



**Future Care** Capital

**Report**

# Developing a Value Framework for Medical Imaging Data

**Prepared for the National Consortium of  
Intelligent Medical Imaging (NCIMI)**

*Annemarie Naylor MBE, April 2021*





## **About FCC**

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.

## **About the Author**

Annemarie Naylor is Director of Policy and Strategy at Future Care Capital. She has a background in public policy working with local, regional and central government in the UK. She is the author of numerous publications in the health and care space with an emphasis upon data-driven innovation and the deployment of new technologies.

## **About the Report**

The work described in this report was undertaken with funding from the National Consortium of Intelligent Medical Imaging (NCIMI). We would like to thank all the participants who contributed to the research, and NCIMI for their support throughout the project.

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## Introduction

Prior to the public health emergency announced by the World Health Organization (WHO) in January 2020, there was growing awareness of the potential for clinical, economic development and commercial value to flow from healthcare data controlled by the UK's National Health Service (NHS). As a result, the Department of Health and Social Care (DHSC) published a *Code of Conduct for Data-driven Health and Care Technology*<sup>1</sup> and an addendum detailing commercial principles that were designed to create the right framework to realise the benefits of healthcare data<sup>2</sup>. The Department for Business, Energy and Industrial Strategy (BEIS), meanwhile, invested £50m in five centres for digital pathology, radiology, integrated diagnostics, AI and machine learning<sup>3</sup>, and a further £35.5m in Digital Innovation Hubs led by Health Data Research UK (HDR-UK)<sup>4</sup> which now function as centres of excellence with expertise and tools to maximise the insights and innovations developed using healthcare data.

Future Care Capital (FCC) has written extensively about information sharing and data institutions in health and care<sup>5</sup>, the value of healthcare data<sup>6</sup> and the scope for it to stimulate economic development<sup>7</sup>. It has also contributed to research conducted by Reform about the use of NHS controlled data by corporate entities<sup>8</sup> and work undertaken by Imperial College London exploring the importance of patient involvement in the use of healthcare data<sup>9</sup>. It is against this backdrop that the National Consortium of Intelligent Medical Imaging (NCIMI) – one of the five centres funded by Innovate UK through the 'Data to Early Diagnosis and Precision Medicine' challenge - approached FCC in Autumn 2019 to explore the scope to develop a value framework for medical imaging data.

Eighteen – unprecedented - months have passed and the importance of data is, perhaps, more widely recognised now than ever before as a result of the COVID-19 pandemic. Policymakers and commissioners in health and care, front-line professionals, researchers and corporate entities are all operating in an increasingly 'data intensive' environment. A Joint Biosecurity Centre provides evidence-based analysis, assessment and advice to inform local and national decision-making in response to COVID-19 outbreaks<sup>10</sup>. A COVID-19 Data Store has been established to assist in monitoring the spread of the virus and ensure that appropriate services and support is made available to patients<sup>11</sup>. HDR-UK has scaled the National Core Studies programme which is using health data to inform our near- and long-term responses to COVID-19<sup>12</sup>, and the general public is encouraged to make use of assorted 'symptom checkers'<sup>13</sup> as well as a bespoke NHS Covid App linked to Test and Trace services<sup>14</sup>. The datafication and digitisation of health and care services has, then, proceeded at break-neck pace - adding impetus to established calls for technological transformation to improve patient experience and population health outcomes, whilst delivering on the Government's Industrial Strategy and, more recently, its *Plan for Growth*<sup>15</sup>.

All of this has taken place along with Brexit – which has implications for data protection, digital trade and the regulation of next-generation medical devices - and some measure of 'business as usual', in respect of which, DHSC has taken a number of steps of import to NCIMI's work. It has, for example, amended its Code of Conduct – now referred to as a *Guide to Good Practice for the Use of Digital Technology in Health and Care*<sup>1</sup> – as well as issuing Digital Technology Assessment Criteria (DTAC) to afford staff, patients and citizens confidence that the digital health tools they use meet its clinical safety, data protection, security, interoperability and other standards<sup>16</sup>. It has also established the NHS AI Lab<sup>17</sup> and a Centre for Improving Data Collaboration (CIDC)<sup>18</sup> within NHSX to ensure that publicly funded health organisations are well-placed to scope and enter into data sharing arrangements with Higher Education Institutions (HEIs) and commercial entities for research and



commercial purposes. Looking ahead, the UK Government has announced plans to publish a dedicated Health and Care Data Strategy, building upon its Integration and Innovation White Paper<sup>19</sup>, which will include provisions to ensure that the NHS receives a 'fair share' of the benefits flowing from data deals it enters into with third parties. The National Data Guardian will, for its part, report and consult on statutory guidance flowing from its public dialogue about the use of health and care data for public benefit<sup>20</sup>.

This report details the approach taken by FCC to scoping a value framework for medical imaging data given the context outlined above and our findings. An assessment of the implications of developments associated with the public health emergency for the Consortium's forward plan is beyond the scope of our work. We, nonetheless, acknowledge that emergency measures impacting information governance<sup>21</sup>, investment in the National COVID-19 Chest Imaging Database (NCCID)<sup>22</sup> and AI Validation<sup>23</sup>, as well as plans to develop a National AI Medical Imaging Platform (NMIP), are of material importance to NCIMI's future role in the healthcare data ecosystem, its impact and its sustainability - as is, potentially, a significant procurement exercise managed by NHS Shared Business Services for the Provision of Artificial Intelligence, Imaging and Radiotherapy Equipment, Associated Products and Diagnostic Imaging at the time of writing<sup>24</sup>.





## Our Approach

The advice and guidance available to NHS organisations that seek to enter into data collaborations and pertinent agreements with third parties remains limited from the point of view of 'value creation'. In our experience, this is because policymakers and healthcare professionals tend to emphasise the importance of compliance with data protection provisions and 'information governance', rather than developing and/or implementing frameworks and guidance concerning other steps in the 'data value chain' that result in the creation and deployment of new treatments and technologies<sup>i</sup>.

This has, understandably, given rise to important work undertaken by, for example, the Office of the National Data Guardian for Health and Social Care<sup>25</sup>, Understanding Patient Data<sup>26</sup> and One London<sup>27</sup>, who have sought to actively involve individual data subjects or advocate for the 'patient perspective' in the evolution of policy and practical tools. It has, also, enabled clinicians to engage in research reliant upon healthcare data that is governed by legally compliant processes and pertinent ethical codes. It has, however, had the effect of skewing attention and effort towards what might best be described as the 'basics', 'plumbing' or consideration of healthcare data standards, interoperability, linking and sharing - leaving markedly less bandwidth amongst policymakers to determine evidence-based priorities for investment and activity that should make use of healthcare data to transform outcomes for patients and populations, and to explore what more/different may be needed to assist NHS organisations and third parties to create value collaborative fashion using healthcare data<sup>ii</sup>.

At the outset, then, our work was designed to involve researchers, charities, industry representatives (ranging from SMEs to multinationals) and financial/commercial professionals within the NHS in exploring how best to collectively steward the *value* derived from healthcare data, rather than duplicate work already undertaken to explore the attitudes of individual data subjects to aspects of information governance in healthcare provision, service planning and research. Specifically, we sought to understand whether there was scope for the range of partners involved in NCIMI to distil and agree strategic priorities such that a differential value framework could be developed to guide agreements between publicly funded healthcare organisations, HEI's, charities and commercial entities underpinned by medical imaging data.

