Project Reg: AIH

IKIGAI LAW

British
High Commission
New Delhi

UK LEARNING TOUR: FINDINGS AND FOLLOW UP PAPER

INDEX

PROJECT REG-AIH

A mutual learning programme on artificial intelligence and machine learning in healthcare by the British High Commission in India and Ikigai Law

I. BACKGROUND:

Aim of the UK Learning Tour:

India and the United Kingdom (**UK**) are pursuing a common vision for strategic partnership through an ambitious India-UK Roadmap to 2030. A key pillar of this partnership is sharing knowledge and expertise on artificial intelligence and promoting dialogue in research and innovation. On the back of this vision, the British High Commission, New Delhi (**BHC)** partnered with Ikigai Law (**Ikigai**) to facilitate dialogue on 'building bridges on regulatory approaches to artificial intelligence/ machine learning (**AI/ML**) enabled health tech' (**Reg-AIH Programme/ Programme**).

The objective of the Programme was to a) examine the relevant regulatory landscape in India b) undertake a comparative study of UK approaches to use of AI/ML in healthcare and c) identify partnership ideas to develop Indian regulatory frameworks via bi-lateral expert-to-expert exchange. It brought together experts from India and the UK to explore ideas for partnership between both the nations on use of AI/ ML in healthcare. For this, a cohort of experts in India was identified from across governments, regulatory authorities, academia, research, start-ups and technology developers to participate in the Programme.

The Indian cohort was taken on a week-long learning tour (**Learning Tour**) to the UK for discussions and meetings with a wide range of stakeholders and meet with a group of UK experts in the subject. This document captures the Learning Tour and the Indian cohort's learnings from it.

Credits: UK Learning Tour

The BHC and Ikigai Law are immensely grateful to the UK experts who took out time and shared their perspectives and knowledge on various issues relevant to AI/ML enabled healthtech including regulatory approaches to the subject. We are also thankful to the organisations that hosted the Indian cohort during the course of the Learning Tour. It would have been impossible to execute without their support, especially since the BHC and Ikigai planned and coordinated the entire Learning Tour remotely from India.

We want to thank the following organisations/institutions for hosting the Indian cohort - (i) The Dover House – London Headquarters of the Scotland Office; (ii) The Alan Turing Institute at the British Library; (iii) Institute of Directors, Pall Mall and the University of Southampton; (iv) Somerville College, University of Oxford; (v) Oxford India Centre for Sustainable Development; (vi) BDO UK Office; (vii) Tech UK; and (ix) India Council Office, UK FCDO.

We would also like to thank the following experts for sharing their knowledge, experience and expertise on a range of topics relevant to AI/ML in healthcare. The Indian cohort gleaned an immense insight into UK's approach to regulations encouraging and overseeing innovation in AI/ML in healthcare.

1. **Ahamat Gazi,** Head of AI Assurance, Center for Data Ethics and Innovation
2. **Arora Siddharth**, Programme Director, Oxford India Centre for Sustainable Development
3. **Austin Shiraz,** MD, Scribe Tech
4. **Balaram Brhmie**, Head of AI Research & Ethics, NHS AI lab.

5. **Bamford Dan**, Deputy Director AI Awards, Accelerated Access Collaborative
6. **Bannister Peter**, Vice President, Ada Health
7. **Martin-Immanuel Bittner**, CEO, Arctoris
8. **Bockarie Tahir**, NHS England
9. **Braun Harald**, COO, I5 Health
10. **Cave Alison**, Chief Safety Officer, Medicines and Healthcare Products Regulatory Agency
11. **Cerwonka Allaine,** Director of Turing International and Associate Director, AI for Science & Government Programme
12. **Day Jonathan,** Senior Director, Congenica
13. **Finbow Anthony,** CEO, Eagle Genomics
14. **Flockenhaus Moritz**, Policy Manager, AI Taskforce Lead Care Quality Commission
15. **Hall Dame Wendy**, DBE, FRS, Regius Professor of Computer Science, Associate Vice President (International Engagement), Executive Director of the Web Science Institute at the University of Southampton.
16. **Hall Jennifer**, Senior Data Scientist, NHS AI Lab Skunkworks
17. **Halner Andreas**, COO and **Junetha Syed**, Chief Scientist, Oxcan
18. **Harrison Mike,** Global Director, Compliance, Behold.ai Technologies Limited
19. **Harwich Eleonora**, Head of Collaborations, NHS AI Lab, NHSX
20. **Heneghan Carl**, Professor, Oxford Center for Evidence Based Medicine
21. **Jaokar Ajit, Professor,** University of Oxford
22. **Jarratt Emily,** Health and Public Services Lead at the Center for Data Ethics and Innovation
23. **Jessa Fatema,** Chief Pharmaceutical Officer's Clinical Fellow, Office for Digital Health, NICE
24. **Kaul Lakshmi,** Head and Representative, UK Confederation of India Industry
25. **Lemarchand François**, Senior AI Lab Data Scientist, AI Imaging Team, NHS AI Lab

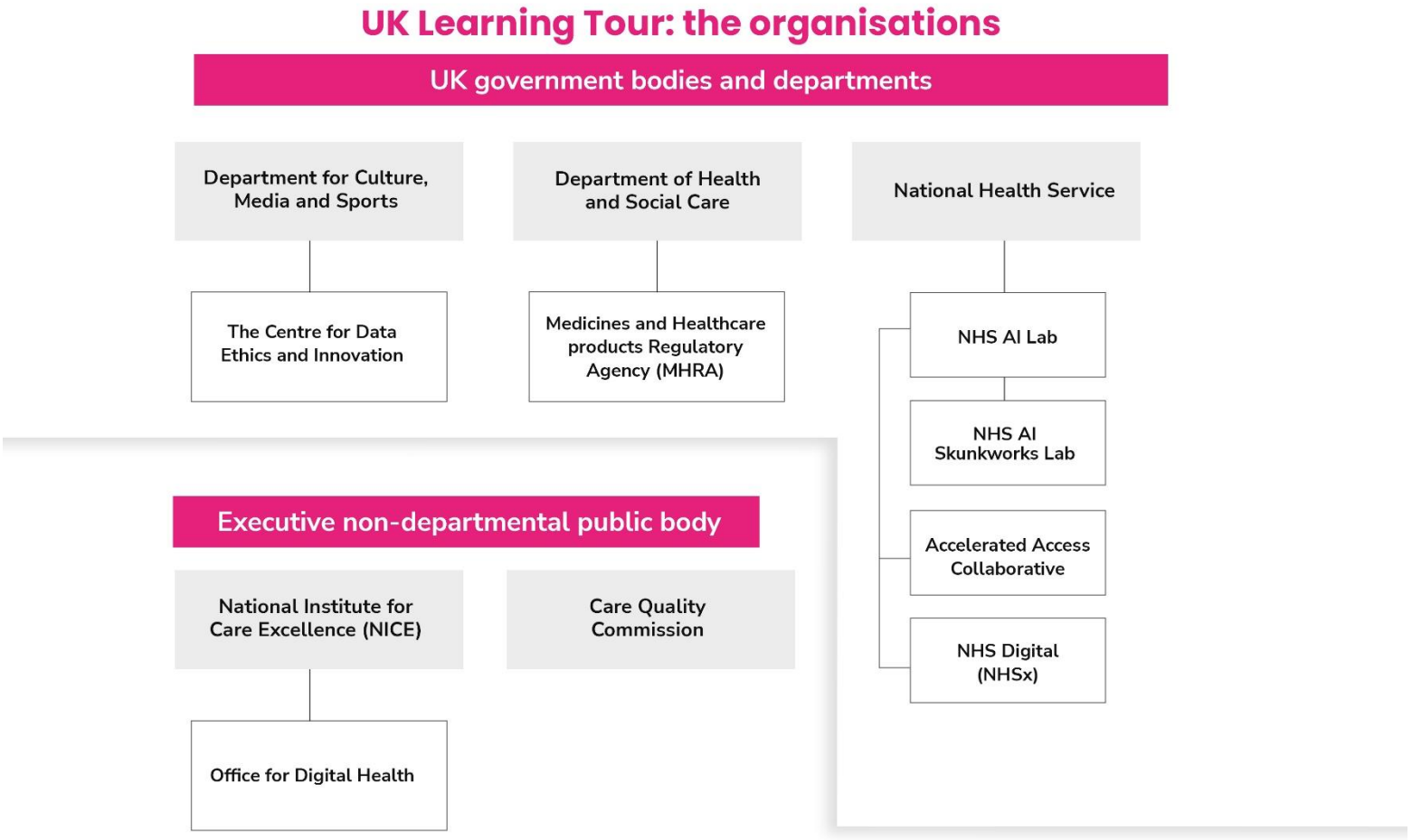
26. **McGuire Alistar**, Head of Department and Chair of Health Economics at the Department of Health Policy, London School of Economics
27. **Morley Jessica**, Oxford Internet Institute and Policy Lead, Oxford Data Lab
28. **Murrey James**, Head of Partnerships, Entrepreneurship Center, Said Business School, University of Oxford.
29. **O'Boyle Damian,** Director of Client Services, Healthy.io
30. **O'Donnel Fionntan**, Senior Data Technologist, Open Data Institute.
31. **Ordish Johan**, Head of Software and AI, Medicines and Healthcare Products Regulatory Agency
32. **Palser Tom,** Associate Medical Director for Quality, Honorary Lecturer & Consultant Surgeon - UHLeicester & Methods Analytics
33. **Patel Manish**, NHS Technology Transfer Service, Imperial College
34. **Pinilla-Dominguez Pilar,** Associate Director – NICE International
35. **Psaraska Jana,** Policy Manager, International Trade, Tech UK
36. **Rasalingham Simon,** COO, Behold.ai Technologies Limited
37. **Shah Param,** Director, UK FICCI
38. **Straitt Andrew,** Associate Director, Ada Lovelace Institute
39. **Symons Joshua**, Director of Data Design and Architecture, UK Health Security Agency and Imperial College, London
40. **Tasioulas John**, Professor of Ethics and Legal Philosophy, Director of the Institute of Ethics in AI, University of Oxford.
41. **Tunbridge Graeme**, Senior Vice President, Global Regulatory and Quality, Medical Devices, British Standards Institute
42. **Turpin Rob**, Head, Knowledge Solutions Division, British Standards Institute
43. **Udani Mikesh**, Co-founder and CEO, Albus Health
44. **Wallace-Davies Nii Lante,** VP Customer Service, Orcha

