FICCI Inputs on
Health Data Retention Policy- 2021

The consultation paper on proposed Health Data Retention Policy is indeed a very well-thought-out and a comprehensive document.

FICCI had shared the paper with all its health sector members. The feedback received has been compiled as below:

General Comments:

- There are already some existing guidelines in India on data retention. E.g - (i) PDP Bill, (ii) DISHA, (iii) The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, (iv) The Clinical Establishments (Registration and Regulation) Draft Rules 2010, (v) EHR Standards 2016. Once this policy comes into effect, there will be a lot of confusion in the industry as to which policy to comply with and which is relevant for the sector. Hence to clear this ambiguity, it is suggested that NHA should clarify the same in the consultation paper and make it clear that notwithstanding anything to the contrary, the provisions of the policy shall supersede all other policies in cases of conflicts
- Members suggested implementation of a central archival model for situations when a healthcare entity goes out of business, data for holding can be transferred. This will help a new industry (healthcare data archival) to grow around it.
- Members sought information in detail in case of conflicts between the PDP Bill and the Policy, how will they be addressed?
- All data must be anonymised by removing all PHI (personal health identifiers) and then storing them in cloud-based servers permanently for further reference and analysis with respect to evidence-based analytics, epidemiology, clinical data analytics, use in machine learning, and artificial intelligence-enabled healthcare applications

Specific Comments:

Page / Section	Topic	Remarks / Suggestions
Page 9 Section 1.3	Scope of Consultation Paper	The scope of this policy should be applicable for the entire healthcare ecosystem in India (option 1 of subsection 3.1 of chapter 3). This will ensure that there is a uniform and standard approach towards health data retention in the entire country, covering the entire spectrum of healthcare. It will also ensure ease of adaptability in case of any future changes in the policy. Also, more clarity is required whether this Policy will lead to the enactment of any new laws or amendments to any existing laws that may be applicable to the first approach or the second approach?
Page 12 Section 1.7.2	Rollout of ABDM Building Blocks	As part of building blocks- are there any plans to integrate nurses, pharmacists, physiotherapists, occupational therapists etc. also

Page 13 Fig 2	ABDM Building Blocks	Health Researchers may also be defined as one of the Users for the data
Page 13 Section 1.7.3	The ABDM building blocks have enabled new foundational capabilities including:	In case the standardization of formatting of health records is not mandatory, more information is needed on how data exchange will occur Formats may be made including components which are standardized and mandatory whereas some components which may be non-mandatory/optional/modifiable
Page 15 Section 2.1	1. Importance of Health Data Retention 2. Policy should cover the below requirements	Definition – 'procedure **for** violation or breach of the policy' may be substituted with 'procedure **in case of** violation or breach of the policy' The requirements may also include Savings by avoidance of generating multiple paper copies of the records for various purposes like seeking care, seeking insurance, settling bills etc.
Page 16 Section 2.2	Existing Guidelines for Health Data Retention in India	It is suggested to share the current international best practices compared to our practices as a learning from the countries who have already implemented guidelines
Page 18 Section 2.3.1	Generation and Exchange of Health Records	More clarity is sought if patient health data will not be stored centrally then how will this function with increasing number of providers shifting to cloud-based systems
Page 19 Section 2.3.3	Health Data Management Policy • Para 4 • Para 5	A clear interpretation is required on clause 26.6 w.r.t Health Data Management Policy It was suggested to use a robust cloud-based system also for the smaller diagnostic centers/clinics
Page 21 Section 3.1.2	Option 2 – Healthcare entities opting-in for ABDM	Apart from larger healthcare entities and insurers, who all can be opted-in if interested and if significant benefits would be provided to them e.g. highly subsidized govt approved data centers
Page 23 Section 3.2	Key Issues for Consultation	Suitable guidelines may be mentioned step-wise with incentivisation of every next step for the entities.
Page 24 Section 4.1	Retention Duration for Health Data	The proposed duration of data retention is recommended only for establishments that are obliged to store data locally and have no recourse to store them in cloud-based data servers. There should be a single, well-articulated data retention strategy
Page 25 Section 4.2	Storage and Maintenance of Health Data Retention	It is suggested that the HIMS system providers may be given a mandate that the data policies must be adhered to by their solutions. Non-compliant softwares may be de-licensed. In case of small clinics, a diluted guideline may be laid so the regulation does not become prohibitive for them.