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<sup>i</sup> In Taking Next Steps to Harness the Value of Health and Care Data (2019), FCC was only able to obtain Intellectual Property (IP) policies for 105 NHS Trusts. As such, only 50% of Trusts appeared 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 a FOIA request we issued) were the least likely to report having an IP policy.

<sup>ii</sup> Whereas this served as NCIMI and FCC's starting point in Autumn 2019, FCC acknowledges the formal launch of the within NHSX in November 2020, which is intended to resource this work in future.



The approach we envisaged involved:



1. Distilling strategic priorities linked to harnessing the value of the data the consortium controls and/or generates in discussion with members



2. Developing a differential value framework to guide agreements about the data, insights and tools expected to flow from data access/sharing arrangements with third parties



3. Testing different 'value judgements' in relation to broad-ranging data sets to evaluate their relative strengths/weaknesses



4. Disseminating the lessons learned in practical settings linked to NCIMI's work to inform the emergent national policy-making framework

A high-level audit of medical imaging data controlled by or of interest to Consortium members would, we hypothesised, enable us to arrive at strategic priorities and draw down value judgements which we, indicatively, categorised in terms of their:



#### Clinical value

Whether the data can be used to glean insights with clinical, direct health outcomes or research output benefits arising from its use.

*E.g. Could the data contribute to the development of new treatments and/or health technologies?*



#### Economic Development value

Whether use of the data will deliver stimulus and economic growth.

*E.g. Could the data be used to inspire growth of homegrown SMEs?*



#### Commercial value

Whether the data can be used to generate monetary returns.

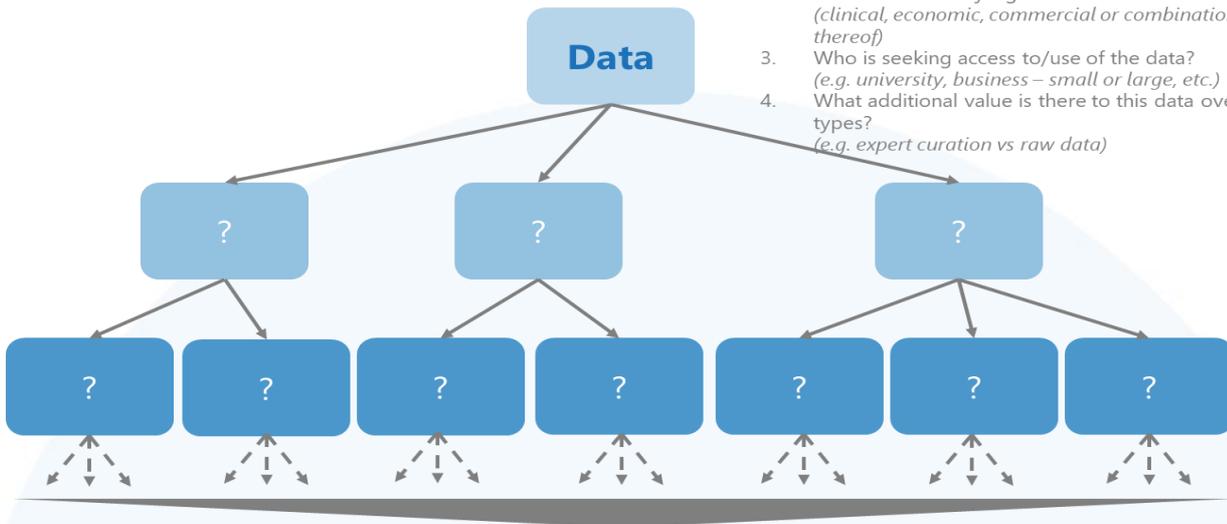
*E.g. Could the data be deployed to generate a financial return?*

The output from the data audit and the defined value judgements could then be used to create a *decision tree* which would facilitate selection of the best model to use for any data agreements and, thereby, enable the creation/extraction of optimum value:



**Sample questions:**

1. What type of data is it?  
(e.g. x-ray, CT scan, MRI)
2. What is the value judgement?  
(clinical, economic, commercial or combination thereof)
3. Who is seeking access to/use of the data?  
(e.g. university, business – small or large, etc.)
4. What additional value is there to this data over other types?  
(e.g. expert curation vs raw data)



**Most appropriate data arrangement model**

In developing a differential value framework to guide agreements about the data, insights and tools expected to flow from data access and sharing arrangements with third parties, additional considerations to input to the decision tree would include legal advice and financial modelling work.

We then envisaged testing different ‘value judgements’ in relation to broad-ranging data sets to evaluate their relative strengths and weaknesses. By engaging with key stakeholders in a mini-summit process, we intended to analyse the motivations and needs of different groups involved in the Consortium to feed into a grand summit which would bring different groups together to test, align and agree upon a common set of rules designed to *collectively steward value from data* within the framework.

**Mini summits with individual stakeholder groups**

Test developed framework to explore priorities, requirements and value judgements of individual groups with objective to understand pinch-points and work towards alignment

**Convene grand summit to bring stakeholders together**

Collaborative conversation to test and agree a framework and set of standards that works for everyone

**Agree a common set of rules to collectively steward value from data within the framework**



However, of necessity, our activities evolved in response to the public health emergency and, in particular, the availability of colleagues whom we had hoped to engage in-person through the process of deliberative summits outlined above. Instead, FCC conducted desktop research and a series of online interviews which gathered views from the perspective of different Consortium members about a number of real-world scenarios that we subsequently mined for key themes.

### ***Phase 1 – Desktop Research and Legal Review***

We undertook initial literature review as well as speaking to Information Governance colleagues in Oxford to garner an appreciation NCIMI and the medical imaging datasets to be controlled by or generated in conjunction with the Consortium. We then co-designed a legal brief and worked with Anthony Collins Solicitors LLP to produce a detailed Legal Review of the Research and Commercial use of Healthcare Data<sup>28</sup>.

The Review provides details of relevant laws and regulations concerning personal data and individual rights, data processing and intellectual property as they relate to healthcare and, in particular, medical imaging data. As an adjunct to the Review development process, FCC provided advice to NCIMI about the implications of COPI notices issued by the Secretary of State for Health and Social Care which impacted the design of the national thoracic database designed to support the efforts of researchers during the COVID-19 pandemic<sup>29</sup>.

Our Phase I findings were disseminated online and shared with attendees of Cog-X: the Global Leadership Summit and Festival of AI & Emerging Technology in a panel event about commercialising NHS data in June 2020. The Legal Review was also cited in the Centre for Data Ethics and Innovation's AI Barometer<sup>30</sup> and disseminated by FCC at its virtual launch event. In July, FCC further explored the findings in contributing to NCIMI's podcast<sup>31</sup>.

### ***Phase 2 - Case Studies and Stakeholder Interviews***

A number of case studies were developed, based upon real-life scenarios from NCIMI projects, to illustrate the nature of requests for access to and usage of medical imaging data from a range of commercial entities. These case studies were then used in a series of virtual discussions with key stakeholders associated with the Consortium's work to tease out the extent to which different requests were adjudged to be 'fair' and, in particular, how different stakeholders view related constraints and potential benefits.