45. **Yong May,** Senior Research Software Engineer, The Alan Turing Institute and Research Software Engineer, Health Challenge Lead

The Learning Tour paper:

This paper captures key learnings from the five-day Learning Tour organised for the Indian cohort to meet with their UK counterparts. It also documents the perspectives shared by UK experts.

II. AN OVERVIEW OF THE LEARNING TOUR:



Outside of Government

Academia, research institutes & charities

- Alan Turing Institute
- Ada Lovelace Institute
- Open Data Institute
- Department of Health Policy, London School of Economics
- Unversity of Oxford
- Oxford Center for Evidence Based Medicine
- University of Southampton

Private sector & Trade bodies

- TechUK
- British Standards Institute
- UK FICCI
- UK Confederation of India Industry
- BeholdAI
- Oxcan
- Healthy.io
- Albus Health
- Orcha
- Eagle Genomics
- Congenica
- Arctoris
- Ada Health
- Methods Analytics

The Indian cohort travelled to the UK for a five-day Learning Tour from March 14 – March 18, 2022. Through the five days, the Indian cohort met with 40 experts in the UK from across government bodies, regulators, departments, research labs, academic and research institutions, and start-ups. Key themes for discussion were use of AI/ML in public health, overview of the UK's AI regulatory landscape, approach to making rules and policies for AI/ML (e.g., on data governance and management, and balancing innovation and safety), and ethics, and public health governance. The cohort also met with various start-ups and research institutes.

Some issues raised by the Indian cohort were on how different AI/ML use cases pose unique challenges to regulators, at each stage of the product lifecycle. This includes challenges related to gathering the data needed to build AI/ML tools, ensuring the AI/ML tool is working as intended, and exercising oversight. Safe sharing of patient data (i.e., sharing data while protecting patient rights and privacy) and access to data is key to fuelling AI/ML innovations. Diversity in patient data is important for tackling algorithmic biases. Similarly, where the AI/ML tool is used as a medical device, it needs to be evaluated based on the risk it poses to patients. Once the AI/ML medical device is deployed for patient use, it also needs to be evaluated periodically to ensure it is providing consistent quality of care.

The meetings set up in the UK were aimed at helping cohort members delve into these questions. Through the Learning Tour, cohort members gained 360-degree insight into the UK's approach of regulating and encouraging AI/ML innovation in healthcare. A detailed day-wise summary of each UK expert's presentations and thoughts is in *Annexure 1* (Summary of meetings with UK organisations and their speakers).

III. LEARNINGS FROM THE UK ECOSYSTEM:

Broadly, the UK experts' presentations are indicative of an ecosystem that is fairly advanced in its approach to AI/ML in healthcare. There is focussed effort to encourage innovation through (i) funding, (ii) advisory services to navigate laws/standards, (iii) encouragement of inter-disciplinary research and collaboration for ethical innovation and deployment of AI/ML; and (iv) support to ensure real-world applicability of innovations. However, the UK's approach is not without its challenges. Innovators and companies have to navigate a labyrinth of laws and interact with multiple regulators, at different points of a tool's lifecycle. Ethical innovation and deployment of AI/ML appears to be an ongoing discussion in the UK, with separate toolkits, checklists, guidance documents, and standards being released periodically by various organisations.

This section summarises the key themes emerging from the discussions with UK experts.

1. **Navigating the web of agencies and institutions** Multiple regulators oversee various aspects of AI/ML tools, software as medical devices (**SaMD**), and AI as medical devices (**AIaMD**), including data protection, clinical evaluation, research, and innovation. Navigating this landscape can be challenging for the industry and the innovators. There is a need for connecting these regulators and for bridging the gap between the regulators and the industry/innovators.[1] Organisations like the Accelerated Access Collaborative (**AAC**) also provide support in connecting healthcare service providers to industry innovators to accelerate impactful and cost-effective products.[2] The NHSx and NHS AI Lab have created the Multi-Agency Advisory Service (**MAAS**), which is in beta phase, to

[1] See Jessica Morley, Oxford Internet Institute and Policy Lead, Oxford Data Lab's presentation summary from Day 3 of Learning Tour.
[2] https://www.nice.org.uk/aac

support industry and innovators navigate this landscape.[3] MAAS will be a single platform providing advice and guidance, on navigating the various applicable laws and regulators. MAAS has connected with Medicines and Healthcare products Regulatory Agency (**MHRA**), Care Quality Commission (**CQC**), National Institute of Health and Care Excellence (**NICE**), and Health Research Authority (**HRA)**[4] for this purpose. The need to create champions of and avenues for cross stakeholder engagement and collaboration was a key theme which emerged throughout.

2. **Navigating the laws: multiple laws for different uses of AI/ML in healthcare.**

Multiple laws/ standards govern various aspects that impact AI/ML innovation, evaluation, use, and oversight. Data sharing is a good example. Several issues exist there:

a. There are multiple data protection laws and norms (Data Protection Regulation, General Data Protection Regulation, Common Law duty of Confidentiality, and Caldicott Principles) for innovators, researchers, and manufacturers to comply with.
b. There are different standards for using data in research. Data is often not clean or usable, with clinicians and researchers annotating and recording health data differently. Data is also scattered across institutions. Additionally, ensuring that the use of data results in an inclusive AI/ML tool or system, free of biases, and performing within designated parameters (e.g., false positives being within permissible limits), is also a challenge.

AIaMD also has multiple standards to meet (similar to any medical device) before the product can be used in a clinical setting (i.e., by a doctor or patient).[5] In addition, there may be further regulatory considerations for AIaMD within the normal SaMD evaluation and approval processes. This can be due to the unique challenges faced in creating and safely using AIaMD (e.g., explainability/ evidencing the AIaMD's safety for use, or ensuring that

[3] See Eleonora Harwich (Head of Collaborations, NHS AI Lab) presentation summary from Day 1 of the learning tour.
[4] https://www.nhsx.nhs.uk/ai-lab/ai-lab-programmes/regulating-the-ai-ecosystem/the-multi-agency-advice-service-maas/
[5] See Alison Cave, (Chief Safety Officer, MHRA) and Johan Ordish, (Head of Software and AI, MHRA)'s presentation summary from Day 5 of the learning tour.

changes in the AIaMD were changes intended by the manufacturer).[6] Entities like the MHRA, British Standards Institute (**BSI**), NICE set and oversee standards for evaluation, research, and approvals for generating proof of concept and for subsequent marketing of medical devices.[7]

Regulations are also evolving as regulators and industry continue to grapple with different aspects of AI/ML. Discussions on AI/ML regulations are taking place in many regulatory regions and meetings occur bi-tri-laterally (e.g., in the United States, UK, and India) and through multinational forums (e.g., European Union, International Medical Devices Regulators Forum).

For instance, the MHRA is the UK statutory regulator for ensuring the safety of medicines and medical devices. It sets legal requirements on manufacturers of medical devices (including AIaMD) and produces guidance in assisting the market in meeting its safety obligations. Additionally, the MHRA oversees pre-market clinical trials (called Clinical Investigations), holds a registry of products and provide humanitarian exceptional authorisations as required. NICE on the other hand, sets national best practice clinical guidance, recommendations on the adoption and use of technology in healthcare and assess the cost impact of widescale adoption of new technologies. This is to ensure that UK patients and public get the most value from their expenditure on innovation in healthcare.

