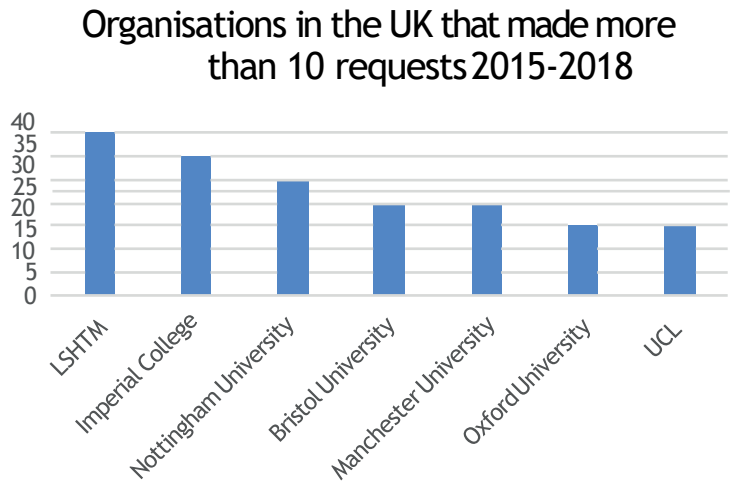
CPRD Data: Analysis

Approved requests to use CPRD data
- 2016/17: 168
- 2017/18: 175
(compares with median requests per NHS Trust of 17 in each year for the 85% of Trusts that responded to our FOI request)



Most requests came from Higher Education Institutions (321) - followed by pharmaceutical companies (96).
Among requests from the UK, 72% came from Higher Education Institutions and 12% from pharmaceutical companies
Among requests from the USA, 41% came from pharmaceutical companies and 27% from Higher Education Institutions

Country of request	Total number of requests 2015-2018	Number of organisations within country
UK	321	From 72 organisations
USA	63	From 27 organisation
Canada	39	Of which 37 from one organisation (McGill University)
Switzerland	21	Of which 18 from one organisation (Basel University)
Netherlands	14	Of which 13 from one organisation (Utrecht University)
Germany	13	Of which seven from one organisation (Boehringer-Ingelheim)
Belgium	5	From three organisations
Sweden	5	Of which four from one organisation (Astra-Zeneca)
Singapore	5	From one organisation (Observational and Pragmatic Research Institute)
Denmark	4	Of which three from one organisation (Novo- Nordisk)
France	4	From four organisations
Australia	2	From one organisation
Luxembourg	2	From one organisation
Spain	2	From two organisations
Israel	1	

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CPRD Data: Analysis

Echoing our own audit of data requests from third parties of NHS Trusts, **the largest proportion of requests originated from Higher Education Institutions**, followed by pharmaceutical companies.

Although the majority of requests to access/use CPRD data originated within the UK, **a not insignificant proportion came from institutions overseas**, demonstrating international demand from researchers and commercial entities for well- structured and well-managed databases in health and care.

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NIHR Data: Overview

The NIHR publishes an annual league table of research activity in NHS Trusts – where the highest ranked is involved in the greatest number of clinical research studies.

In the league tables for 2016/17 and 2017/18:

- All members of the Shelford Group were ranked in the top 15 for each year;
- those non-Shelford Group Trusts in the top ten each year were: Leeds, Nottingham, Barts Health and Southampton; and
- the top 3 trusts in the league table were each involved in 500+ studies.

We cross-referenced the returns from our Freedom of Information request about interest in data **controlled** by NHS trusts, with NIHR rankings and the involvement of Trusts in clinical studies involving the **generation** of new data.

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NIHR Data: Analysis

According to Dr Jonathan Sheffield, Chief Executive Officer, NIHR Clinical Research Network: ***"The [NIHR] league table is really about giving research opportunities to all patients in the NHS."***

However, analysis of the league table revealed that in 2017/18, the top 15 (7%) Trusts each had 300 or more studies attached to them, involving a total of 216,448 participants, while the bottom 70 (30%) Trusts each had 35 or fewer studies attached to them, involving a total of 44,655 participants.

As such, the top 7% of Trusts involve almost **five times as many participants** in research as the bottom 30% of Trusts in the league table.