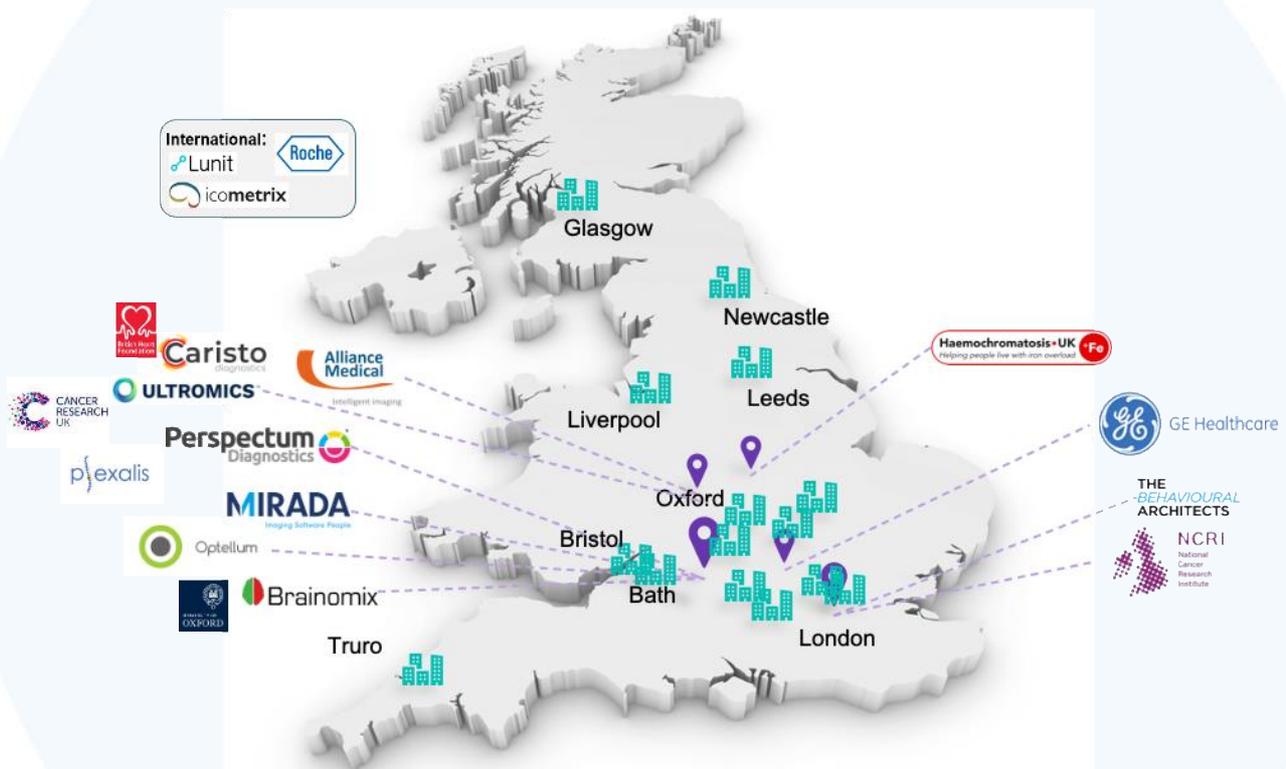
In total, eight stakeholder interviews were conducted, and a presentation of the key findings made to NCIMI Board Members in Autumn 2020, before being disseminated by NCIMI at a British Institute of Radiology conference in January 2021. FCC's work for NCIMI also informed work undertaken for the Centre for Improving Data Collaboration in Spring 2021.

This report for NCIMI details key findings from FCC's desk research, the Legal Review and subsequent stakeholder interviews.



## About NCIMI, its Partners and Projects

The National Consortium of Intelligent Medical Imaging (NCIMI) aims to revolutionise healthcare through Artificial Intelligence (AI) and comprises a partnership between NHS trusts, companies, universities, charities and patient groups coordinated by the University of Oxford. The Consortium is led from the University at the Big Data Institute and its mission and purpose is to facilitate collaboration for clinical impact from multi-modal AI. Clinical partners are based at NHS Trusts and Boards that span the length and breadth of the UK - from Glasgow to Truro and across the Thames Valley and London. Individual clinical leads include global experts from across the country to address unmet needs in cancer, cardiovascular diseases and metabolic health across the whole NHS.



Innovation takes place across sector boundaries and the Consortium has brought together partners to enable this innovation to happen with greater speed and impact. A major barrier to progress in AI in medical imaging is the lack of standardised and accessible imaging data for the development, evaluation and validation of AI algorithms. The development of AI software solutions requires high-quality, labelled, curated and validated data.

NCIMI supports a network of NHS Trusts in providing data from their systems to support AI development. It has invested in the expertise to ensure that data is of high quality, consistent, annotated and curated as needed. The de-identified data is held within its central databank to support specific project activity and access is governed by a Data Access Committee using FAIR (findable, accessible, interoperable and reusable) principles for scientific data management and stewardship.



NCIMI supports AI development, training and validation across various stages of development - including initial project scoping and pilot data collection, large data set acquisition, development for algorithm training and validation, reader studies and real-world evaluation. It can support single-site studies to explore areas of unmet need where imaging and AI may have novel applications. Following early-stage R&D, there may be what NCIMI terms a beta-AI solution. Such projects are likely to involve greater data volume and possibly more sites, to develop robust, diverse training data sets. NCIMI supports data provision from across its network of partners, to ensure diverse high-quality data for further training and internal validation. It can also support external testing by providing 'unseen' real-world data sets, evaluation against current readers in clinical practice and real-time evaluation in clinical practice - together with real-world testing in care settings to develop evidence of efficacy and preliminary proof.

NCIMI and its partners are currently working on 18 exemplar projects that are delivering against unmet need using tens of thousands of medical images generated through CT, PET and MRI scans as well as X-rays and echocardiograms. The projects span: breast, spinal and lung cancer, cardiovascular conditions, chronic backpain, COVID-19, critical care, diabetes, endometriosis, haemochromatosis, mesothelioma, obesity, stroke and PET/CT workflow challenges. For further information about each exemplar, please see: Appendix.

<b>Exemplar Project</b>	<b>Imaging Modality</b>	<b>Size of data set</b>	<b>NHS Partners</b>
<b>AI and Cardio CT Scans</b>	<b>CT</b>	<b>54,000</b>	<b>6</b>
<b>AI and Lymphoma</b>	<b>PET/ CT</b>	<b>2,400</b>	<b>5</b>
<b>Childhood Obesity</b>	<b>MRI</b>	<b>2,500</b>	<b>3</b>
<b>Critical Care X-ray</b>	<b>X-ray</b>	<b>32,500</b>	<b>14</b>
<b>Diabetes and Imaging</b>	<b>MRI</b>	<b>1,000</b>	<b>3</b>
<b>Early diagnosis and treatment planning for Endometriosis</b>	<b>MRI</b>	<b>100</b>	<b>1</b>
<b>EchoGo for Chemo</b>	<b>Echocardiograms</b>	<b>54,000</b>	<b>4</b>
<b>Enhancing PET-CT workflow and data quality</b>	<b>CT</b>	<b>3,000</b>	<b>6</b>
<b>Haemochromatosis</b>	<b>MRI</b>	<b>1,000</b>	<b>4</b>
<b>HOST</b>	<b>CT</b>	<b>15,392</b>	<b>5</b>
<b>Improving Lung Cancer Treatment</b>	<b>CT</b>	<b>150,000</b>	<b>14</b>
<b>Lung Cancer Prediction</b>	<b>CT</b>	<b>4,000</b>	<b>11</b>
<b>Mapping Organ Health following COVID-19</b>	<b>MRI</b>	<b>TBC</b>	<b>2</b>
<b>POST: Using AI to assess long-term lung damage due to COVID-19</b>	<b>MRI, CT</b>	<b>6,000</b>	<b>2</b>
<b>Predict Meso</b>	<b>MRI</b>	<b>6,000</b>	<b>3</b>
<b>Stroke and AI</b>	<b>CT</b>	<b>N/A</b>	<b>5</b>
<b>Automated Screening Tool for Spinal Cancers</b>	<b>MRI</b>	<b>3,000</b>	<b>1</b>
<b>Chronic backpain</b>	<b>MRI</b>	<b>2,500</b>	<b>14</b>