However, there are initiatives and technology platforms in the pipeline, that may help innovators/ researchers navigate the web of laws better. For instance, the National Data Guardian (**NDG)** provides guidance on navigating and meeting the requirements of the various data protection laws and norms.[8]

3. Building an innovation ecosystem

[6] See Alison Cave, (Chief Safety Officer, MHRA) and Johan Ordish, (Head of Software and AI, MHRA)'s presentation summary from Day 5 of the learning tour.
[7] See Eleonora Harwich (Head of Collaborations, NHS AI Lab) presentation summary from Day 2 of the learning tour.
[8] See Brmie Balaram's presentation summary from Day 2 of the Learning Tour.

It is challenging for a viable idea to gather funding across stages of research, evaluation and market entry. Innovators and researchers need support not just through funding/ grant opportunities. But also, through opportunities to safely gather evidence and test AI/ML tools before they even go for clinical evaluation as AIaMDs (or if they are not AIaMDs, for other regulatory approvals).

Several organisations in the UK provide support across stages of the product – from ideation to proof of concept, to further research and evaluation with larger participants, to clinical/regulatory evaluation, and marketing and adoption. The AAC is one such organisation that accelerates research and adoption in phases, i.e., through four programmes- idea, proof of concept and early-stage research, real-world testing and late-stage research, adoption and spread.[9]

Similarly, the Innovative Devices Access Pathway (IDAP) is a joint initiative of the MHRA and NICE. Through the IDAP, the Office of Digital Health (ODH) works jointly with MHRA and others to create a new pathway which offers supported access route for innovative medical technologies, diagnostic and digital devices. To be eligible for this pathway, technologies must be innovative, meet a critical unmet need in the health and care system and be able to demonstrate some evidence of safety. The new pathway includes safety assessments and testing though sandboxes, post market surveillance, and evidence generation for health technology assessments.[10]

NICE aims to support the NHS health and care system as well as help innovators via their topic intelligence workstream. This is a system led approach which aims to match the health and care system needs with high value digital health technologies. These technologies either have regulatory approval or show plausible promise based on

[9] See Dan Bamford (Deputy Director AI Award, Accelerated Access Collaborative)'s presentation summary from Day 1 of the Learning Tour
[10] Fatema Jessa (Chief Pharmaceutical Officer's Clinical Fellow, Office for Digital Health, NICE) and Pilar Pinilla-Dominguez (Associate Director – NICE International)'s presentation summary from Day 5 of the Learning Tour.

an early value assessment but do not yet have the required evidence levels to inform national guidance. The contingent approval pilot aims to support innovators, of high value digital health technologies by advising on the correct evidence generation outputs to gather the required real-world evidence within the health and care ecosystem, of their AI/ML's utility whilst risks are being carefully managed with the eventual aim being to support a health technology assessment once the required evidence has been generated.

Also, different agencies fund research, innovation, and deployment of AI/ML tools in healthcare. AAC supports innovators and research through various funds (e.g., through AAC pathway transformation fund and the innovation and technology payment) and a training programme for clinical entrepreneurs.[11] NICE partners with the AAC, NHSx (now NHS Transformation Directorate) and the National Institute for Health Research (NIHR) to support the AI in Health and Care by informing the evidence generation and evaluation of successful technologies. This award makes funding available to accelerate the testing and evaluation of the most promising AI technologies which meet the strategic aims of the NHS Long Term Plan and supports technologies across the spectrum of product development stages. [12]

4. Powering the innovation, testing, and adoption of AI/ML tools with data

Usable data (e.g., patient records, disease manifestation-related indicators, etc.), is in short supply. This is because data is fragmented across health systems, and often in different forms (e.g., inconsistent use of terminology). Additionally, navigating multiple data protection laws and the siloes of data reduces the quality and kinds of data innovators/researchers have at their disposal. The proposed National Medical Imaging Platform (**NMIP**) by the NHS

[11] See Dan Bamford (Deputy Director AI Award, Accelerated Access Collaborative)'s presentation summary from Day 1 of the Learning Tour
[12] Allaine Cerwonka, (Director of Turing International and Associate Director, AI for Science & Government Programme) and May Yong, (Senior Research Software Engineer at The Alan Turing Institute and Research Software Engineer, Health Challenge Lead)'s presentations' summaries, from Day 2 of the Learnings Tour

is an example of a platform that enables the collection and sharing of useful data, while making conscious choices around ethics and privacy. For instance, conducting Algorithmic Impact Assessments (**AIAs**) is a pre-requisite when innovators/researchers apply for data access.[13] iCARE also has initiatives to help in safe and ethical sharing of patient data.[14] iCARE collaborates with multiple institutions for data sharing across different specialities. Different hospitals send NHS substantive data relevant to their specialities.

One solution which was brought up by a number of speakers, and which is being keenly explored, is the use of "synthetic" data. This is data that is derived from real-world data- but without the privacy harms associated with real-world datasets.[15]

5. Making sure AI/ML tools cater to the public need

A key theme that emerged through all five days of the Learning Tour, was the value and mechanisms for ensuring patient and/or public involvement in AI/ML based research, innovation, evaluation, and adoption. The CQC assesses regulated activities (e.g., diagnostic, or surgical procedures) for registration under the Health and Social Care Act, 2008. This ensures that the AI/ML tool being used for such regulated activities are needed, helpful, and safe for public use, based on the health challenges faced by the public.[16] Similarly, the AAC ensures patient and public involvement throughout its accelerated innovation adoption process, to ensure relevance of the AI/ML tool for the public.[17] Similarly, when innovators approach the NHS AI Skunkworks Lab, it organises deep-dive workshops with

[13] See Brmie Balaram's presentation summary from Day 2 of the Learning Tour.
[14] See Manish Patel, (Head of NHS Technology transfer, NHS England)'s presentation summary from Day 1 of the Learnings Tour.
[15] See Jennifer Hall (Senior Data Scientist, NHS AI Lab Skunkworks), May Young (Senior Research Software Engineer at The Alan Turing Institute and Research Software Engineer, Health Challenge Lead), and Rob Turpin (Head, Knowledge Solutions Division, BSI)'s presentations' summaries from Day 1, 2, and 5 of the Learning Tour, respectively.
[16] See Moritz Flockenhaus, (Care Quality Commission)'s presentation summary from Day 2 of the Learning Tour.
[17] See Dan Bamford, (Deputy Director AI Award, Accelerated Access Collaborative)'s presentation summary from Day 1 of the Learning Tour.

various experts, to give the innovator a 360-degree perspective on their innovation.[18] Alan Turing Institute partners with industry, government, clinicians, etc., to ensure multiple perspectives are accounted for in innovation and research.[19]

IV. THE INDIAN COHORT'S OBSERVATIONS ON THE INDIAN AND UK ECOSYSTEMS

The cohort observed many similarities and also many differences between the approaches in both countries. There are multiple regulators, standards, and laws to comply with for AI/ML related research, innovation, testing and evaluation, deployment, and oversight. The laws and regulators can be applicable at the same time or at different points in the lifecycle of the AI/ML tool. The UK has however made a far more concerted effort to break silos and create institutional channels for collaboration between the numerous stakeholders by creating agencies responsible for ensuring coordination.

Similarly, there are data access challenges in both countries. Data should be usable by AI/ML. That is, if a scan is a chest x-ray, the terms used to describe the x-ray and its findings should be standardised across all chest x-rays. If there is inconsistency in terms used, it may impact the quality of the algorithm.[20] Additionally, data is often stuck in silos, across health information systems of hospitals, and dashboards/systems that are a part of public health schemes. Consolidating them is a challenge because health information systems are not always interoperable. This reduces the availability of quality data. India is actively in the process of digitising public health records and can gain valuable lessons from the UK's experiences.

[18] See Jennifer Hall (Senior Data Scientist, NHS AI Lab Skunkworks)'s presentation summary from Day 1 of the Learnings Tour.
[19] See Allaine Cerwonka, (Director of Turing International and Associate Director, AI for Science & Government Programme) and May Yong, (Senior Research Software Engineer at The Alan Turing Institute and Research Software Engineer, Health Challenge Lead)'s presentations' summaries, from Day 2 of the Learnings Tour.
[20] https://www.habiledata.com/blog/why-data-annotation-is-important-for-machine-learning-ai/#:~:text=Data%20annotation%20ensures%20that%20AI,do%20%E2%80%93%20and%20to%20make%20predictions.

Both countries have similar regulations in certain areas as well. For instance, India follows a similar risk-based classification of SaMDs as the UK.[21] India also has guidelines for software validation, to ensure the software is performing as intended, and is reliable.[22] However, the conversation around trust, ethics, and safety of AI/ML and data sharing is further along in the UK. Because of the presence of strong privacy laws for many years, these considerations are far more ingrained in the approaches being taken in the UK. For example, the ODH's Algorithmic Impact Assessment that has multiple stages, and publications of results helps build trust in AI/ML tools and the use/sharing of health data.

Given the multiple points of similarity between the landscape in the two counties, there are certainly aspects where India can benefit from the lessons that the UK has learnt through its journey. As India works towards creating its homegrown regulatory approach, it need not reinvent the wheel, but instead can focus on adapting the frameworks to better suit the challenges that are unique to India.

