Project Reg: AIH

IKIGAI LAW

British
High Commission
New Delhi

SHORT PROGRAMME EVALUATION REPORT

INDEX

KEY ABBREVIATIONS

Term	Abbreviation
Accelerated Access Collaborative	AAC
Artificial intelligence/machine learning	AI/ML
AI as a Medical Device	AIaMD
British High Commission, New Delhi	BHC
British Standards Institution	BSI
Bureau of Indian Standards	BIS
Care Quality Commission	CQC
Central Drugs Standard Control Organisation of India	CDSCO
Confederation of Indian Industry	CII
Department of Biotechnology, Government of India	DBT
Department for International Trade- UK	DIT
Department of Pharmaceuticals, Government of India	DoP
Department of Science and Technology, Government of India	DST
Department for International Development- UK	DFID
Department for Promotion of Industry and Internal Trade, Government of India	DPIIT
Directorate General of Foreign Trade, Government of India	DGFT
Electronic Health Record	EHR
Federation of Indian Chambers of Commerce & Industry	FICCI

Foreign, Commonwealth and Development Office - UK	FCDO
Ikigai Business Consulting and its affiliates	IL
Indian Council of Medical Research	ICMR
Ministry of Electronics and Information Technology, Government of India	MeitY
Ministry of External Affairs, Government of India	MEA
Ministry of Health and Family Welfare, Government of India	MoHFW
Medicines and Healthcare products Regulatory Agency- UK	MHRA
Medical Technology Assessment Board of India	MTAB
National Health Authority of India	NHA
National Health Service - England	NHS
National Institute for Health and Care Excellence - UK	NICE
National Institute for Health Research- UK	NIHR
National Institution for Transforming India, Government of India	NITI Aayog
NHS Technology Transfer	NHS TT
Office of the Principal Scientific Adviser, Government of India	PSA
Overseas Development Institute - UK	ODI
Software as Medical Device	SaMD
Science, Technology, Engineering and Mathematics	STEM
UK India Business Council	UKIBC
University Grants Commission of India	UGC
US Food and Drug Administration	USFDA

SHORT PROGRAMME EVALUATION REPORT – 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

March 31, 2022

I. Executive Summary

Under the auspices of the UK-India Tech Partnership, the BHC worked in conjunction with IL on a mutual learning programme between India and the UK. The vision was to build bridges between both the nations on regulatory approaches to AI/ML enabled health tech (**Reg-AIH Programme/Programme**). The purpose of the Programme is to enable India and UK's Vision 2030[1] set by Prime Ministers Modi and Johnson.

The Programme drove conversations between experts from India and the UK. It also explored joint research and engagement on regulatory approaches to use of AI/ML enabled healthtech. Specifically, it supported Indian stakeholders in a) examining the relevant regulatory landscape in India b) undertaking a comparative study of UK approaches to use of AI/ML in healthcare and c) identifying partnership ideas to develop Indian regulatory frameworks via bi-lateral expert-to-expert exchange.

This is an unprecedented Programme, which has facilitated a platform for both the countries to share technical knowledge and expertise on use of AI/ML in healthcare. It has also helped promote dialogue in research and innovation for businesses of both the nations. Through this, India and the UK could achieve their joint vision for frontier technology to be a force for good in the world, anchored in democratic values.

[1] https://www.gov.uk/government/publications/india-uk-virtual-summit-may-2021-roadmap-2030-for-a-comprehensive-strategic-partnership/2030-roadmap-for-india-uk-future-relations

II. Summary of the Programme

The Programme was executed in several milestones. A cohort of Indian and UK healthtech experts was constituted to have substantive conversations and explore partnership ideas on regulations for AI/ML enabled healthtech. The experts were brought together on a week-long learnings trip in the UK[2]. Prior to that, the Indian cohort was briefed on the Indian regulatory landscape to ensure a uniform understanding of the space. The Indian cohort also undertook brain storming sessions using case studies to identify pain-points and areas for work in India. A snapshot of the milestones is set out below.

1. Constitution of expert cohorts (**Milestone 1**):[3] The goal was to constitute a cohort of experts who have the requisite expertise, experience and understanding of use of AI/ML in healthcare.

   For the Indian cohort, key stakeholders from the government (NHA, CDSCO etc.), academia, healthtech companies, ethics scientists and clinical researchers (cohort/experts) were identified. This was done by first preparing an extensive stakeholder map followed by a rigorous vetting process of the shortlisted candidates. Experts who work at the intersection of regulation, public policy, technology, healthcare were mapped. Keeping in mind the objectives of the Programme, invitations to the candidates were extended strategically, accounting for cancellations and other contingencies.
   Please refer to *Annexure 1* for the final list of India cohort members.

   For the UK cohort, the UK healthcare ecosystem was mapped, which included NHS England, CQC, NICE, MHRA, relevant academic and research institutions among others. Key stakeholders from these organizations/bodies, along with healthtech startups, industry associations were brought together for engaging discussions/seminars with the Indian cohort.

[2] Interactions between the Indian and UK experts took place in London and Oxford.
[3] The process for constitution of the Indian cohort was undertaken from December 2021 – February 2022.

Please refer to *Annexure 2* on the agenda and the UK cohort members for more details.

2. Briefing on the Indian regulatory landscape (**Milestone 2**):[4] To facilitate a constructive and forward-looking engagement between the Indian and the UK cohorts, a briefing paper on the relevant Indian regulatory landscape was drafted. The briefing paper helped ensure that the Indian cohort was briefed and aligned on the objectives of the Programme, technical aspects of the regulatory landscape in India, emerging issues and opportunities in AI/ML enabled healthtech. The briefing paper provided a snapshot of the regulatory, legal and policy environment applicable to healthcare delivery using AI/ML tools. This included briefs on Medical Devices Rules 2017, Telemedicine Practice Guidelines, Information Technology Act, 2000, MeitY's 'National Programme for AI' among others. It also mapped out and explained the role of key government bodies relevant in this sector such as the MoHFW, MeitY, CDSCO, NHA, among others

   The briefing paper identified some high-level issues for discussion, such as management of health data, clinical evaluation of AI/ML tools for safe human use, understanding liability of technology service/software providers, post market surveillance for oversight. It also set the tone for the upcoming sessions and meetings in the Programme.
   Please refer to *Annexure 3.1* for the briefing paper on Indian regulatory landscape.

3. Webinar on the Indian regulatory landscape (**Milestone 3**):[5] A webinar on the Indian regulatory landscape was conducted for the Indian cohort to come together and discuss the current landscape, pressing issues and solutions for the sector. It was conducted through case studies based on different kinds of products/ practices that rely on AI/ ML, such as clinical decision support systems. This helped identify key questions/ themes for subsequent meetings, especially with the UK cohort. For instance, one of the case studies revolved around

[4] The briefing paper was first shared with the Indian cohort on 03 February 2022.
[5] Webinar I was conducted on 08 February 2022.

dissecting the possible regulatory challenges with an app that detects cancer through an AI/ML tool. Some of the key themes that emerged were on:

- Use and availability of data, ensuring its integrity, interoperability and intelligence;
- Managing individuals' consent;
- Approaches to regulate software as an SaMD, including the need for a separate standalone regulator to oversee the evaluation, use and monitoring of SaMDs;
- Policy makers to consider (a) level of human intervention needed with an AI/ML tool's use; (b) the level of contact with patients' bodies; and (c) the use case (e.g., as an SaMD) for a balanced, safe regulation;
- Ensuring scientific rigour, transparency, and consistency in evaluating SaMDs for use in clinical settings;
- Liability of technology service providers for their tools; and
- Regulation based on use case, risks, and level of human intervention/interaction, for each tool's approval.

Please refer to *Annexure 3.2* for the presentation depicting the Indian framework and case studies.

4. Webinar on the UK regulatory landscape and discussion on pain points of the Indian regulatory system (**Milestone 3**):[6] This webinar was divided into two parts. First was a high-level briefing of the UK's healthcare and regulatory landscape relevant to the project. It touched upon the relevant regulators in the UK and their ongoing policy efforts to build a sound system for AI/ML enabled healthcare.

[6] Webinar II was conducted on 28 February 2022.

The second part of the webinar, again, relied on case studies derived from real world products. A case study on the use of AI/ML tools in a hospital's administrative system was discussed. Some of the key discussions/takeaways were:

- Issues around cyber security, bias and liability in case of failure of technology.
- The need for evidence-based guidance, interoperability and standardizing IT communication protocols, cybersecurity, post market surveillance, regulating futuristic AI/ML tools etc.

The two webinars also set the tone and agenda for the week-long UK learning tour.
Please refer to *Annexure 3.3* for presentation on UK regulatory landscape in brief and case studies.

5. UK learnings tour (**Milestone 4**):[7] The tour was curated to facilitate meetings between the Indian cohort and a wide range of stakeholders from the UK i.e. the UK cohort. Detailed sessions were conducted by a total of 40 stakeholders from the NHS, NHS AI Lab, the MHRA, NICE, University of Oxford, ODI, several healthtech startups, among others. The intent was to delve deeper into all issues relevant to using AI/ML in delivering healthcare. For instance, issues on use of data and health data management, ethics, algorithmic biases, regulatory approaches to using software as a medical device and using software to deliver healthcare generally. The tour also included a trip to Oxford for a deep dive into the issues with some of the leading academics in this space. It also included a special session with the Alan Turing Institute (which is the national institute for data science and artificial intelligence, with headquarters at the British Library) for more insight behind setting up of such an institute, its functions and some of its key projects in healthcare.

   The learning tour was a good starting point for identifying and defining the contours of UK - India Tech Partnership, especially in healthtech. It may also facilitate better market access between both the nations. The tour also helped to assess the scope and appetite for collaboration in AI/ML in healthcare. The UK experts spoke about the government's focused effort to encourage innovation through funding, inter-disciplinary

[7] The UK learning tour was from 14 March – 18 March 2022.

research and support to ensure real-world applicability of innovations. They also discussed how innovators and companies have to navigate through several laws and interact with multiple regulators, at different points of the AI tool's lifecycle.

Post the tour, a detailed learnings paper identifying key themes emerging from the discussions with UK experts was drafted. It also enlisted the key takeaways and recommendations from the UK learnings tour. A summary of the key takeaways from the learnings tour is set out below:

a. **Multiple regulators:** Like in India, the UK has multiple regulators that oversee various aspects of AI/ML tools, SaMD, and AIaMD including data protection, clinical evaluation, research and innovation. Hence, there is a need for connecting these regulators and for bridging the gap between the regulators and the industry/innovators. Organisations like the AAC, NHS AI Lab or even the MAAS help in department coordination and working towards enabling innovators to navigate the regulatory web.
b. **Multiple laws:** Multiple laws/ standards govern various aspects that impact AI/ML innovation, evaluation, use, and oversight. Data sharing is a good example of this. Regulations are also evolving as both regulators and industry continue to grapple with different aspects of AI/ML. Discussions on AI/ML regulations are taking place globally at the national (e.g., in the US, UK, and India) and multinational levels (e.g., European Union, International Medical Devices Regulators Forum).
c. **Building an innovation ecosystem:** Innovators and researchers need opportunities to safely gather evidence and test AI/ML tools prior to clinical evaluation such as in case of AIaMDs. They also need support on funding/ grant opportunities. In UK, the Office for Digital Health at NICE and the Innovative Devices Access Pathway, work towards supporting innovators. They enable this through safety assessments, testing through sandboxes, post market surveillance, and evidence generation for health technology assessments.
d. **Data is critical for using AI/ML:** 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 access to quality and variety of data to the innovators/researchers. Hence, initiatives enabling institutions to share patient data in a safe and ethical manner is necessary. UK's iCARE collaborates with multiple institutions for data sharing across different specialties. Also, NHS's proposed National Medical Imaging Platform is an example of a platform that enables the collection and sharing of useful data, while making conscious choices around ethics and privacy

e. **Public need should be paramount:** There is a need for mechanisms ensuring patient and/or public involvement in AI/ML based research, innovation, evaluation, and adoption. Organisations like the CQC, AAC, NHS Skunkworks Lab, among others work towards ensuring that using AI/ML tools is regulated, helpful, and safe for public use. This is based on the public health challenges identified by these organizations.

f. **Indian cohort's takeaways:** During the Programme, the Indian cohort shared their views on how there's a need to:
    - Incentivize the clinical community to participate at various stages of innovation;
    - Focused funding in healthcare-related AI/ML research;
    - Streamline and optimise the links in the regulatory chain;
    - Create synergies and coordinate efforts between different departments and regulators;
    - Harmonise regulations with international standards;
    - Sustain incubators, encourage entrepreneurs and build capacities;
    - Integrate ethical considerations, independent review and monitoring in development as well as deployment; and
    - Improve advocacy, public engagements/ trust building, transparency and accountability in collaborations and data sharing.

Please refer to *Annexure 2* for the detailed agenda of the UK learnings tour and *Annexure 3.4* for the full learnings paper along with annexures.

III. Way Forward - Partnership ideas and future advocacy initiatives:

In India, AI/ML related research, regulation and adoption in healthcare is still evolving. One key takeaway from the UK learning tour was that building infrastructure and resources is equally important as diving deeper into regulatory approaches. This section, therefore, suggests partnership ideas from an academic, R&D, upskilling etc perspective in addition to regulatory approaches to using AI/ML in healthcare. The table identifies key themes, ideas for collaboration, reasons for such collaborations and the end goal.

Sr. No.	Partnership objectives: WHAT?	Need for partnership: WHY?	Partnership ideas: HOW?
1.	**Knowledge sharing** *Cost*[8]***:MEDIUM***	Both India and the UK have a web of stakeholders in its healthcare and AI ecosystem. This includes the government, regulators, research institutions and standard setting bodies. Multiple stakeholders can result in duplicity of efforts. A common bi-lateral platform for	**a. India-UK Reg-AIH Board:** *Idea:* Reg-AIH Board can be constituted which allows different agencies to interact with each other, share knowledge and learnings over the years. This can be set up on similar lines of what AAC does for the UK's healthtech eco-system. The AAC is a powerful platform that brings together industry, government, regulators, and patients for knowledge sharing. It also helps focus on patient-centric research and innovation.

[8] Cost is defined to included finances, human effort and time required to execute the partnership idea.

		sharing learnings on regulatory approaches to using AI/ML in healthcare will be beneficial for both nations. 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).	*Who:* Such a board can have agencies like the AAC, NICE, UK Health Research Authority, MHRA, from the UK and MoHFW, DoP, CDSCO, NITI Aayog, ICMR from India. **b. Training sessions and knowledge sharing seminars:** *Idea:* Trainings help in commercialization of an industry. It can provide support from technology discovery to the diffusion. Further, training sessions and knowledge exchange seminars will bridge the gap between the research and how it is carried out on the ground. *Who*: This can be undertaken in collaboration with MHRA, NHS TT, BSI from the UK and BIS, ICMR, MTAB and CDSCO from India. ***Outcomes****:* Having a board for sharing learnings will help reduce duplicity of effort in the AI/ML enabled healthtech space. Since the UK has gone through this learning curve before, Indian regulators/ agencies could draw from those experiences to develop means for coordination. It could also provide a pathway to help industries connect with different government agencies and regulators in India or even in the UK.

2.	**Harmonization of regulations/ synchronization between regulators/ease of doing business.** *Cost:**LOW***	Inconsistent and diverse regulations/standards hurt businesses with global ambitions. It specifically affects smaller businesses disproportionately. To give effect to both the nations' bilateral trade ambitions, it is vital to strengthen ease of doing business norms. Efforts for building regulatory approaches to AI in healthcare is at its nascency in India. Bilateral cooperation can help align both nations' approaches on certain issues. Indicatively, this can include AI risk assessment, process standardisation for ethics reviews, international AI standards, conformity assessment of AI products, among other themes.	**Government led:** **a. Harmonization of regulations:** *Idea:* Explore common ground in regulations/ standards along the lines of the 'Good Machine Learning Practices' drafted by US FDA, MHRA and Canada Health. *Who:* This can be explored through collaboration between policy making bodies and subject experts between the two nations. Strong champions from the UK and India would be needed to take the initiative further. NICE from the UK and NITI Aayog along with MoHFW from India could partner for such an imitative. **b. Setting up regulatory sandboxes:** *Idea:* Set up regulatory sandboxes to test AI products for safe healthcare delivery in both nations. This will create a safe space for testing new regulatory processes on a global scale. *Who:* This can be initiated by the UK Information Commissioner's Office[9], MoHFW and NITI Aayog. **c. Bilateral treaties:**

[9] The ICO works closely with innovators and businesses which are creating products and services which utilize personal data in innovative and safe ways. It does so through regulatory sandboxes.

			Idea: Using industry as a catalyst, facilitate a bilateral treaty between India and UK on SaMD/AIaMD trade and/or regulations that impose a 'minimum common regulatory standard for AI in healthcare' between the signing countries. *Who:* This can be on the lines of the bilateral agreement on cyber-relationship, between India and UK. Under this agreement, the nations have agreed to an overarching cyber-relationship framework that enables the development of a common and shared understanding of international cyber activity[10]. The MoHFW and UK's Health Department, under the aegis of their respective external ministries, can spearhead this initiative. **Industry led:** **d. Industry associations led push for reforms:** *Idea:* Relevant Industry associations /institutions with common agendas can be set up to push for regulatory reforms in AI/ML enabled healthtech. It can be a new industry body dedicated towards supporting businesses with insights, network, policy advocacy etc. Alternatively, it can be set up as a focused wing under existing associations such as Tech UK or UKIBC.