Page 26 Section 4.2.2	Maintenance and Exchange of Health Data	The vendors to be assessed first for ensuring their compliance to avoid any breach is acceptable. Alongside, Government can also consider licensing the vendors who are compliant with the policy guidelines
Page 26 Section 4.3	Data Classification for Health Data	What is the minimum retention period for each type of health data collected and the proper ways to inform the relevant individuals in a timely and transparent manner? Also, the healthcare entities may be given the freedom to further subclassify the data classification heads mentioned in the policy, for their internal use, as required
Page 41 Section 5.4	Proposed Health Data Retention Governance Structure	Further information is required about the governance structure for the implementation of health data storage Also, whether there are any further restrictions on the use of anonymized data under the purview of ABDM, and if such restrictions will be consistent with the requirements of Personal Data Protection Bill?
Annexure	1. Whether there is a need for a Health Data Retention Policy and will Indian healthcare ecosystem benefit from such a Universal Data Retention Policy and what should be the key elements of this policy?	Yes, there is a need for Health Data Retention Policy as healthcare access and availability of resources, personnel, supply chains, and associated infrastructure is need of the hour. Readily accessible data has driven decision-making in high-income countries, and its lack thereof in other countries has hampered weaker healthcare systems. The Indian healthcare ecosystem will benefit from such a Universal Data Retention Policy. The key elements of the said policy must be:- (i) It must take into account the concerns of all relevant stakeholders; (ii) Ethical consideration of the data principal's rights; (iii) It must be transparent; (iv) It must not discriminate between the local and external players; (v) It must have a clear and liberal approach towards data localisation. (vi) Ownership of data and maintain high privacy standards Also, the major key elements from the Insurance stand-point should be to mandate the patient consent to share the data with patient's health insurance as well. Especially when the patient is authorizing the provider to collect money from Insurance against the delivered treatment or healthcare services. It access should not be limited to Government organizations, patients and Doctors for healthcare decision making. There is a need to improve the health information systems and make better use of data for quality, safety and performance gains and to advance medical treatments and practices only with strong health data governance frameworks can governments safely enable data use to improve health care quality and performance. Eight key data governance mechanisms support strengthening national health information systems and enabling multi-country

		projects to improve the public's health: 1. Health information system 2. Legal framework 3. Public communication 4. Certification or accreditation of processors. 5. Project approval process 6. Data de- identification 7. Data security and management 8. Data governance review cycle Benefits: Rights to health, Societal values toward health, health care quality & efficiency, and scientific discovery & innovation.
	2. How should the guiding principle of this policy be determined for the benefit of stakeholders and ease of adoption by varying sizes of entities deciding to opt in for ABDM?	Members recommended an accreditation process to ensure ease of adoption across the industry. Largely, the policy should help reduce healthcare cost and improve outcomes to benefit the population. From adoption standpoint, blanket coverage should be avoided. Providers or Enterprises empanelled with the Insurance/ Ayushman Bharat, or any other form of sponsorship should be the first target and later, attempt should be made to get the other entities to adopt it. The guiding principle of the proposed policy must be as follows:- (i) The policy must have a robust system of compliance and aligned with the data retention laws and rules or regulations etc.; (ii) The data retention practice of storing and managing personal health data and records must be for a designated purpose and period of retention may be decided accordingly. (iii) Since a large quantity of health data in the country is produced by the private sector including non-governmental organisations, colleges, and research institutes in the health sector, the government must, therefore, engage with private healthcare providers to facilitate access of this data for research which shall serve nothing but public interest; (iv) The proposed policy must provide guidance on providing ethical and practical access to such health data, particularly for researchers and smaller research institutions.
	3. As per Option 1, it has been proposed that the policy would be applicable to all healthcare entities from health data retention perspective. As per Option 2, the policy will be applicable only to entities participating in ABDM? Which would be a better option for the scope of the health data retention policy?	Option 1 may not be feasible to begin with in a large and diverse country like India. Therefore, the proposed policy should first focus on the entities participating in ABDM and gauge its success before expanding its scope to a much larger group. Alternatively, in phase 1 Option 2 should be the best option. In phase 2 Option 1 should be implemented. A phased approach will be pivotal to address implementation challenges as they unfold during the pilot phases and will help us identify various implementation challenges.