NIHR ranking in 2017/18	Trust name	Number of requests according to FCC FOIA audit*
1	Newcastle upon Tyne Hospitals NHS Foundation Trusts (550)	average 100 requests per year; accepting 20-25%
2	Guy's and St Thomas' NHS Foundation Trust (500)	Cited S12 exemption
3	Oxford University Hospitals Foundation Trust (517)	Cited S12 exemption
4	Leeds Teaching Hospitals NHS Trust (451)	average 14 requests per annum: 33-45% accepted
5	Nottingham University Hospitals NHS Trust (434)	Cited S12 exemption
6	Barts Health NHS Trust (429)	No reply
7	University College London Hospitals NHS Foundation Trust (427)	No reply
8	Imperial College Healthcare NHS Trust (422)	No reply
9	Sheffield Teaching Hospitals NHS Foundation Trust (414)	Cited S12 exemption
10	University Hospital Southampton NHS Foundation Trust (413)	average 700 requests per year, no info on % accepted
11	Cambridge University Hospitals NHS Foundation Trust (398)	No reply
12	Manchester University NHS Foundation Trust** (369)	Cited S12 exemption
13	King's College Hospital NHS Foundation Trust (352)	No reply
14	University Hospitals of Leicester NHS Trust (328)	Cited S12 exemption
15	University Hospitals Birmingham NHS Foundation Trust (298)	No reply

* Corresponds to trust in 2017/18 ranking

** Same trust; renamed after merger

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Intellectual Property Policies: Context

We obtained Intellectual Property (IP) policies for 105 NHS Trusts via our FOI request and through desk research – as such, only 50% of Trusts appear to have developed and/or published an IP policy.

Trusts in London, the West Midlands and the North West (which reported the highest number of requests to access/use data from third parties according to our FOI request) were the least likely to report having an IP policy. However, when looking at types of trust, Acute and Mental Health trusts (which receive the highest number of requests by Trust type) were more likely to have an IP policy than Ambulance or Care trusts.

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Intellectual Property Policies: Analysis

We designed and deployed a framework for IP Policy Analysis and looked at 1/3 of policies obtained in-depth – a cohort of x32 policies:

- x24/32 policies analysed refer to DH guidance published and not updated since 2002 (by an organisation which no longer exists)
- only x2 policies in total make any explicit reference to data protection or GDPR
- x27/32 offer an explicit incentive for employees but amounts vary between different Trusts and within STPs (see: below)

Employee Incentives

- x10 Trusts offer incentives of 35% or less - regardless of the revenue generated – and, in almost all cases, this is where profit is split three ways between the Inventor, their Department and the Trust
- x7 Trusts offer the Inventor 50% or more in respect of relatively low revenues (e.g. up to £25k), then 35-40% for amounts up to £200k, and then a lower proportion thereafter
- x6 Trusts offer significant incentives – in these trusts, the Inventor is awarded 50% or more of revenues up to £200k (nb: the proportion tends to diminish thereafter).
- x2 Trusts offer the Inventor a share on a case-by-case basis
- x2 Trusts differentiate between research and non-research staff – in one trust, research staff get no share of revenues at all whereas, in the other, they receive significantly less than non-research staff.

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Intellectual Property Policies: Analysis

We also analysed IP Policies based upon the local Sustainability and Transformation Partnership (STP) they belonged to:

- There are no STPs that are fully covered in terms of IP policies
- The most covered in our cohort are Cambridgeshire, Durham, Darlington, Teesside, Hambleton, Richmondshire & Whitby - with five out of six covered
- The least covered are Somerset - where none of the three trusts have a policy - and Norfolk & Waveney - where none of the six Trusts have a Policy

In some STPs, employee incentives provided for in IP policies are consistent, whereas in others they differ substantially - for example:

- All three Trusts in Staffordshire and Stoke-on-Trent STP offer lower incentives to employees.
- Of the five Trusts which comprise Cambridgeshire & Peterborough STP, three offer significant employee incentives, whereas two offer lower incentives (where profit is split three ways between the Inventor, their Department and the Trust - regardless of the revenue generated).