[10] https://mea.gov.in/bilateral-documents.htm?dtl/29831/IndiaUK_List_of_MOUs https://mea.gov.in/bilateral-documents.htm?dtl/29831/IndiaUK_List_of_MOUsAgreementsInitiatives_during_the_visit_of_Prime_Minister_to_UK_London_April_18_2018

			Who: Industry associations with healthcare or tech based objectives and interests in India and UK. For instance, Tech UK/UK Tech-Nation, UKIBC, FICCI, CII, Alliance for Telemedicine Registry and Evaluation, Nathealth. ***Outcomes***: • Many frameworks on AI regulation and ethics have emerged from multi-stakeholder processes convened by academia, advocacy organizations, think tanks, and others in the past. A similar approach can be taken on this subject too. Such processes can also operate as aides to domestic policy making. • Given that both countries have committed to reciprocating ease of doing business, regulatory compliance relaxations and uniformity could further bolster trade relations[11].
3.	**Research and development** *Cost: **HIGH***	The current AI/ML healthcare landscape in India is still evolving, complex and scattered. The UK's journey in this space can be studied, especially since the healthcare	**a. Establish India-UK AI health research centers:** *Idea*: Establishment of an India-UK AI health research center or center of excellence/labs. These labs can have a special mandate of translating academic research to commercial product development. Here researchers and innovators can collaborate to find and solve for new use cases, share knowledge, promote entrepreneurship etc. This

[11] https://www.businesstoday.in/opinion/columns/story/enhanced-business-ties-first-step-towards-uk-india-free-trade-pact-294909-2021-05-03

		sector often relies on global publications and shared data. Lastly, bilateral research and development initiatives can contribute towards innovation and problem solving.	can be an initiative like the UK-India education and research initiative.[12] *Who:* From India, PSA, NITI, MeitY, MoHFW, ICMR and experts from academia and research. From the UK, NHS AI lab, NIHR, Alan Turing Institute, can work with the Indian stakeholders. Further, innovators and the clinical/medical community (such as medical professionals under the NHA and NHS) from both nations can play a key role in helping translate the academic research to viable commercial product development. **b. Investment in AI research**: *Idea:* Increasing investment in AI based research in healthcare by providing more data, experts and tools. Focus should be on finding the problem and not technology. *Who:* This can be executed through partners collaborating with the Oxford's Schwarzman Centre, Saïd Business School, Imperial College from the UK and Indian Institutes of Technology and Management and other leading research focused institutes in India. **c. Establishing a UK-Indian ethics body for research and innovation:**

[12] http://www.ukieri.org/

			Idea: A well-defined pathway is needed to develop and integrate ethics policies or guidelines in AI research and innovation. Improving collaborations while working on mechanisms for data sharing, data security while protecting the interests of the patients is needed. *Who*: A body can be constituted of experts on ethics associated with NHS and Oxford Policy Centre from the UK and DHR, Niti Aayog and ICMR from India. ***Outcomes**:* • Dedicated R&D along with these initiatives will allow the research to reach the innovators, build solutions and identify existing problems and lacunae. • Bringing together of diverse perspectives from academia, technology experts, healthcare experts in R&D undertakings will be useful. Especially because if the AI/ML tool doesn't account for diversity, it is not ethical.
4.	**Technical upskilling, training and capacity building of**	The healthcare workforce needs to be trained to fully realise the potential of AI/ML tools. Training will also make healthcare delivery efficient, safe and accessible. The	**a. Reskilling/training programs:** *Idea:* Conducting reskilling/training programmes for doctors, allied healthcare professionals, hospital tech staff, healthtech platform builders etc. This can be a two-way partnership where healthcare service providers with advanced training can train/upskill their counterparts. Such

	human resources *Cost:* ***MEDIUM***	healthcare workforce will require digital skills and a deeper understanding of the relevant laws/regulations.[13] Training, upskilling and development of human workforce in India would require resources, expertise and implementation of systems that have been successful before – like the UK's.	training programmes can be conducted at a local/district level to ensure feasibility and maximum sharing of knowledge. *Who:* From the UK, experts from NHS trusts, AAC, NHSx, hospitals etc. From India, hospitals, medical colleges, NHA, state run health departments, among others. **b. Technical courses and STEM:** *Idea:* Conceptualize technical courses and seminars for stakeholders in the AI/ML health value chain in India. This can be executed in the form of AI courses or components in master's and doctoral programs offered by both the nations by incorporating more STEM (including AI) in the curriculum. *Who:* This can be overseen by the ICMR, UGC and the National Medical Commission in collaboration with University of Oxford, Imperial and King's colleges etc. A similar tie-up is already underway between the University of Oxford and College of Engineering, Pune on using AI in agriculture. **e. Synthetic data registries:**

[13] https://www.oecd.org/health/health-systems/Empowering-Health-Workforce-Digital-Revolution.pdf

			Idea: The NHS Trusts can work with the Indian government agencies and think tanks to create synthetic data registries. With the Indian government laying impetus on building 'open' digital repositories of health data, the NHS can share its expertise to build disease specific registries. This could involve projects which are patient-centric, safe to use, sustainable and accessible. *Who:* NHS Trusts, NHS AI Lab from the UK and NHA, MeitY from India. **f. Infrastructure building:** *Idea:* The UK can share knowledge, expertise and collaborate with Indian stakeholders to build architecture/APIs to digitize hospital infrastructure and harness the power of AI. *Who:* This can be set up and undertaken under the Indo-UK Institute of Health programme,[14] executed by the NHS trusts in India. ***Outcomes**:* • Proper training, awareness and upskilling of stakeholders can translate the innovate to actual use, at scale.

[14] https://www.iuih.co.uk/

			• This will also ensure uniformity in determining legal liabilities of a medical practitioner and safe patient outcomes.
5.	**Dialogue and diplomatic exchange** *Cost:* ***MEDIUM***	Bilateral cooperation is required for AI/ML enabled healthtech development and application. There is a need for developing research and literature that can be the basis for future policy making initiatives or feed into discussions on bilateral free trade agreements etc.	**a. Roundtables and workshops:** *Idea:* Conducting routine roundtables and workshops between the counterparts of India and UK. These will help share knowledge and upcoming developments. The end goal of such workshops can be publishing domain specific reports that identify regulatory, technical, research and infrastructure opportunities and challenges. *Who:* As a starting point, a workshop between the BIS and BSI can be undertaken on standard setting for use of AI/ML tools in diagnostics or medical consultation. Similar workshops can be held between leading academicians and innovators of the two nations. This could be on the lines of the Reg-AI Programme, which brought together a diverse set of stakeholders to identify regulatory approaches in AI/ML in healthcare. ***Outcomes:*** • Literature and research generated can form the basis for future policy making. This could be on the lines of the

			policy brief, by the World Health Organization on 'Ageism in artificial intelligence for health'.[15] ● These initiatives will create forums and platforms for debate and discussions on themes beyond overarching issues like ethics and governance that have already been the focus of discussion in existing international forums. ● Dedicated workshops can focus on solving future potential problems such as changing patterns of diseases, ageing population, lack of progress on chronic diseases, lack of medicine accessibility etc. ● This will also influence bilateral and multilateral trade talks to account for the need for bilateral cooperation.
6.	**Facilitating commercial partnerships** *Cost:**HIGH***	Businesses need fiscal incentives and a conducive regulatory environment to innovate, experiment and scale up their healthtech product offerings in India.	**a. UK-India Grand Challenge:** *Idea:* A 'UK-India Grand Challenge' can be initiated to build innovative solutions for healthcare challenges involving Indian and UK innovators. The outcomes of this challenge could be incubated through incubation centres in either of the nations. *Who:* It could be set up on similar lines of the UK-India Startup Launchpad Initiative[16] run by DPIIT, Startup India

[15] https://news.un.org/en/story/2022/02/1111562
[16] https://www.startupindia.gov.in/content/sih/en/international/UK_India_Startup_Launchpad.html

			and UK's DFID. MeitY, MoHFW, university incubators can also be included in it. **b. Funding programmes:** *Idea*: UK is one of the major investors in India. Funding programmes for identifying and undertaking innovative, long-term and high-risk projects can be explored. *Who*: It can be executed under the existing efforts of entities like UK Innovate, UK Government Investments, Ministry of Commerce, MeitY and MoHFW. ***Outcomes:*** • These initiatives could act as an incubator and create an environment for innovation, while providing innovators commercial benefits. • It will also allow businesses to take advantage of digital supply chains and create products using models built in UK and India. This will contribute towards the bilateral trade and digital economy goals.
7.	**AI/ML focused tech projects for social good**	Tech collaboration between researchers, innovators and regulators in the UK and India could help solve issues for social good. Especially, when	• **Investment promotion:** *Idea:* Mobilizing finance for projects which focus on social good through AI/ML use in health. For instance, the UK has undertaken extensive work on COVID datasets and

	Cost: ***MEDIUM***	the technology involved raises questions around ethics, transparency, accountability and explainability. In the past, collaborative projects deploying AI/ML in healthcare have reaped benefits. For instance, the Cambridge-Chennai Centre Partnership on Antimicrobial Resistant Tuberculosis came up with an ML approach to understand how mutations affect human genetic diseases. This was funded by UK's Medical Research Council and DBT.[17]	Simulacrum.[18] Learnings can be shared with their Indian counterparts, to facilitate adoption of projects at similar scale or dealing with similar issues. This could be executed like the 'Indo-UK Climate Finance Leadership Initiative' which is working to eliminate barriers to investment and create market conditions to drive more capital in the energy sector. *Who:* DIT from the UK could work with Invest India (India's investment promotion and facilitation agency). • **Demand Signaling:** *Idea:* 'Demand Signaling' is a process which flags the most attention needing problems to innovators- who can then come up with solutions. In the UK, it is undertaken by the NHS AAC which publishes reports to signal the pressing research needs (such as on mental health, disability etc.) to NIHR, other stakeholders. This can be extended in India. *Who:* This can be executed through knowledge sharing partnerships similar to the UK-India Future Networks Initiative,[19] which aimed to create more diverse, innovative and secure telecoms supply chains, through collaborative

[17] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022125/UKRI_India_impact_report.pdf
[18] A cancer data registry based on synthetic data by NHS
[19] https://www.ukifni.org/#:~:text=The%20UK%2DIndia%20Future%20Networks,in%20Beyond%205G%20and%206G.

			efforts. This can be done through a collaboration between India's NHA and UK's NHS AAC. ***Outcomes:*** Given UK's expertise and both the countries' vision to enable 'tech for good', a collaborative effort will help accelerate innovation, knowledge sharing and entrepreneurship. This will also enable a more 'find the problem' vision as opposed to 'find the technology'.

Annexure 1:

Indian cohort members

Annexure 1: Indian cohort members

Sl	Name	Designation
1.	Bunty Kundnani	Head of Regulatory Affairs, Qure.ai
2.	Tapan Pati	Director Legal – South Asia, Johnson and Johnson
3.	Abhijit Ghosh	Assistant Drugs Controller (Medical Devices), Central Standard Drugs Control Organisation, Government of India
4.	Professor Rajendra Pratap Gupta	Public health expert and former advisor to Union Minister for Health and Family Welfare
5.	Shayanika Hazarika	Director – healthcare enterprise commercial, Microsoft India
6.	Ashish Srivastava	Technology Advisor, Women and Child Department, Government of Karnataka
7.	Dr. Roli Mathur	Scientist F & Head, Bioethics Unit, Indian Council for Medical Research
8.	Sridhar P	CEO and co-founder, Ubiqare Health Pvt. Ltd.
9.	Dr. Niranjan Joshi	Associate Programme Lead, digital health & innovation deployment, Centre for Cellular and Molecular Platforms.
10.	Chockalingam M.	Tech Lead, API implementation, Tamil Nadu e-Governance Agency, Government of Tamil Nadu

	Experts from Ikigai Law	
11.	Sreenidhi Srinivasan	Principal Associate, Ikigai Law
12.	Aman Taneja	Principal Associate, Ikigai Law
13.	Rutuja Pol	Senior Associate, Ikigai Law
	Members from the FCDO	
14.	Karen McLuskie	Deputy Director for Technology, British High Commission New Delhi
15.	Shubham Srivastava	Programme Manager (Tech) British Trade Office, New Delhi
16.	Shirley Williams	Protocol Visits Team, Protocol Directorate, FCDO

Annexure 2:

UK learning tour agenda
and UK cohort

Project Reg: AIH

IKIGAI LAW

British
High Commission
New Delhi

Briefing booklet on the UK learning trip

March 13 – March 19, 2022

Date: Monday, March 14, 2022

Venue: All day at The Dover House, London HQ – Scotland Office, Whitehall, London, SW1A 2AU

Time	Agenda
0900	Depart for the venue
0930	Proceed for security check to enter venue
1000 - 1300	***Session 1: Use and scaling up of AI/ML tools in public healthcare, deployment of AI in the NHS especially via start-ups***
1000	**Daniel Bamford,**Deputy Director AI Award, Accelerated Access Collaborative at NHS England *Topic*: Briefing on the NHS AI Lab's Accelerated Access Initiative and its role in use of AI/ML in healthcare. Q&A
1100	**Jennifer Hall**, Senior Data Scientist, NHS AI Lab Skunkworks, *Topic*: Role of NHS AI Lab's Skunkworks, team in supporting and upskilling trusts in the ethical applications of AI in healthcare. Q&A
1200	**Manish Patel,** Head of NHS Technology Ttransfer service, Imperial College *Topic*: Evolution of technology transfer in the NHS, particularly from an AI perspective. Q&A
1300 – 1400	

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1430 – 1700	***Session 2: Overview of the UK healthcare and its regulatory space.***
1430	**Eleonora Harwich,** Head of Collaborations, NHS AI Lab, NHSX *Topic*: Detailed background on how AI is organized in health and care landscape in the UK. This will include 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 will highlight some of the barriers faced by the system, as well as the work that is put in place to try and overcome these barriers. It will also highlight the work on the NHS AI Lab.
1515	**Jo Denson**, Senior Innovation Manager, NHS England and few start-ups from the AAC. *Topic*: Delve deeper into the working of the AAC and role played by the start-ups in helping governments use technology in public health.
1545	Q&A and discussions with the speakers.
1900	*Early dinner organized by FCDO*

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

Date: Tuesday, March 15, 2022

Venue: The Dover House; Alan Turing Office-British Museum; University of Southampton, Pall Mall

Time	Agenda
0900	Depart for the venue
0930	Proceed for security check to enter venue
1000-1330	***Session 1: Approach to policy making on rules/principles of AI/ML, especially on data governance and management, balancing innovation and safety***
1000	**Gazi Ahamat,** Head of AI Assurance, Centre for Data Ethics & Innovation (CDEI) *Topic*: How AI Assurance will enable trustworthy adoption of AI and what it will take to develop a robust, mature ecosystem of AI assurance.
1025	**Emily Jarret,** Senior Policy Advisor, Centre for Data Ethics & Innovation (CDEI). *Topic*: CDEI's Model for Responsible Innovation, a framework that articulates practical methods and interventions that help achieve the necessary conditions for responsible innovation, and therefore the trustworthy implementation of data-driven technology.
1055	**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.
1125	**Brhmie Balaram,** Head of 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.

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1155	**Moritz Flockenhaus,** Care Quality Commission (CQC) *Topic*: CQC's role & strategy, touchpoints with AI, collaboration to streamline regulatory pathways and the safe & effective adoption of AI
1225	Q&A and discussions with the speakers.
1330 – 1430	*Working Lunch*
1500	Arrive at venue 2 – Alan Turing Institute, British Museum
1530	**Dame Wendy Hall,** DBE, FRS, Regius Professor of Computer Science, Associate Vice President (International Engagement), and is an Executive Director of the Web Science Institute at the University of Southampton. *Topic*: Speak about her work in AI, including with the UK government's AI review and UK AI Council.
1615	**Alistar McGuire,** Head of Department and Chair of Health Economics at the Department of Health Policy, London School of Economics *Topic*: Work undertaken in his department on health economics and its relevance to AI/ML in healthcare.
1630	Q&A and discussion with the speakers
1700	Depart for venue 3 – University of South Hampton, Pall Mall
1730	**Panel discussion:** The future of IOT and disruptive technologies in the UK-India bilateral corridor: Changing the world for the better. *Dinner to follow at the same venue*

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

Date: Wednesday, March 16, 2022

Venue: Oxford: All day – Somerville College, Oxford India Sustainability Institute, Margaret Thatcher room

Time	Agenda
0800	Depart for Oxford
1000 - 1300	***Session 1: Interactive session on research in AI/ML in healthcare, other aspects of digital healthcare, data, ethics and public health governance.***
1000	**Siddharth Arora,** Programme Director of the Oxford India Centre for Sustainable Development (OICSD) *Topic*: Aim and scope of work done at the OICSD with an AI/ML use in healthcare lens.
1015	**Carl Heneghan,** Oxford Center for Evidence Based Medicine, Member working on digital healthcare and medication *Topic*: The regulatory and evidence requirements for ensuring Artificial Intelligence 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 effective interventions are developed and implemented.
1040	**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.

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1105	**John Tasioulas,** Director, The Shwarztman Center - University of Oxford *Topic*: Aims of the Institute for Ethics in AI and give illustrations from my own work on AI and the law and AI and health. **Ted Lechterman,** Research Fellow, Institute for Ethics in AI and Wolfson College *Topic*: AI and democracy.
1135	Q&A and discussion with the speakers
1300-1345	*Working Lunch*
1400-1600	***Session 2: Interaction with start-ups from Oxford's various research institutes: Startups/ early-stage spinouts that are using AI/ML in healthcare and allied biomedical settings (genomics, bioinformatics, etc.)***
1400	**Martin-Immanuel Bittner,** CEO, Arctoris *Topic*: The rise of technology-enabled and especially AI-driven drug discovery companies and 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.
1430	Start-ups from the Oxford incubator (Erstwhile) and the Oxford SAID Business School. Q&A with the speakers
1600	Walking around the historical town of Oxford
1800	Depart for London *Dinner in London – no commitments.*

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

Date: Thursday, March 17, 2022
Venue: BDO Offices, Baker Street; TechUK Office, 10 St Bride Street, London EC4A 4AD

Time	Agenda
0930	Depart for venue
1030 - 1300	***Session 1: Use of data in AI/ML tools, data privacy, cyber security and data management.***
1030	**Fionntan O'Donnel,** Senior Data Technologist, 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 assurance and data standards can help AI be more trustworthy, both for those who built it and those who are affected by it. The talk will discuss some of the practices we need in the new area of AI assurance.
1100	**François Lemarchand,** Senior AI Lab Data Scientist, AI Imaging Team, NHS AI Lab *Topic*: As the Covid-19 pandemic began, the National Covid Chest Imaging Database was set up and has since collected over 43,000 x-rays and CT scans from patients across the UK for AI research. We will address the reasons for keeping a part of the data unseen from AI developers, how we can use it to evaluate the performance of automated tools to detect Covid symptoms, and how this influences how AI tools are trained and tested.
1130	Q&A and discussions with the speakers

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1200	**Joshua Symons,** Director of Data Design & Architecture, UK Health Security Agency *Topic*: Data requirements for safe AI, AI regulation and data regulation including mass surveillance, and future data architecture to support best Q&A and discussions.
1300-1430	*Working Lunch*
1430	Arrive at venue 2 – WIPRO Innovation Hub.
1430 onwards	***Session 2: Industry best practices and exploring opportunities for strategic partnerships.***
1440	**Ruben Rasalingham,** COO and Mike Harrison, Global Director, Compliance, Behold.ai Technologies Limited
1450	**Michael Kipping,** Director, Medical Market, Element Materials Technology
1500	**Anthony Finbow,** CEO, Eagle Genomics
1510	**Harald Braun,** COO, I5 Health
1520	**Nii Lante Wallace-Davies,** VP Customer Service, Orcha
1530	**Shiraz Austin,** MD, ScribeTech
1540	**Capita**
1550	**Jonathan Day,** Senior Director - RA/QA, Congenica

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1600	**Objectivity**
1610	**Concentrix**
1620	**International Business Machines Corporation (IBM)**
1630	**Lakshmi Kaul,** CII
1640	**Sue Daley,** Director Tech and Innovation, TechUK
1650	**Param Shah,** FICCI
1700	Open Discussion and industry mixer
	Depart for Hotel (post mixer) *Dinner – no commitments*

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

Date: Friday, March 18, 2022

Venue: The Dover House, London HQ – Scotland Office, Whitehall, London, SW1A 2AU

Time	Agenda
0900	Depart for the venue
0930	Proceed for security check to enter venue
1000 - 1330	***Session: Regulatory approach to software as medical device, post market surveillance and oversight***
1000	**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.
1045	**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.
1105	**Rob Turpin,** Head, Knowledge Solutions Division, BSI *Topic*: Work done by the BSI on standardisation of AI/ML as a medical technology. This includes collaborations with regulators and other standards development organisations,

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

1125	**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.
1145	**Jeanette Kusel,** Director and **Pillar Pinila-Dominguez**, Associate Director, NICE International *Topic*: NICE's work relevant to digital healthcare, specifically from an AI/ML perspective.
1205	Q&A and open discussion with the speakers
1335	Depart for lunch
1500	Farewell and discussion on takeaways and learnings. *Dinner and rest of the evening – no commitment.*

**Items in the agenda may change owing to COVID 19 and the ongoing Ukraine crisis.*

March 19, 2022: Depart for India/other commitments

Annexure 3:

Documents

Annexure 3.1:

Briefing paper on Indian regulatory landscape

LEGAL AND REGULATORY LANDSCAPE GOVERNING THE AI-HEALTHCARE SECTOR IN INDIA - A BRIEFING PAPER

INTRODUCTION

This paper presents a snapshot of Indian laws and policies relevant to using technology in delivering healthcare. It is a part of the mutual learning programme on 'building bridges on regulatory approaches to artificial intelligence and machine learning (**AI/ML**) enabled healthtech' between India and the UK (**the Programme**). This Programme is aimed at creating learnings and driving policy discussions for enabling safe use of AI/ML in healthcare in India. To guide discussions, the paper provides a snapshot of the government bodies/regulators, laws, and policies relevant to healthcare delivery powered by AI/ML tools.