	4. How such a policy should be implemented given limitations in terms of infrastructure, capability, and sufficient understanding of health data in the healthcare ecosystem?	Given the country's large and diverse population and the limited infrastructure, the proposed policy should be rolled out in a phased manner with clear target groups and the latter must be given sufficient time to comply with the policy. Early adopters may be incentivized, with more and more partners on board, penalties can be imposed for non-compliant parties later. A Multi fold action would be critical for the success of execution encompassing the following three points: a) Provider's standpoint - The minimum efforts at the provider/enterprise's end with incentives would be the key factor. b) Patient stand point – It would be important to gain the confidence of the patient that this data is protected. Defaulters would be penalised such that their accreditation/Licencing would be at stake. c) Development of data Standards-Data standards are created to ensure that all parties use the same language and the same approach to sharing, storing, and interpreting information. In healthcare, standards make up the backbone of interoperability — or the ability of health systems to exchange medical data regardless of domain or software provider. It usually takes two to three years to develop a new standard and ensure that it works properly. The entire cycle typically consists of the following steps. Identifying business needs. Stakeholders (care providers, hospitals, health plans, or software vendors) identify business needs and submit requirements for a standard to a standard development organization or SDO. Workgroup collaboration. The task to develop a standard is assigned to a workgroup, that may include clinicians, healthcare administrators, health information professionals, software developers, and experts in regulatory requirements. The workgroup designs the standard draft along with the implementation plan. First balloting. Stakeholders give feedback on the draft and the workgroup incorporates it into the standards. Then, all participants vote for draft standards ready for piloting. Piloting. Healthcare systems and / or software vendors pilot the draft version of standards and provide feedback. Second balloting. The workgroup incorporates feedback from piloting and sends the draft for the second balloting. Upon receiving comments, the workgroup makes all necessary improvements. Finally, workgroup members and stakeholders vote to approve the draft as a normative standard for use. Implementation and maintenance. The SDO implements standards, fixes issues, and collects feedback to make improvements. Key standard developers and types of standards: There are over 40 SDOs operating in the US healthcare field and accredited by the American National Standards Institute (ANSI) or

		the International Organization of Standardization (ISO). The list of the largest and most recognized SDOs include: • HL7 — Health Level 7 International, • NCDPD — National Council for Prescription Drug Programs, • IHTSDO — International Health Terminology Standards Development Organizations, • Direct Trust Standards, • CDISC — Clinical Data Interchange Standards Consortium. Main standards created by SDOs and widely used across healthcare organizations fall into four large groups: terminology standards, content standards, data exchange or transport standards, and privacy and security standards.
	5. As ABDM has a provision for opt-out, in such a scenario what may be the possible implications from the perspective of health data retention?	In such a scenario, the policy should have a standardised approach to health data retention with relevant regulatory and legal safeguards. Electronic, Physical or Original Form of retention should continue to be acceptable for data retention and this shall serve the interest of clinical establishments and health care providers that may have decided to opt-out of ABDM. Also, opting out should have a higher penalty which in turn would force the enterprises to not even consider opting out. At the same time – Before opting out Enterprises should be mandated to convert the data in electronic format from audit standpoint. By doing this eventually the transition to digitization would be seamless. There should be data retention rules applicable for 10 years period even if opt out occurs or not
	6. Should a blanket retention duration be adopted for all health records in India or different schedules be defined as per a classification? Which is a better approach of retention?	Blanket retention duration is the best approach from every conceivable aspect currently. The usefulness of the data doesn't deteriorate over time. The storage costs are getting less and less with each passing day. Blanket retention duration from last visit should also work the best for all the states. The example of HIPAA for health data across the US is provided-In the US, the privacy and security standards for medical information are outlined by the Health Insurance Portability and Accountability Act (HIPAA). Among other things, it formalizes the use of ICD-10-CM, CPT, HCPCS, CDT, and NDC codes in medical billing. HIPAA Privacy Rule applies to individual medical records and other personal health information. It sets limits on the use and sharing of patient data for health plans, healthcare providers, and other players. The rule also empowers patients to freely access their medical records and request corrections to them.