V. THE COHORT'S TAKEAWAYS

As noted in the briefing paper[23] and pre-Learning Tour seminars,[24] the conversations around AI/ML research and adoption are in at an early stage. The Indian government has put out various policy papers with suggestions on

[21] Rule 4, Medical Device Rules, 2017
[22] Essential Principles for safety and performance of medical devices guidelines, April 19, 2018 (Available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Essentialprinciples.pdf)
[23] Authored and shared by Ikigai with the Indian cohort via email dated Feb 03, 2022
[24] Authored and shared by Ikigai with the Indian cohort via emails dated Feb 09, 2022 and March 03, 2022 respectively

encouraging AI/ML research and adoption.[25] Some state governments have also delved into this subject.[26] The time is ripe for diving deeper into conversations for enabling safe and ethical research, innovation, and adoption of AI/ML. This section captures some of the key focus areas relevant to safely boosting AI/ML innovation and adoption in India. The focus areas are based on the learnings and observations described earlier.

1. **On funding**:

   There is a need for focussed funding in healthcare-related AI/ML research. This can be through short-term grants, long-term grants, or fiscal support and tax rebates. The government should ensure that a wide range of innovators, researchers, and companies have access to such funding. And funding needs to be of realistic amounts in terms of market requirements. In addition to funding, incentivization of the clinical community at various stages to ensure the research translates into commercial use is equally important.

2. **On regulators**:

   There is a need to streamline and optimise the links in the regulatory chain, which cuts across multiple government bodies, departments, and ministries, at the union and state levels. The government could consider a single-window (akin to the Sugam Portal for approvals of new drugs in India)[27] or platform where innovators can process their licenses and meet regulatory requirements. This will significantly enhance ease of doing business.

[25] Ministry of Electronics and Information Technology's papers- https://www.meity.gov.in/writereaddata/files/Committes_A-Report_on_Platforms.pdf ; https://www.meity.gov.in/writereaddata/files/Committes_B-Report-on-Key-Sector.pdf; https://www.meity.gov.in/writereaddata/files/;Committes_C-Report-on_RnD.pdf ; and https://www.meity.gov.in/writereaddata/files/Committes_D-Cyber-n-Legal-and-Ethical.pdf | Niti Aayog's papers on responsible AI- https://indiaai.gov.in/research-reports/responsible-ai-part-1-principles-for-responsible-a and https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pd | AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf
[26] Tamil Nadu's Safe and Ethical Artificial Intelligence Policy, 2020, https://elcot.in/sites/default/files/AIPolicy2020.pdf
[27] https://cdscoonline.gov.in/CDSCO/homepage

3. **On inter-agency coordination**:

   AI/ML needs focussed funding, oversight, and research. To accomplish this, regular meetings and discussions between regulators and government departments are important. An inter-ministerial committee or autonomous body can be set up to create synergies and coordinate efforts between these departments and regulators.

4. **On regulations**:

   While it may not be possible to establish global standards for ethics or evaluations, harmonising regulations to the extent feasible with global standards will enhance market opportunities for Indian researchers, innovators, and companies. Coordinating with international associations like the International Medical Devices Regulators Forum, and organisations in the UK (e.g., MHRA and NICE) would help in this regard.

5. **On encouraging AI/ML innovation, research, deployment and sharing of knowledge**:

   Capacity building is a key component. Regulators/government bodies/departments must work to create and sustain incubators and entrepreneurs for AI in healthtech. Organisations like the Indian Council of Medical Research (**ICMR**) can also engage in capacity building with researchers, government officials, innovators, companies, etc.

   Consistent standards related to AI/ML products and performance are also important. The Bureau of Indian Standards (**BIS**) should work towards such standards. This will open up global markets for Indian companies. BIS can reform or create new standards through its sub-committees. Additionally, re-examining or creating new standards can be commissioned by the National Health Authority, Niti Aayog, or the Office of the Principle Scientific Advisor.

There is a need for bottom-up collaboration (stewardship of international best practices among the innovation community) and top-down collaboration (bringing relevant governmental agencies on a common platform for a broader dialogue).

Annexure 1: Organisations and speakers in the UK

This section will have a summary of points raised by each organization and speakers from it. The speakers will be organised thematically. The themes will include:

Day 1 | March 14, 2022, | Monday

Speaker details	Summary of presentation
Dan Bamford, Deputy Director AI Award, Accelerated Access Collaborative (**AAC**) Topic: Briefing on the NHS AI Lab's AAC and its role in use of AI/ML in healthcare.	An overview of how multiple entities coordinate to accelerate research and adoption of innovations. Entities coordinating include patient groups, government bodies, industry, and NHS bodies. His presentation highlighted: • How research and innovation are linked to the needs of patients, the NHS, and the public at large. • The AAC accelerates research and adoption in phases, i.e., through four programmes- idea, proof of concept and early-stage research, real-world testing and late-stage research, adoption and spread. • Patient and public involvement runs through all four programmes. Additionally, AAC supports innovators and research through various funds (e.g., through AAC pathway transformation fund and the innovation and technology payment) and a training programme for clinical entrepreneurs.
Jennifer Hall, Senior Data Scientist, NHS AI Lab Skunkworks	An overview of how the lab helps innovators achieve a proof of concept for their innovations. She also delved into how innovators need and use health data in their AI/ML innovations. Her presentation highlighted: • Any innovator can approach the Skunkworks lab for guidance on getting a proof of concept for their ideas.

Topic: Role of NHS AI Lab's Skunkworks team in supporting and upskilling trusts in the ethical applications of AI in healthcare.	• NHS AI Lab's Skunkworks team holds deep dive workshops to provide 360-degree perspectives on an innovator's AI/ML tool. Indicatively, this includes perspectives from public policy experts, clinicians, scientists, and subject matter experts. • How health data is not easy to source, as it is often scattered across systems and in differing formats. Synthetic data is used to tackle the problem of data paucity. Synthetic data is health data that is derived from real life health data.
Manish Patel, Head of NHS Technology Transfer, Imperial College Topic: Evolution of technology transfer in the NHS, particularly from an AI perspective.	An overview of how the NHS scaled up its activities in supporting AI/ML innovations for healthcare. His presentation highlighted: • NHS led projects have proof of concepts before going for larger testing/evaluation. • There are regulatory issues related to data use, intellectual property, ethics and governance, and approvals for software as medical devices (SaMD). He noted that on data ownership, innovators do not "own" the data, rather they license it for certain limited purposes. • The role of initiatives like iCARE (i.e., collaboration of multiple institutions for data sharing of specialties.) Different hospitals send NHS substantive data relevant to their specialities.
Eleonora Harwich, Head of Collaborations, NHS AI Lab, NHSX	Her presentation included a brief overview of the key stakeholders involved, organization of the healthcare system, an overview of the data landscape and key regulations governing it. It also highlighted some of the barriers faced by the system, as well as the work that is put in place to try and overcome these barriers in addition to talking about the NHS AI Lab. Her presentation highlighted:

Topic: Detailed background on how AI is organized in health and care landscape in the UK.	• How the NHS AI lab advances safe regulation and increases trust in AI/ML products through its structured programmes. NHS AI lab has 6 delivery programmes (e.g., the Skunkworks Lab, AI ethics initiative) that are provided under 3 service programmes (strategy and policy, collaboration and engagement, and project management office). • The numerous regulators, government bodies, research institutes and labs involved in AI/ML innovation, evaluation, and oversight. • Importance of simplifying this regulatory journey for the health-tech industry. One mechanism for this is the Multi-Agency Advisory Service (**MAAS**). MAAS will be a one stop shop for innovators to understand regulatory requirements, and how to phase in their implementation whilst developing an AI product.
Tahir Bockarie, NHS England	An overview of how the NHS works with the AAC and the role played by the start-ups in helping governments use technology in public health.
Damian O'Boyle, Director of Client Services, Healthy.io	An overview of Healthy.io's AI/ML tool 'minuteful kidney'. This tool helps users detect chronic kidney disease early, through tests at home.
Tom Palser, Associate Medical Director for Quality, Honorary Lecturer & Consultant Surgeon - UHLeicester & Methods Analytics	An overview of how natural language processing (**NLP**) in AI can help reduce overloading of medical staff. His presentation highlighted: • The NLP pipeline includes the following stages - (i) input - exploratory data analysis; (ii) output – entity recognition; (iii) pre-processing which leads to data preparation; (iv) output - topic modelling and (v) output - classification. • Methods Analytics works with a variety of government bodies like the NHS and the Ministry for Health and Social Care.

