2019

(updated in February 2020)

Data-driven healthcare: regulation & regulators

Reporting of the findings & methodology

#reformregulation

REFORM

In collaboration with NHSX

INTRODUCTION

This project provides an overview of the regulatory process in England for data-driven technologies in healthcare from idea generation, through to development, compliance with regulation and post-market surveillance. It highlights the regulatory requirements at each stage of the innovation pathway and describes the remit of each regulators and statutory bodies. It focuses on data-driven technologies using data held by NHS organisations to develop health and social care products.

In so doing the project sheds light on points of tension in the innovation process. There five broad categories of tension points:

(1) **Misconceptions**. Regulation or guidance is clear but 'wrongly' interpreted on the ground
(2) **Complexities.** Regulation itself might not be fit for purpose or complex to navigate
(3) **Gaps.** There are at times gaps in the remit of regulators and statutory bodies or overlapping remits
(4) **Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.
(5) **Coordination and oversight.** There is a lack of oversight of the whole regulatory process for data-driven technologies as no single body is responsible for it. There is also a lack coordination between different organisations (i.e. statutory bodies, regulators and other NHS organisations)

With a better use of the current regulatory framework and through a better definition of the role of regulators such issues might be mitigated against.

This project does not include a full description of reimbursement mechanisms or commissioning processes to purchase data-driven technologies in healthcare as there are various other maps that exist to highlight those elements.

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1 TENSION POINTS

This section provides a summary of the tension points identified in the journey map for data-driven technologies in healthcare. These will be presented in the order in which they appear on the map starting with the issues around data access, proof of concept and finally with regulatory compliance and post-market surveillance. A short section has been included summarising some of the tension points in the 'commissioning, reimbursement and market access routes' of the innovation process.

1.1 DATA ACCESS

The table below describes the tension points identified in the data access stage of the innovation process.

Point of tension	Description	Category	Stakeholders
Data quality	There is a lack of transparency over data quality prior to accessing data. Innovators have no idea of the state in which the data is before accessing it (i.e. no idea about coverage, integrity, timeliness, completeness and validity). NHS Digital provides assurance for data quality through the data quality maturity index (link), which provides an overview of data quality in the NHS based on voluntary submissions by NHS organisations. This gives a broad idea about data quality and not a detailed view of the quality of a specific data extract.	**Gaps.** There are at times gaps in the remit of regulators and statutory bodies or overlapping remits	NHS Digital, NHSX, NHS England & Improvement
Legal basis for disclosing / processing data	There are differences in how people interpret the legal basis for disclosing and processing confidential patient information and they may not have a legal basis for the disclosure. When disclosure of patient data takes place outside of the care team people have difficulties in determining if the purpose of the data processing is (a) for individual care or (b) secondary uses (i.e. for improving health, care and services through research and planning sometimes known as secondary uses). In addition,	**Misconceptions**. Regulation or guidance is clear but 'wrongly' interpreted on the ground	ICO, NDG, HRA, NHS Digital, NHSX, NHS England & Improvement

	people have difficulties determining what types of secondary uses are classed as research. **Scenario:** An innovator developing software using medical data that will eventually be used for individual care. **Common misconception:** The legal basis is direct care. **Clarification:** Developing or testing a product (that might eventually be used for individual care) using data held by health and care organisations is regarded as a secondary use. To satisfy common law either explicit consent must be secured or support under the Health Service (Control of Patient Information Regulations) 2002 - often known as 'section 251 support'. It is also regarded as research which means that the HRA should be involved. In some instances, people also find it difficult to determine what constitutes a breach in confidentiality and what constitutes processing. **Scenario:** A Trust receives a data request for anonymised data, and it proceeds to anonymise the data. **Common misconception:** The Trust can simply proceed to anonymise any data it holds. **Clarification:** The Trust should consider whether the process of anonymisation may involve a disclosure under Common law of Confidentiality and is likely to be processing of personal data under data protection law. This means that any organisation anonymising data should consider their legal basis for doing so, and this will be dependent upon who is doing the anonymisation and the purpose for which that data is being anonymised. The organisation must be clear on how they satisfy both the common law duty of confidence and data protection when processing data to render it anonymous.		