An example of the impact of NCIMI's work includes work with GE Healthcare to deliver a real-world evaluation and validation of the Pneumothorax detection algorithm within the X-Ray Critical Care suite, where Oxford University Hospitals NHS Foundation Trust, is providing the clinical leadership on the project. This project is embedding AI into non-radiologist uses and generating the clinical evidence needed to support broad adoption. NCIMI also supports companies which have grown out of the Oxford ecosystem, such as Brainomix, which now has a footprint across 200 hospitals globally. Working with NCIMI, the Oxford Academic Health Science Network (AHSN) and NHS England, Brainomix has the AI enabled e-Stroke deployed across the Thames Valley. e-Stroke supports both specialist and non-specialist clinicians to interpret stroke brain scans in real-time and to identify patients who need urgent treatments or transfer to a specialist hospital. Using the e-Stroke mobile app, doctors can then securely share brain scans with specialists at other hospitals, bringing expert decision making to all hospital Emergency Departments 24/7. This technology has been deployed across the Thames Valley and, with support from NCIMI, is now being assessed across multiple regional stroke networks. The pandemic has seen NCIMI pivot to support partners in responding to the public health emergency. It has, for example, supported Perspectum and Alliance Medical with the COVERSCAN study, and the software developed by the company has now received MHRA approval, as well as bringing in new partner Icometrix, where NCIMI will deliver a clinical validation study for their COVID CT algorithm against COVID data gathered by partners across the Consortium.

The partners and projects outlined here underline the need for expert brokers, like NCIMI, which operate to facilitate innovation through streamlined access to medical imaging data from multiple data controllers, the provision of value-add services to corporate entities operating at different stages in their development and scales, as well as tailored support for collaborative working between the NHS, academia and industry in relation to particular health challenges.





## Legal Review

In scoping the parameters of a value framework for medical imaging data on behalf of NCIMI, FCC commissioned a detailed review of research and commercial use of healthcare data in the UK<sup>32</sup> from Anthony Collins LLP which provides an analysis of the legal issues surrounding the potential ownership and exploitation of health data. The review is available online and provides information about relevant laws and regulations on personal data and individual rights, data processing and intellectual property. It is presented in three sections:

**Part 1** – individual rights including personal data, special category data and biometric data.

**Part 2** – data sets and processing including consent to data processing, legal grounds for processing health data without consent, data anonymisation and pseudonymisation and the impact of the Human Rights Act and GDPR.

**Part 3** – exploitation of intangible property including intellectual property, personal data as intellectual property and requirements for sharing and commercialising personal data by an NHS organisation.

Crucially, it does not constitute legal advice or cover:

- legal or regulatory changes introduced as a result of the COVID-19 pandemic;
- legal or regulatory changes that subsequently came into force as a result of Brexit from January 1st 2021; or
- legal provisions impacting commercial data and/or intellectual property valuation methods.

It is, nonetheless, intended to serve as a useful resource and generated the following headline conclusions:

- 1) Whilst there are some legal obligations and regulatory guidance which emphasises the need to strike a 'fair deal', there is a significant gap in recommendations which outline how this can be achieved in practice. The legal and regulatory gap leaves NHS data controllers exposed: they are required to protect the financial value of the personal data they hold, and the commercial opportunities created by medical research, without proper explanation of how that value is to be calculated.
- 2) Whilst the Courts may conclude that a decision taken by a public authority is invalid on the grounds of illegality, procedural unfairness and irrationality, it is the market which is the ultimate arbiter of 'value', not the Courts, and why the state should seek to encourage healthy and competitive markets. As a result, legal action concerning the use of health data will generally be limited to breach of a data or intellectual property rights (concerning the data subject or the intellectual property owner respectively) or a failure to follow due process (by the public body sharing or exploiting the data), but the Courts are not the appropriate forum to determine the 'value' of health data in monetary terms.
- 3) The starting point in any proposed use of personal data is for each party to 'get its house in order'. This requires understanding and complying with the law around the rights of individuals and the criteria that must be satisfied to carry out data processing activities. The



legal issues surrounding medical research are some of the most complex to navigate. This is due to several factors, including: the newly enhanced and developing area of personal data rights; the technical specialism of managing intangible assets / intellectual property rights as distinct from the control of data in and of itself; the multi-layered and often contradictory legislation applicable to the NHS; the political sensitivities surrounding the NHS, its unique access to large-scale, sensitive data and concerns about its current and future funding model.

- 4) Once organisations understand what data they hold in respect of individual data subjects, there is then an opportunity to combine it and process the resulting data set. Processing data on this larger scale can create new challenges to the rights of data subjects and broader public duties must be considered.
- 5) Effective management of data can lead to the creation of new data sets which could have significant value as intangible assets. As a general principle, there is no property right in information itself. There are no intellectual property rights in plain facts - these only arise when facts are arranged into databases. While individual items of information do not attract property rights, compilations of data may be protected by copyright and/or Database Right, and the data sets and the scientific progress created by their analysis is commercially exploitable or may otherwise be offered, shared and used for a public benefit. The Review discusses the potential for health data to become an intangible asset and the framework in which this value could/should/must be realised.

Ultimately, the Review found that the legal framework governing the UK's healthcare ecosystem offers little to guide the development of multi-stakeholder agreements that are underpinned by medical imaging data sourced from a number of data controllers in the development of AIs - as distinct from more conventional, bilateral 'data deals' - and which necessitate some readily intelligible way in which to approach the sharing or redistribution of any value they might help to create. It also found that the interests of the commercial and public sectors are unfairly balanced under the existing legislative framework governing the use and exploitation of healthcare data - at times, leading to valuable data sets being shared at an undervalue as well as putting individuals' rights and freedoms 'at risk'.

NCIMI will, therefore, need to ensure that any value framework for medical imaging data it might develop and deploy in practice addresses and/or helps overcome these challenges. Here, however, it is important to acknowledge that the analysis of legal issues FCC commissioned on behalf of NCIMI - whilst broad-ranging - is still, necessarily, limited in scope from the point of view of the data value chain. Crucially, it neglects to explore other *types* of value (for example, clinical, population health, economic development value) and, therefore, should not underpin an holistic value framework or be viewed in isolation from other 'value levers' that the Consortium might wish to exert in relation to particular needs and/or aims.