Table of contents:

1. OVERVIEW OF AI/ML IN HEALTHCARE IN INDIA

Emerging technologies (e.g., AI/ML) are increasingly being harnessed for better healthcare delivery and patient outcomes. AI/ML methods are used in a variety of healthcare applications, including for medical imaging and diagnostics, patient monitoring, and drug discovery.[i] AI/ML tools are used in services like hospital management systems (e.g., tools that help doctors and hospital staff to coordinate patient's treatment or better hospital administration)[ii], and in data-processing services (e.g., software solutions used for managing clinical trials,[iii] or for drawing insights from patient data). Health data pooling also (i.e., 'data lakes' and 'data warehouses') utilises troves of health data, to extract insights through algorithms for public health policymaking, patient treatment plans etc.[iv]

In India, among other things, AI/ML tools are being used for monitoring tuberculosis, providing telemedicine services, and reading diagnostics scans such as ECGs, X-rays, and retinal images.[v] Data pooling is used to estimate morbidity of persons in the insurance pool, to determine insurance pay-outs.[vi]

AI/ML tools are increasingly being used on their own as 'medical devices', where they directly aid diagnosis or treatment. Such tools are categorised as 'software as a medical device' (SaMDs).[vii] Driven by extensive and diverse patient datasets, SaMDs help in diagnosis, disease/risk mitigation or treatments.[viii] Examples of SaMD include Arterys Cardio DL (an AI software analysing cardiovascular images)[ix] and Koios DS for breast (a ML based diagnostic software for detecting cancerous lesions).[x] These devices have been approved by the US Food and Drugs Administrator. In India, standalone software like 'Ataxiagraph with interpretive software',[xi] and 'electrocardiograph software for home use'[xii] are two examples of standalone software recognised by the Indian drugs regulator.

PM Modi: "AI will play a major role in empowering agriculture, health and creating urban infrastructure such as reducing traffic jams…It remains our collective responsibility to ensure trust in how AI is used. Algorithm transparency is key to establishing this trust. Equally important is accountability. We must protect the world against weaponization of AI by non-state actors".

Source: https://www.hindustantimes.com/india-news/pm-modi-calls-for-use-of-ai-in-health-farm-sectors/story-ITU6WcmQCWo7MX7y3XFCZN.html

In India, we need greater guidance on how AI/ML can safely be used in healthcare. For instance, studies show that logistical difficulties such as storing, processing of data or algorithmic biases affect patient outcomes.[xiii] To enable adoption at scale for digital healthcare, the use of AI/ML tools must be reliable, safe and accountable.

Under the Constitution of India, 'public health' is a subject for state governments.[xiv] However, AI/ML in healthcare bears national relevance. The paper, therefore, focuses on the relevant laws, ministries, departments, and autonomous bodies at the union government level. It also provides a sampling of state-level initiatives to regulate and encourage emerging technologies like AI/ML.

2. SNAPSHOT OF GOVERNMENTS AND REGULATORY BODIES GOVERNING HEALTHCARE AND AI/ TECHNOLOGY

Several ministries, departments, autonomous bodies, and regulators oversee implementation of laws and making of policies on AI/ML and healthcare generally. We provide a snapshot below and details in Annexure I.

Healthcare-related:

i. *Union Ministry of Health and Family Welfare (**Health Ministry**)* is the Central Government ministry responsible for laws and policies governing healthcare and executing public health initiatives.
   - Directorate General of Health Services (**DGHS**): coordinates with states on implementing public health-related schemes; is a repository of technical expertise on various aspects of public healthcare in India.
     - Central Drug Standards Control Organisation of India (**CDSCO**): – sectoral regulator for 'drugs' and 'medical devices' that oversees setting of standards, evaluation, licensing, and post-market surveillance of medical devices
     - State Drugs Standards Control Organisations (**SDCO**): States sectoral regulator that are empowered to evaluate and provide licenses for sale and manufacture of Class A and B medical devices and undertakes inspections.

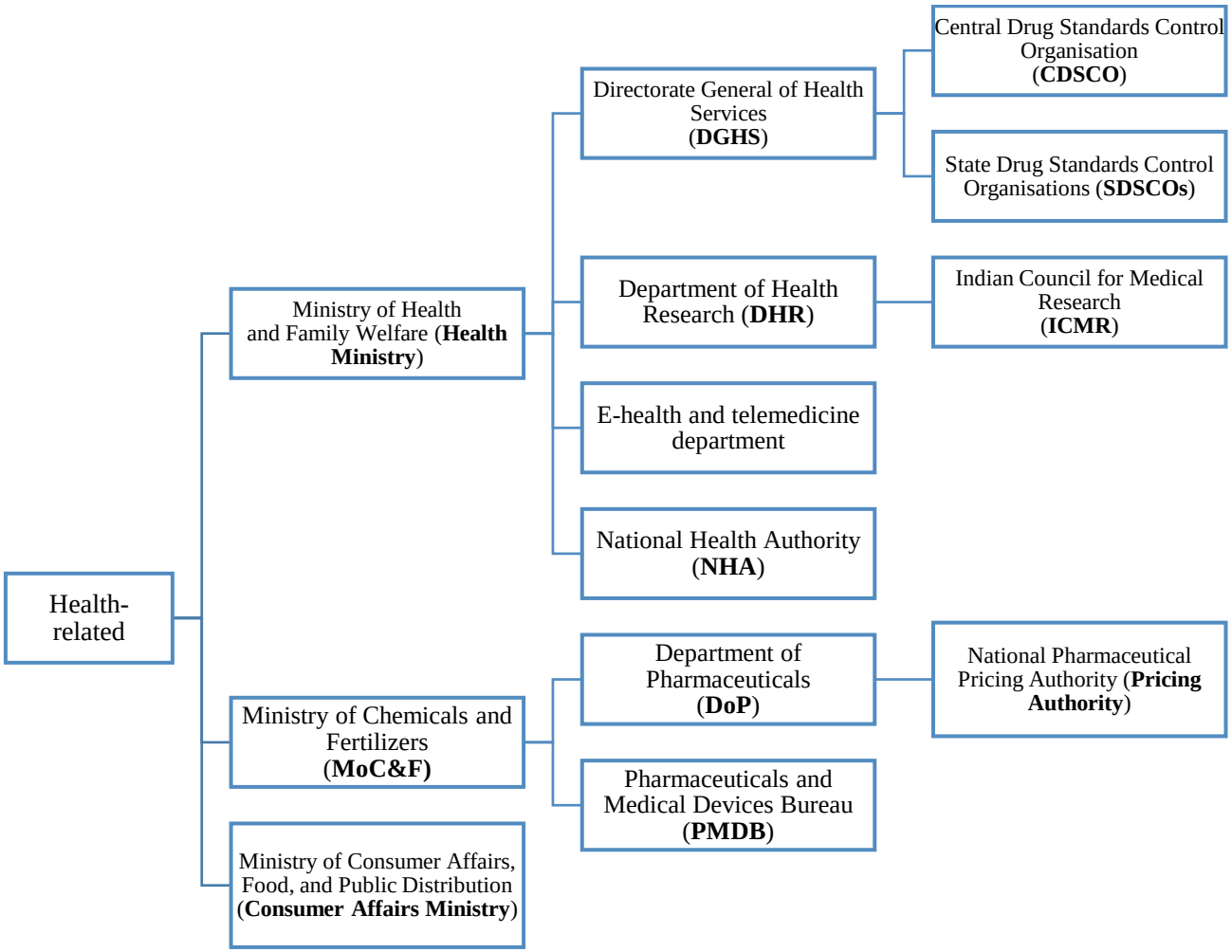
   - Department of Health Research (**DHR**): encourages research, translates research into products, and encourages synergy between public and private sector towards these ends.
     - Indian Council for Medical Research (**ICMR**): encourages biomedical research and helps solve public health challenges.

   - E-health and telemedicine department: coordinates technology components of various public health schemes and encourages digital health.

   - National Health Authority (**NHA**) – nodal authority for administering India's Ayushman Bharat Digital Health Mission and runs a sandbox to encourage testing, innovation of technology tools intended to enable safe delivery of healthcare.

ii. *Ministry of Chemicals and Fertilizers (**MoC&F**)* oversees policy making related to chemicals, fertilizers, and pharmaceutical products.
   - Department of Pharmaceuticals (**DoP**): governs pricing and availability of medicines, protection of IP, and international commitments
   - National Pharmaceutical Pricing Authority (**Pricing Authority**): is an independent regulator overseeing drug pricing, including for medical devices like cardiac stents, and hip and knee replacements.
   - Pharmaceuticals and Medical Devices Bureau of India (**PMDB**) – implements union government scheme to increase access to generic drugs and medical devices.

iii. *Ministry of Consumer Affairs, Food, and Public Distribution (**Consumer Affairs Ministry**)* is responsible for consumer welfare. Governs packaged commodities and distribution of essential commodities.

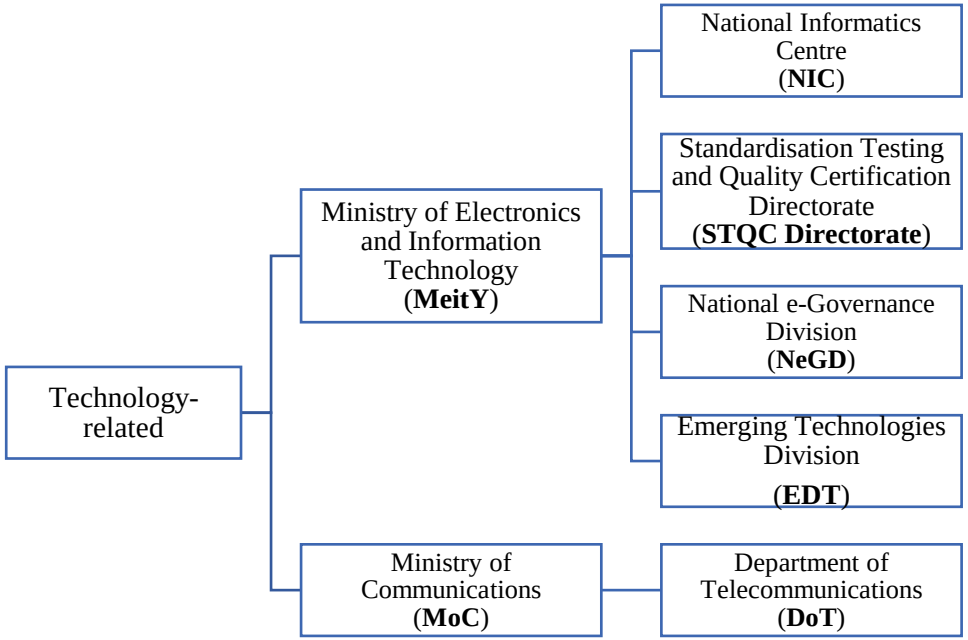


Technology-related

i. *Ministry of Electronics and Information Technology (**MeitY**):* nodal Central Government ministry for technology; supports other government departments in their digital initiatives. This includes being the line ministry for encouraging adoption of emerging technologies like AI/ML through its 'Emerging Technologies Division'.[xv]

- Emerging Technologies Division (**ETD**): The ETD works on policies for emerging technologies like AI/ML, virtual reality, and blockchain, internet of things (**IoTs**).[xvi]
- National Informatics Centre (**NIC**): provides dashboards and portals for various government initiatives, including websites for public health initiatives like 'e-Hospital',[xvii] and the 'National Health Mission'.[xviii]
- Standardisation Testing and Quality Certification Directorate (**STQC Directorate**): conducts testing, training, audit, and certifications to assure processes, software products and systems. The STQC also tests solutions from technology service providers hoping to integrate in the NHA's sandbox for the Ayushman Bharat Digital Health Mission.[xix]
- National e-Governance Division (NeGD): has been tasked with the implementation of the National Programme for AI.[xx]

ii. *Ministry of Communications (**MoC**)'s Department of Telecommunication* enables growth of telecommunications sector and digital economy. Additionally, the Telecommunication Engineering Centre sets standards for telecommunication network equipment, services, and interoperability.[xxi]



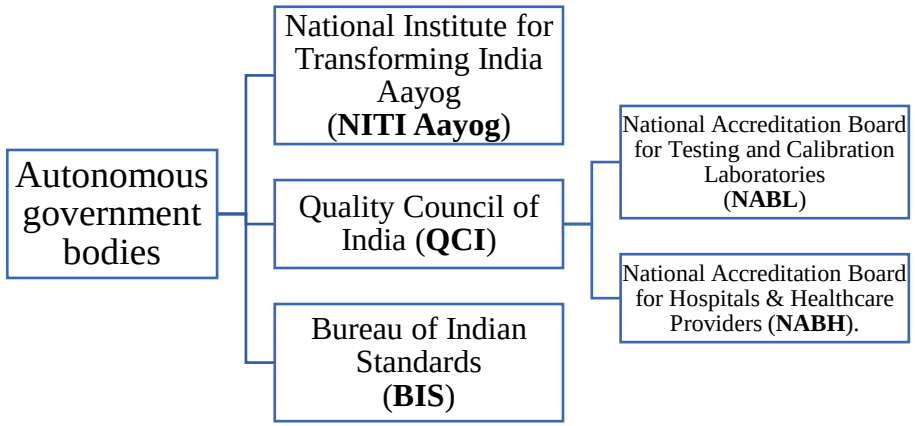
Autonomous government bodies:

This section captures certain autonomous government bodies frame policies and set standards to ensure the quality of healthcare and technology related products:

i. *National Institute for Transforming India Aayog (**NITI Aayog**) – the Indian* government's think tank that develops policy initiatives. The Niti Aayog has released whitepapers and supported government initiatives on harnessing frontier technologies across sectors like health (e.g., the National Digital Health Mission's blueprint). It has also set up autonomous bodies like the Atal Innovation Mission to encourage innovation.

ii. *Quality Council of India (**QCI**)* - autonomous society that sets standards for products and services in various industries and certifies them for their compliance to the standards. It also sets standards for operating a variety of healthcare-related facilities (e.g., clinics, hospitals).
  - National Accreditation Board for Testing and Calibration Laboratories (**NABL**)
  - National Accreditation Board for Hospitals & Healthcare Providers (**NABH**).

iii. Bureau of Indian Standards (**BIS)** – is a sectoral regulator that creates uniformity in standards, marking, and quality of goods, to ensure minimal health hazards.



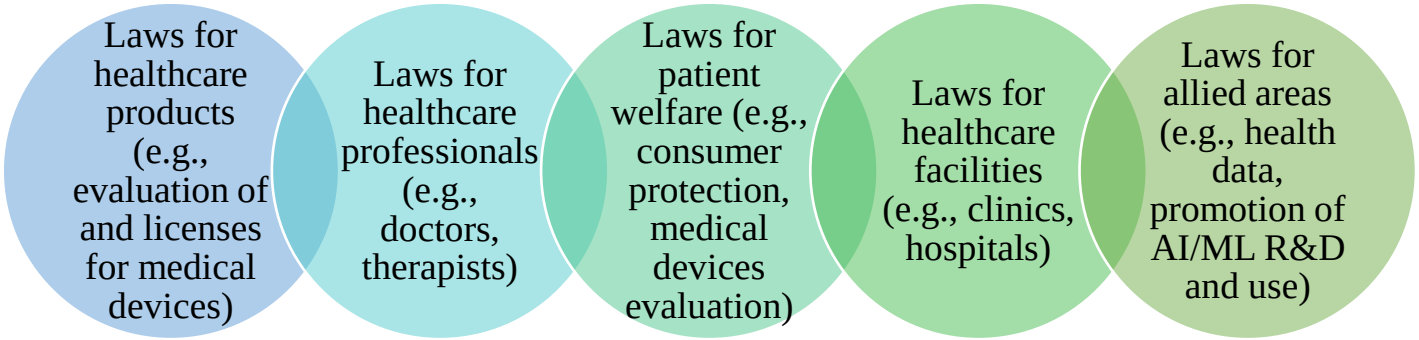
Key takeaways/points for consideration:

- There are multiple ministries overseeing law/policymaking and implementation in both healthcare and technology.
- This is done through various departments and by establishing autonomous bodies that are vehicles for research, innovation, standard setting, and certification of compliance with standards set.
- Often these ministries/departments/autonomous bodies coordinate (e.g., the STQC and the NHA).

3. OVERVIEW OF RELEVANT LAWS

This section provides a snapshot of the relevant laws governing healthcare and healthtech in place currently.

(A) Healthcare/healthtech laws:



Laws governing various aspects of healthcare include- (i) the evaluation, licensing, and oversight of healthcare products (i.e., drugs, medical devices, 'new drugs', gene therapy and blood/plasma-related products); (ii) telehealth and online sale of medicines; (iii) training of healthcare professionals

(e.g., curriculum and accreditation of doctors, nurses, dentists), and allied healthcare professionals (e.g., community health workers, therapists); and (iv) healthcare facilities (e.g., clinics, hospitals, laboratories, and diagnostic facilities).

i. *Healthcare products – regulation of medical devices (including software functions)*:

a. Product regulation

Medical devices (hardware and software) are regulated under the Drugs and Cosmetics Act, 1940, and corresponding medical devices-related rules and notifications). Additionally, the CDSCO or the SDSCOs oversee the licensing and evaluation of the medical devices, depending on their risk classification (i.e., A, B, C, D).

- The Medical Devices Rules, 2017 (**MDR 2017**): It regulates the manufacture, import, and sale of medical devices based on their risk benefit analysis.[xxii] The CDSCO grants requisite approvals to manufacture, sell, test, or import a medical device.[xxiii] The CDSCO and state drug regulators collectively ensure quality of a medical devices (i.e., through its licensing and approval processes);[xxiv] inspect medical devices manufacturing and testing facilities;[xxv] undertake post market surveillance[xxvi] and set standards for medical devices regulation. Medical devices listed by the Health Ministry, irrespective of risk classification and contact with the human body (i.e., in vitro medical devices and medical devices), require licenses for sale, manufacturing, and import.
- Standalone software as medical device: In February 2020, the CDSCO expanded the definition of 'medical devices' to include software components and software using medical devices.[xxvii] This means that software functioning as medical devices will be 'validated' (i.e., tested) before being approved by the regulator.[xxviii] The CDSCO has provided guidance documents on applying for various licenses for medical devices[xxix] and evaluates certain drugs such as 'new drugs'[xxx] and class C and D medical devices. Most recently, it classified 60 software functions as medical devices (e.g., electrocardiograph software for home use, and insulin pump therapy adjustment calculator for healthcare professionals).[xxxi]
- Essential Principles for safety and performance of medical devices guidelines' 2018: Validation of a medical device, before its approval is based on these guidelines. They lay out principles for safety and efficacy of software components and standalone software.[xxxii] They include (a) repeatability, reliability, and performance based on the intended use of the software; and (b) using principles of development lifecycle, risk management, verification, and validation of a software. [xxxiii]

b. Product and healthcare service liability:

The Consumer Protection Act, 2019 (CPA 2019: It protects interest of consumers in relation to goods and services and establishes authorities to redress consumer disputes.

- Goods: It imposes product liability on manufacturers,[xxxiv] sellers,[xxxv] and product service providers[xxxvi] even in the absence of fault or negligence. No-fault liability provision of the CPA 2019 may be applicable on manufacturers of medical devices, including hardware supporting AI/ML functions and assistive devices.