Legal basis for processing data	Despite there being clear guidance from the ICO and the GDPR, there are differences in how people interpret their roles (i.e. controller or processor) within a data sharing agreement. In practice this can lead to a discrepancy between the roles specified in the agreement and actual behaviours, for example, a data processor behaving like a joint controller. In health research the data Controller is generally the research sponsor. A Processor can only act upon the written instructions of a Data Controller. If the Processor wishes to change how the processing is done, it must obtain written permission from the Data Controller to do so. **Scenario:** A company is processing data on behalf of a Trust. **Common misconception:** the company have full agency to decide how it will process the data. **Clarification:** A processor have some degree of freedom as to how the data should be processed but should always check with the controller before implementing that decision. A Processor can only act upon the written instructions of a Data Controller. If the Processor wishes to change how the processing is done, it must obtain written permission from the Data Controller to do so.	**Misconceptions**. Regulation or guidance is clear but 'wrongly' interpreted on the ground	ICO, HRA, NDG, NHS Digital, NHSX, NHS England & Improvement
Tension in legislation	GDPR and the Common Law Duty of Confidence can sometimes appear to conflict with each other, creating concern for people in understanding how to uphold Confidentiality, and knowing when data can be shared lawfully. The ICO (as the UK Regulator for Data Protection law) has produced guidance on lawful processing under GDPR and Data Protection Act 2018. The Health Research Authority and MRC Regulatory Support Centre have guidance on the interplay between Data Protection, Confidentiality and research.	**Complexities.** Regulation itself might not be fit for purpose or complex to navigate	HRA, GMC and NDG

	The General Medical Council has developed a tool to help people navigate Confidentiality and data sharing (link).		
Impact of a future change in the landscape	The creation of the 'National Centre of Expertise' (link) within NHSX might have an impact on the process for accessing data. **Questions:** how exactly it will interact with the data access process? Will it oversee data access requests & negotiate commercial models at this early stage?	N/A	NHSX and the Office for Life Sciences (OLS)
Lack of standardisation	Differences in how people interpret information governance, data protection and the lack of contract standardisation means that there are many types of data sharing agreements between NHS organisations and the private sector. Some variation is necessary to tailor the contracts to the specificities of a project, but more standardisation could help reduce unnecessary variation. NHSX should be putting in place standard data sharing contracts by 2021.	**Coordination and oversight.** There is a lack of oversight of the whole regulatory process for data-driven technologies as no single body is responsible for it. There is also a lack coordination between different organisations (i.e. statutory bodies, regulators and other NHS organisations)	NHSX
Lack of information transparency	Innovators can find it challenging to know what type of data is held by some NHS organisations (e.g. NHS Trusts). This has an impact on the success of the request as they might not be able to comply with the data minimisation principle or request data that actually exists.	N/A	NHS England & Improvement
Data quality & bias	No regulator or statutory body is responsible for evaluating the quality of the data being accessed. As mentioned previously, NHS Digital has data quality assurance responsibilities, but they do not look at policing bias in medical data. The ICO is not responsible for data quality issues unless it relates to the integrity of that data as it's a requirement under the GDPR.	**Gaps.** There are at times gaps in the remit of regulators and statutory bodies or overlapping remits	ICO, Equality and Human Rights Commission, NHS Digital, NHSX, NHS

	Data could be regulated as a medical device if placed on the market as an accessory to a device. **Questions:** could the integrity principle in the GDPR be used to police data quality? Could the Equality Act 2010 be used to police bias in data?		England & Improvement, MHRA
Impact of a future change in the landscape	Currently a notional threat rather than a real threat - Potential threat of model inversion attacks with the use of certain types machine learning models used to create synthetic data and federated models of learning (link).	N/A	ICO, NHS Digital and NHSX
Impact of a future change in the landscape	HDRUK's Digital Innovations Hubs (link) will have an impact on accessing data in healthcare. Questions remain as to: The actual impact of these Hubs on the ease of access. Will these hubs become data controllers or joint controllers? What type of governance model will they operate under? Will the work (link) by the Open Data Institute on Data Trusts have an impact on the governance models of the Data Hubs?	N/A	N/A

1.2 PROOF OF CONCEPT

The table below describes the tension points identified in the proof of concept stage of the innovation process.