		HIPAA Security Rule defines what electronic health information must be protected and what technologies, policies, and procedures must be in place to ensure the appropriate level of security. A 10-year retention rule is often applied It may become inherently exceedingly complex to ensure compliance with an extensively classified data at present. If at all we may use some very broad categories like OPD records, IPD records, Surgical records, Death records etc. to begin with. Granularity may be built in as we have more users onboarded and more user comfort.
	7. How granular should data classification be? Is more granularity required beyond that presented in the sections above? Addressing this aspect of the Health Data Retention Policy would help assess whether minimalist data classification – pertaining only to inpatients and outpatients - would suffice the purpose of health data retention. A minimalist data classification would have both advantages and disadvantages. Please suggest your view in this regard.	We recommend complete granularity on Terminology of standards and data classification as below. Health data may be exchanged without terminology standards, but there's no guarantee that all parties will be able to understand and use it. The absence of a unified vocabulary leads to miscommunication, and in healthcare it can literally be a matter of life and death. To avoid ambiguity and enhance the clarity of content, healthcare systems rely on code sets and classification systems representing health concepts. CD-10-CM codes for diagnoses. The ICD-10, Clinical Modification (CM) is the US version of the International Classification of Diseases, created and maintained by the World Health Organization (WHO). In the United States, ICD codes are revised by the Centres for Medicare and Medical Services (CMS) and the National Center for Health Statistics (NCHS). In October 2020, the 10th revision of the code replaced the previous ICD-9-CM version. It contains over 500 updates, including new codes for vaping-related disorders and COVID-19. The number of codes in the new version amounts to 68,000. Globally, Hospitals mainly use these codes for billing and reimbursement. Nationally and globally, the ICD serves as a universal tool to track morbidity and mortality statistics. Under the ICD-10-CM, every disease or health condition is assigned a unique code three to seven characters long. he first three elements represent a unique category, the second three digits describe aetiology, anatomic site, severity, and other vital details, while the seventh character — or extension — specifies an episode of care for injuries, poisonings, and other conditions with external causes. In 2022, the 11th revision of ICD codes will take effect, adding two numbers for a more detailed diagnosis. The Current Procedure Terminology or CPT is a code system maintained by the American Medical Association (AMA). It describes outpatient services and procedures for treatment tracking and billing purposes. Each code contains five digits or four digits and one letter and is assigned to a particular procedure. It is essential for getting payments from health plans. In a bill for reimbursement, a CPT number is paired with an ICD-10-CM code. If the service is not relevant to the diagnosis, the insurance company can reject the claim. Say, a doctor is not supposed to send a patient with stomach ulcers for a chest X-ray. Healthcare Common Procedure Coding System is an extended version of the CPT used to bill Medicare, Medicaid, and other health plans.