- Services: The consumer can file a complaint against deficiency of services[xxxvii] which includes negligence resulting in harm and withholding relevant information.[xxxviii] Deficiency in services has been invoked against healthcare professionals under the Consumer Protection Act, 1986.[xxxix] However, the jurisprudence is yet to develop on liability against technology service providers for health-app or telemedicine platforms under the CPA 2019.

ii. ***Telehealth and online sale of medicines:***

a. Telemedicine Practice Guidelines (**TPG**): Aims to facilitate telemedicine practice. Key features:[xl]
   - Registered medical practitioners (RMP): They can provide consultation through remote means such as text, audio call, email, and video.[xl] Appropriateness of remote consultation is left to the RMP's judgement on a case-by-case bases.[xli] Remote consultation in emergencies is excluded.[xlii] Records of the consultation provided need to be maintained by the RMP[xliii] and she/he cannot prescribe drugs and narcotics under schedule X of the Drugs and Cosmetics Act, 1940.[xliv]
   - Technology platforms: Technology service providers need to (i) conduct due diligence before listing any RMP on its platform;[xlv] (ii) notify the Board of Governors in the event of non-compliance by an RMP;[xlvi] (iii) establish mechanism for grievance redressal.[xlvii] Tech platforms that do not abide by the TPG can be blacklisted.[xlviii]
   - Use of AI/ML: New technology can be used to assist RMP with patient evaluation and diagnosis, with a caveat that the final counselling must only be carried out by an RMP.[xlix]

b. E-pharmacies: During the pandemic (2020), to ensure easy access to medicines, the Health Ministry issued a notification allowing home delivery of Schedule H drugs based on prescription but stopped short of recognizing e-pharmacies.[xiii] Interestingly, the Health Ministry attempted to regulate the online sale of medicines through e-pharmacies via a draft law in 2018. [l] The draft aimed to regulate and enable operations of e-pharmacy platforms in India. The draft suggested measures for maintaining patient confidentiality, data protection measures such as localization.[li]

iii. ***Training of healthcare professionals:***

a. The National Medical Commission Act, 2019 (**NMC Act**) and Dentists Act, 1948 (**Dentists Act**): The NMC Act and Dentist Act regulate the study and practice of 'registered medical practitioners' (i.e., doctors) and dentists[lii] in India respectively. It creates a National Medical Commission[liii] (**NMC**) and State Medical Councils (**SMC**).[liv] Setting standards for training of doctors in using digital health tools will come under the purview of the NMC.

Dr. R. S. Sharma pointed to AI/ML increasing efficiency in healthcare delivery in India by stating that- *"this kind of digital communication will render cost effective services through access to large pool of clinicians and will help generate relevant data for health policy makers not only in modern medicine, preventive medicine, traditional system of medicines and Yoga for more inclusive healthcare system through interventions like artificial intelligence (AI) and machine learning (ML)."*

Source: https://cio.economictimes.indiatimes.com/news/next-gen-technologies/ai-and-data-analytics-is-the-future-of-the-indian-healthcare-system-rs-sharma-nha-chief/83423164

iv. ***Healthcare facilities*:**

a. Clinical Establishment (Registration and Regulation) Act, 2010 (**CERRA**): Council for Clinical Establishments at the centre (**NCCE**) and at various states (**SCCE**) are established under the law.[lv] The NCCE compiles and publishes a national register of clinical establishments, classifications of clinical establishments, sets standards etc.[lvi] The SCCEs on the other hand are in charge of implementation of those standards.[lvii] The NCCE has set minimum standards for various categories of clinical establishments.[lviii] For instance, hospitals must inspect and conduct annual maintenance of medical equipment.[lix]

Key takeaways/points for consideration:

- The law related to medical devices and liability for healthcare products and services is evolving.
- Emerging technologies like AI/ML used in healthcare will require creative interpretations and innovating policymaking to ensure safe adoption of AI/ML. This may include recalibration of curriculums for healthcare professionals, the manner of 'software validation' for standalone SaMDs and setting standards for use of AI/ML by healthcare facilities.
- Liability of technology platforms and service providers requires clarity.

(B) Technology laws:

This section provides a snapshot of technology related laws relevant to enabling the safe use of AI in India. Broadly, the relevant laws can be categorised as: (i) laws governing technology platforms that provide intermediary services; and (ii) laws governing the use and management of data. Dos and don'ts for providers of AI/ML tools in healthcare and their of use of data for designing/providing their tools, are key considerations for enabling safe use of AI/ML in healthcare.

i. Laws related to intermediary liability:

a. Information Technology Act, 2000 (**IT Act**): The IT Act facilitates electronic commerce and enables the union government to regulate electronic communications. This includes telemedicine related applications that connect doctors and patients.[lx] Technology platforms that facilitate telemedicine, may be considered as 'intermediaries' and thus have additional obligations to avoid intermediary liability.[lxi] These obligations include:

- Due diligence obligations under the Information Technology (Intermediary Guidelines and Digital Media Ethics) Rules, 2021 such as- publishing privacy policies and terms of use;[lxii] informing users (e.g., doctors) to publish certain kinds of content;[lxiii] having grievance redressal mechanisms;[lxiv] and reporting cyber incidents to the 'Indian Computer Emergency Response Team'.[lxv]
- Address to requests to take down content from the union government[lxvi] and ensure that such telemedicine technology providers do not knowingly transmit certain kinds of content (e.g., sexually explicit content, content depicting children in a sexually exploitative manner).[lxvii]

b. Consumer Protection (**E-Commerce**) Rules, 2020: It regulates digital platforms for electronic commerce. The definition of e-commerce includes telemedicine platforms and health aggregating services. Sellers of goods and services: Nodal officers need to be appointed to ensure compliance with the rules[lxviii] and establish a grievance redressal mechanism.[lxix] Further, sellers need to disclosure requirements on quality, warranty etc.[lxx] For healthcare professionals providing online consultation, the mandatory disclosure requirements under the rules apply in conjunction with the professional responsibility of disclosing risk attached to medical treatment.[lxxi]

*Hypothetical example: A medical device, 'X' has an insulin syringe and is stuck to the skin of a diabetic patient. It uses AI/ML powered tools to analyse sugar levels of the diabetic patient and pumps insulin based on the insights given by the algorithm. In the event the DP Act is a law, such a medical device will not only be regulated by the CDSCO but also the Data Protection Authority (**DPA**) that may be established under the DP Act. CDSCO will give license and conduct post market surveillance of the product. DPA will regulate the collecting and processing of personal data with the medical device.*

ii. Laws and developments related to data protection:

India does not have a comprehensive specific data protection law at present. Basic data protection requirements are currently housed under the Information Technology Act, 2000. Clarity on permissible data management practices will be key to innovation and offering AI/ML in healthcare. Data is needed to train algorithms and to provide services such as prediction, diagnostics, etc. This section therefore (i) dives into the data protection

requirements under the Information Technology Act, 2000 and corresponding rules; (ii) extracts relevant points from India's forthcoming data protection law; and (c) captures other initiatives to guide the use of health data specifically.

b. *The current law:*

- The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (**SPDI Rules**): The SPDI Rules, under the IT Act consider 'physical, physiological and mental health condition', 'sexual orientation', 'medical records and history', and 'biometric information' as sensitive personal information or data (**SPDI**).[lxxii] In the absence of a national data protection law, the SPDI Rules govern processing of SPDI.
    - Health data is considered SPDI. Entities processing SPDI include telemedicine platforms, software used by hospitals to store patient records, health applications on smart devices storing health data etc. For instance, onwards sharing of private pictures of patients (without a patient's prior consent), shared during a tele-consultation among medical professionals may violate patient privacy. [lxxiii]
    - The entities must: (a) provide clear and accessible privacy policies;[lxxiv] (b) take consent before processing SPDI;[lxxv] (c) inform users that they will be collecting SPDI; (d) inform users why and how they collect SPDI;[lxxvi] and (e) inform users of who will have access to their SPDI.[lxxvii] Users, including patients have the right to access and correct their SPDI stored by entities,[lxxviii] and withdraw consent for processing their SPDI.[lxxix]

c. Upcoming data protection law:

- *Data* Protection *Bill, 2021* (**DP Bill, 2021**): A comprehensive law that governs the processing, use, and transfer of various categories of personal data and protects a user's privacy.[lxxx]
    - Personal and sensitive-personal data: It applies to personal data (e.g., a patient's name), and sensitive personal data (e.g., a patient's records of blood pressure along with his name). Health and genetic data are considered sensitive personal data.[lxxxi] Entities processing personal data should have a privacy by design policy that indicates how they will protect users' data.[lxxxii]
    - Principles of processing personal data: Users must be given notice at the time of their personal data being collected.[lxxxiii] Users must give their consent for processing their personal data.[lxxxiv]
    - Individual (users) rights: Users have rights under the DP Bill, 2021, such as: (a) to seek confirmation and access to the personal data processed (e.g., the right to see what health scans a company is processing);[lxxxv] (b) to erasure and correction of records (e.g., a patient should have the right to correct or delete their health information on a company's server, where it is inaccurate or outdated);[lxxxvi] (c) data portability (e.g., a patient should be able to get an electronic form of their health data from the current company, to port the data to another company, where possible)[lxxxvii] and right to be forgotten (e.g., a patient should have the right, where possible, to have their health data removed from the servers of the company).[lxxxviii]
    - Data Fiduciaries (**DFs** i.e., entities collecting and determining how personal data is processed) and Data Processors (**DPs**): A data fiduciary decides the purpose and means of processing. A data processor processes data on behalf of a data fiduciary. Examples of DFs can include telemedicine platforms aggregating diagnostic labs, and healthcare professionals. DFs must draft privacy by design policy[lxxxix] and maintain algorithmic transparency.[xc]

- Significant data fiduciaries: In some cases, data fiduciaries may be considered 'significant data fiduciaries' based on the volume of data they process or the use of new technologies for processing data like.[xci] This attracts additional compliance obligations to such entities. Significant data fiduciaries also need to conduct data protection impact assessment. [xcii]

d. *Other initiatives to regulate health data:*

- A draft bill called 'Digital Information Security in Healthcare Act' (**DISHA bill**)[xciii] was published, which proposed to establish a 'National Digital Health Authority' and regulate data processing by entities such as health insurance companies, pharmaceutical companies etc. [xciv]
- Most recently, the NHA released, a 'Health Data Management Policy' (HDMP) for health data management in the 'Ayushman Bharat Digital Health ecosystem'.[xcv] The HDMP is applicable to all entities participating in the Ayushman Bharat Digital Health Mission (i.e., hospitals, doctors, patients, technology service providers, etc.).[xcvi]

Key takeaways/points for consideration:

- Harnessing health data is key to developing better quality AI/ML tools for healthcare.
- Algorithmic transparency and cybersecurity considerations will be paramount in enabling safe harnessing of health data for AI/ML tools.

4. Central/state government policies encouraging AI/ML innovation

Shri. Jitendra Singh, acknowledged the additional power of AI/ML in shaping and growing the Indian economy, noting that- *"Artificial intelligence, as one of the frontier technologies, is shaping India's present and future economy. The country has started seeing the impact of artificial intelligence across healthcare, agriculture, education, governance and financial services."*

Source: https://www.business-standard.com/article/economy-policy/artificial-intelligence-shaping-india-s-economy-says-jitendra-singh-121121601281_1.html

This section captures policy papers currently applicable and relevant to the use of AI/ML in healthcare.

i. *MeitY s 'National Programme for AI':*

a. In April 2021, MeitY launched a 'National Programme for AI' (**NPAI**) under which high-value data sets in the public sector, would be identified and provided access for AI models.[xcvii] The National e-governance division of the MeitY has been tasked with the implementation of the NPAI.[xcviii]

b. Under this, 'Centres for Transformational AI' would be set up to identify data sets across sectors and make them available for AI-modelling.

ii. *Tamil Nadu - The Tamil Nadu Safe and Ethical Artificial Intelligence Policy, 2020:*

a. Overview of issues and solutions*:*

- Provides guidelines to regulate use and development of AI in the state. The policy is applicable to entities controlled by state government, including public sector units, trusts, cooperatives, and societies[xcix] and shall be implemented by the Department of Information Technology of the Tamil Nadu government. [c]
- It identifies medical diagnosis, law enforcement etc. as prevalent AI use cases and provides for an AI sandbox for start-ups and individuals to encourage innovation.[ci]

b. The policy recognizes transparency, equity, privacy, data protection, data deficit and fairness as guiding principles to regulate AI.[cii] It states that poorly designed AI systems, specifically deployed sectors such as healthcare, law enforcement and banking, may interfere with constitutionally guaranteed right to life and freedom.[ciii]

c. Recommendations for compliance with guiding principles:

- The use of DEEP-MAX Scorecard which is a point-based rating system for AI systems on seven key parameters including diversity, equity, ethics, privacy, and data protection etc.[civ]
- The state government will provide guidelines on AI certification which may include display of the DEEP-MAX scorecard.

iii. *Telangana - Information and Computer Technology (ICT) policy (2021-2026):*

a. It stresses on the use of emerging technologies such as AI and blockchain to promote development in the allied IT sectors such as healthcare. In this regard, it focusses on the need for policies to promote digital literacy, skill development and cyber-security.[cv]

b. The government also aims to integrate emerging technology with platforms such as MeeSeva 2.0 and T-app folio, to ensure equitable access to government services, [cvi] including healthcare.[cvii]

c. The Telangana government has also collaborated with Intel India, Public Health Foundation of India and International Institute of Information Technology to set up INAI (Intel AI), which is an applied AI research centre in Hyderabad. INAI will focus on solving challenges in India's healthcare.[cviii]

iv. *Karnataka - Karnataka Information Technology Policy, 2020-2025*:

a. It talks about leveraging capacity in emerging technologies including AI.[cix]

b. To bolster innovation, the Karnataka government's Open Data Initiative aims to ensure ready availability of new data sets.[cx] However, the policy does not place specific emphasis on regulating the use of AI/ML.

Key takeaways/points for consideration:

- Union and state governments are thinking about harnessing AI/ML for social good (e.g., increasing access to healthcare)
- Key considerations are ethics, tackling bias, and data protection.

5. The evolution of AI/ML governance in India:

This section captures policy papers released by various government departments with suggested approaches to encourage AI/ML research, development, and use in India. Briefly, MeitY is working to implement a 'National Programme on AI' (discussed below). This programme builds on the work done by the Niti Aayog, and the committees set up by the MeitY to address issues related to the safe adoption of AI/ML (see discussion on the Niti Aayog and the committees below).

i. NITI Aayog's three papers (2018, and two in 2021) on AI:

Niti Aayog[cxi] has put forth policy documents on how AI use should be regulated and encouraged in India, namely- (a) National Strategy for AI (**2018 paper**); (b) 'Approach Document for India Part 1, Principles for Responsible AI' (**February 2021 paper**); (c) 'Approach Document for India Part 2, Responsible AI: operationalising principles for responsible AI' (**August 2021 paper**).

a. National Strategy for AI (**2018 paper**)

- It identified five barriers to the growth of AI/ML use in India- (a) lack of expertise in research and use of AI; (b) absence of data ecosystems; (c) low public awareness and high resource cost for adoption of AI; (d) privacy and security related concerns; and (e) the lack of a collaborative approach for AI adoption and use.
- It proposed setting up Centre of Research Excellence or 'CORE' and International Centres of Transformational AI or 'ICTAI' to improve AI-related research in India. CORE would focus on improving AI understanding and research, while ICTAI would develop and deploy research.[cxii]

- The 2018 paper also notes that if a marketplace model (the National AI Marketplace or 'NAIM') that focuses on data collection, aggregation, annotation, and deployable models, is adopted, it will address all barriers to deploying AI.[cxiii]

b. Approach Document for India Part 1, Principles for Responsible AI' (**February 2021 paper**)
- Covers 'system considerations' (i.e., privacy risks, security risks, and risks of exclusion of users of AI/ML tools) and 'societal considerations' (i.e., impact of use of AI/ML on society, and job creation).[cxiv]
- Called for the creation of principles that guide the use and innovation in AI/ML,[cxv] and for the government to consider identifying research areas for technology tools to create responsible AI/ML.[cxvi]
- Discussed the fundamental rights listed in the Constitution as the foundation for principles to guide the use of AI/ML in India.[cxvii] Talks about seven guiding principles to guide the use and research in AI such as principles on:[cxviii] (a) safety and reliability; (b) equality; (c) inclusivity and non-discrimination; (c) privacy and security; (d) transparency; (e) accountability; and (f) protection and reinforcement of positive human values.

c. Responsible AI: operationalising principles for responsible AI (**August 2021 paper**):[cxix]
- It calls for operationalising the principles for responsible AI through education, training, and various compliance mechanisms. For instance, for start-ups, the August 2021 paper suggests that assigning accountability to a member of the leadership team would help ensuring responsible AI use. Similarly, the August 2021 paper also suggested training and education on the principles of responsible AI and leveraging technology tools.[cxx]
- It discusses 'ethics-by-design' by mandating the use of the listed responsible AI principles by public sector procurement, which will then trickle into the approach and products of the private sector.[cxxi]
- Lastly, it proposes the establishment of the Council for Ethics and Technology, an independent think-tank interfacing with all ministries and departments.[cxxii]

ii. Ministry of Electronics and Information Technology's 'Artificial Intelligence Committees' reports':

In 2018, **MeitY**[cxxiii] set up four AI committees for (a) platforms and data for AI; (b) leveraging AI for identifying national missions in key sectors; (c) mapping technology capabilities, key policy enablers across sectors, skilling and reskilling, and research and development; and (d) cybersecurity legal, safety, and ethical issues.[cxxiv] These committees released a report each highlighting the following points:

a. On platforms and data for AI': Creation of a National Artificial Intelligence Resource Platform, that would be the central open hub for knowledge integration and dissemination of the learnings. This platform would have to be monitored by a technical committee, and would, after accounting for privacy and cybersecurity considerations be a platform for encouraging data sharing on AI-related learnings.[cxxv]
b. On leveraging AI for identifying national missions in key sectors': Identifies areas like agriculture, food, health, persons with disabilities, and public safety etc as areas where AI use can be encouraged through missions.[cxxvi] In healthcare, the report suggests creation of an AI-primary

healthcare centre to help triage patients, providing support to healthcare workers and doctors alike, in invasive procedures and in diagnostics, etc.[cxxvii]

c. On mapping technology capabilities, key policy enablers across sectors, skilling and reskilling, and research and development': Recommends a model AI policy, and incorporation[cxxviii] of the Information Accountability Foundation's principles (**IAF**) for responsible handling of information.[cxxix] It also calls for among other things (a) fuelling AI innovation; (b) addressing global challenges with AI (e.g., for accelerating cancer research); (c) governments to create environments that allow experimentation; (d) upskill a workforce for AI use and innovation; (e) governments to partner with industry and academic institutions for innovation and development; (f) implementing privacy by design and robust policies for data protection; and (g) standing for accountability of AI by requiring the government to determine which AI use cases require algorithmic transparency.[cxxx]
d. On cybersecurity, legal, safety, and ethical issues' – Identifies cybersecurity, data privacy, and ethical issues while deploying AI tools. It recommends investments in creating tools/techniques to tackle algorithmic biases, creation of guidelines on ethical use and research in AI/ML with civil society and industry, raise public awareness on the use of AI/ML etc.[cxxxi]

iii. Department of Telecommunication's (Ministry of Communication) Committee on Standardisation of AI report:

The Committee on Standardisation of Artificial Intelligence (**CSAI**) released a draft framework of the Indian AI Stack in September 2020 (**CSAI framework**). In healthcare, the CSAI framework highlights the potential of AI-driven diagnostics, personalized treatment, early identification of potential pandemics as beneficial use cases of AI.[cxxxii] It suggests that an AI stack will tackle some of the barriers such as algorithmic biases, contamination of data as a result of inconsistent/missing information, and lack of an ecosystem providing proper safeguards, through codified procedures. The AI stack would be comprised of the following layers: (i) infrastructure layer;[cxxxiii] (ii) storage layer;[cxxxiv] (iii) computer layer;[cxxxv] (iv) application layer;[cxxxvi] (v) data/information layer;[cxxxvii] and (vi) security and governance layer.[cxxxviii] Together, these layers will enable differentiation between public and private data sets (computer layer), manage consent and provide access to data sets for use in AI/ML innovation (infrastructure layer and data layer), keep track of all transactions (application layer), and secure all data sets across layer (security and governance layer).*Department for Promotion of Industry and Internal Trade's (**DPIIT**) taskforce on AI:*

In 2018, DPIIT's AI Task Force launched a report on how India's AI thrust should look like (**Taskforce report**).[cxxxix] The Taskforce report suggests (a) creation of a National-AI Mission (NAIM); (b) setting up data banks, exchanges, and ombudsmen for the availability of cross-industry data; (c) setting of standards on issues like data privacy and storage, and for interoperability; (d) setting enabling policies (e.g., data-related policies and tax incentives for adoption of AI); (e) focussing on skill development in AI research and use; and (f) participation in international standards setting and in bilateral/multilateral partnerships for sharing of best practices in regulation of AI.[cxl]

Key takeaways/points for consideration:

- Policies and papers from government bodies prefer a 'layered' or 'stacked' approach to using technology to enable AI/ML use and innovation.
- Interoperability and ecosystems are key features of technology use to enable AI/ML use and innovation.
- Principle-based approach to encouraging AI/ML use and innovation.