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Intellectual Property Policies: Analysis

Does the Trust make explicit in its IP Policy that its priority or principal aim is to improve the health and care of patients in the UK?	Does the Trust's IP Policy outline how it will quantify associated benefits?	Does the Trust's IP Policy outline how it will guarantee mutually beneficial and fair terms when entering into an arrangement with an employee and/or third party?	Does the Trust's IP Policy make explicit reference to Board Member responsibilities?	Does the Trust's IP Policy set out how it will not undermine, inhibit or impact the ability of the NHS at a national level to maximise the value or use of NHS data?	Does the Trust's IP Policy preclude exclusive arrangements?	How does the Trust's Policy ensure that arrangements are transparent and clearly communicate them so as not to undermine public trust in wider government data policies?	Does the Trust's IP Policy make explicit mention of the National Data Guardian and/or the National Data Guardian's Data Security Standards?
1/3	No	Yes/No	No	No	No	N/A	No

When analysed in relation to the guiding principles for commercial deals involving NHS data that were proposed by the Office for Life Sciences in the Life Sciences Sector Deal (December 2018), none of them were reflected in the IP policies we analysed, where one in three explicitly stated the Trust's priority or principal aim is to improve the health and care of patients in the UK when engaging in the development of Intellectual Property.

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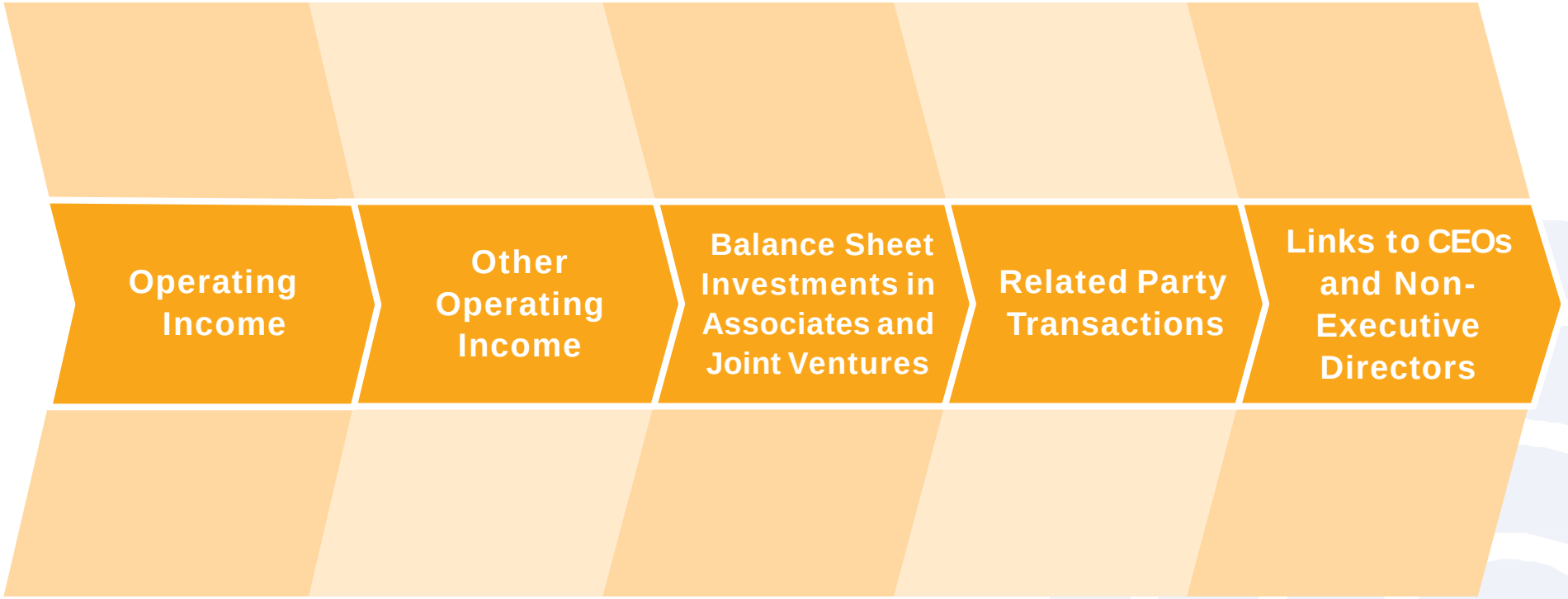
Financial Deep-dive: Methodology



We also tested an approach to examine the financial arrangements linking NHS Trusts to income generating Special Purpose Vehicles/spin-outs to garner a picture of equity stakes and/or income generation from 'data deals' involving them.