Topic: Using Natural Language Processing to improve learning from healthcare complaints	

Day 2 | March 15, 2022, | Tuesday

Speaker details	Summary of presentation
Eleonora Harwich, Head of Collaborations, NHS AI Lab, NHSX Topic: Regulation by design - optimizing the regulatory pathway and the NHS AI Lab's role in it.	A deeper dive into how multiple regulators pitch it at different points of the life cycle of AI/ML ideation, research, proof of concept, testing and evaluation, licensing (approvals), deployment, and post-market surveillance. Her presentation highlighted: • How innovators can get access to health data for innovation and research purposes. Innovators must make a request and demonstrate need for the data. Innovators will have to follow data protection principles enshrined in data protection laws and policies (e.g., Data Protection Regulation, General Data Protection Regulation, Common Law duty of Confidentiality, and Caldicott Principles). Innovators must also consider if their idea complies with the Human Rights Act and the Equality Act 2010. Innovators requests are dealt with by NHS Digital. If an innovator's request is approved, the innovator must follow the (i) data sharing framework contract; (ii) data sharing agreement; and (iii) other standard processes- (a) strategic research agreement and (b) data processing agreement and processing control.

	• The UK's Information Commissioner's Office (**ICO**) provides guidance on data protection elements. The Health Research Authority (**HRA**) assesses the governance and legal compliance for research projects involving health and care data. The Confidentiality Advisory Group (**CAG**) should be contacted for access to confidential patient information without consent in England and Wales, where it is needed for both research and non-research projects. CAG provides an online decision tool to ascertain whether a project can be classified as research or not.[28] The National Data Guardian (NDG) advises the health and care system to ensure citizens' confidential information is safeguarded securely and used properly.[29] NDG provides guidance on the uses of healthcare data through the establishment of the Caldicott Principles.[30] NHS Digital provides the Data Access Request Service.[31] Similarly, the Independent Group advising on the release of data reviews data access requests to NHS Digital.[32] NHS Digital runs data sharing audits. NHS Digital also has data quality assurance responsibilities, and reports on data quality through the Data Quality Maturity Index.[33] • Entities like the Medicines and Healthcare products Authority (MHRA), British Standards Institute (BSI), National Institute for Health and Care Excellence (NICE) play a key role for proof of concept and subsequent market approvals for medical devices. The MHRA also exercises post market surveillance through

[28] http://www.hra-decisiontools.org.uk/research/
[29] https://www.gov.uk/government/organisations/national-data-guardian
[30] https://www.gov.uk/government/publications/the-information-governance-review
[31] https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process
[32] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data
[33] https://digital.nhs.uk/services/data-access-request-service-dars/data-sharing-audits; https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/data-quality

	manufacturer reporting issues and by inspections undertaken by approved bodies (e.g., BSI) on behalf of MHRA.
Brhmie Balaram, Head of AI Research & Ethics, NHS AI lab. Topic: Present the work by the AI Ethics Initiative to date, with a focus on how it will make a difference to the development and deployment of [imaging-based] screening and diagnostic AI.	Her presentation highlighted: • Models of data stewardship, that list practices of data collection, management, and use of data for AI research. The National Medical Imaging Platform (**NMIP**) is one such proposed model. It will have a centralised database to enable AI research & development. It will also collate medical images for training and testing AI systems in healthcare. • Improving data sharing for AI research by piloting an 'Algorithmic Impact Assessment' (**AIA**), developed by the Ada Lovelace Institute. The AIA will include two exercises. Exercise A will be an initial assessment by the team requesting data. The initial assessment and application for data will be sent to the NMIP. After initial filtering, the NHS AI Lab will organise participatory workshops on the team's project, thus completing Exercise B. The team will revisit the results (e.g., templates, documents), of Exercise A based on results of Exercise B. Next to make a 'data access decision' reports by both Exercises A and B are reviewed by a Data Access Committee. This report is then published publicly on the NMIP website. The report is revisited periodically throughout the team's project, as it develops. • NHS AI Lab is also developing standards for the data underlying AI systems. This is to ensure inclusivity and generalisability. In the pipeline there are also toolkits and platforms for ensuring AI tools work for all populations (e.g., the

	retina imaging system ARIAS), and that trust is built for using AI tools in healthcare (toolkit being developed with Sloan Foundation and Wellcome Trust).
Moritz Flockenhaus, Policy Manager, AI Taskforce Lead Care Quality Commission (**CQC**) Topic: CQC's role & strategy, touchpoints with AI, collaboration to streamline regulatory pathways & the safe and effective adoption of AI	An overview of the CQC's role in ensuring real-world applicability of healthcare services, by assessing whether the service is safe and effective (among other things). His presentation highlighted: • CQC's scope includes regulating legal bodies providing 'regulated activities' like diagnostic or surgical procedures. • Such activities require to be registered under the Health and Social Care Act, 2008. • The accountability of software providers (companies) was demonstrated with the help of a case study. Companies are required to ensure that clinicians evaluate the results emerging from their software. This is a condition of their registration.
Dame Wendy Hall, DBE, FRS, Regius Professor of Computer Science, Associate Vice President (International Engagement), Executive Director of the Web Science Institute at the University of Southampton. Topic: Speak about her work in AI, including with the UK	An overview of the AI industry in the UK including the UK government's AI roadmap and AI council. Her presentation highlighted: • Why retaining talent is key • Ensuring diversity in AI, which necessitates interdisciplinary teams working together. Lack of diversity in AI/ML means the AI tool is not ethical

government's AI review and UK AI Council.	
Alistar McGuire, Head of Department and Chair of Health Economics at the Department of Health Policy, London School of Economics. Topic: About the work undertaken in his department on health economics and its relevance to AI/ML in healthcare	An overview of public health challenges globally, and the promise AI/ML holds for tackling some of these challenges. His presentation highlighted: • Adoption of AI/ML must be planned and strategic, where data governance is a key component. AI/ML adoption in healthcare must be a part of an overarching digital strategy and capacity building must be done for institutions (e.g., regulators). • How public health is *the* area where data, and specifically big data, can change the game. Data can be sourced from non-traditional sources (e.g., social media, web searches and environmental data), for research and innovation. Data will enable precision healthcare, especially for at-risk populations. This will help public health interventions be more targeted and meaningful. • The need for more technology interventions to show evidence of meaningful clinical outcomes (e.g., improvement in state of health).
Allaine Cerwonka, Director of Turing International and Associate Director, AI for Science & Government Programme (ASG).	An overview of the Alan Turing Institute (**ATI**)'s work and collaborations in AI/ML research and innovation. Her presentation highlighted: • The use of sector specific programmes for AI/ML research and innovation. Indicatively, the sectors include defence, security, finance, urban analytics, health and medical sciences. ATI has 450 Alan Turing fellows across various universities.

Topic: Overview of the Alan Turing Institute's work	• ATI has partnerships (with both public and private organisations). It has a network of industry, charity, government partners, university members, and strategic investments from government (e.g., include Accenture, Bill and Melinda Gates Foundation), HSBC, Roche, Astra Zeneca, NHS, Microsoft, UNDP, ICO, Intel, and Toyota Mobility Foundation).
May Yong, Senior Research Software Engineer at The Alan Turing Institute and Research Software Engineer, Health Challenge Lead Topic: Research Engineering Health Challenge: Revolutionise Healthcare	An overview of how the Alan Turing Institute confronts various challenges related to healthcare. Her presentation highlighted: • How Alan Turing Institute aims to ensure data ethics and security, incorporation of multiple perspectives (e.g., from industry, academia, and research engineers), and that research results are reproducible. • Access and sharing of data are the biggest hurdles. This is because of the need to comply with numerous laws and the time it takes to finally get access. Data driven infrastructure is absent, making it harder to get data that is standardised in terminology and form. • Data security is also a major concern. Synthetic data is one way to ensure data security.

Day 3 | March 16, 2022, | Wednesday

Speaker details	Summary of presentation
Siddharth Arora, Programme Director of the Oxford India Centre for Sustainable Development (**OICSD**)	An overview of the work being done by OISCD in AI/ML, telemedicine, and neurological conditions like Parkinson's. His presentation highlighted: • OISCD's key objectives - (i) promote inter-disciplinary research on sustainable development between India and the UK; (ii) increase scholarships for research in

Topic: Aim and scope of work done at the OICSD with a AI/ML use in healthcare lens	India; and (iii) foster India-UK ties and create platform for discussing India's challenges. In a way, the objectives of Reg:AIH were aligned with that of the OISCD. • OISCD's Parkinson's research includes a mobile app that patients can use to input various data points (e.g., voice, balance, gait, dexterity, reaction time, rest tremor, postural tremor). • The mobile app can then help patients seek the nearest hospital/facility for help. This includes routing based on proximity and wait times.
Carl Heneghan, Oxford Center for Evidence Based Medicine, Member working on digital healthcare and medication Topic: The regulatory and evidence requirements for ensuring AI improves patient outcomes, the opportunities that lend themselves to improving health and wellbeing, and how to build capacity in evidence-based methods to ensure cost	An overview of how technology can be used in creating innovative care/treatment that is actually useful in addressing patients' concerns. His presentation highlighted: • A core issue is bridging the divide between science, innovation, and clinical practices. For instance, while there are over 4000 innovations, very few actually get translated to clinical practice. • Therefore, evidence, of how these innovations help in improving healthcare outcomes is key to translating the innovations to clinical use. • Tools are needed to help researchers/innovators integrate clinical expertise with patients' values. The best available research evidence with clinical expertise and patient values is integrated using AI tools. For instance, patients living with Rheumatoid Arthritis, are perpetually tired. They require solutions for this exhaustion and are less interested in being treated in hospital; which is something clinicians would want. AI tools help in clinical decision making for issues such as this.