Point of tension	Description	Category	Stakeholder(s)
Validation of algorithms	There is no harmonised standard for validating algorithms under current directives (IEC 82304-1:2016 includes validation for health software). Regulators have not yet found a way to assess the regulatory compliance of certain types of algorithms, particularly those using machine learning (see further explanation in regulatory compliance and post market surveillance).	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA, NHS Digital

Data access	Potential new data access request if data for validation was not requested initially. This might occur when an organisation has failed to assess, at the early stages of the project, the data they would require for validating their solution. This can potentially create delays in the process and result in a higher financial cost to the manufacturer.	N/A	N/A
Intellectual property rights	Potential issues with the apportioning of intellectual property (IP) rights when doing research project with private sector (i.e. how to apportion foreground IP). In addition, under UK law, software falls under copyright regulation & cannot be patented.	N/A	NHSx (Centre for Expertise), Office for Life Sciences.
Public acceptance	Public perception and acceptability of a research project will be affected by who performs the research (e.g. academia, the private sector, etc.). Studies have shown that the public are reticent about data being used for commercial purposes.	N/A	N/A
Clinical evidence standards	There is some confusion as to what constitutes sufficient 'clinical evidence' to demonstrate compliance with CE marking under the current regulation. However, with the introduction of the New Medical Device Regulation (MDR) 2020 and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 expert panels will be set up to help assess high-risk devices and stipulate the evidence needed prior to their CE marking. There is some uncertainty as what will happen post-Brexit, as expert panels are appointed at EU Commission-level. NB: UK regulations may be dated 2020 depending on Brexit.	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA, Notified bodies
Routes to evidence collection	There is some confusion regarding the alternative routes for collecting clinical evidence available to manufacturers to prove the safety and performance of	**Uncertainties.** There are some uncertainties about how to regulate certain	MHRA, Notified Bodies and NICE

	their product. This poses a challenge for manufacturers who often find themselves unable to discern between which evidence collection methods and techniques are most robust/effective. Manufacturers might run clinical trials unless equivalence can be shown to devices already on the market which is unlikely unless manufacturers have access to the source code of the "equivalent" device. The lack of standardised guidance and metrics also impacts on the ability of NHS commissioners to effectively assess and compare the quality and performance of the products they are procuring. Brexit may prevent clinical trials being performed in the UK as the regulations require evidence is gathered "in the Union".	technologies or evidence needed to demonstrate the performance of product.	
Evidence for commissioning and reimbursement	There is still some confusion on the ground about evidence standards. Following NICE's evidence standards is not a mandatory process.	**Misconceptions**. Regulation or guidance is clear but 'wrongly' interpreted on the ground	NICE
Ethics frameworks	Different frameworks for assessing ethics across NHS Trusts. This is particularly true for devices not undergoing the HRA's ethics approvals process (e.g. non-CE marked devices not conducting medical research). This leads to different approaches to ethics compliance on the ground.	**Coordination and oversight.** There is a lack of oversight of the whole regulatory process for data-driven technologies as no single body is responsible for it. There is also a lack coordination between different organisations (i.e. statutory bodies, regulators and other NHS organisations)	HRA, NHS England and Improvement

Detailed findings

1.3 REGULATORY COMPLIANCE AND POST-MARKET SURVEILLANCE

The table below describes the tension points identified in the regulatory compliance and post-market surveillance stage of the innovation process.

Point of tension	Description	Category	Stakeholders
Validation of algorithms	A gap exists in the evaluation methods available to know if an algorithm is working well. This is due the fact that: • There is no standard method for validating algorithms particularly those using machine learning. It is crucial that the data used to validate a machine learning algorithm is entirely different from the data it has been trained on. This has created issues around the availability of validation sets. The MHRA and NHS Digital are collaborating on a research project looking at the use of synthetic data to validate algorithms (nb. this is at a proof of concept stage). This would provide a solution to availability of validation dataset as an infinite amount synthetic data can be created from a given dataset. • There are uncertainties over how to detect issues of overfitting a model and a model's external validity and scalability (e.g. algorithm trained on data from trust A might not work for trust B). It is crucial that manufacturers adjust the intended use claims accordingly with their known unknowns in order to avoid liability issues.	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA and NHS Digital