6. HIGH-LEVEL ISSUES FOR CONSIDERATION

Based on the discussion above, the following issues merit deeper consideration, to create an enabling regulatory framework for AI/ML use in healthcare:

- Health data management and to harness it with appropriate consent, for improving AI/ML's capabilities.
- Clinical evaluation of AI/ML tools for safe human use.
- Training and coordination for government departments (e.g., the Data Protection Authority, the CDSCO, the STQC and the NHA) to evaluate algorithmic transparency and data integrity of an AI/ML tool.
- The principles that should guide regulations on AI/ML use in healthcare.
- Maintaining balance – enabling innovation and ease of doing business with light touch regulation.
- Understanding liability (and compliance requirements) of technology service providers and software developers.
- Role of post market surveillance for oversight and regulation of this space.

Annexure I:

An overview of relevant ministries, government departments, and regulators

Healthcare:

i. Ministry of Health and Family Welfare (Health Ministry)

The Health Ministry is responsible for making and implementing laws and policies governing healthcare and oversees multiple public health initiatives. Relevant stakeholders include:

a. Directorate General of Health Services (**DGHS**): Coordinates with states on implementing public health-related schemes and oversees the drugs regulation of India. The DGHS also helps states in implementation of center sponsored public health schemes via its subordinate offices and institutions across the country. DGHS is also a repository of technical expertise on various aspects of public healthcare in India.[cxli]
   - Central Drug Standards Control Organisation of India (**CDSCO**): – Under the DGHS, the CDSCO oversees setting of standards, evaluation, licensing (e.g., import, manufacture, sale), and post-market surveillance of healthcare products (e.g., drugs, medical devices, gene therapy products, etc.). It is headed by the Drugs Controller General of India.
   - State Drugs Standards Control Organisations (**SDCO**): States also have their respective state drugs control organisations who provide licenses to certain healthcare products. SDCOs can evaluate medical devices with a risk A or B classification (e.g., continuous glucose monitors retrospective data analysis software).[cxlii] They can also appoint inspectors for drug and medical device manufacturing facility inspections.

b. Department of Health Research (**DHR**): It hosts the National Ethics Committee Registry for Biomedical and Health Research , which approves conducting of clinical trials.[cxliii] It encourages research, innovation and public and private partnership to better healthcare.[cxliv]
   - Indian Council for Medical Research (**ICMR**):[cxlv] It is tasked with encouraging biomedical research and has contributed to finding practical solutions for public health challenges, like the COVID-19 pandemic.[cxlvi] To advance biomedical research, the ICMR has even endeavoured to provide guidelines for various aspects of biomedical research (e.g., the National Ethical Guidelines for Biomedical Research involving Human Participants).[cxlvii]

c. E-health and telemedicine department: It coordinates the technology components of various public health schemes (e.g., setting up the National Health Portal)[cxlviii], and for encouraging digital health (e.g., working on electronic health records standards).[cxlix]

d. National Health Authority (**NHA**): It is responsible for implementing two key programmes - India's public health insurance scheme i.e., Ayushman Bharat Pradhan Mantri Jan Arogya Yojana[cl] and program to create a national digital health eco-system i.e., the Ayushman Bharat Digital Health Mission (**ABDHM**).
   - The NHA sets standards for implementation of both programmes and works with state health authorities to implement them. For instance, the ABDHM architecture includes building blocks like registries of health facilities and healthcare professionals, a universal

digital health ID for patients, a digital locker to store health records, and a unified health interface that ensures patients and doctors can interact irrespective of the technology application.[cli] The unified health interface will also create an information highway (i.e., a health data exchange layer) for the lawful, safe, harnessing of health data (with patient consent). [clii]

- The NHA also runs a sandbox for interested technology providers and healthcare-related entities (e.g., hospitals, professionals, labs, etc.) to integrate in the ABDHM ecosystem and test their solutions.[cliii] The ABDHM's strategy overview document suggests that the ABDHM can be used as an opportunity to incorporate AI/ML and other emerging technologies, to create a wholistic digital health ecosystem.[cliv]

*ii. Ministry of Chemicals and Fertilizers (**MoC&F**)*

The MoC&F oversees policy making related to chemicals, fertilizers, and pharmaceutical products. Relevant departments/regulators under MoCF include:

a. Department of Pharmaceuticals (**DoP**): It looks into issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to the pharmaceutical sector.[clv] The DoP's work requires coordination with other ministries like the Health Ministry.
b. National Pharmaceutical Pricing Authority (**Pricing Authority**): Attached to the DoP,[clvi] the Pricing Authority is an independent regulator overseeing the pricing of drugs. It does so, using the 'Drugs Price Control Orders', released under the Essential Commodities Act, 1955.[clvii] In the past, the Pricing Authority has regulated prices of knee and hip implants and coronary stents, by capping their prices.
c. Pharmaceuticals and Medical Devices Bureau of India (**PMDB**) - The PMDB was created for the implementation of the Pradhan Mantri Jan Aushadi Paryiyojana (PMBJY), a scheme sponsored by the union government to increase access to generic drugs and medical devices. To do this, the PMBJY aims to establish ''Janaushadi Kendras' nationally.

*iii. Ministry of Science and Technology (**MoST**)*

The MoST consists of the Department of Science and Technology (**DST**), the Department of Biotechnology, and the Department of Scientific and Industrial Research (**DSIR**). DST is the nodal department for organising, coordinating, and promoting science and technology in India.[clviii] This includes formulating policies such as the Science, Technology, and Innovation Policy, 2013.[clix] The DSIR oversees the Centre for Scientific and Industrial Research (**CSIR**), which encourages crowd-sourced and open-innovation research ideas and innovative technology solutions.[clx] CSIR has formed theme directorates to enhance its research and development focus areas to include industry and other stakeholders.[clxi] The 'theme directorates' includes 'healthcare'[clxii] and within (a) genomic route to preventative healthcare; and (b) drug discovery and devices.[clxiii]

Technology:

i. Department of Telecommunications, Ministry of Communications (DoT)

The DoT under the Ministry of Communications seeks to act as enabler for the growth of the telecommunications sector and a digital economy in the country. It set up a committee to look into creating an AI stack. The committee's report is captured above (Section 5 of the briefing paper).

*ii. Ministry of Electronics and Information Technology (**MeitY**)*

MeitY performs a variety of functions related to law and policymaking and supporting other government departments in their digital initiatives.[clxiv] It also oversees:

a. Emerging Technologies Division (ETD): The ETD works on policies for emerging technologies like AI/ML, virtual reality, and blockchain, internet of things (**IoTs**). It oversees centres of excellence for IoTs, and virtual and augmented reality, and committees set up to study various aspects related to enabling safe use of AI/ML. [clxv]
b. National Informatics Centre (**NIC**): It provides dashboards and portals for various government initiatives
c. Standardisation Testing and Quality Certification Directorate (**STQC Directorate**): It conducts testing, training, audit, and certifications to assure processes, software products and systems.[clxvi] For instance, to integrate into the ABDHM, entities need to have their software vetted by the STQC.[clxvii] It has released policy documents and papers like the 'Vision 2035: public health surveillance in India, a white paper'.[clxviii] The health vertical advises and supports government departments involved in public health like the Health Ministry, NHA, DoP, and state and local authorities.[clxix]
d. National e-Governance Division (**NeGD**): The NeGD was set up as an autonomous business division of the MeitY to implement the 'National e-Governance Plan'[clxx]. It provides technical assistance to government departments, and framing core policies in this regard. It has been tasked with implementing the NPAI.[clxxi]

Government bodies:

Autonomous bodies set up by the Indian government are responsible for driving policies or setting standards for the safe manufacturing and use of healthcare and technology. Some of the bodies listed below also certify products:

*i. National Institute for Transforming India Aayog (**NITI Aayog**)*

- Niti Aayog is the government's think tank that develops policy initiatives for the government's consideration and acts as a though leader on issues across the spectrum.
- It comprises of several verticals or cells (e.g., data management and frontier technologies, science and technology, and social sectors like health),[clxxii] and works with several attached autonomous bodies (e.g., Atal Innovation Mission).[clxxiii]
- This includes publishing reports like the 'Healthcare Artificial Intelligence Catalyst Pilot Study' (July 2021)[clxxiv] and the 'Home-based management of COVID-19: best practices adopted by states' (November 2021).[clxxv]

*ii. Quality Council of India (**QCI**)*

- The QCI[clxxvi] is an autonomous society which establishes an accreditation structure across the country, to standardise the quality of products and services.

- It has multiple divisions such as the National Accreditation Board for Testing and Calibration Laboratories (**NABL**) and the National Accreditation Board for Hospitals & Healthcare Providers (**NABH**). The NABL and NABH have standards for operating a variety of healthcare-related facilities (e.g., labs, hospitals, blood banks, clinics, etc.). NABL and NABH have accreditation committees, which facilities can apply to for certification.

iii. *Bureau of Indian Standards (**BIS**):* It is a statutory body[clxxvii] to create uniformity in *standards*, marking, and quality of goods and ensures reliability and quality of goods.[clxxviii] This includes goods that pose minimal health hazards to consumers. The BIS ensures standardisation through certification and testing.[clxxix] The BIS certifies and recognises laboratories that conduct testing and certification for ensuring that a product meets BIS' standards. The BIS' departments[clxxx] publishes standards. For example, the 'Medical Equipment and Hospital Planning Department' has published 1485 standards for various aspects of medical equipment and hospitals. They include standards on health informatics, electromedical diagnostics imaging and radiotherapy equipment, and equipment used for surgeries, persons with disability, and laboratories.[clxxxi] For instance, under 'health informatics' there are standards for 'categorial structure for terminological systems of surgical procedures'.[clxxxii]

---

[i] Fei Jiang (et al), 'Artificial Intelligence in Healthcare: Past, Present and Future' *Stroke and Vascular Neurology* (2017) <https://svn.bmj.com/content/svnbmj/2/4/230.full.pdf> accessed on 25 January 2022.
[ii] Microsoft AzureAI is one such tool. See here for more: https://aka.ms/healthusecase
[iii] https://www.businesswire.com/news/home/20210301005165/en/Saama-Teams-With-Oracle-to-Offer-Life-Sciences-Industry-AI-Enabled-Applications-to-Accelerate-Clinical-Trials
[iv] https://www.mobihealthnews.com/news/contributed-top-10-use-cases-ai-healthcare
[v] https://healthmanagement.org/c/healthmanagement/issuearticle/ai-and-healthcare-technology-in-india-opportunities-challenges-and-emerging-trends
[vi] See 'Searchlight Health', https://cis-india.org/internet-governance/ai-and-healthcare-report at p. 38
[vii] SaMDs are described by the International Medical Devices Regulators forum as software intended to be employed for medical purposes, without being a part of the hardware of the medical device. IMDRF Software as a Medical Device (SaMD) Working Group, 'Final Document' (18 September 2014) <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf> accessed on 25 January 2022.
[viii] Christopher J. Kelly (et al), 'Key challenges for delivering clinical impact with artificial intelligence' (2019) BMC Medicine <https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-019-1426-2> accessed on 25 January 2022.
[ix] https://medicalfuturist.com/fda-approved-ai-based-algorithms/; US FDA approval number K163253
[x] https://medicalfuturist.com/fda-approved-ai-based-algorithms/ ; US FDA approval number K190442
[xi] Device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed and provides interpretation or clinical implication of the measurement. See, Health Ministry notification dated September 2021 for more - https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==
[xii] Device intended for home use which creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. See, Health Ministry notification dated September 2021 for more - https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==
[xiii] Christopher J. Kelly (et al), 'Key challenges for delivering clinical impact with artificial intelligence' (2019) BMC Medicine <https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-019-1426-2> accessed on 25 January 2022.
[xiv] Entry 6, List II, Seventh Schedule, Constitution of India.
[xv] https://www.meity.gov.in/emerging-technologies-division

[xvi] https://www.meity.gov.in/emerging-technologies-division
[xvii] https://www.nic.in/products/e-hospital/
[xviii] https://nhm.gov.in/index4.php?lang=1&level=0&linkid=11&lid=15
[xix] Para 8.1.4. and 8.1.5., NDHM Sandbox: enabling framework v1, August 2020, https://abdm.gov.in/assets/uploads/Sandbox_Guidelines_v6.pdf
[xx] https://www.meity.gov.in/content/national-e-governance-division
[xxi] https://www.tec.gov.in/tec-functions
[xxii] Rule 4, Medical Devices Rules, 2017
[xxiii] Rules 8(1) and (2), Medical Devices Rules, 2017
[xxiv] Rules 8(1) and (2), Medical Devices Rules, 2017
[xxv] Rules 42, 56m and 70, Medical Devices Rules, 2017
[xxvi] Rule 3(zl), Medical Devices Rules, 2017
[xxvii] S.O.E.648(E), February 11, 2020 (Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA)
[xxviii] First Schedule, Part I (iii), Medical Devices Rules, 2017
[xxix] See the following links for more information: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidance-document-for-Registration-of-Non-Notified-Medical-Devices..pdf; https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/digosfaq19.pdf
[xxx] Rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019, lists certain types of drugs as 'new drugs', including those drugs that are to be sold with modified or new claims including indication, route of administration, dosage and dosage form.
[xxxi] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==
[xxxii] Para 5.8 of the 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)
[xxxiii] Para 5.8 of the 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)
[xxxiv] Section 84, Consumer Protection Act, 2019
[xxxv] Section 86, Consumer Protection Act, 2019
[xxxvi] Section 85, Consumer Protection Act, 2019
[xxxvii] Section 2(6)(iii), Consumer Protection Act, 2019
[xxxviii] Section 2(11)(i) and (ii), Consumer Protection Act, 2019
[xxxix] Indian Medical Association vs. V.P. Santha, 1995 SCC (6) 651
[xl] Chapter II, technology used and modes of communication, Telemedicine Practice Guidelines, 2020, at p.14-15
[xli] Para 3.1.1., Telemedicine Practice Guidelines, 2020, at p. 16
[xlii] Para 4.5., Telemedicine Practice Guidelines, 2020, at p. 32
[xliii] Para 3.5.1. Telemedicine Practice Guidelines, 2020, at p. 18
[xliv] Para 3.7.1., 'Prohibited List', Telemedicine Practice Guidelines, 2020, at p. 20-21
[xlv] Para 5.2., Telemedicine Practice Guidelines, 2020, at p. 33
[xlvi] Para 5.3., Telemedicine Practice Guidelines, 2020, at p. 33
[xlvii] Para 5.6., Telemedicine Practice Guidelines, 2020, at p. 33
[xlviii] Para 5.7., Telemedicine Practice Guidelines, 2020, at p. 33
[xlix] Para 5.4., Telemedicine Practice Guidelines, 2020, at p. 33
[l] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTkzOQ==
[li] https://www.ikigailaw.com/the-e-pharmacy-story-in-india/
[lii] Section 3, Dentists Act, 1948 and Section 24, Dentists Act, 1948
[liii] Section 4, The National Medical Commission Act, 2019
[liv] Section 30, The National Medical Commission Act, 2019

[lv] The following states and union territories have implemented this law- Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Bihar, Rajasthan, Uttar Pradesh, Uttarakhand, Jharkhand, Assam, Haryana, and all Union Territories except the NCT of Delhi.
[lvi] Section 5 Clinical Establishment (Registration and Regulation) Act, 2010
[lvii] Section 8(5) Clinical Establishment (Registration and Regulation) Act, 2010
[lviii] http://clinicalestablishments.gov.in/En/1070-draft-minimum-standards.aspx
[lix] http://clinicalestablishments.gov.in/WriteReadData/885.pdf
[lx] S. 6-A, Information Technology Act, 2000
[lxi] S. 79-A, Information Technology Act, 2000
[lxii] Rule 3(1)(a), Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021
[lxiii] Rule 3(1)(b), Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021
[lxiv] Rule 3(2), Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021
[lxv] Rule 3(1)(l), Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021
[lxvi] Section 69A, Information Technology Act, 2000
[lxvii] Section 67, 67A, and 67B, Information Technology Act, 200
[lxviii] Rule 4(1)(b), Consumer Protection (E-Commerce) Rules, 2020
[lxix] Rule 4(2)(d) and Rule 4(4), Consumer Protection (E-Commerce) Rules, 2020
[lxx] Rule 6(5)(g), Consumer Protection (E-Commerce) Rules, 2020
[lxxi] https://consumeraffairs.nic.in/theconsumerprotection/consumer-protection-e-commerce-rules-2020
[lxxii] Rule 3(iv), (v), and (vi), Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxiii] S. 66A, 66E, 67 and 67-E, Information Technology Act, 2000
[lxxiv] Rule 4, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxv] Rule 5, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxvi] Rule 5, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxvii] Rule 5, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxviii] Rule 5(6), Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxix] Rule 7, Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.
[lxxx] https://www.ikigailaw.com/wp-content/uploads/2019/12/IkigaiLaw_PDP-Checklist_11122019.pdf
[lxxxi] Clause 2(41) DP Bill, 2019
[lxxxii] Clause 22, DP Bill, 2019
[lxxxiii] Clause 7, PDP Bill, 2019
[lxxxiv] Clause 11, DP Bill, 2019
[lxxxv] Clause 17 DP Bill, 2019
[lxxxvi] Clause 18 DP Bill, 2019
[lxxxvii] Clause 19 DP Bill, 2019
[lxxxviii] Clause 20 DP Bill, 2019
[lxxxix] Clause 22, DP Bill, 2019
[xc] Clause 23(1)(f), DP Bill, 2019
[xci] Clause 23(1)(h), DP Bill, 2019
[xcii] Clause 27, DDP Bill, 2019
[xciii] Interestingly, in 2019, the Health Ministry forwarded the draft DISHA bill to MeitY for its inputs. MeitY informed the Health Ministry that it was also working on a data protection law for all sectors. As a result, the work done for the DISHA bill, was subsumed under MeitY's then draft data protection law. See the reply of the then Minister of State for Health and Family Welfare, Shri, Ashwini Kumar Choubey, in the Rajya Sabha, to question asked on the matter, here: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1578929
[xciv] https://abdm.gov.in/documents/health_management_policy and https://www.nhp.gov.in/NHPfiles/R_4179_1521627488625_0.pdf
[xcv] https://abdm.gov.in/publications/policies_regulations/health_data_management_policy