effective interventions are developed and implemented.	
Jessica Morley, Oxford Internet Institute and Policy Lead, Oxford Data Lab Topic: Governing data and AI for Health: Developing an International Understanding. She will cover the main issues that need considering and recent policy developments in the UK and abroad.	An overview of the data-related and regulatory challenges to the growth of AI/ML use in healthcare. Her presentation highlighted: • Health data is usually made for clinical use and not for research. This means the data is not uniform in terminology and presentation, making research, innovation and verification difficult. An additional step is needed to clean and annotate data sets before the data is usable by AI. • There is a need for 'regulations as service', where regulators and regulations review the AI product across its lifecycle. The current siloed approach to regulation is challenging to navigate. An interconnected approach would make the whole process clean, safe, and impactful. • AI algorithms tend to cut across borders, with technology companies working across the globe on the same product. Therefore, international consensus on regulating AI/ML and related issues (e.g., data protection) is essential to encouraging innovations that can be used globally.
John Tasioulas, Professor of Ethics and Legal Philosophy, Director of the Institute of Ethics in AI, University of Oxford	An overview of the discourse around ethics and AI/ML use in healthcare. His presentation highlighted: • The need for examining the applicability of western standards of ethics, to the contexts of other countries. He highlighted that ethics can have different meanings and standards in different societies and we be mindful of that.

Topic: On aims of the Institute for Ethics in AI and give illustrations from my own work on AI and the law and AI and health.	• The value of building consensus among democracies to create minimum standards of ethics. This exercise should include even democracies that are not liberal. • The importance of both the means and the ends, where AI use in healthcare is concerned. That is, it is important to get good healthcare outcomes from using AI tools, but the process to arrive at those AI tools and the actual use of those AI tools is just as important as the outcomes.
Ajit Jaokar, Professor, Oxford University Topic: Skilling and training people in AI/ML.	An overview of the course he leads at the University of Oxford on full stack AI/ML. His presentation highlighted: • Oxford University approach to teaching, research, and innovations in AI/ML is a unique one. AI/ML teaching, research, and innovation are considered an inter-disciplinary exercise. It calls in subject-matter experts where necessary (e.g., ethicists to advise on the ethical aspects related to the project in question). • There are ways for interested people to transition to AI/ML related careers. Oxford does have courses for such training and upskilling, as do many other universities.
Martin-Immanuel Bittner, CEO, Arctoris Topic: The rise of technology-enabled and especially AI-driven drug discovery companies and	An overview of the drug discovery process, players, and evolution and where AI/ML is being used in this process. His presentation highlighted: • The rise in AI led drug discovery or AI Drug Discovery (**AIDD**). AI is being used for drug discovery related activities like understanding mechanisms of the disease, aggregating and synthesizing information, establishing biomarkers, and designing and running clinical trials (including the recruitment of trials' participants, i.e., patients/public).

how the biotech and pharma ecosystem is currently undergoing significant change. AI-driven biotech companies and their implications on the generation and structure of training/ input data, as well as IP ownership and regulation.	• High quality, structured, annotated, comparable, and above all, reproducible data for training and model validation is essential for AIDD. There is a huge deficit of such quality data in biomedical research currently. For better quality data, robotics can be used to generate and capture data. This data can be used with AI for drug discovery. • There are risks with AIDD. Algorithmic transparency and fairness are some risks. AI algorithms should be assessed based on the risk they pose to patients. Additionally, industry and regulators should come together to create strong governance frameworks for AI regulation and oversight. Industry associations can play a key role in coordinating between regulators and industry players for safe AI innovation, evaluation, use, and oversight.

Day 4 | March 17, 2022, | Thursday

Speaker details	Summary of presentation
Fionntan O'Donnel, Senior Data Technologis, Open Data Institute. Topic: AI is a complex technology and can be hard to trust, and therefore use, in high-risk situations. Good practices around data	An overview of safe data sharing which accounts for data subject's rights and autonomy, and the need to research/innovate. His presentation highlighted: • The different types of data about an individual (personal, sensitive, behavioural), and about society, and the different occasions where trust in public sector data collection and management was lost. • The ten elements of data trustworthiness organised in levels: (i) level 1- legal standing and compliance, privacy and security, financial stability, revenue generation, readiness and mitigation; (ii) level 2 – skills and knowledge, organisation governance and oversight, quality and accuracy; (iii) level 3 –

assurance and data standards can help AI be more trustworthy, both for those who built it and those who are affected by it. His talk will discuss some of the practices we need in the new area of AI assurance.	engagement and accountability, ethics and transparency; and (iv) level 4 – active and positive impact. • The importance of both trust (i.e., people do in fact trust the organisation) and trustworthiness (i.e., an organisation and its practice are worthy of trust) of organisations and their data practices.
François Lemarchand, Senior AI Lab Data Scientist, AI Imaging Team, NHS AI Lab Topic: The National Covid Chest Imaging Database and its work using AI.	The lab has collected over 43,000 x-rays and CT scans from patients across the UK for AI research. He talked about the reasons for keeping a part of the data unseen from AI developers, how they use it to evaluate the performance of automated tools to detect Covid symptoms, and how this influences how AI tools are trained and tested. An overview of how AI/ML was used during the covid-19 pandemic, to demonstrate AI-validation (i.e., the process of evaluating an AI model's performance for ensuring it behaves as indicated by the AI developers. And to uncover potential biases and risks. His presentation highlighted: • The AI lifecycle, which includes the following stages: (i) business and use case development; (ii) design phase; (iii) selecting training and test data; (iv) building; (v) testing and validation (i.e., AI validation); (vi) deployment; and (monitoring). AI validation cannot be fully automated but it can be optimised using technology. • The AI lifecycle was explained in the context of the National Covid Chest Imaging Database (NCCID)'s work. The NCCID is a collection of digital medical images of the chest (X-ray, CT scans, MRIs), which can safely and securely share medical imaging for AI algorithm development and performance.

	The NCCID's data controller is the Royal Surrey, and the NCCID has data from 27 hospital trusts in the country. • The NCCID randomly splits data received in a 50:50 ratio for (i) training AI developers; and (ii) for validation set to test model performance. The NHS then contracts with vendors under certain conditions (e.g., NHS does not share intellectual property, and does not publish validation results without approval of vendor), to create solutions to detect COVID-19/its symptoms. Vendors too had conditions (e.g., being selected for this process could not be equated to receiving regulatory approval. Through these limited tests, biases and errors were identified and investigated further.
Sessions with start-ups on industry best practices and exploring opportunities for strategic partnerships.	
Jana Psaraska, Policy Manager, Tech UK Topic: Introductory remarks for the session with start-ups	An overview of Tech UK's work in AI/ML before setting the context for the discussion with various start-ups.
List of start-ups that presented: • Simon Rasalingham, COO and Mike Harrison, Global Director, Compliance,	An overview of their products, and the challenges they have faced in research, innovation, interacting with regulators, and sourcing funding for these activities. • Behold.ai's state of the art deep learning algorithm reads medical scans (e.g., CT scans) to enable diagnosis.

Behold.ai Technologies Limited • Anthony Finbow, CEO, Eagle Genomics • Harald Braun, COO, I5 Health • Nii Lante Wallace-Davies, VP Customer Service, Orcha • Shiraz Austin, MD, Scribe Tech • Jonathan Day, Senior Director, Congenica	• Eagle Genomics aims to accelerate meaningful innovation for pharmaceuticals, food, agri-bio, and beauty products, by analysing microbiome data through AI/ML algorithms. • I5 Health provides AI/ML tools for consolidating information from various sources and generating meaningful insights for a variety of health-related activities (e.g., clinical research, public health, diagnostics, etc.) • ORCHA supports Health Authorities with the development of frameworks and accreditation schemes to assess digital healthcare applications for their safety, technical security, information governance & country specific requirements. ORCHA provides the technology for delivering assessment of healthcare applications at scale and platforms to distribute the assessed health apps to healthcare professionals and patients. • Scribe Tech works with the NHS and other organisations to provide technology support in speech, dictation, and medical note taking. • Congenica provides AI/ML tools for rapid genomic analysis.