	• There are uncertainties about how to deal with the 'tail end problem' (or black swan events & adversarial attacks) – how does an algorithm perform when its presented with a case scenario it has never seen before?		
Explainability	There is some uncertainty over how to operationalise the GPDR's explainability principle. The Information Commissioner's Office (ICO) and The Alan Turing Institute are collaborating to create practical guidance to assist organisations with explaining artificial intelligence (AI) decisions to the individuals affected (link). However, there are explainability requirements in the regulation of devices. Manufacturer needs to be able to explain the algorithm to show that they follow regulations.	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	ICO
Impact of a future change in the landscape	The New Medical Device Regulation (MDR) 2020 and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 will have an impact on: • The risk classification of devices. Many devices & software will be upclassified based on a reassessment of risk (i.e. most class I will become class II). The IVDR 2022 will introduce a whole new risk classification system. • The Notified Bodies' capacity to carry out conformity assessments due to increased demand & to the fact that there are only a few Notified Bodies in whole of Europe who can provide accreditations under MDR & IVDR. This creates long waiting lists	N/A	Notified Bodies, NHS England & Improvements and NHSX

	• Current providers with CE marking needing to be upclassified might lose their CE mark due to long waiting lists		
Bias & data quality	No regulator or statutory body is responsible for evaluating the quality of the training data. Data could be regulated as a medical device if placed on the market as an accessory to a device.	**Gaps.** There are at times gaps in the remit of regulators and statutory bodies or overlapping remits	ICO, Equality and Human Rights Commission, NHS Digital, NHSX, NHS England & Improvement
No registry of CE-marked devices	There is currently no registry of CE marked devices & in vitro diagnostic medical devices held by regulators which means it is impossible for them to keep track of products. This information is kept confidentially by notified bodies. However, with the MDR 2020 & IVDR 2022 there will be an EU-level registry of medical devices and in vitro diagnostic medical devices (EUDAMED link). There will be a UK register of new devices post Brexit, but not on the same scale as EUDAMED.	N/A	MHRA and Notified Bodies
Data storage and backups	There is some uncertainty over who provides assurance of data storage, backups and certified deletions	**Gaps.** There are at times gaps in the remit of regulators and statutory bodies or overlapping remits	NHS Digital and ICO
Liability	Current tools to enforce liability (i.e. product liability and clinical liability) are clear if the fault lies with the manufacturer it falls under product liability, if not it is a clinical liability claim. However, there been concerns over issues of liability apportioning for decision support tools as there is currently no legal precedent in Case Law. The MDR 2020 & IVDR 2022 will cover some	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA

	aspects of product liability and patient harm for manufacturers, notified bodies and clinical investigator		
Updates	There is an uncertainty over the number/types of updates that would trigger a big enough change in the product or software that it would have to go through regulatory compliance again. However, the MDR 2020 & IVDR 2022 will contain information about when medical devices & in vitro diagnostic device will require an updated unique device identification number (UDI) to manage system updates. In addition, the MDR will include a significant change: "modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channel for interoperability."	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA
Lack of a definition of 'system'	The MDR's current definition of a system is "'a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose". This means that there when bolting devices or accessories into an existing system, the regulation does not cover the system as a whole unless the medical devices and accessories are placed on the market together (link). Question: should whole systems be regulated? If so, how?	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	MHRA and Notified Bodies
Service regulation	Uncertainty about how the CQC should regulate and inspect a digital-data-driven.	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	CQC

Real world evidence	There is a lack of standardised framework for gathering real world evidence	**Uncertainties.** There are some uncertainties about how to regulate certain technologies or evidence needed to demonstrate the performance of product.	NIHR, WHO, etc.

1.4 COMMISSIONING, REIMBURSEMENT AND MARKET ACCESS ROUTES FOR DATA-DRIVEN TECHNOLOGIES

The points of tension outlined in the table below correspond to the barriers faced by entrepreneurs and private sector organisations in the development and commercial deployment of data-driven products within the NHS. The role of regulators and statutory bodies is therefore not considered in this analysis.