		HCPCS (pronounced hick-picks) has two levels. Level 1 duplicates CPT codes and identifies services and procedures ordered or delivered by physicians. Level 2 contains codes with one letter followed by four numbers. Supported by the CMS, it identifies services, supplies, and products not included in the CPT — like durable medical equipment, prosthetics, or drugs. Current Dental Terminology is developed and maintained by the American Dental Association (ADA) for electronic communication of dental services. Basically, CDT code covers oral health and plays the same role in dentistry as CPT code in general healthcare. SNOMED CT stands for Systematized Nomenclature of Medicine – Clinical Terms and is owned by the IHTSDO. Recognized as a common language for medical terms in 50 countries, it enables care providers to accurately input patient data to the EHR system, aggregate information, and share it across health systems. SNOMED CT encompasses far more concepts than ICD-10-CT. While the latter is limited to disease classification, the former covers symptoms, clinical findings, procedures, situations, substances, devices, and family history — in other words, almost any aspect related to healthcare delivery. Logical Observation Identifiers Names and Codes or LOINC is a set of identifiers for laboratory tests and clinical observations. It was created by the Regenstrief Institute with HL7 interoperability standards in mind. It covers the entire scope of existing lab tests and a broad range of clinical concepts and measurements. Backed by the American Clinical Laboratory Association (ACLA) and the College of American Pathologists, LOINC codes are widely adopted by large commercial laboratories, hospitals, research institutions, and government agencies related to healthcare. The National Drug Code (NDC) is a unique digit identifier for human medications in the US. The coding system was created to facilitate processing of claims and drug data sharing. Currently, the codes are published on all drug packages and inserts. The code contains three segments. The first five numbers represent a labeller (manufacturer, repackage, or distributor) and are assigned by the US Food and Drug Administration (FDA). The next two sections — 3-digit product and 2-digit package codes — are created by the labeller.
	8. How in your view will a detailed granular data classification enable a better health data retention? Please suggest your view on the classification of health record types as proposed above or if any further granularity is necessary and what are the overarching benefits for different stakeholders?	Content or document standards dictate the structure of electronic documents and types of data they must contain. They ensure that medical data is properly organized and represented in a clear and easy to understand form. • C-CDA for arranging clinical Documents-Consolidated Clinical Document Architecture designed by HL7 is the primary framework for creating electronic clinical documents in the US. It specifies how to structure medical records and how to encode data elements for exchange. • The standard allows for capturing, storing, accessing, displaying, and transmitting both structured and unstructured information, including texts, images, and sounds. Care providers can use different C-CDA document templates satisfying various data exchange scenarios —

		such as the following: The Consultation Note template representing a response to the request of a practitioner for an opinion from another practitioner; the Continuity of Care Document (CCD) template to capture content that is critical to effectively continue care. This includes family history, allergies, information on recent hospital encounters. The primary purpose of the CCD document is to exchange data on a patient being transferred from one healthcare setting to another; the Discharge Summary template to capture information about a patient's admission to a hospital and the continuation of care after discharge; and the Diagnostic Imaging Report template to convey an interpretation of image data. C-CDA documents contain a human-readable part that can be displayed on a web browser, and a machine-readable Extensible Markup Language (XML) part intended for automated data processing.HL7 version 2 and 3 for packaging data. A key difference between an HL7 document (C-CDA) and an HL7 message is that the former is basically an electronic representation of a physical document while the latter is a packet of data sent from one system to another.US healthcare relies primarily on version 2 and 2.x messaging that is supported by every EHR system. Version 3 is widely adopted across the world, but not in the USA. • Each HL7 message does its specific job identified by its name that contains 3 characters. The widely-used message types are-VXU messages to send vaccination history, ADT messages so send demographic updates, QBP messages to request immunization history, and RSP messages to return immunization history.HL7 version 2 message • Each message is composed of several string-like segments, each starting with a 3-character name. Segments, in turn, contain fields that carry data elements. • US Core Data for Interoperability or USCDI is not a document or messaging standard, but a mandatory set of content pieces' hospitals must share on a patient's request via APIs. The most granular parts of information — data elements — are aggregated in larger data classes like Patient Demographics, Health Concerns, Medications, Procedures, and more. In 2020, the Office of the National Coordinator for Healthcare IT (the ONC) finalized the first version of the USCDI standard. The second release will be available for public feedback in 2021. The granularity in classification is sufficient along with a scope for exceptions. More granular the data, more it benefits the stakeholders at the same time requires effort in maintaining it