Day 5 | March 18, 2022, | Friday

Speaker details	Summary of presentation

Alison Cave, Chief Safety Officer and Johan Ordish, Head of Software and AI, Medicines and Healthcare Products Regulatory Agency Topic: Outline the breadth of uses of AI in medicines and as a medical device, the opportunities and challenges AI poses for regulation and demonstrate how MHRA and the wider UK life science community are grasping these opportunities and responding to those challenges.	An overview of the promise health technologies hold in tackling healthcare challenges, and how regulations and regulators must meet the complexities posed by AI/ML use in healthcare. Their presentation highlighted: • The breadth of AI's applicability in healthcare (e.g., diagnostics, triaging, screening, management of chronic diseases), complexity (e.g., clinical calculators of one device having multiple layers of AI necessary for their functioning), expertise (e.g., of pharmaceutical sector going digital), and qualifications (e.g., different approvals for SaMDs/ in vitro medical devices, or software that are part of hardware as components/accessories). • The challenges of generating 'safety signals' (i.e., that the SaMD is performing as intended), for SaMDs, because the harms from SaMDs are often indirect. However, it is possible to report indirect harm by reporting false positives/false negatives if they fall outside the declared performance. • AI as medical devices (**AIaMD**) is a subset of SaMDs. Evaluation of AIaMDs can see the following additional challenges- (i) interpretability of AIaMD, (ii) evidencing AIaMD, and (iii) adaptivity of AIaMD. Additionally, there are numerous axes of change to be considered, as AI can pose novel challenges or heighten existing issues. • All medical devices, other than the lowest risk category of Class 1, are reviewed prior to being placed on the market by approved bodies (AB) such as the BSI. The accreditation side of BSI (and other UK ABs) house the expertise required to assess the diverse range of medical device products on behalf of the MHRA, who in turn regulates the ABs directly. BSI is also home to the UK standards

	body that creates, maintains, and works to globally harmonise standards documents that assist manufacturers in meeting their regulatory requirements. • In the healthcare space alone there are around 270 standards that harmonise with medical device regulations. Both regulatory guidance and standards are rapidly expanding areas of AIaMD, where improved standardisation promotes both safety and speed to market through clarity.
Graeme Tunbridge, Senior Vice President, Global Regulatory and Quality, Medical Devices, British Standards Institute. Topic: BSI's approach to the regulation of medical devices incorporating AI and plans to become an AI notified body under the proposed EU AI Regulation	An overview of the challenges faced while evaluating AI/ML products. His presentation highlighted: • The need for a broad set of principles that manufacturers can apply, such that the standards are applicable globally. • Reiterated the challenges with data quality and inclusivity. Currently, manufacturers must train the AI thrice to ensure its applicability. • AI/ML tools should be used to aid healthcare. AI/Ml tools can claim to be better than human interventions but their main role is to aid human interventions.
Rob Turpin, Head, Knowledge Solutions Division, BSI Topic: Work done by the BSI on standardisation of AI/ML	An overview of the standards needed to sustain AI/ML research, innovation, development, and use. His presentation highlighted: • The need for- (i) risk management standards; (ii) research and innovation with AI/ML (e.g., standards for using synthetic data); and (iii) establishing a standards hub, which BSI is doing with Alan Turing Institute. The standards hub focuses on healthcare as well.

as a medical technology. This includes collaborations with regulators and other standards development organisations, and how it will remain as a key focus area during 2022.	• Finding ways to make globally harmonised standards for AI/ML innovation, evaluation, use, and oversight.
Peter Bannister, Vice President, Ada Health Topic: Embracing the creative constraints of regulatory approaches: how to use compliance and safety to drive product improvements with SaMD.	Drawing on his roles as both Healthcare Executive Chair of the Institution of Engineering and Technology and as honorary Professor at the University of Birmingham Centre for Regulatory Science and Innovation, Peter presented an overview of how Ada Health: • Partners with institutions like University of Birmingham, NHS, NIHR, etc., help accelerate research. • The circle of AI/ML innovation includes- (i) capturing requirements; (ii) creating design specifications; (iii) verifying design; (iv) validating the product designed; and (iv) post market testing. • There are challenges with building truly representative data sets, and with mitigating data biases.
Fatema Jessa, Chief Pharmaceutical Officer's Clinical Fellow, Office for Digital Health, NICE	An overview of the Office for Digital Health's (**ODH**) mandate, focus areas, and work. The ODH provides leadership on the evaluation of the value of digital health technologies. Their presentation highlighted: • ODH has 6 key workstreams ranging from very early support to developers (through the Innovative Devices Access pathway) all the way through to getting

Pilar Pinilla-Dominguez, Associate Director – NICE International Topic: NICE's work relevant to digital healthcare, specifically from an AI/ML perspective.	a digital health technology into the system and exploring ideas like contingent approval for AI/ML tools. ODH works with government bodies like the MHRA, and others for implementing these 6 workstreams. For instance, as part of its Innovative Devices Access Pathway (IDAP), ODH works with MHRA and others to create a new pathway for medical devices. The new pathway includes safety assessments and testing through sandboxes, post market surveillance, and evidence generation for health technology assessments. ODH also works with NHSx MAAS initiative (described above). • ODH also works with NHSx, NHS, AAC, and the National Institute for Health Research to provide grants for research. This is done through the "AI in Health and Care Award". • ODH uses NICE's 'evidence standard for digital health technologies', which is a clinical risk classification-based evaluation of AI/ML tools being used in healthcare. AI/ML tools are slotted into different tiers of risk. Different tiers require different kinds of evidence to prove the safety of the AI/ML tool. • NICE is also working to create 'Topic Intelligence' for AI/ML tools that show promise but don't yet have sufficient evidence to be considered for NICE's guidance. Topic Intelligence will have a list of digital health technologies which have 'plausible promise' (i.e., which have good quality evidence of patient and system benefit but don't yet meet NICE's guidance standards). Once listed, the tools can be put to further research to establish their safety. The aim is to support developers collect evidence within the system through NICE's new contingent approval pilot product.

Annexure 2: Indian cohort's reflections from the Learning Tour

This section captures the reflections of the Indian cohort on the approaches of India and the UK to regulating and encouraging AI/ML research, innovation, evaluation, use, and oversight. It also captures the Indian cohort's ideas for further research and potential collaborations with the UK government or organisations in the UK.

1. The similarities in India and UK's approach to regulating and encouraging AI/ML in healthcare

a. **Universe of regulators and laws is a complex web to navigate**: India and the UK have ministries, departments, and autonomous bodies tasked with making policy/law, exercising oversight, and encouraging research, in AI/ML in healthcare. Innovators, researchers, and manufacturers thus, have to navigate a labyrinth of regulators to get approvals for research, innovation, evaluation/testing, marketing, and post-market surveillance.

b. **Similar regulatory approaches:** India and the UK follow a risk-classification based regulation of medical devices.[34] Innovators and manufacturers in both countries need regulatory approvals for clinical research, evaluation, and marketing of medical devices. Both countries have laws looking into the welfare of patients.[35]

c. **Data-related challenges**: Availability of data seems to be an issue in the UK as well. Additionally, health data is scattered and not uniform in formatting and terminology. This is seen especially in the difference between the clinicians recording heath data and researchers recording of health data. India is also seeing a digital health push through the Ayushman Bharat Digital Health Mission (**ABDM**), which recognises the need to integrate all digital

[34] Medical Devices Rules, 2017 in India. In the UK and devices must conform to the UK MDR 2002, the EU MDR (until 30 June 2023), or the EU IVDR (until 30 June 2023) in order to be registered with the MHRA.
[35] Consumer Protection Act, 2019 in India. The Health and Social Care Act, 2008 in the UK.

health records on one platform.[36] The ABDM has a 'unified health interface', which will operate a health information exchange for easy and safe data sharing across institutions.[37] However, this mission is in its infancy, and needs to be built out quickly. While building the ABDM out, a key thrust should be to build out mechanisms that enable innovators to quickly build quality products.[38]

2. The differences in India and UK's approach to regulating and encouraging AI/ML in healthcare

a. **Inter-agency co-ordination:** In the UK, agencies/mechanisms exist to coordinate between various research trusts, and in some cases regulators as well. This is not the case in India. Bodies like AAC, NICE, NHS AI Lab, NHS Digital establish guidelines, mechanisms for collaborating and synergising across various agencies.

b. **Focussed effort to support innovators**: This is a key takeaway from emerging themes discussion above. One can see how support is provided or facilitated at every stage of AI/ML tool; from mere ideation, to basic testing, to formal trials/or testing, to evaluation, and marketing. The UK ecosystem goes beyond funding opportunities or proof of concept. The UK ecosystem also provides support to ensure the real-life applicability and adoptability of the AI/ML tool or AIaMD. That is, AI/ML tools or AIaMDs are analysed and supported through the lifecycle of the innovation and marketing processes. This is something Indian entrepreneurs and researchers need, so to as to reduce failures of conversion from the proof-of-concept stage to production stage.[39]

c. **Strong government backing for innovation**: The Indian government provides grants for research in AI/ML (e.g., the Department of Science and Technology, the National Research Foundation, and the Department of Biotechnology

[36] https://abdm.gov.in/home/abdm
[37] https://abdm.gov.in/home/digital_systems
[38] Suggested by Sridhar P, CEO and co-founder, Ubiqare Health Pvt. Ltd., via email dated March 23, 2022
[39] See, https://www.manufacturingtodayindia.com/sectors/guest-column-poc-is-not-enough

through the Biotechnology Industry Research Assistance Council or "BIRAC").[40] This is sometimes done in partnership with the private sector.[41] However, there is scope to streamline these grants and funding opportunities in a focussed manner. For instance, the work of the AAC in walking with innovators through their journey from ideation, validation, and approvals, with funding, could be replicated here in India. Similarly, the strategic investments made by the UK government to ATI can be considered.