## Stakeholder Interviews

The concept of a 'fair deal' with regards to data sharing from a patient or public perspective has already been explored extensively. For example, it provides a focus for work undertaken by Understanding Patient Data that is outlined in its *Foundations of Fairness* report and which recommends:

- (1) all data partnerships must aim to improve health and care;
- (2) NHS bodies need consistent support and guidance to negotiate fair terms;
- (3) fairness requires public accountability, good governance and transparency; and
- (4) citizens want to be involved in decision-making<sup>32</sup>.

Value return to the NHS for access to healthcare data can, of course, take many forms – for example, Imperial College London continues to explore:

- getting free or discounted access to products developed from the data
- receiving a one-off payment in exchange for data access or a series of one-off payments based on regulatory and commercial milestones
- receiving royalty payment or share of the revenue from the products that are developed using the data (including by leveraging shared ownership of intellectual property generated in connection with the partner's data mining)
- receiving a share of the profits of the company commercialising the data
- receiving a share of the equity in the company commercialising the data
- receiving a so-called golden share, which in specific predetermined circumstances can out-vote all other shares in the company commercialising the data.

Sitting as it does between patients, NHS organisations and commercial users of medical imaging data, NCIMI acts as a neutral broker or 'data institution' that needs some way in which to decide when the terms of data sharing are justified and when they are not and how best to share or redistribute any value that its partners might collaborate to create. Whilst it must take into account patient and public attitudes toward fairness, then, it must also consider complex demand and supply factors as well as its own sustainability.



Accordingly, a number of case studies were developed, based on real-life scenarios from NCIMI projects, to illustrate the nature of requests for access to and usage of medical imaging data from a range of commercial entities:



### SCENARIO ONE

- X15 sites comprised of large trust hospitals and small district general hospitals
- Requests from enterprises <50 employees
- Types of data: clinical records; coronary computed tomography angiography; non-contrast CT scans of the chest
- Retrospective anonymised and pseudonymised



### SCENARIO TWO

- X20 sites comprised of large trust hospitals and small district general hospitals
- Requests from SMEs <50 staff pre-profit generating; a multinational healthcare tech company; a multinational pharma and diagnostic company
- Types of data: clinical records; CT scans; PET CT digital pathology images; blood samples for biomarker analysis; prospective anonymised and pseudonymised data



### SCENARIO THREE

- X1 site – a large academic hospital treating ~2 million patients per annum
- Request from a UK SME >50 staff (profit-generating)
- Types of data: PET CT scans with annotations of images by NHS clinical experts



### SCENARIO FOUR

- X7 sites comprised of large academic hospital treating and small district generals
- Requests from: SME <50 staff (pre-profit generating); multinational healthcare tech company
- Type of data: CT cans; clinical records

These case studies were then used in a series of virtual discussions with key stakeholders associated with the Consortium's work - the aim: to tease out the extent to which different requests were adjudged to be 'fair' and, in particular, how different stakeholders view related constraints and potential benefits:



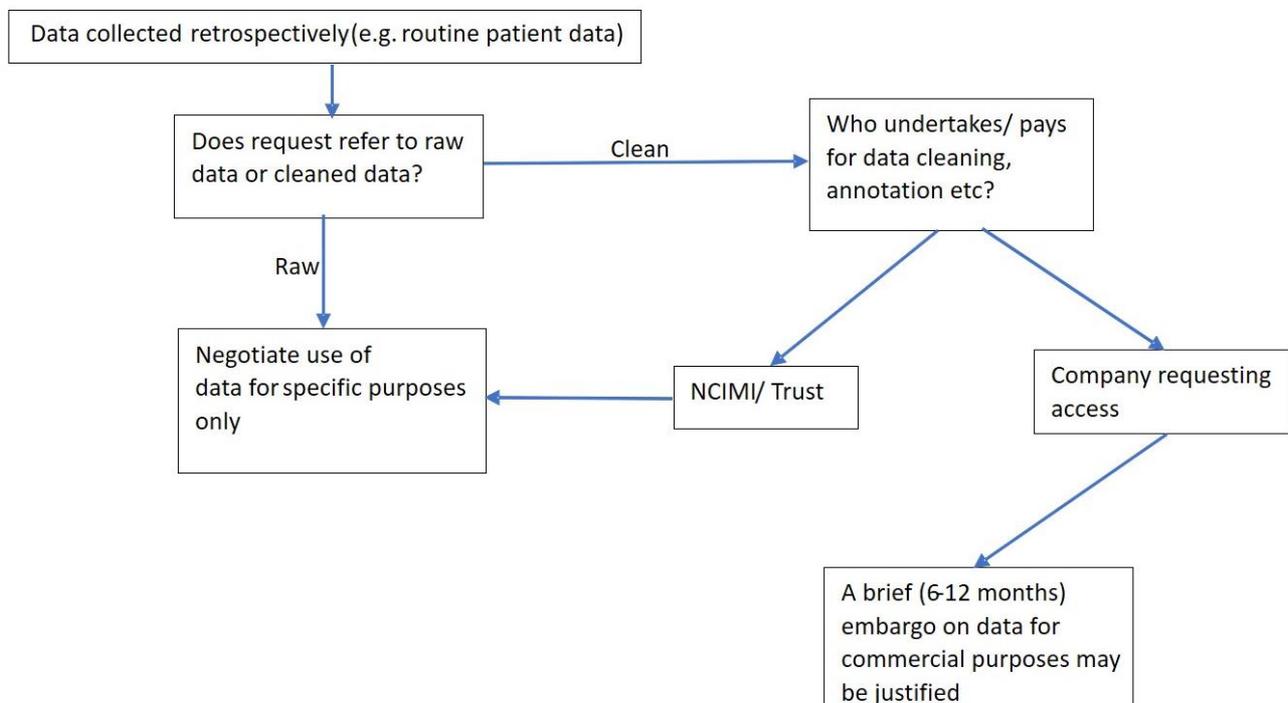


Our interviews with key stakeholders involved in NCIMI revealed a number of common themes impacting perceptions of fairness:

- Should retrospective and prospective healthcare data be considered in the same way?
- How should we approach 'value judgements' when an agreement is underpinned by raw as compared with cleaned and distinct from curated data?
- What role, if any, should embargoes and exclusivity play in collaboration agreements, given that they can assist SMEs to engage in innovation underpinned by healthcare data and, thereby, stimulate economic development value?
- Should the size, scope and maturity of a third-party seeking access to healthcare data impact value judgements and related agreements?
- How should we manage different and, potentially, contradictory stakeholder perspectives to facilitate win:win agreements?