	9. What should be the ideal duration for these different health data types?	It will depend upon the different health data types. It may be noted that any patient health information of the past can prove useful to provide the best available treatment for any ailments. Furthermore, storing data in electronic form does away with many of the significant logistical constraints, such as safe and secure storage space of such data in physical form. Also, health data of any kind forms a very good basis for future advancement of medical and diagnostic techniques. A detailed granular health data classification should not only be limited to the improvement of treatment regime but also to provide better healthcare within sanctioned GDP 10 years
	10. While ABDM proposes that all entities opting to join NDHE must be able to retain health data in electronic format, and other entities of the healthcare ecosystem may consider physical or original formats, what options should be made allowable as part of the policy being proposed? Health data records can be only digital, only physical, or combination in any hospital. Accordingly, the question arises whether all the above considerations should fall under one policy or under separate/independent policies?	Considering that this is going to be mammoth endeavour, the focus to begin with should be in creating the perfect framework for retaining health data in the electronic format in accordance with the requirements & objectives of the ABDM. The framework for the electronic format should be such that it is adaptable that can assimilate future convergence of policies/framework for physical or original formats. Such a strategy shall also allow a smooth and seamless transition from the current practice to the one that is eventually aimed for under the ABDM. A single policy as an overarching policy should be devised with clear areas of demarcation for separate identification of other areas/sub sections Moreover, scanned records may not be economically viable and would require a large the volume of storage space needed as against pure digital records. Digital health records for storage should be promoted
	11. Should there be a provision for extension of duration or retention of health data under the policy being proposed? What considerations should be made in defining the guidelines, allowing for such an extension?	Yes, there should be for personal health data. Ideally, health data should be retained for as long as it is logistically possible. Such data being stored in the electronic form can also serve as a very useful repository for health & medical research of the future. It is well established that historical data can prove to be helpful reference materials that supports advancement in specialised medical & diagnostic tools/techniques. Since the storage of data in electronic form is logistically more convenient and cost effective than physical storage, the current minimum retention period prescribed under the extant guidelines cannot be deemed appropriate. Therefore, the framework should allow for the lengthiest minimum retention period possible. However, the proposed framework should ensure that interest of the data principal should be paramount and therefore, always protected always. Additional consent of the data principal should be obtained to extend the period of retention after the minimum retention period. Further, such data can only be made available for research or otherwise in an anonymized form. These policies/guidelines may be reviewed regularly with incorporation of best global and local practises. By default, there should be defined extension period.

		Beyond the defined extension period further extension should not be permitted. The only exception to be considered is listed below a) Clinical trials b) Medico legal cases c) IRDA specified Insurance requirement
	12. Who shall have the apex authority to oversee and implement health data retention? Which entity as part of the ecosystem should be rolling out this policy at the macro-level?	For a uniform application of the strict standards that the framework proposes to lay down, there should one apex authority for the entire country (eg NHA) However, considering the diversity and the federal structure of the country, any such apex authority should have representations from each state, each having equal say in the affairs of the authority. It should also allow representations from the public and from relevant industries to ensure a wholistic approach in all decision-making processes. Regional or satellite offices may also be set-up for such an authority to make it accessible to all concerned in the country. Optimal decision making about potential statistical and research uses of personal health data can only be achieved if there is an overarching data governance framework in the country that has been aligned to minimise societal risks and to maximise societal benefits from data uses.
	13. How can smaller clinics or centres, both public and private, build capability in a timely and cost-efficient manner to take responsibility of data retention for long time periods?	International collaboration in this dynamic area is also essential. Sharing information about best practices and lessons learned in health data governance needs to circulate widely; and movement toward common best practices should be supported, so that multi-country statistical and research projects that benefit the public's health are feasible. This ideally should be out of scope in the initial Phase (phase 1) as mentioned in one of the responses above. In Phase 2 the price capping should help seamless transition. The reason is because of the government mandate the digitalization would be in demand and the monopolist behaviour of the suppliers may seep in. So strict vigilance on the adherence of the EHR/PHR will play critical role. The framework should allow such smaller clinics to pool resources to set-up a common accredited facility. Alternatively, the framework can encourage accredited third-party service providers to set up common facilities which any clinics or centres can utilize for a fee. Mobile friendly off-line capability can also be provided to such centerers