d. **Ethical health data sharing is important**: The current law allows simple consent-based sharing that is limited to the purpose the data was collected for. For example, a patient living with diabetes taking part in clinical trial not consent to his heart data to be monitored. Or processed to understand long term cardio prognosis for a diabetes patient individually and for diabetes patients collectively. The same patient may however, only consent to his blood sugar levels being collected over time, stored, and processed for the study. Health data records in India are typically in rudimentary form and are often not interoperable, with healthcare institutions using outdated legacy information technology systems for managing their patients. As mentioned earlier, the ABDM hopes to address some of these challenges through its unified health interface, and its ABDM ecosystem building blocks (e.g., unique patient identification or "ABHA", digital lockers for patient health records, and registries of healthcare professionals and facilities).[42]

3. Drawing from the similarities and differences to build India's healthcare-related AI/ML capabilities

[40] For instance, https://dst.gov.in/serb-dst-partners-intel-india-launch-first-its-kind-initiative-advance-deep-tech-based-research. See also, https://indiaai.gov.in/article/ai-in-india-initiatives-from-the-indian-government-in-2021. See also, https://birac.nic.in/cfp_view.php?id=83&scheme_type=1
[41] See https://www.dqindia.com/dst-intel-india-announce-partnership-increase-opportunities-artificial-intelligence-deep-technologies/
[42] https://abdm.gov.in/home/digital_systems

a. **Better mechanisms for innovators and researchers to interact with regulators, government bodies, and research institutes:** There is a need for initiatives like the AAC[43] and the NHS' MAAS in India. This will help companies, and researchers navigate interactions with various regulators. In the UK, there is concerted effort amongst regulators and other stakeholders to set up the right enabling infrastructure that supports innovators. The concerted effort appropriately balances regulation and oversight with support to innovators. Bodies like AAC, NICE, NHS AI Lab, NHS Digital establishing guidelines, mechanisms for collaborating and synergising across various agencies.[44]

b. **Tailor regulatory frameworks to the specific needs of each use case of AI/ML in healthcare:** When it comes to regulating AI/ML use in healthcare, the approach should be different strokes for different folks. There are multiple use cases of AI/ML in healthcare. We need a differentiated approach to regulating each use case.[45] The unique challenges posed by AI/ML must be accounted for in India's present regulations; where AI/ML is regulated as an SaMD.[46] Initiatives like the AAC and the NHS' MAAS can be replicated in India to help start-ups navigate regulations.

c. Identifying focus areas, principles, and organisations to build India's healthcare AI/ML capabilities:

i. *Key focus areas to boost safe healthcare AI/ML innovation and adoption:*. There is need to ensure 3 key dimensions of AI/ML use, (i) safe data sharing (e.g., for proof of concept and innovation); (ii) regulatory approvals depending on the use case, software validation (e.g., ensuring safety for Indian use if the software was developed in another country); and (iii) bioethics (e.g., how patient safety was incorporated into the software's development and its use).

[43] Suggested by Ms. Shayanika Hazarika, Director Healthcare at Microsoft| Board Member, HIMSS India in her LinkedIn post https://www.linkedin.com/posts/shazarika29_regulatory-ai-ml-activity-6911358124880715776-3bLn?utm_source=linkedin_share&utm_medium=member_desktop_web
[44] Suggested by Sridhar P, CEO and co-founder, Ubiqare Health Pvt. Ltd., via email dated March 23, 2022
[45] Suggested by Mr. Abhijit Ghosh, Assistant drugs controller (medical devices), Central Drug Standards Control Organisation, via email dated March 23, 2022.
[46] Suggested by Mr. Tapan Pati (Director - legal, South Asia) in his personal capacity, via email dated March 23, 2022

Any government department/ministry/body tasked with creating harmony amongst regulators/government bodies would need to oversee these dimensions and be able to successfully liaise with the innovator and research communities.

ii. *Line ministries/departments to lead the charge in boosting safe healthcare and AI/ML innovation and adoption:* There were discussions on what an enabling framework for AI/ML use in healthcare would look like, and which government body should lead the charge towards this framework. Some suggested Niti Aayog and Ministry of Health Family Welfare (**Health Ministry**),[47] while others suggested the ICMR or Department of Pharmaceuticals.[48] One suggestion called for the Ministry of Science and Technology to steer an inter-ministerial committee comprised of the Health Ministry, Ministry of Electronics and Information Technology, Niti Aayog, National Medical Commission, ICMR, Department of Biotechnology, Department of Science and Technology, Council of Scientific and Industrial Research, Office of the Principle Scientific Advisor to the PMO, University Grants Commission and others. The committee would also need to have subject experts from technology, medicine, ethics, and social health sciences.[49] No consensus was reached on the specific government body.

iii. *Ethical considerations should be a part of boosting healthcare AI/ML innovation and adoption:* Additionally, it was pointed out that an enabling regulatory framework should revolve around the principles of ethics and caters to the needs of the public. The regulatory framework should have clear and transparent clauses and encourage equity as well as accountability. The framework should empower independent decision making while taking care of inherent biases and conflicts of interest. The regulatory framework should provide detailed guidance, standard operating procedures and frequently asked questions and FAQs for improved understanding among the developers. This will

[47] Suggested by Mr. Bunty Kundnani, Head – regulatory affairs, Qure.ai, via email dated March 23, 2022
[48] Suggested by Professor Niranjan Joshi, Associate Programme Lead, Digital Health & Innovation Deployment · Centre for Cellular and Molecular Platforms (C-CAMP), via email dated March 23, 2022, and on the learnings call organised for cohort members on March 21, 2022.
[49] Suggested by Dr. Roli Mathur, Head – Bioethics Unit, Indian Council of Medical Research, via email dated March 23, 2022

help developers adhere to the regulatory framework. The regulatory framework should have structures that are accessible and that facilitate, handhold, and help.[50]

iv. *Ethical and safe data sharing while boosting healthcare AI/ML innovation and adoption:* An enabling framework must provide ways to share data safely and ethically. The underlying patient data research and development of SaMDs can be liberalised to address challenges faced during the research and development and clinical use phases. Similarly, continuous real world data inputs are helpful in refining AI tools. Finally, using globally harmonising SaMD standards will make it easier for Indian SaMD manufacturers get approval in overseas markets. If globally harmonised standards are not adopted in India, it may act as a regulatory hurdle for Indian companies looking to expand overseas.[51] Several cohort members noted the value of using synthetic data sets as well.[52]

4. Suggesting areas for deeper research and partnership with UK organisations based on the learnings

a. **Further study/research**:

i. Coordination amongst regulators and government research bodies. Deeper dives into how NICE, MHRA, NHS, and NHSx coordinate their activities. This will help the Indian stakeholder to derive India specific learnings for them. For example, is there an inter-ministerial/departmental steering committee helping these organisations coordinate their activities? If yes, how frequently do they meet? What activities do they coordinate on (e.g., grant decisions)?

ii. Examining whether there is a role for synthetic data in research in India, and if yes, how to enable it safely.

iii. Need for capacity building of regulators to keep up with the evolution of AIaMD and other AI use cases

[50] Suggested by Dr. Roli Mathur, Head – Bioethics Unit, Indian Council of Medical Research, via email dated March 23, 2022
[51] Suggested by Mr. Tapan Pati (Director - legal, South Asia) in his personal capacity, via email dated March 23, 2022
[52] Suggested by Ashish Srivastava, Technology Advisor to the Women and Child Department, Government of Karnataka, via email dated March 23, 2022. And Mr. M. Chockalingam, Consultant - AI | ML, Tamil Nadu e-Governance Agency.

iv. Identifying how to risk classify AIaMD, and what kind of evidence is needed to prove that an AIaMD is performing as intended.

b. **India-UK collaborations and funding and AI/ML-related innovation challenges**:

i. Joint grant funding by India and the UK on the lines of INDO-USSTF for AI in healthcare.[53]

ii. Hosting a 'UK-India Grand Challenge' for common challenges in healthcare in U.K and India (e.g., Geriatric care, non-communicable diseases, and women's health).[54]

iii. Facilitating a collaboration between NICE - NITI Aayog. This would help with joint development and harmonisation of regulatory standards.[55]

iv. Ideate UK-India tech fellowships for entrepreneurs from the UK-India to work together on AI/ML use in healthcare.[56]

v. Building synthetic data registries can be an important point of collaboration between the UK and India. India can collaborate with the UK in setting up registries like the NCCID for cancer and other diseases (e.g., anaemia, chronic obstructive pulmonary disease, and cardiovascular diseases).[57]

[53] Suggested by Professor Rajendra Pratap Gupta, founder of Health Parliament and former advisor to Union Health Minister, via email dated March 23, 2022
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[57] Suggested by Ashish Srivastava, Technology Advisor to the Women and Child Department, Government of Karnataka, via email dated March 23, 2022.