[xcvi] Para 2, Health Data Management Policy, https://abdm.gov.in/publications/policies_regulations/health_data_management_policy
[xcvii] https://www.thehindubusinessline.com/info-tech/govt-to-launch-national-programme-on-ai-soon/article34284443.ece
[xcviii] https://negd.gov.in/node/70
[xcix] Pg. 21
[c] Pg. 46
[ci] Pg. 45
[cii] Pp. 22- 27
[ciii] Pg. 18
[civ] Pg. 29
[cv] Pg. 25
[cvi] Pg. 27
[cvii] Pg. 37
[cviii] https://analyticsindiamag.com/what-are-the-key-ai-initiatives-of-indian-government/
[cix] Pg. Pg. 8
[cx] Pg. 25-26
[cxi] https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf (February 2021), and https://indiaai.gov.in/documents/pdf/NationalStrategy-for-AI-Discussion-Paper.pdf (June 2018)
[cxii] https://indiaai.gov.in/documents/pdf/NationalStrategy-for-AI-Discussion-Paper.pdf (June 2018), at p. 7-8
[cxiii] https://indiaai.gov.in/documents/pdf/NationalStrategy-for-AI-Discussion-Paper.pdf (June 2018), at p. 7-8
[cxiv] https://indiaai.gov.in/research-reports/responsible-ai-part-1-principles-for-responsible-ai
[cxv] https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf at p. 31
[cxvi] https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf at p. 36
[cxvii] https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf at p. 38-39
[cxviii] Niti Aayog, Responsible AI, Principles of responsible AI, https://www.niti.gov.in/sites/default/files/2021-02/Responsible-AI-22022021.pdf (February 2021), at p. 41-42
[cxix] https://www.niti.gov.in/sites/default/files/2021-08/Part2-Responsible-AI-12082021.pdf
[cxx] https://www.niti.gov.in/sites/default/files/2021-08/Part2-Responsible-AI-12082021.pdf at p. 27
[cxxi] Para 4.1.7., Niti Aayog, Responsible AI, Principles of responsible AI, https://www.niti.gov.in/sites/default/files/2021-08/Part2-Responsible-AI-12082021.pdf (August 2021, at p. 27
[cxxii] Para 3.52-3.55, Niti Aayog, Responsible AI, Principles of responsible AI, https://www.niti.gov.in/sites/default/files/2021-08/Part2-Responsible-AI-12082021.pdf (August 2021, at p. 22
[cxxiii] https://www.meity.gov.in/artificial-intelligence-committees-reports
[cxxiv] https://www.meity.gov.in/writereaddata/files/constitution_of_four_committees_on_artificial_intelligence.pdf
[cxxv] https://www.meity.gov.in/writereaddata/files/Committes_A-Report_on_Platforms.pdf
[cxxvi] https://www.meity.gov.in/writereaddata/files/Committes_B-Report-on-Key-Sector.pdf
[cxxvii] https://www.meity.gov.in/writereaddata/files/Committes_B-Report-on-Key-Sector.pdf at p.16
[cxxviii] https://www.meity.gov.in/writereaddata/files/Committes_C-Report-on_RnD.pdf at p.43
[cxxix] IAF's principles include: (a) Organization commitment to accountability and adoption of internal policies consistent with external criteria; (b) mechanisms to put privacy policies into effect, including tools, training and education; (c) systems for internal ongoing oversight and assurance reviews and external verification; (d) transparency and mechanisms for individual participation; and, (e) having a means for remediation and external enforcement. See here: http://informationaccountability.org/
[cxxx] https://www.meity.gov.in/writereaddata/files/Committes_C-Report-on_RnD.pdf at 45-46
[cxxxi] https://www.meity.gov.in/writereaddata/files/Committes_D-Cyber-n-Legal-and-Ethical.pdf at p. 26-29
[cxxxii] AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 10, para 2.5.
[cxxxiii] Infrastructure layer sets up a common data controller to ensure proper monitoring, data privacy and include multi-cloud scenarios. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 28, para. 5.21
[cxxxiv] Storage layer divides data storage into fast/hot data, cold data, and warm data according to differences in frequency and manner of storage. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 27, para. 5.20

[cxxxv] Computer layer will ensure that AI/ML processes as well as data analytics will happen in this layer through defined data structures, proper interfaces, and protocols. It will enable a distinction between public, shared and private data sources so that AI/ML algorithms can be applied against relevant data fields. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 24-45

[cxxxvi] Application layer uses a set of tools and services designed to host and execute software and applications. It will also house a defined service framework to keep track of all transactions across the stack. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 23, para 5.5

[cxxxvii] Data layer will support proper consent framework for access of data by/for the customer. This layer will also provide a web-based user interface (UI) designing tools to create, modify, test, and deploy different UI scenarios. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 23, para 5.3

[cxxxviii] Security and governance layer will create defined data structures, to ensure safety and security of AI services across all layers. Possible measures adopted in this layer include encryption at different levels, setting up of a security dictionary, cryptographic supporting, etc. See- AI Standardisation Committee, 'Indian Artificial Intelligence Stack' (2 September 2020) <https://www.tec.gov.in/pdf/Whatsnew/ARTIFICIAL%20INTELLIGENCE%20-%20INDIAN%20STACK.pdf>, at p. 23, para 5.32

[cxxxix] https://dpiit.gov.in/sites/default/files/Report_of_Task_Force_on_ArtificialIntelligence_20March2018_2.pdf

[cxl] https://dpiit.gov.in/whats-new/report-task-force-artificial-intelligence, at p. 46-51

[cxli] https://dghs.gov.in/

[cxlii] https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==

[cxliii] See point 10 in the list of functions, https://dhr.gov.in/about-us/about-department

[cxliv] https://dhr.gov.in/about-us/about-department

[cxlv] https://main.icmr.nic.in/

[cxlvi] https://www.icmr.gov.in/ctestlab.html

[cxlvii] https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

[cxlviii] A portal to provide information on public health tips and government health-related schemes etc. https://www.nhp.gov.in/about-national-health-portal_pg

[cxlix]https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwi8s5CBo8X1AhWRzzgGHexEARgQFnoECAMQAQ&url=https%3A%2F%2Fwww.nhp.gov.in%2FNHPfiles%2FEHR-Standards-2016-MoHFW.pdf&usg=AOvVaw0BolASWu2nsKrfqph4KRgS

[cl] https://pmjay.gov.in/about/nha

[cli] https://abdm.gov.in/home/digital_systems

[clii] https://abdm.gov.in/assets/uploads/consultation_papersDocs/Synopsis_Consultation_Paper_on_UHI.pdf and https://abdm.gov.in/Home/collaborative_development

[cliii] https://sandbox.abdm.gov.in/

[cliv] https://abdm.gov.in/publications/ndhm_strategy_overview

[clv] https://pharmaceuticals.gov.in/business-allocation

[clvi] Government of India resolution dated August 29, 1997. See https://www.nppaindia.nic.in/en/about-us/about-national-pharmaceutical-pricing-authority/ and https://www.nppaindia.nic.in/en/about-us/resolution-govt-of-india/.

[clvii] See Section 2A and the Schedule to the Essential Commodities Act, 1955, which lists 'drugs' as an essential commodity, https://www.indiacode.nic.in/handle/123456789/1579?sam_handle=123456789/1362

[clviii] https://dst.gov.in/introduction

[clix] https://dst.gov.in/st-system-india/science-and-technology-policy-2013

[clx] https://www.csir.res.in/about-us/vision-and-mission

[clxi] https://www.csir.res.in/readbook?bid=MTQ4MjQ0&submit=view

[clxii] https://www.csir.res.in/readbook?bid=MTQ4MjQ0&submit=view

[clxiii] https://www.csir.res.in/readbook?bid=MTQ4MjQ0&submit=view

[clxiv] https://www.meity.gov.in/about-meity/functions-of-meity

[clxv] https://www.meity.gov.in/emerging-technologies-division

[clxvi] https://www.stqc.gov.in/about-stqc

[clxvii] https://ndhm.gov.in//assets/uploads/Sandbox_Guidelines_v6.pdf

[clxviii] https://www.pib.gov.in/PressReleasePage.aspx?PRID=1680519
[clxix] https://www.niti.gov.in/verticals/health-and-family-welfare
[clxx] https://www.meity.gov.in/content/national-e-governance-division
[clxxi] https://www.meity.gov.in/content/national-e-governance-division
[clxxii] https://www.niti.gov.in/index.php/objectives-and-features
[clxxiii] https://www.niti.gov.in/index.php/objectives-and-features
[clxxiv] https://www.niti.gov.in/sites/default/files/2021-08/HAICReportNITIAayog.pdf
[clxxv] https://www.niti.gov.in/sites/default/files/2021-11/State-practices-on-home-based-care-forCOVID-19.pdf
[clxxvi] See Memorandum of Association, 1997, here https://qcin.org/moa
[clxxvii] The Bureau of Indian Standards Act, 2016 has replaced this law, and has reinforced the activities of the BIS. https://www.services.bis.gov.in:8071/php/BIS_2.0/eBIS/about-standards/
[clxxviii] BIS replaced the Indian Standards Institution, which was established in 1947. https://www.services.bis.gov.in:8071/php/BIS_2.0/eBIS/about-standards/
[clxxix] https://www.bis.gov.in/index.php/the-bureau/about-bis/
[clxxx] https://www.services.bis.gov.in:8071/php/BIS_2.0/bisconnect/dgdashboard/committee_sso/
[clxxxi] https://www.services.bis.gov.in:8071/php/BIS_2.0/dgdashboard/published/subcommtt?depid=NjQ%3D&aspect=&from=&to=
[clxxxii] https://www.services.bis.gov.in:8071/php/BIS_2.0/bisconnect/standard_review/Standard_review/Isdetails?ID=MjMzNTk%3D

Annexure 3.2:

Webinar I presentation

IKIGAI LAW

Project Reg-AIH

Enabling AI/ML use in healthcare in India

Webinar I: Indian regulatory landscape relevant to AI/ML and healthcare.

IKIGAI LAW

Webinar overview

- Get to know us (BHC and Ikigai Law)
- Get to know you
- Briefing paper
  - Discussion on key issues, case studies
  - Identification of issues for the trip, discussions,
- Closing remarks.

Project Reg-AIH

Get to know us

British
High Commission
New Delhi

British High Commission
Vision 2030, India – United Kingdom

IKIGAI LAW

Ikigai Law

Get to know you

IKIGAI LAW

AI/ML in healthcare: what's happening in India?

AI/ML use cases in India and globally?

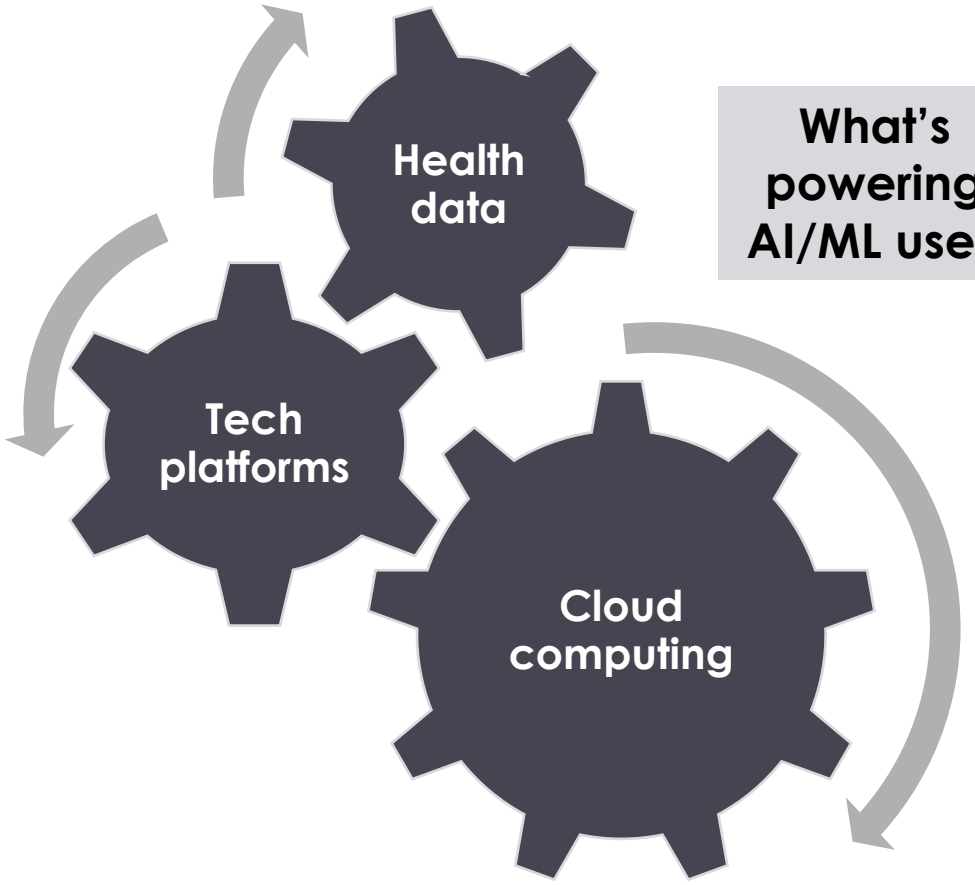
What is needed to drive AI/ML adoption in healthcare?

IKIGAI LAW

AI/ML use

What's AI being used for?

What's powering AI/ML use?



IKIGAI LAW

What does India's legal landscape look like?

A snapshot of the relevant laws.

IKIGAI LAW

Snapshot of laws

Tele-communication technology platforms	• Telemedicine Practice Guidelines, 2020 • Consumer Protection (E-commerce) Rules, 2020 • Intermediary Guidelines 2021
Healthcare-related products	• Drugs & Cosmetics Act, 1940 and Rules 1945 • Medical Devices Rules, 2o17 and related notifications • Consumer Protection Act 2019 and E-commerce Rules 2020
Health data	• Information Technology Act, 2000 and IT (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 • The Data Protection Bill, 2021 • Health Data Management Policy under the ABDHM programme
Healthcare professionals	• National Medical Commission of India Act, 2020 • National Commission for Allied Health Professionals, 2021 • Liability- Indian Penal Code, 1860 (criminal)/Consumer Protection Act 2019 (civil)
Healthcare facilities	• Clinical Establishment (Registration and Regulation) Act, 2010

IKIGAI LAW

Current policies

MeitY's National Programme for AI	Identify high value data sets in public domain	Provide data sets for AI/ML-based modelling
TN's Safe and Ethical Artificial Intelligence Policy, 2020	DEEP MAX scoring system to review AI/ML	Certification of AI/ML tools based on score
Telangana's Information and Computer Technology (ICT) policy (2021-2026)	Calls for using of AI/ML in healthcare	Highlights need for policies on cybersecurity, skilling, & digital literacy

IKIGAI LAW

Policies in discussion

Body	Recommendations
Niti Aayog's 2018 paper	•2018 paper – identified barriers to growth of AI. Recommended creation of 'CORE' and 'ICTAI.'
MeitY's committees on AI (2018)	•Committee on platforms and data – called for creation of a National Artificial Intelligence Resource Platform. •Committee on leveraging AI identified sectors like health for AI use. •Committee on key policy enablers and capability mapping – identified principles for AI use, similar to Niti Aayog's papers •Committee on cyber security – investing in technology tools to tackle problems emanating from AI use.
DPIIT's taskforce on AI (2018)	•Creation of NAIM and data exchanges for cross-industry data •Setting standards for data management and interoperability •Skill development •International partnerships
DoT's committee on standardization of AI	•A layered approach to AI •Six layers working in tandem •Layers will help manage consent, differentiate public-private data sets, maintain security, provide access to data sets, and record all access.
Niti Aayog's 2021 papers	•Feb 2021 – identified principles to guide responsible use of AI •August 2021 - Ethics by design. Establishing 'CET'.

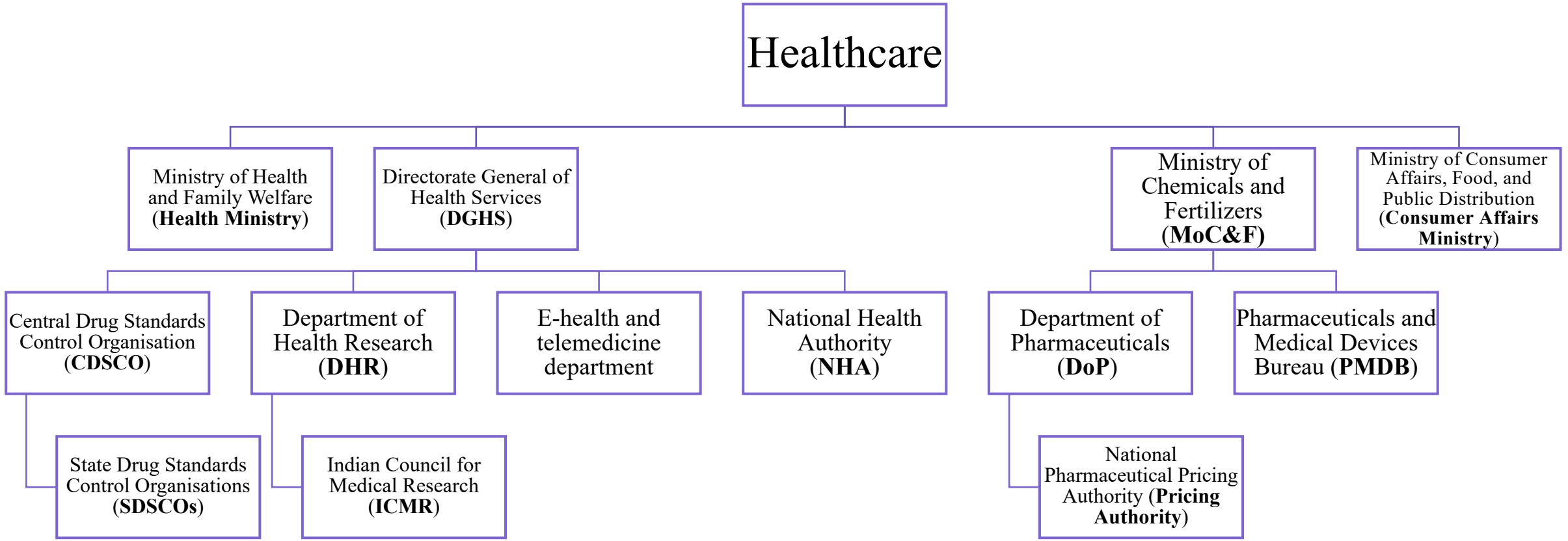
IKIGAI LAW

What does India's regulatory ecosystem look like?

A snapshot of the relevant ministries, departments, autonomous bodies, and regulators.