	14. How can business continuity be ensured in case of fall of the establishment, platform or service providers?	Members suggested a regular update of the digital platform and maintenance will prevent this. Not only that but the efficient processes at the provider and Insurance end will lead to seamless business continuity. Health data standards challenges and possible solutions to them. The following are some key areas to elaborate on: • Transformation of diagnoses, procedures, services, treatment plans, and other concepts into medical codes involves a lot of manual work, performed by specially trained professionals. Today coders rely on computer-assisted coding systems. However, the speed and accuracy of the translating process are far from perfect. • To that end, big hopes are pinned on AI-fuelled software capable of identifying correct codes and suggesting them for experts to review. Currently, such intelligent systems make coding faster, however, they can't fully replace humans and automate the entire process. • Need for mapping between codes-Each code in healthcare does its own job: SNOMED enables physicians to draw a detailed clinical picture of a patient treated, ICD-10 briefly describes diagnoses, CPT summarizes services. • Standard development organizations try different options to address mapping challenges. Say, SNOMED CT runs Mapping Project Group that is working on automated methods of linking two terminologies. • Lack of compatibility between old and new standards-To comply with existing interoperability rules, hospitals must ensure the availability of content defined by USCDI through FHIR-based APIs. But let's face the truth: Most EHR systems were built with a view to old standards. Some of them can do no more than importing and exporting HL7 v2 messages. Others mainly rely on C-CDA documents. • No two-way communication between patients and EHRs-FHIR standard allows patients to get health data via apps of their choice. However, this is a one-way street as EHRs grant read-only access to their systems. A person can request information but have no means to control and change it through the app. • Many industry experts argue that the lack of two-way communication between medical apps and EHR systems is the next biggest challenge for healthcare. And sooner or later, it will require creating new data standards. How can stakeholders impact the situation and contribute to better communication between all parties? The answer is to actively participate in standard development processes, submit feedback, and share their ideas with the standards community.

		Also, only accredited platforms and service providers should be allowed to participate. If in the event, an establishment or service provider are unable to continue its participation, the framework should allow another accredited party to take over records from such parties with consent of the data principal. The party taking over the records should be bound to the same terms and conditions as the original party.
	15. Will the governance model as per Health Data Management Policy be sufficient for the retention policy?	Current Governance mechanism is dependent on Human intervention. Retention policy may need revision to identify the defaulters automatically. This will help the audits to be done more frequently and identify the potential damage in early stage. It will be important to put in place a Data governance framework aligned to maximise benefits and minimise risks for the following areas: a) Health information system b) Legal framework c) Public communication d) Certification or accreditation of process e) Project approval process f) Data de- identification g) Data security and management h) Data governance review cycle For better and strict enforceability, the governance model should be made statutorily relevant.
	16. How will the policy regulation be enforced and what should be the structure across relevant entities responsible for retaining the health data?1	For better and strict enforceability, the governance model or the policy regulation should be statutorily relevant. However, in the initial and development phase, the participants may be contractually bound to follow the governance model and such contracts should contain strict penal provisions for any breach of duty and deviation from the laid down model and security obligations. Furthermore, only accredited parties may be allowed to participate. Such accreditation should be on renewable basis and for a specific period only and be capable of being withdrawn in case of any breach of their obligations or rights of the data principals. Modalities should be built in for the relevant authority to be able to blacklist a firm breaching its obligations for a specified period as well. To avoid complication, it should be enforced uniformly across all the states. Members also suggested that the responsibility of maintaining data should be a restricted to 3 level Level 1 – Storage responsibility Level 2 – Transactional level responsibility. Level 3 – Compliance and audit (State level from NDHM stand

		point) Internal auditors from Individual hospital stand point) Further, legal frameworks continue to be renewed to reflect societal values and to address the requirements of a changing health information landscape. On-going collaboration among stakeholders in the development and use of health data, including legal experts, regulators, statisticians, IT professionals, policy makers, researchers, providers and patients, is essential to developing balanced policy decisions
	17 How should the implementation of the policy be done in case the policy is made applicable for the ecosystem beyond ABDM?	It should be undertaken phase-wise and the next phase should be considered only after all flaws and inherent problems identified in the initial phases are rectified and ironed out. • Phase 1 – All Tertiary care hospitals in tier 1 cities should be targeted first. • In phase 2 – It should be extended to the secondary care hospitals. • In phase 3 – All secondary care and Tertiary care centres to be covered. • Phase 4 – It should be extended to the Primary care centres and independent clinics and minimising societal risks. Furthermore, legal rights of the parties who have not consented to participate in the ABDM eco-system may have to be taken into consideration as any legal challenges in court of law will only delay implementation of this flagship and landmark scheme. Further, a resource sharing model can be used on a cost sharing basis between facilities with differing infrastructure levels
	18. Is there an alternative model or policy approach which could be considered?	The current approach seems appropriate. Moreover, it is advisable to conduct a multi-country study and ensure that the international best practices which are feasible in the Indian context, be studied, considered, and adapted for the country.