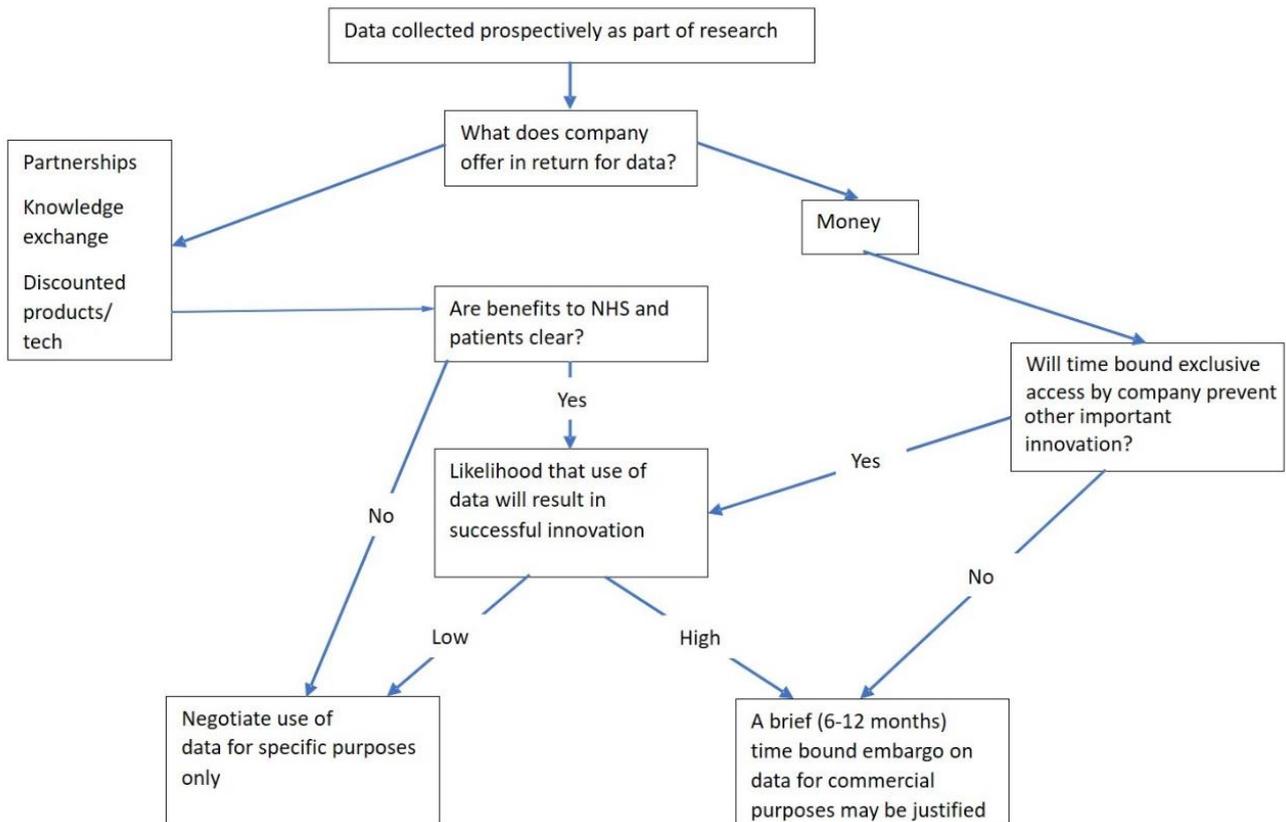
They also gave rise to the development of decision trees of the kind we had originally envisaged following qualitative analysis of the value judgements stakeholders articulated – for example:

### Retrospective data: raw or clean?





## Prospective data: financial or in-kind benefits?



The work we undertook underlined the diversity of stakeholder perspectives involved in value creation using healthcare data. It also pointed toward the inevitability of 'value judgements' being misaligned in the absence of legal provisions or a policy framework to guide multi-lateral negotiations between data controllers and processors – or, else, some way in which to strike a balance between different 'value levers' outside of such negotiations. FCC understands these levers as driving, respectively, clinical, social, economic development, environmental and commercial value. The extent to which one is prioritised in any given deal or arrangement will be coloured by the healthcare challenge identified; the population(s) it affects; the maturity and interest of research and corporate entities capable of and/or interested in responding to the challenge; and the potential/scope for any response to generate a commercial return – whether in the near- or longer term.



As a Consortium led by the University of Oxford that is funded by Innovate UK which has an explicit economic development remit, and that specialises in brokering access to and supporting usage of medical imaging data, NCIMI will evolve its own value framework per the value levers below:



Ultimately, our activities gave rise to a number of high-level recommendations for NCIMI:

- (1) Archetypal data sharing agreements might, in future, be distilled from the scenarios we explored. Whilst a 'one size fits all' approach is neither feasible nor desirable, some way in which to categorise NCIMI's offer to different data 'suppliers' and 'customers', governed by a bespoke value framework, would make sense.
- (2) Archetypal agreements should reflect health data markets segmented by the type of data provided by a broker over time, but those markets remain under-developed in the UK at present and are subject to a number of factors beyond NCIMI's control, such that there is a risk potential 'customers' go elsewhere.
- (3) Data brokers differ from both 'suppliers' and 'customers' – they require their own distinctive rationale, business model and ethical framework, which is liable to be impacted by founders and funders over time, and this needs to be clarified/evolved so that NCIMI can successfully move beyond the initial phases of its development as well as react to potentially disruptive developments.



## Conclusion

The National Consortium of Intelligent Medical Imaging (NCIMI) aims to revolutionise healthcare through Artificial Intelligence (AI) and comprises a partnership between NHS trusts, companies, universities, charities and patient groups coordinated by the University of Oxford. It approached FCC in Autumn 2019 to explore the scope to develop a value framework for medical imaging data, because the advice and guidance available to NHS organisations that seek to enter into data collaborations and pertinent agreements with third parties was deemed limited from the point of view of 'value creation'. In our experience, this is because policymakers and healthcare professionals tend to emphasise the importance of compliance with data protection provisions and 'information governance', rather than developing and/or implementing frameworks and guidance concerning other steps in the 'data value chain' that result in the creation and deployment of new treatments and technologies.

The datafication and digitisation of health and care services has, since, proceeded at break-neck pace in response to the COVID-19 pandemic. There is, now, a well-resourced NHS AI Lab as well as a dedicated Centre for Improving Data Collaboration (CIDC) housed within NHSX whose remit it is to support the health and social care sector to enter into data-sharing partnerships that benefit the NHS, patients and the public. The CIDC has published a guide to good practice for digital and data-driven health technologies with innovators in mind. It is also expected to flesh out the 5 guiding principles outlined in its guide: *Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation*<sup>2</sup> to inform the decisions taken by NHS organisations in the near future. The extent to which that work responds to the challenges our work for NCIMI identified is unclear at the time of writing.

In the course of our research and stakeholder interviews, we found that:

- Whilst there are some legal obligations and regulatory guidance which emphasises the need to strike a 'fair deal' between NHS organisations and third parties that seek to collaborate, there is a significant gap in recommendations outlining how this can be achieved in practice. Legal action concerning the use of health data will generally be limited to breach of a data or intellectual property rights (concerning the data subject or the intellectual property owner respectively) or a failure to follow due process (by the public body sharing or exploiting the data), but the Courts are not the appropriate forum to determine the 'value' of health data in monetary – or other - terms. Policymakers should, then, develop pertinent guidance and exercise appropriate levers ('carrots and sticks') to ensure that guidance is used/adhered to throughout the healthcare ecosystem.
- The legal framework governing the UK's healthcare ecosystem offers little to guide the development of multi-stakeholder agreements that are underpinned by medical imaging data sourced from a number of data controllers in the development of AI - as distinct from more conventional, bilateral 'data deals'. A readily intelligible way in which to approach the sharing or redistribution of value that data collaborations involving multiple NHS stakeholders might help to create is needed to overcome challenges associated with diverse organisations approaching their responsibilities as independent legal entities and interpreting 'fair deals' in different (potentially, conflicting) ways.