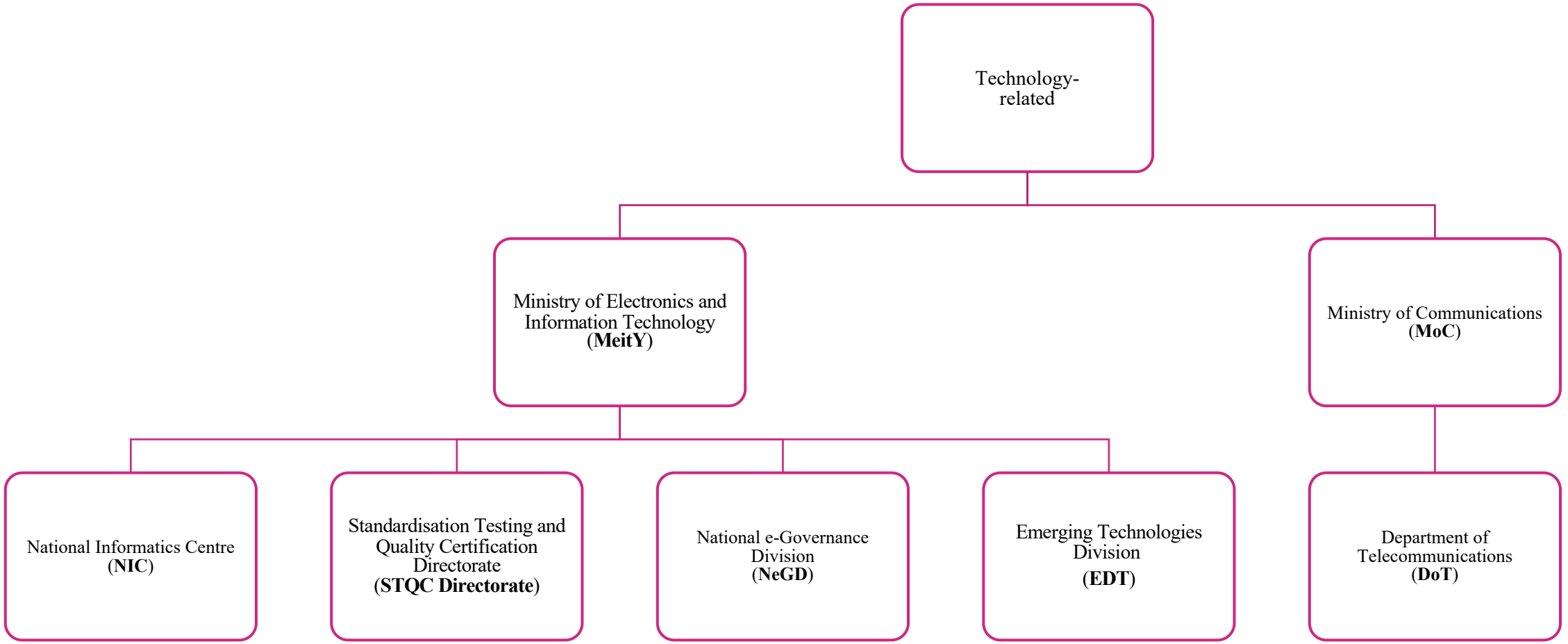
IKIGAI LAW

Government and regulatory landscape



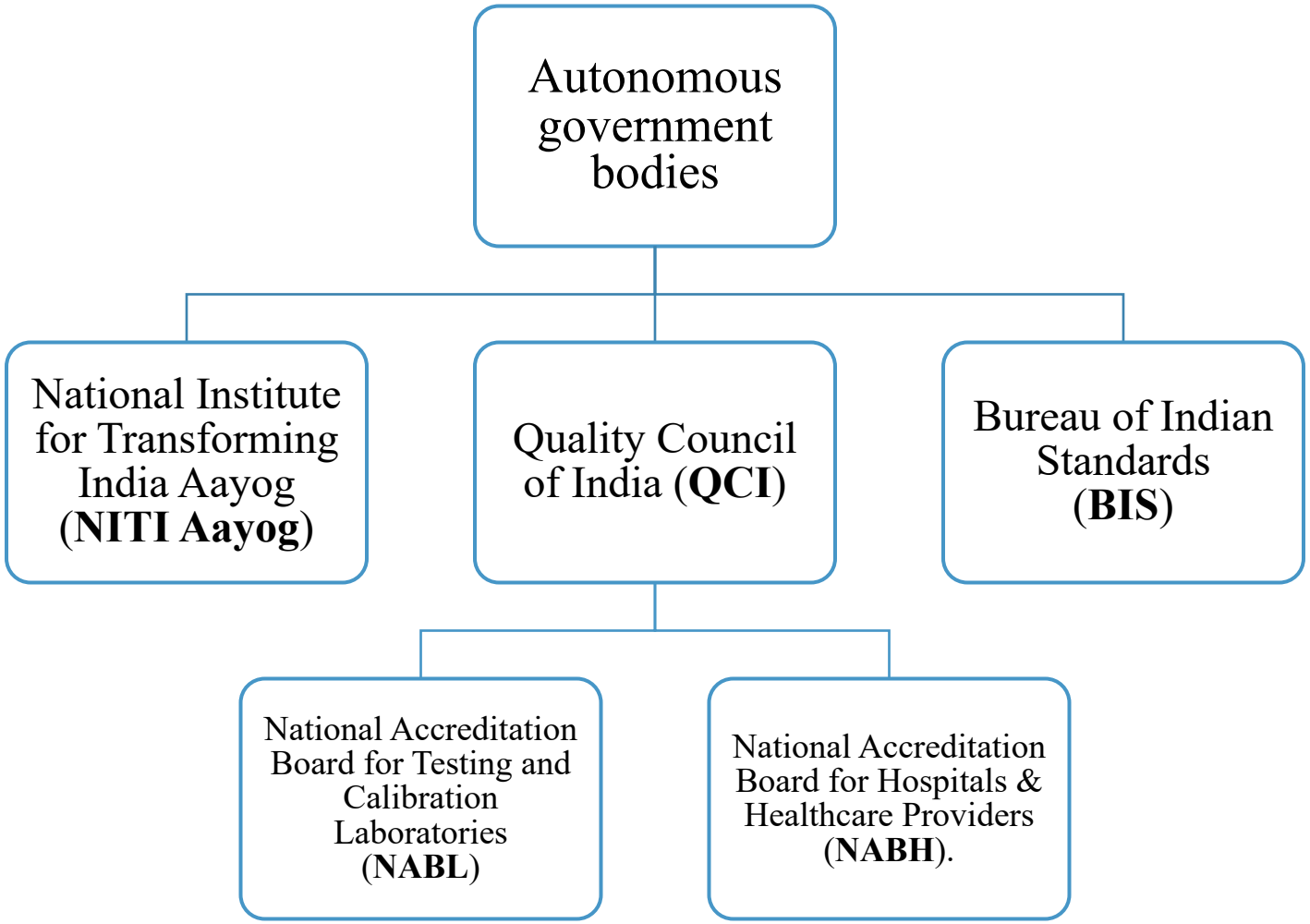
IKIGAI LAW

Technology-related ministries, departments, and regulators



IKIGAI LAW

Autonomous government bodies



IKIGAI LAW

Driving AI/ML adoption in healthcare

- Standardised and readable health data
- Mechanisms to ensure safety and quality of AI/ML tools (e.g., ethics, bias, etc.)
- Regulatory oversight (e.g., post market surveillance, accountability of AI/ML developers)
- Inputs from healthcare professionals on the realities of healthcare delivery
- Human resource training and management
- Infrastructure development for R&D, and use, powered by PPP

IKIGAI LAW

Case study 1: App detecting skin cancer

An application (app) that is able to detect skin cancer.

- Takes a photo of skin lesions or moles.
- Data fed into an AI/ML algorithm to determine the values and any potential health risks.
- You can share your readings with your doctor directly through the app.

IKIGAI LAW

A little something to think about…

Are all AI/ML tools used in healthcare 'medical devices'?

What is a software developer's (e.g., Apple or Samsung) accountability for their healthcare software (e.g., EKG smart watch applications by Apple is US FDA approved) in case of harm to patients?

How do we ensure an AI/ML tool is reliable across populations and age groups?

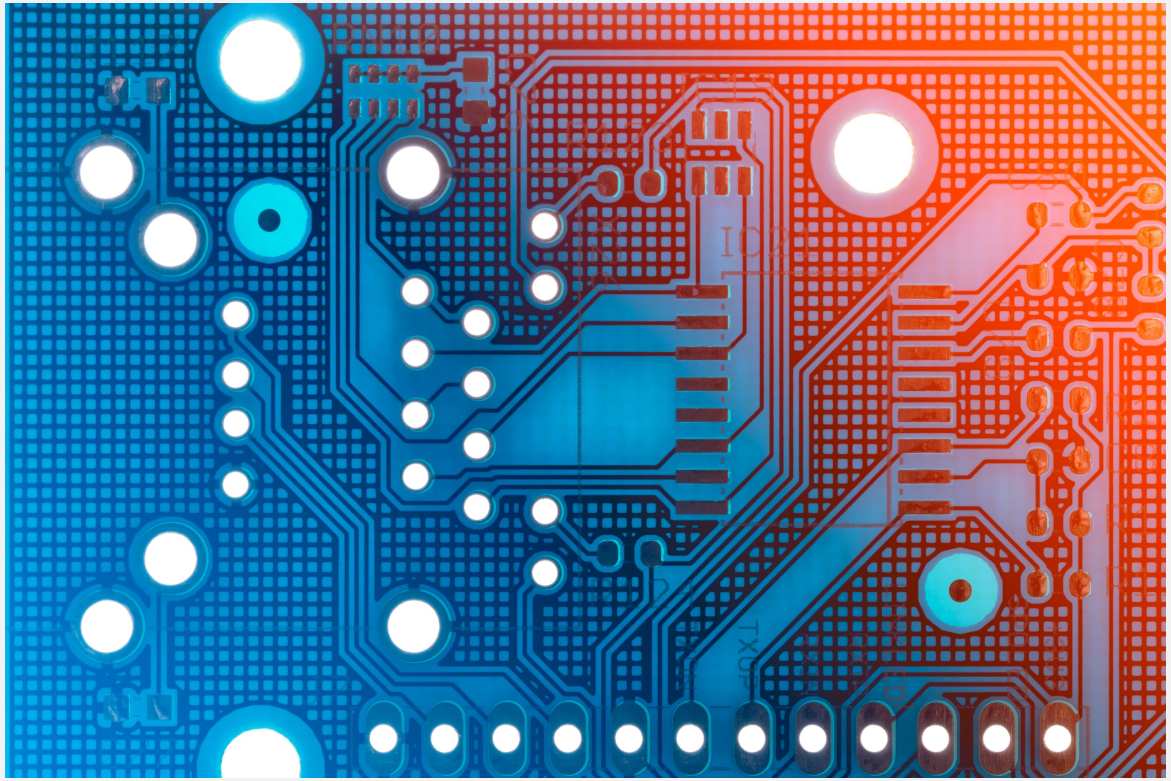
If AI/ML tools can reduce doctors' work, should that include diagnostics/prescription? If yes, under what circumstances/guidance?

IKIGAI LAW

Case study 2: smart city and healthcare

A smart city with AI-powered solutions for different activities. Built through PPP models.

- Across hospitals- AI/ ML powered “Clinical Decision Support System’ (CDSS) to help doctors in diagnosis, recognise symptoms, suggest treatment options.
- When a person walks into a hospital, their body vitals are scanned- they’re assigned risk classifications and sent to appropriate department/ doctor based on this automated assessment.
- Patient entry is streamlined- facial recognition tech deployed for Aadhaar verification.



IKIGAI LAW

A little something to think about...

- Diversity
- Equity and fairness
- Ethics
- Privacy and data protection
- Misuse protection
- Audit and transparency
- Cross geography and society

D
E
E
P
M
A
X

IKIGAI LAW

Case study 3: AL/ML powered chatbots

A mental health application uses an AI/ML powered chatbot to help patients through various mental health challenges.

- Suggests helplines, provides resources
- Directs you to appropriate service provider- counsellor, psychiatrist
- Data fed in the chats is used to train further AI sets- to be able to offer better interventions.

IKIGAI LAW

A little something to think about...

Incorporating privacy by design approach

How much data is too much data?

How long should AI/ML tools have access to the data?

How will AI/ML tools affect the right to be forgotten?

Challenges in off-shore data transfer for analytics, etc.

IKIGAI LAW

Key issues for consideration

Turning issues into opportunities for conversation, mutual learning, and building an enabling legal and regulatory landscape for AI/ML in healthcare.

IKIGAI LAW

Key themes

- Principles of data protection v/s providing access to data for AI/ML tools.
- Clinical evaluation of AI/ML tools.
- Capacity building for regulators.
- Principles governing AI/ML use across healthcare segments.
- Light touch regulation for balancing safety with ease of doing business.
- Accountability of technology service providers and software developers.
- Effective use of ‘post-market surveillance’ to improve AI/ML SaMDs.

IKIGAI LAW

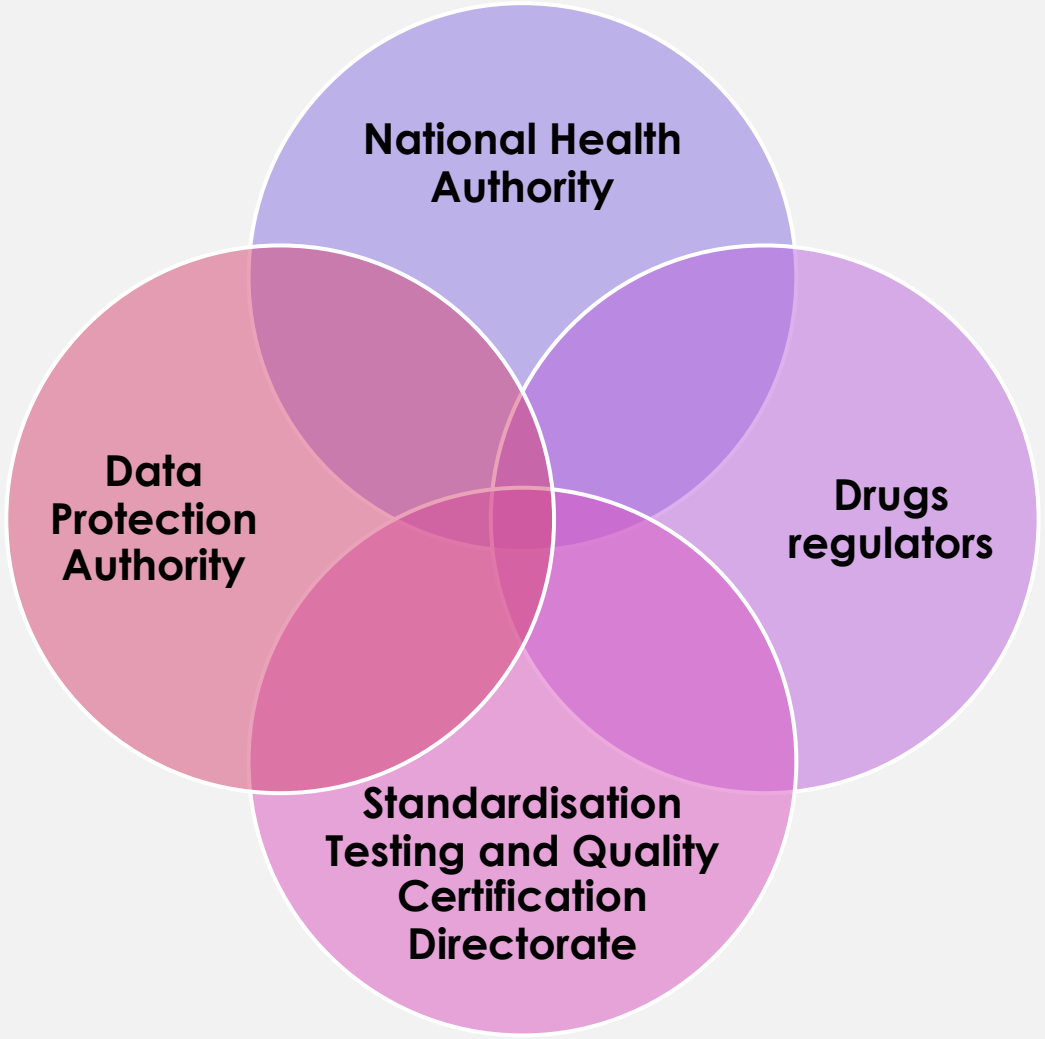
Additional case studies

Additional case studies and points for consideration.

IKIGAI LAW

Case study : Who is evaluating AL/ML tools?

- AI/ML tools can be used across segments of healthcare, including those that are patient facing (SaMDs).
- Multiple government bodies may have a role to play in how health data is used by such tools.



IKIGAI LAW

A little something to think about...

- Enabling seamless coordination between government bodies.
- Setting standards for regulating evolving tech.
- What kind of post-market surveillance for evolving tech?
- Cybersecurity concerns with SaMDs and AI/ML tools.
- Clinical evidence for proving safety of AI/ML tools.

IKIGAI LAW

Case study: IoTs/hospital management

A leading hospital uses internet of things to connect all its medical devices, computer equipment, and patient wearables.

- The hospital uses smart stethoscopes as part of their cardiac care.
- For homecare, cardiac patients are given a ‘smart stethoscope’, and BP machine and asked to download a mobile application.
- The stethoscope and BP machine transmit readings to the mobile application.
- The smart stethoscope is equipped with an AI/ML tool that can sense risk of cardiac arrest. It can alert emergency medical professionals (e.g., ambulances).
- All devices are linked to the hospitals cloud server.

The hospital has a power failure leading to loss of services (in-patient and at home).

IKIGAI LAW

A little something to think about…

How do hospitals plan for such large scale use of AI/ML tools?

Who is accountable in case of glitches in transmission of medical readings?

Should hospitals work with the software developers/manufacturers to keep improving the tools?

How do hospitals plan to test such tools for their efficacy in capturing medical readings?

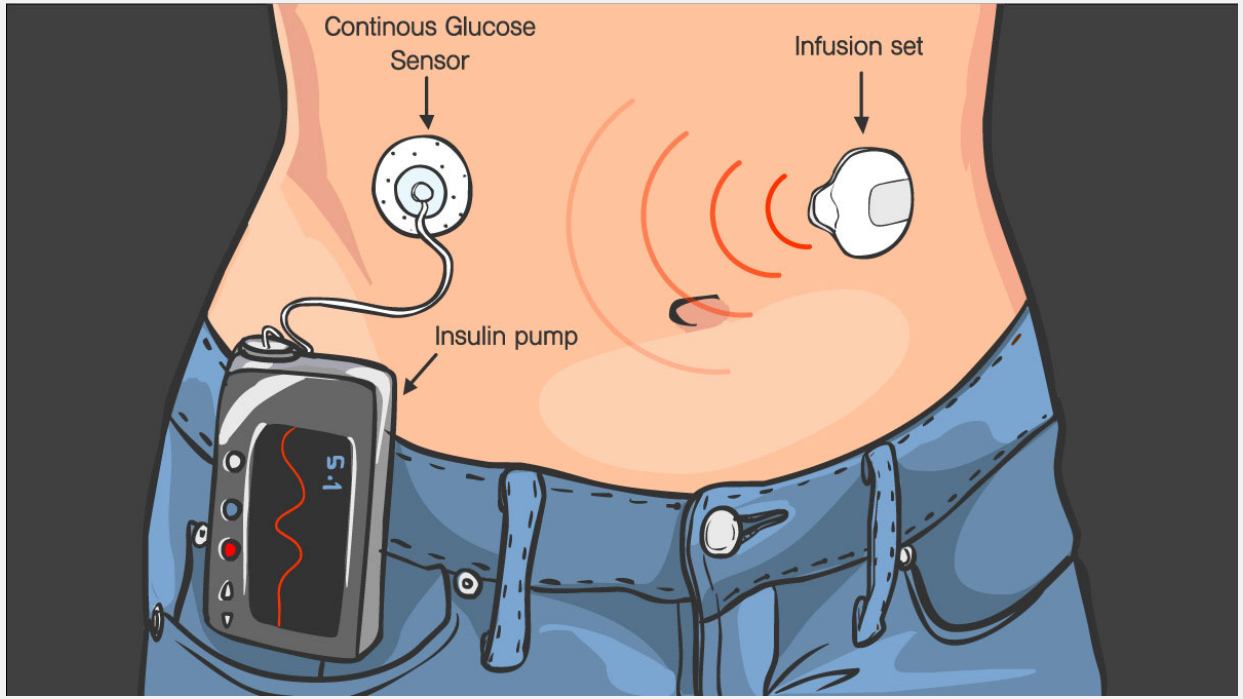
IKIGAI LAW

Case study: ethics and cybersecurity

Ethical hacker group ‘B+’ wants to teach a medical device company a lesson on health data vulnerabilities.

- Hacks the CEO’s insulin pump device.
- Causes fluctuations in the amount of insulin released each dose.
- CEO needs hospitalisation to bring his values back to normal, and to re-calibrate the device.

Other users of the insulin pump are unaware of this vulnerability.



Thank you!

British
High Commission
New Delhi

IKIGAI LAW

Annexure 3.3:

Webinar II presentation

IKIGAI LAW

Project Reg-AIH

Building bridges on regulatory approaches to AI enabled health tech

Webinar II: Deep dive into AI/ML issues in healthcare via case studies

IKIGAI LAW

Webinar overview

- Recap and summarize Webinar 1
- Snapshot of UK laws and government bodies
- Common challenges
- Case studies

IKIGAI LAW

Recap

Principles of data protection v/s providing access to data for AI/ML tools.

Clinical evaluation of AI/ML tools.

Capacity building for regulators.

Principles governing AI/ML use across healthcare segments.

Light touch regulation for balancing safety with ease of doing business.

Accountability of technology service providers and software developers.

Effective use of ‘post-market surveillance’ to improve AI/ML SaMDs.

IKIGAI LAW

What does the UK's legal landscape look like?