In particular, we hoped to understand the scale of 'data deals' entered into between Shelford Group Trusts and third parties, loosely defined in our methodology as equity stakes (associates, subsidiaries and JVs), with a focus or particular interest in patient and other health data, to help us address their under-representation in our FOI analysis cohort.

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Financial Analysis

When we examined Annual Reports with a focus on 'the finances', we looked at

- Operating income from patient services – but this did not prove to be of direct relevance to our question;
- Other Operating income - this is relevant but is in the range of £100m-£250m across the Shelford Group, without any consistent or clear breakdown of sources at a more granular level than e.g. "R&D £x, PFI Transitional Support £y, Other £z". So, further specific inferences were not possible from the accounts and notes. Relevant revenues will be included in this line but cannot be extracted from the information available.
- Balance Sheet investments in Associates and Joint Ventures - these were listed somewhat consistently, but details in notes were sparse, and this is likely only a small subset of relevant 'deals'. It is, however, worth noting that many investments in Associates were valued at zero – i.e. they are loss-making.
- Related Party Transactions which are the in-goings and outgoings from subsidiaries/associates/JVs – this, again, could have some relevance but suffers from the same subset issues for making broad inferences. NB: most were in deficit - i.e. invested more money into these than they received from them.
- CEOs and Non-Executive Directors and their recorded interests on official registers where available - this raised some interesting connections but did not necessarily indicate an official relationship or contractual arrangement. This is also a very manual exercise and incomplete from this source because the registers are not necessarily the most up to date and, in some cases, appear to be incomplete.

Ultimately, this line of enquiry proved wanting for the lack of consistent and publicly available information - which raises important questions about the scope for the NHS to offer a comprehensive audit trail to data subjects about how data about them is being used and/or their value is being harnessed.

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Financial Deep-Dive: Analysis

We are unable to read-across from publicly available information about facilitating access to/usage of existing data controlled by NHS Trusts to any income that might be generated by the same. We are also unable to read- across from publicly available information about participation in clinical trials to either direct or indirect commercial returns for individual NHS Trusts. As such, the extent to which facilitating access to and/or usage of data **controlled** by NHS Trusts is more or less valuable than participation in clinical trials to **generate** new data is not readily discernible at this time.

Neither, then, is the 'size of the overall prize' – when viewed solely from a commercial perspective - such that we are of the view that supply and demand factors cannot be used straightforwardly to determine the financial value of Trust data revenues/assets to the NHS (whether existing or potential) at this time.

NB: we acknowledge that our analysis reflects the outcomes of a limited exercise with a narrow focus on commercial value and does not therefore capture or reflect any social and economic development value that pertinent Trust activities might also be generating.

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Conclusions

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Conclusion

"The future is here –
it's just not evenly distributed"

William Gibson, Science fiction writer

There appears to be a discrepancy in the potential for NHS Trusts of different types and in different places to harness the value of health and care data – whether we are talking about providing access to existing data that Trusts **control**, new data that Trusts might work with third parties to **generate** through participation in clinical trials or simply having an appropriate **intellectual property** policy and, with it, a transparent approach to commercialisation.

There might be a tacit (or, even, explicit) acceptance that some NHS Trusts will benefit more than others from data-driven innovation because of their proximity and ties to Russell Group universities and the R&D ecosystems in which they're involved and invested. Then, again, there might not.

Our concern is that this could be at odds with the Government's stated intention: to 'maximise the value of healthcare data whilst ensuring a fair distribution of associated benefits'.

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Recommendations

At the very least, we recommend Government:

1. mandates **standard returns** from health and care organisations so that data supply, demand and commercialisation activities are **transparent;** and

2. considers carefully how to introduce related measures into the already complex landscape for **mapping**, **managing and** accounting for health and care data and the Intellectual Property it plays a role in developing.

Ultimately, it is our view that individuals ought to be able to understand and have a say and/or stake in how the social, economic development and commercial value of health and care data about them is being harnessed via a readily intelligible and trustworthy feedback loop – but, we acknowledge that Government needs to start somewhere.

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Download the Data

Auditing Demand for Health and Care Data (Data Table)
Analysis of NHS Trust Intellectual Property Policies
The Shelford Group Financial Analysis

Read the Discussion Paper

Taking Next Steps to Harness the Value of Health and Care Data

Contact Us research@futurecarecapital.org.uk

Research

Dr Josefine Magnusson, Senior Research Officer – Future Care Capital

To be cited as

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