- A legal or commercial review which approaches value from the point of view of 'intellectual property' is apt to neglect other types of value (for example, clinical, population health, economic development value) and, therefore, should not underpin an holistic value framework or be viewed in isolation from other 'value levers' that an NHS organisation might wish to exert in relation to particular needs and/or aims. FCC understands these levers as driving, respectively, clinical, social, economic development, environmental and commercial value. The extent to which one is prioritised in any given deal or arrangement will be coloured by the healthcare challenge identified; the population(s) it affects; the maturity and interest of research and corporate entities capable of and/or interested in responding to the challenge; and the potential/scope for any response to generate a commercial return – whether in the near- or longer term.

Finally, FCC's interviews with key stakeholders involved in NCIMI revealed a number of common themes impacting perceptions of fairness amongst healthcare data 'suppliers' and 'customers':

- Should retrospective and prospective healthcare data be considered in the same way?
- How should we approach 'value judgements' when an agreement is underpinned by raw as compared with cleaned and distinct from curated data?
- What role, if any, should embargoes and exclusivity play in collaboration agreements, given that they can assist SMEs to engage in innovation underpinned by healthcare data and, thereby, stimulate economic development value?
- Should the size, scope and maturity of a third-party seeking access to healthcare data impact value judgements and related agreements?
- How should we manage different and, potentially, contradictory stakeholder perspectives to facilitate win:win agreements?

These considerations should inform the development of national guidance about value creation from healthcare data and its apportionment/redistribution, as well as the value framework that NCIMI deploys specifically in relation to medical imaging data for its purposes.





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## Appendix: NCIMI's Partners and Project Activity

### AI and Cardio CT Scans

Caristo Diagnostics and the University of Oxford have developed a new method for detecting inflammation within the coronary arteries using advanced processing of routine CT scans of the heart. A new measurement, the perivascular Fat Attenuation Index (FAITM) has been developed to capture this information and has been shown to have a striking predictive value for future cardiovascular events. Caristo Diagnostics has recently developed a new algorithm (CaRiTm) which uses AI to analyse features of the arterial wall, the perivascular space (around the arteries supplying blood to the heart) and also fat tissue in the chest. This algorithm increases the predictive value of FAITM technology. The project will collect CT imaging data from all NHS trusts participating in NCIMI who undertake Coronary Computed Tomography Angiography (CCTA). The images will then be used for the optimisation and automation of the CaRiTm technology. If paired patient outcomes data is available, this will be used to train the risk prediction algorithms and make further improvements to FAITM and the CaRiTm platform. This will allow project partners to confirm the specificity, utility and predictive value of the optimised algorithms. If successful, the CaRiTm technology will be deployed by the NHS trusts participating in NCIMI.

**Imaging modality:** CT

**Size of data set:** 54,000

### AI and Lymphoma

PET/CT is used in many cancer types, to detect and determine the spread of disease, monitor treatment response and detect cancer relapse. State-of-the-art clinical PET/CT reading software supports clinicians reading and deriving measurements from the images that inform the doctor's impression and report. Mirada Medical, in collaboration with partners at Leeds Teaching Hospitals and the Alliance Medical Group, is investigating the role that AI and Deep Learning can play in diagnostic nuclear medicine. The partners are working to develop and deploy the next generation of intelligent and integrated imaging solutions for diagnostics applications in the clinic. The solution will build on Mirada's vendor-neutral XD diagnostics software application which is used to read more than half of the PET/CT scans in England & Wales through its partnership with the Alliance Medical Group and the NHS PET scanning program. The aim of this project is to develop software technology that will yield benefits to cancer patients through improved efficiency and accuracy of cancer detection and diagnosis, enabling more comprehensive and personalized diagnostics decisions, and faster cancer treatment delivery for improved patient outcomes.

**Imaging modality:** PET/CT

**Size of data set:** 2,400

### Childhood Obesity

Figures from Public Health England, National Child Measurement Programme 2016/17 which measures 1 million children in English schools, show that 1 in-3 children in Year 6 are overweight or obese, and are twice as likely to be obese as an adult. Childhood obesity is strongly associated with type 2 diabetes, coronary heart disease, cancer, stroke & depression and costs UK society £27-£45 billion per annum. This exemplar will develop a paediatric version of Perspectum Diagnostics MultiOrganScan to combat the urgent need to develop new paediatric specific treatments for childhood obesity.

**Imaging modality:** MRI

**Size of data set:** 2,500



## Critical Care X-ray

The purpose of this collaboration is to further the development of the GE Healthcare's X-ray Critical Care Suite. In order to develop state-of-the-art AI algorithms, large amounts of quality datasets are required for algorithm training, testing, and validation. The robustness and completeness of these datasets directly impact the performance of the algorithm, meaning additional metadata is required in addition to the X-ray image itself.

**Imaging modality:** X-ray

**Size of data set:** 32,500

## Diabetes and Imaging

The UK Imaging Diabetes study project stems from an accelerating societal trend towards obesity, metabolic syndrome and diabetes, producing an epidemic of obesity-related disease, including multi-organ complications from diabetes. The aim of this project is to better understand the impact of diabetes on different internal organs so that we can determine which patients may benefit from different treatments. This will be achieved by collecting a database of data from patients with type 2 diabetes so that we can use advanced MRI image processing to identify patients with more advanced disease and patients with associated diseases in the liver, kidney or the heart.

**Imaging modality:** MRI

**Size of data set:** 1,000

## Early diagnosis and treatment planning for Endometriosis

Endometriosis is found in approximately 10% women in their reproductive years. It is associated with: significant pelvic and abdominal pain during menstruation (dysmenorrhoea); painful intercourse (dyspareunia); and spontaneous pain outside menstrual periods. While minor and moderate endometriosis can be managed in all gynaecology departments, severe cases necessitate complex surgery. This exemplar is distinguished in NCIMI in that it addresses a major healthcare issue that impacts women and aims to reduce the need for laparoscopic diagnoses. The aim is to progress from the starting point to at least a prototype/ solution and a proof-of-concept clinical trial during the initial 3-year period of the project. The data to be gathered by NCIMI will be critical to realising this progress.

**Imaging modality:** MRI

**Size of data set:** 100

## EchoGo for Chemo

New chemotherapeutic agents have improved the treatment of several types of cancer – in particular breast cancer. However, this comes at increased risk of cardiac adverse events. It is proposed within this project that the advance technology platform and image analysis expertise of Ultromics will be combined with the clinical input of partnered clinical sites to address the current unmet needs facing chemotherapeutic patients.

**Imaging modality:** echocardiograms

**Size of data set:** 54,000

## Enhancing PET-CT workflow and data quality

The radiology workforce is overstretched and understaffed, with the latest Royal College of Radiologist Census indicating existing shortfalls in the workforce of as much as 44%. Supporting enhanced workflow and increased data quality from scans can help address existing work backlogs and support radiologists in



focussing on the most critical cases. The study aims to develop and implement machine learning enhanced methods that improve workflow and data quality for PET/CT imaging studies and to produce improvements in healthcare delivery that reduce time and patient radiation dose and increase quality and accuracy of diagnoses while improving the overall workflow.