A snapshot of the relevant laws, policies and regulators

IKIGAI LAW

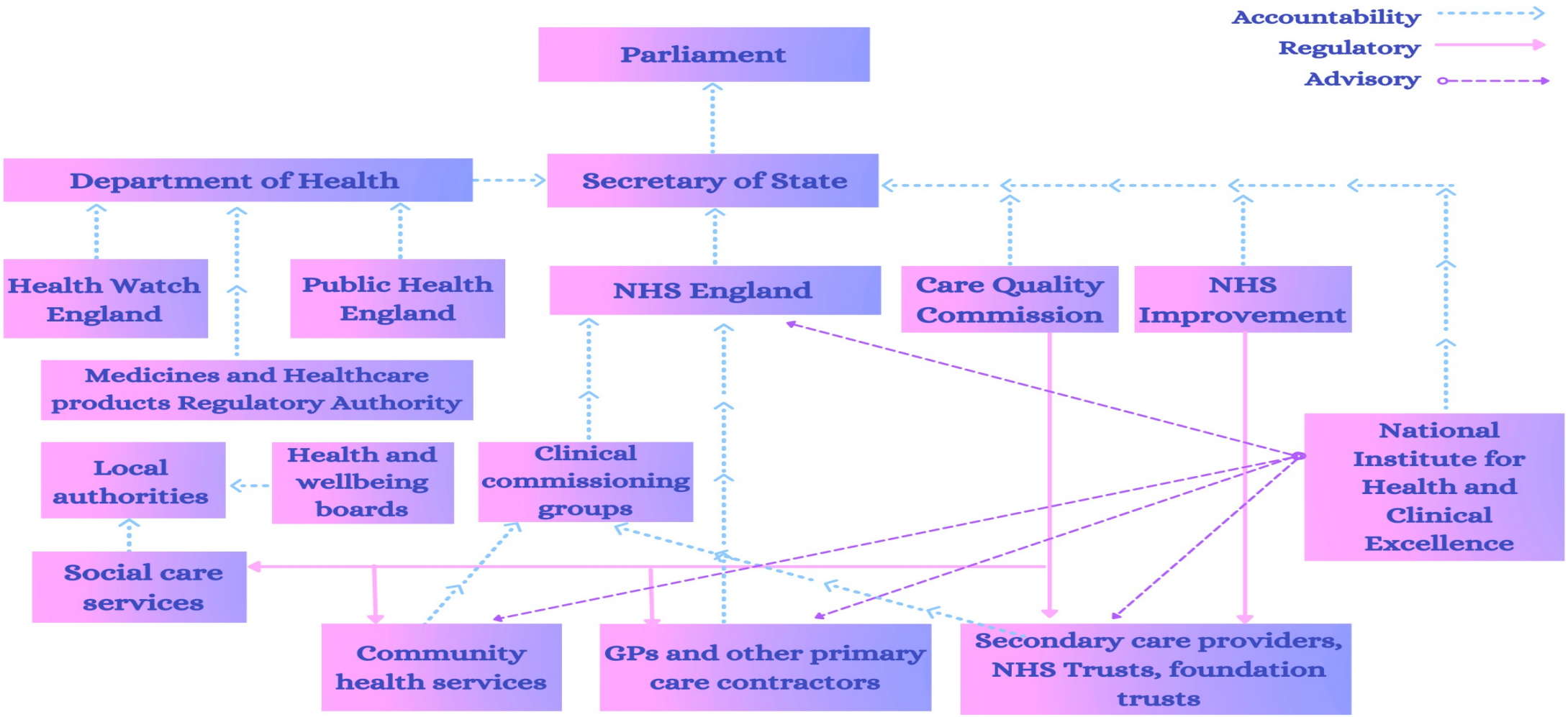
General Overview

- The National Health System (**NHS**), run by the Department of Health oversees the provision of healthcare services in the UK.

- Digital health in the UK is currently governed by a patchwork of different legal regimes and regulatory frameworks and depends on the nature of the product or service.

IKIGAI LAW

Healthcare system mapping: UK



Source: The Commonwealth Fund, England

IKIGAI LAW

AI and digital health bodies

Office for AI

- Part of the Department for Digital, Culture, Media & Sport and the Department for Business, Energy & Industrial Strategy.
- Responsible for overseeing implementation of AI projects

Information Commissioner's Office (ICO)

- Independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals

NHS Digital

- Provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care in England- particularly NHS

NHSX

- Government unit responsible for setting national policies and developing best practices on technology, digital and data, including data sharing and transparency for NHS

IKIGAI LAW

Indicative snapshot of laws and regulations

Healthcare-related products

- Medicines and Medical Devices Act, 2021
- Electronic Commerce (EC Directive) Regulations, 2002
- General Product Safety Regulations, 2005
- MHRA Guidance: Software and AI as a Medical Device Change Programme
- MHRA Guidance: Medical Devices- Conformity Assessment and the CE Mark, 2020
- MHRA Guidance: Medical Device Stand-Alone Software Including Apps, 2017

Health data

- UK's Data Protection Regulation Act, 2018
- NHS: A guide to good practice for digital and data-driven health technologies, 2021
- NHS Act, 2006 – Confidentiality Policy

Healthcare professionals

- Health and Social Care Act, 2012
- General Medical Council: Remote prescribing principles for practitioners, 2021

IKIGAI LAW

Other guidance/ strategy documents

Data and privacy

- NHS: Code of Conduct for data driven health and care technology and Recommendations for AI, ML, Data protection
- ICO: Guidance on artificial intelligence for data protection.
- Proposed an AI auditing framework for implementing data-driven technology solutions safely and legally.

AI governance standards

- MHRA: Recommendations to support AI governance and regulation
- NHS: Algorithmic Impact Assessments (AIAs) in healthcare
- NICE: Proposed an evidence standards framework for digital health technologies
- ICO: Regulation for telemedicine.

AI use and development

- CQC: Recommendations for using machine learning in diagnostic services
- NHS: Draft National Strategy for AI in Health and Care
- General Medical Council: Remote prescribing principles

Software and Medical Devices

- MHRA: Guiding principles for AI/ ML medical device.

IKIGAI LAW

Ongoing projects and initiatives

- National AI Lab

Created to address challenges pertaining to AI by bringing together government, health and care providers, academics and technology companies

- NHS Long Term Plan

10-year strategy for improving, digitizing and reforming the NHS in England

- Internet First Policy

NHS initiative that calls for all new health and social care digital services to be internet facing and existing services to also be transformed

IKIGAI LAW

AI/ML in healthcare: Common pain points for India and UK

- **Safety and efficacy** of using AI/ML tools
- **Privacy and data sharing**
- Health inequalities and bias
- Accountability, classification and legal liability
- Workforce training
- Cyber security and ethics

IKIGAI LAW

How does the NHS use AI/ML?

MEDICAL IMAGING

PATIENT-FACING APPLICATIONS

LOGISTICS AND ADMINISTRATION

TREATMENT PLANNING AND PATIENT MONITORING

IKIGAI LAW

Case study 1: IoTs/hospital management

A leading hospital uses internet of things to connect all its medical devices, computer equipment, and patient wearables.

- The hospital uses smart stethoscopes as part of their cardiac care.
- For homecare, cardiac patients are given a ‘smart stethoscope’, and BP machine and asked to download a mobile application.
- The stethoscope and BP machine transmit readings to the mobile application.
- The smart stethoscope is equipped with an AI/ML tool that can sense risk of cardiac arrest. It can alert emergency medical professionals (e.g., ambulances).
- All devices are linked to the hospitals cloud server.

The hospital has a power failure leading to loss of services (in-patient and at home).

IKIGAI LAW

A little something to think about…

How do hospitals plan for such large scale use of AI/ML tools?

Who is accountable in case of glitches in transmission of medical readings?

Should hospitals work with the software developers/manufacturers to keep improving the tools?

How do hospitals plan to test such tools for their efficacy in capturing medical readings?

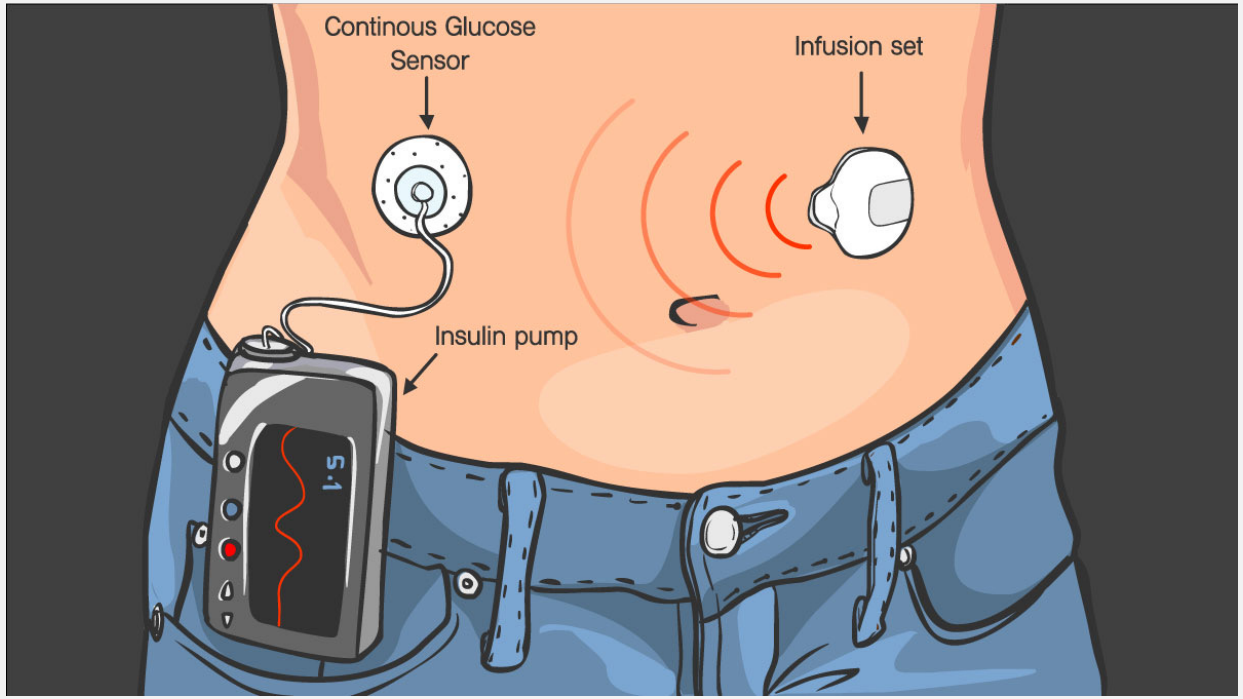
IKIGAI LAW

Case study 2: ethics and cybersecurity

Ethical hacker group ‘B+’ wants to teach a medical device company a lesson on health data vulnerabilities.

- Hacks the CEO’s insulin pump device.
- Causes fluctuations in the amount of insulin released each dose.
- CEO needs hospitalisation to bring his values back to normal, and to re-calibrate the device.

Other users of the insulin pump are unaware of this vulnerability.



IKIGAI LAW

A little something to think about...

Who is accountable in case of glitches in transmission of medical readings?

What is the extent of human intervention required?

Is there an ethical responsibility of the service provider, to notify others?

IKIGAI LAW

Case study 3: AL/ML powered chatbots

A mental health application uses an AI/ML powered chatbot to help patients through various mental health challenges.

- Suggests helplines, provides resources
- Directs you to appropriate service provider- counsellor, psychiatrist
- Data fed in the chats is used to train further AI sets- to be able to offer better interventions.

IKIGAI LAW

A little something to think about...

Incorporating privacy by design approach

How much data is too much data?

How long should AI/ML tools have access to the data?

How will AI/ML tools affect the right to be forgotten?

Challenges in off-shore data transfer for analytics, etc.

IKIGAI LAW

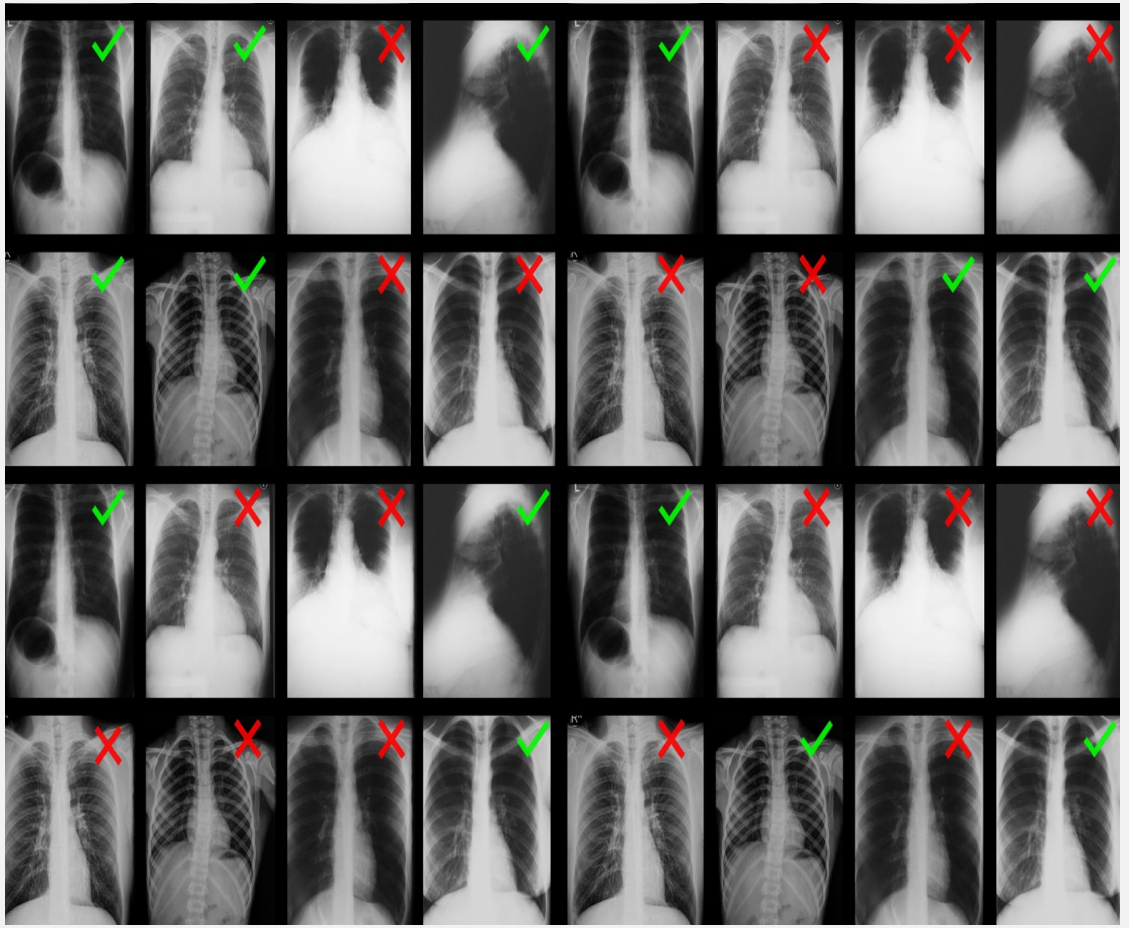
Case study 4: Medical imaging

Problem:

- Doctors often use X-ray imaging to determine the correct placement of the NG tube, but as the esophagus and windpipe are directly in front of each other, it can be hard to tell the two apart.
- Junior doctors with little specialist training are often required to make the decision, rather than experienced radiologists, which can be stressful and carries risk.

Solution:

- LineSafe – deployed by NHS Trusts, aims to solve this problem by using AI to train from X-ray image data and accurately determine whether NG tubes have been placed correctly.



IKIGAI LAW

A little something to think about...

How do hospitals plan for such large scale use of AI/ML tools?

Who is accountable in case of glitches in transmission of medical readings?

Should hospitals work with the software developers/manufacturers to keep improving the tools?

How do hospitals plan to test such tools for their efficacy in capturing medical readings?

IKIGAI LAW

Key issues for consideration

Turning issues into opportunities for conversation, mutual learning, and building an enabling legal and regulatory landscape for AI/ML in healthcare.

IKIGAI LAW

Cohort's bucket list for the learning tour

Where are we? What do we need? And how can we achieve it?

Annexure 3.4:

Learnings paper from the UK learnings tour with annexures

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

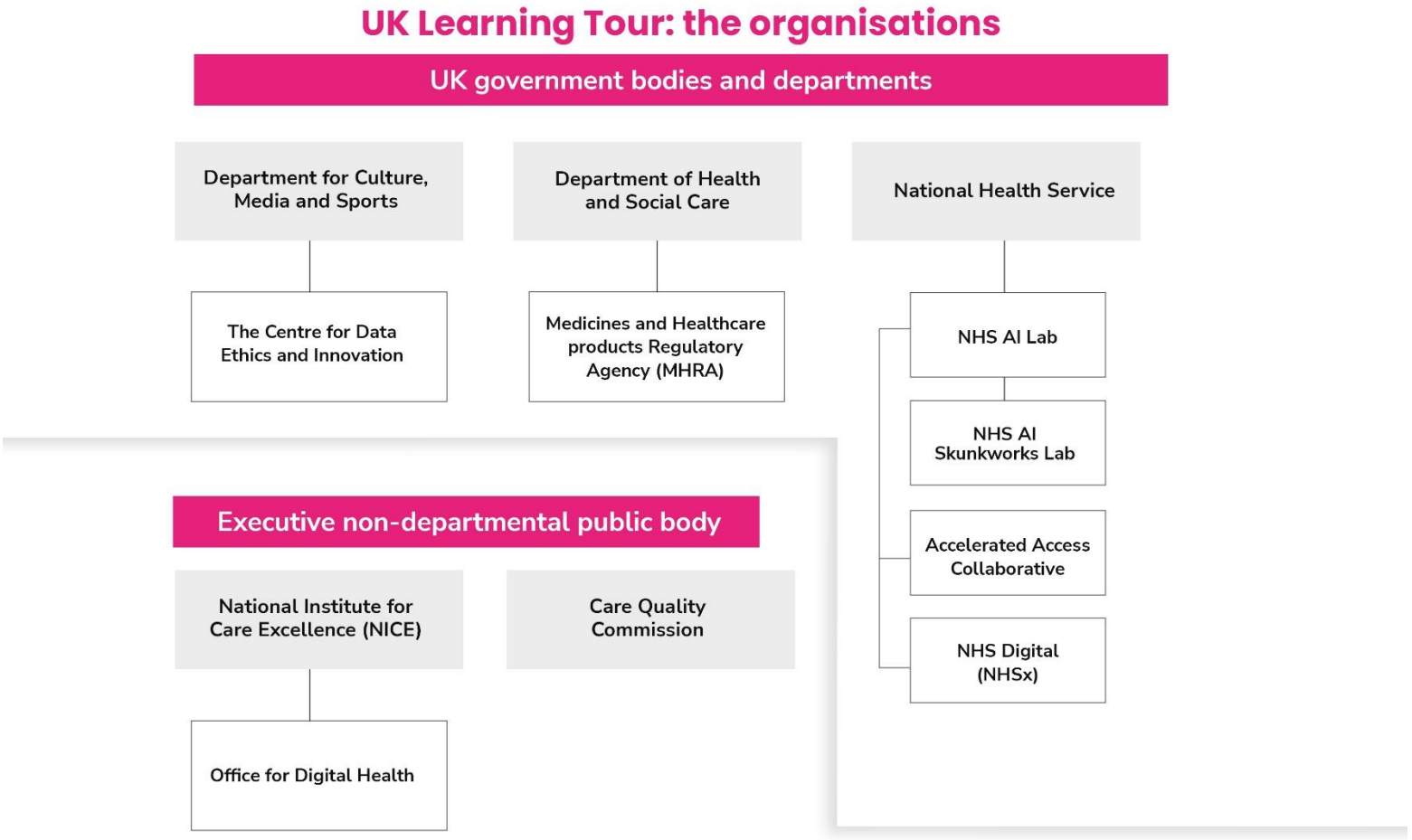
26. **McGuire Alistar**, Head of Department and Chair of Health Economics at the Department of Health Policy, London School of Economics
27. **Morley Jessica**, Oxford Internet Institute and Policy Lead, Oxford Data Lab
28. **Murrey James**, Head of Partnerships, Entrepreneurship Center, Said Business 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
[54] Suggested by Professor Rajendra Pratap Gupta, founder of Health Parliament and former advisor to Union Health Minister, via email dated March 23, 2022
[55] Suggested by Professor Rajendra Pratap Gupta, founder of Health Parliament and former advisor to Union Health Minister, via email dated March 23, 2022
[56] Suggested by Professor Rajendra Pratap Gupta, founder of Health Parliament and former advisor to Union Health Minister, via email dated March 23, 2022
[57] Suggested by Ashish Srivastava, Technology Advisor to the Women and Child Department, Government of Karnataka, via email dated March 23, 2022.