Point of tension	Description
Reimbursement frameworks	Reimbursement frameworks are fragmented and differ between NHS organisations and commissioning bodies. Entrepreneurs are left to navigate a complex landscape and are often unsure about who to approach to discuss endorsement/reimbursement for their innovation.
Local and system priorities	Information on local and system priorities/clinical needs not easily accessible for entrepreneurs, resulting in misalignment of supply and demand for data-driven and digital technologies.
Commissioning models	Current commissioning models and clinical pathway models disincentivise the adoption of new data-digital innovations. Example: where the benefits of the innovation are to be realised in other parts of the system or might require disinvesting in existing services.
External validity and scalability	There are issues with scalability because of: • Problems with external validity of models might limit their scalability (e.g. algorithm trained on data from trust A might not work for trust B) • Variation in data models, interoperability and standards can slow down the scaling of solution beyond a given locality • Commissioning models vary across the healthcare system. However, there are several changes in this space NHS Supply Chain is currently working on aligning procurement rules to the NHS' Code of Conduct for data-driven health and care technology (link). NHSX AI Lab will look at reimbursement models for data-driven and digital products (link).

2 METHODOLOGY

The project was developed through a mixed-methods approach, which included:

- A comprehensive literature review looking at the current regulatory landscape for data-driven innovation in healthcare in England and the role of healthcare regulators and statutory bodies. This also included a review of existing guidance and mapping exercises of the regulatory process and innovation journey for data-driven products.
- Thirty nine semi-structured interviews with subject matter experts from government, academia, industry and statutory and regulatory bodies to understand their views on the current state of healthcare regulation, the current and future role of healthcare regulators and perceived barriers to the development, effective regulation and commercialisation of data-driven products in the NHS. (Full list of interviewees is provided below).
- A series of workshops during the summer 2019 to validate the initial findings of the project and quality-assure the journey map. The first workshop, held on July 10th, convened representatives from relevant regulatory and statutory bodies, including the Information Commissioner's Officer, Care Quality Commission, Medicines and Healthcare products Regulatory Agency, Health Research Authority, the National Institute for Care Excellence and National Data Guardian. A second validation workshop was held on July 17th with entrepreneurs, technology advisors and tech transfer officers to get their views on the current innovation journey and regulatory process for data-driven products, the challenges faced at different stages of the process and ideas for future improvement. Representatives from NHSX were in attendance. A final workshop was held on August 19th with representatives from industry, notified and standards bodies, NHSX, health regulators and statutory bodies.
- Post-workshop validation interviews conducted with experts – who attended the workshops or that we had interviewed – to clarify specific tension points and further quality-assure the map.

2.1 LIST OF INTERVIEWEES

We would like to thank the 39 individuals who participated in the semi-structured interviews for this paper. These interviews were held under the Chatham House Rule.

Liz Ashall-Payne, Chief Executive Officer, Orcha

Tim Atkins, Head of Strategy, Care Quality Commission

Natalie Banner, Lead, Understanding Patient Data

Dr Peter Bannister, Executive Chair, Healthcare Sector, Institution of Engineering and Technology

Victoria Betton, Founder and Director, mHabitat

Julie Bretland, Founder and CEO, Our Mobile Health

Nicki Bromwich, Head of Commercial Development, Oxford Academic Health Science Network

Dame Fiona Caldicott, National Data Guardian for Health and Care in England

Lord Tim Clement-Jones, Former Chair, Lords Select Committee on Artificial Intelligence

Dr Allison Gardner, Programme Director for the Integrated Degree Apprenticeship in Data Science, Keele University

Stephen Gilbert, Clinical Evaluation Director, Ada Health

David Grainger, Devices Software and Apps Manager, Medicines and Healthcare Products Regulatory Agency

Clayton Hamilton, Unit Leader, E-health & Innovation, Division of Information, Evidence, Research and Innovation, World Health Organisation Regional Office for Europe

Simon Harris, Senior Project Manager, East Midlands Radiology Consortium (EMRAD)

Hugh Harvey, Clinical Director, Kheiron Medical (has since changed position)

Rita Hendricusdottir, Programme Manager for Regulatory Training Software, University of Oxford

Julian Huppert, Director, Intellectual Forum, Jesus College, University of Cambridge

Pall Jonsson, Associate Director Science Policy and Research, National Institute for Health and Care Excellence