**Imaging modality:** CT

**Size of data set:** 3,000

### **Haemochromatosis**

Haemochromatosis, also known as iron overload, is the most common genetic disorder, affecting 0.5% of the UK, and leads to symptoms of fatigue and joint pain, and damage to internal organs manifesting as cardiac and liver failure. If detected early, by MRI or genetic testing, it is completely preventable by venesection. Perspectum Diagnostics (PD) developed LiverMultiScan (LMS) which uses T2\* imaging to assess liver iron content (LIC) in order to generate corrected T1 images to measure fibrosis and inflammation in the liver; however, PD's focus has been fatty liver disease rather than iron quantification. In this project, it will optimise its LIC quantification technology through LMS-IRON for the identification and management of iron overload.

**Imaging modality:** MRI

**Size of data set:** 1,000

### **HOST**

COVID-19 appeared in China in late 2019 and has since spread to the rest of the world. It appears to have predominantly respiratory symptoms. The current method of confirming SARS-CoV-2 infection is by using a Polymerase Chain Reaction (PCR) on a nasopharyngeal swab specimen, which has a turnaround time of 24-48 hours in UK centres. CT, CXR and clinical data has been gathered from 6,500 patients to plan develop a scoring system that will allow clinicians to identify patients who may be sent home, require admission and/or require careful monitoring. It may also allow clinicians to identify patients who may require ventilation and those who are at very high risk from the infection and will thus require ventilation to avoid death.

**Imaging modality:** CT

**Size of data set:** 15,392

### **Improving Lung Cancer Treatment**

The earlier that lung cancer is diagnosed, the more likely that treatment will be successful but currently only 16% patients are diagnosed at the earliest stage of the disease.

DART will use NCIMI's established data infrastructure to collect and transfer clinical data, CT scans, digitised images of stained tissue sections (digital pathology) and blood-derived data from the consented participants of the lung cancer screening programme to the NCIMI secure data 'lake' based at the University of Oxford. This will be the first time, these diverse data types have been integrated using Artificial Intelligence algorithms to enable further and improved characterisation of disease than is possible by a radiologist alone. By linking the additional information available at diagnosis to outcome data, we will be able to refine the lung cancer treatment guidelines.

**Imaging modality:** CT

**Size of data set:** 150,000



## Lung Cancer Prediction

Lung cancer is the biggest cause of cancer death in the UK and worldwide, with £307M/year cost to NHS England. Earlier diagnosis is critical for increasing survival, and the current diagnostic pathways can be improved. Optellum has developed a digital biomarker to predict a lung nodules probability of malignancy using AI. However, the indications for use of the first AI are limited to patients with indeterminate pulmonary solid and semi-solid nodules between 5 and 30mm in diameter. Not all patient groups, including those already with a history of cancer can participate. NCIMI is collecting data for Optellum to be able to study the potential to extend its AI to such patients, potentially extending its coverage to many more patients, and increasing its utility to pulmonologists and radiologists reading these difficult cases.

**Imaging modality:** CT

**Size of data set:** 4,000

## Mapping Organ Health following COVID-19

COVERSCAN will map how COVID-19 impacts the health of multiple organs and identify at-risk features for the viral disease, with detailed cross-sectional imaging and genetic studies. The primary objective is to determine the prevalence and degree of lung, heart, kidney, liver, pancreas and spleen injury in a cohort of patients recovering from COVID-19 disease. Over a period of 24 months, the study aims to recruit over 500 patients recovering from COVID-19 disease following SARS-CoV-2 infection. The research also seeks to assess change in the health of multiple organs and whether genetic traits may influence recovery. This project is jointly supported by NCIMI, European Commission (Horizon 2020) and Perspectum.

**Imaging modality:** MRI

**Size of data set:** TBC

## POST: Using AI to assess long-term lung damage due to COVID-19

POST (Post COVID-19 disease follow up imaging using hyperpolarised xenon MRI and CT) is reviewing in detail patients from Oxford that have required hospitalisation with COVID-19, and have had a CT scan as part of their clinical care and to follow-up this sub-group of patients with repeat CT scans and hyperpolarised Xenon MRI, HP 129Xe-MRI. The purpose of this study is to understand in much more detail the effects of COVID-19 on the lungs. We are particularly interested in how long symptoms last and whether we can identify areas on scans that may be the cause of long-lasting symptoms.

**Imaging modality:** MRI, CT

**Size of data set:** 6,000

## Predict Meso

The Predict Meso project is focused on Malignant Pleural Mesothelioma (MPM) which is currently an incurable cancer that develops many decades after inhalation of asbestos dust. The aim of this project is to further develop, and then validate an AI algorithm that may be used to measure the volume of pleural disease in patients with mesothelioma, and more accurately determine disease response. The study will collect data from UK centres looking after patients with malignant pleural mesothelioma (MPM). Using these data, the AI and algorithms already developed by Professor Blyth and Canon Medical Ltd (Anderson et al, Proc 13th IJCBEEST: Bioimaging 2020) will be optimized using MPM CT data transferred from the NCIMI network.

**Imaging modality:** MRI

**Size of data set:** 6,000



## Stroke and AI

Stroke affects 110,000 people each year in the UK and it is the 4th largest cause of death. This project aims to evaluate the ability of an artificial intelligence (AI)-driven imaging support software to improve the delivery of acute stroke care in the Thames Valley stroke network. Identification of patients for interventions requires specialist radiological image interpretation in real-time, which is not readily available in most hospitals. It plans to use AI technology to aid image interpretation by front line physicians, facilitating patient diagnosis and speeding up decision making in this time-critical condition.

**Imaging modality:** CT

**Size of data set:** 0

## An Automated Screening Tool for Spinal Cancers in MRI

The aim of this project is to develop an automated system capable of detecting malignancy in spinal magnetic resonance imaging (MRI). This system will employ the latest methods in computer vision and machine learning and is focused particularly on a) the automatic detection and quantification of bone metastases, where cancer cells migrate from a primary tumour to the bone and b) myeloma, a form of bone marrow cancer. Finding these diseases early and effectively can result in a significant difference in patient quality of life and allow for more effective treatment and pain management. An automated system will give clinicians a vital second opinion, reducing chances that important signs of this disease will be missed and allowing radiologists to direct their attention to scans which need it the most. Automated methods also allow for quick, accurate and reproducible methods of quantifying disease burden, allowing for large-scale studies comparing different forms of treatment in a principled manner.

**Imaging modality:** MRI

**Size of data set:** 3,000

## Chronic Backpain

This study is designed to improve our understanding of chronic back pain by developing a new way to extract information from lumbar MRI (Magnetic Resonance Imaging) scans. The NHS does around half a million MRI scans a year to investigate back pain. MRI scans are a very important part of diagnosis, but many of the changes seen on MRI scans are age related and to date not necessarily tell us much about the patient's diagnosis. This means it is unclear how much the changes we can see on MRI scans are really important. SpineNet has been applied to Symptomatic and Asymptomatic research cohorts, and we have demonstrated that we can demonstrate the different effects of aging and presence/absence of symptoms on several features in Lumbar spine MRI scans. This study will expand this research to further assess the role of MRI scans in assessing chronic pain patients for intervention.

**Imaging modality:** MRI

**Size of data set:** 2,500



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