Indra Joshi, Digital Health and AI Clinical Lead, NHS England (has since changed position)

Dominic King, Health Lead, DeepMind (has since changed position)

Duncan McPherson, Clinical Director Devices, Medicines and Healthcare products Regulatory Agency

Jess Morley, AI subject matter expert, NHSX

Will Navaie, Engagement Manager, Health Research Authority

Jedrzej Niklas, Research Officer, Justice, Equity and Technology, Department of Media and Communication, London School of Economics and Political Science

Johan Ordish, Senior Policy Analyst (Law and Regulation), PHG Foundation

Richard Phillips, Director, Policy and Communications, Association of British HealthTech Industries

Adrian Price, Policy Lead, Innovation and Horizon Scanning, NHSX

Daniel Ray, Director of Data, NHS Digital

Mark Salmon, Programme Director, National Institute for Health and Care Excellence

Mona Sloane, Sociologist and Fellow at The Institute for Public Knowledge, New York University

Jovian Smalley, Group Manager, Engagement, Information Commissioner's Office (has since changed position)

Harpreet Sood, Associate Chief Clinical Information Officer, NHS England

Chris Taylor, Head of Assurance, Information Commissioner's Office

Dr Sophie Taysom, Independent Consultant, Keyah Consulting

Lydia Torne, Managing Associate, Simmons & Simmons

Vishaal Virani, Business Development, Ada Health

Carl Wiper, Group Manager, Information Commissioner's Office

and two individuals who preferred to remain anonymous.

2.2 LIST OF WORKSHOP ATTENDEES

Reform held three quality assurance workshops with various stakeholders to ensure the information presented in the journey maps was accurate and accessible. These were also held under the Chatham House Rule.

Workshop on 10th July 2019

Tim Atkins, Head of Strategy, Care Quality Commission

David Grainger, Devices Software and Apps Manager, Medicines and Healthcare Products Regulatory Agency

Maddy Griffiths, Senior Policy Officer, Regulators' Business Innovation Privacy Hub, Information Commissioner's Office

Mirella Marlow, Programme Director, Devices and Diagnostics Systems, National Institute for Care Excellence

Will Navaie, Engagement Manager, Health Research Authority

Graeme Tunbrige, Group Manager, Devices Regulatory Affairs Medicines and Healthcare Products Regulatory Agency

Dr James Wilson, Panel Member, National Data Guardian

Workshop on 17th July 2019

Fouad Al-Noor, Co-Founder and CEO, ThinkSono

Guy Cohen, Strategy and Policy Lead, Privitar

Clive Collett, Ethics Policy Manager, Health Research Authority

Myles Furnace, Digital Health and Data Lead, UK & Ireland Speciality Care, Ipsen

Michael Garrison, Director, Commercialisation Institute, King's College London

Rita Hendricusdottir, Programme Manager for Regulatory Training Software, University of Oxford

Adrian Price, Policy Lead, Innovation and Horizon Scanning, NHSX

Andrew Smith, Associate Director, Regulation, KPMG UK

Laurence Thorne, Policy Manager, NHSX

Workshop on 19th August 2019

Paul Blakely, Policy Adviser, Office for Life Sciences

Phil Booth, Coordinator, medConfidential

Chris Farrance, Regulatory Affairs Manager, DeepMind

Maddy Griffiths, Senior Policy Officer, Regulators' Business Innovation Privacy Hub, Information Commissioner's Office

Michael Kipping, Innovation Lead, Biomedical Catalyst, Innovate UK

Roberto Liddi, Vice President of Quality and Regulatory, Sensyne Health

Mark Lloyd, Senior Policy Advisor, Whitehall Engagement and Alternatives, Department for Business, Energy and Industrial Strategy

Mirella Marlow, Programme Director, Devices and Diagnostics Systems, National Institute for Care Excellence

Jess Morley, AI subject matter expert, NHSX

Will Navaie, Engagement Manager, Health Research Authority

Chris Sawyer, Innovation Lead for Digital Health and Healthy Ageing, Innovate UK

Paul Sim, KS Medical Devices Knowledge Manager, British Standards Institute

Sheldon Steed, Founder, mumoActive

Eleri Williams, Associate, Hill Dickinson

and one individual who preferred to remain anonymous.

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