Regulatory Landscape

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Challenges from Regulatory perspective

- **Software as a Medical Device**
  - A. Software development lifecycle.
  - B. Product safety and security.
  - C. Data collection, analysis and privacy.

- **Clinical Decision Support Software**
  - A. Development lifecycle.
  - B. Product safety and accuracy.
  - C. Data analysis.

- **Artificial Intelligence/Machine Learning Powered Digital Health Solutions**
  - A. Lack of precision.
  - B. Lack of interpretation.
  - C. Irregularity in analytics.
  - D. Reliance.
  - E. Transparency and governance.
  - F. Long-term cost.

- **Big Data Analytics**
  - A. Lack of interpretation and understanding.
  - B. Misinterpretation of results.
  - C. Lack of training skills.

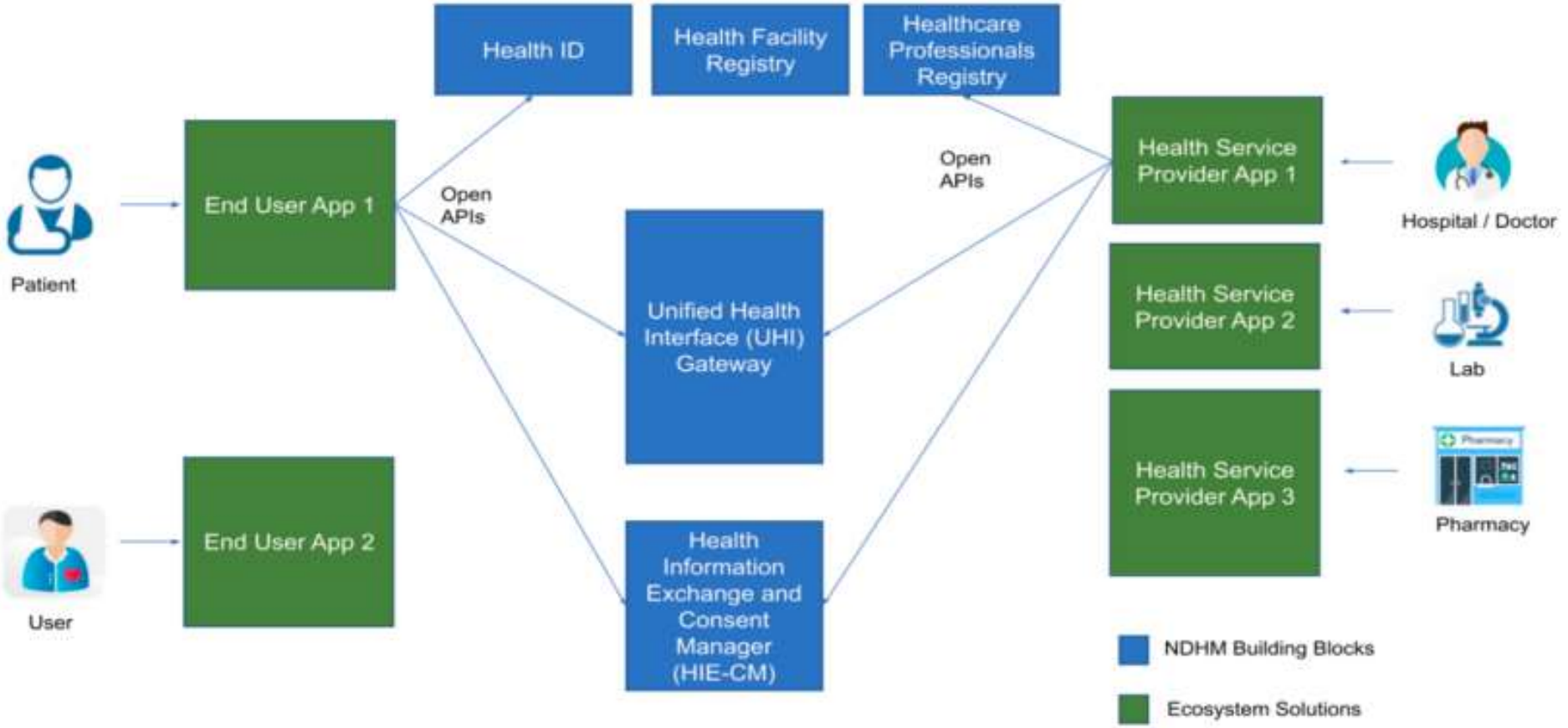
National Digital Health Mission (NDHM) –ABDM

UHI Architecture

UHI will use several NDHM building blocks to enable the interoperable layer for digital health services

national health authority
Ministry of Health and Family Welfare
Government of India

Exchange of Requests and Data in UHI



https://abdm.gov.in:8081/uploads/Presentation_for_UHI_a7037b79d3.pdf

DPDP ACT 2023

- AUGUST 11, 2023, INDIA PASSED THE DIGITAL PERSONAL DATA PROTECTION ACT, 2023 (DPDP ACT).
- THIS NEW LAW GOVERNS HOW PERSONAL DATA IS HANDLED IN INDIA.

- IT AIMS TO PROTECT PEOPLE'S PRIVACY WHILE ALSO ESTABLISHING A FRAMEWORK FOR DATA ACCOUNTABILITY AND GOVERNANCE.

KEY LEGAL OR REGULATORY ISSUES TO CONSIDER FOR USE OF PERSONAL DATA

- MOHFW is promoting its adoption by making standards such as the SYSTEMATIZED NOMENCLATURE OF MEDICINE–CLINICAL TERMINOLOGY free to use in india and establishing an interim national release centre to manage the clinical terminology standard, which is gaining global acceptance among healthcare it stakeholder communities.
- THE MOHFW plans to promote and adopt e-health standards, enforce privacy and security measures for electronic health data, and regulate the storage and exchange of EHRS.

Laws/Regulations directly regulating AI (the "AI Regulations")

Currently, there are no specific codified laws, statutory rules or regulations in India that directly regulate AI.

Nevertheless, various frameworks are being formulated to guide the regulation of AI, including:

- The National Strategy for Artificial Intelligence (June 2018),[1] which aims to establish a strong basis for future regulation of AI in India.
- The Principles for Responsible AI (February 2021),[2] which serve as India's roadmap for the creation of an ethical, responsible AI ecosystem across sectors.
- The Operationalizing Principles for Responsible AI (August 2021),[3] which emphasizes the need for regulatory and policy interventions, capacity building and incentivizing ethics by design with regards to AI.

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Other laws affecting AI

There are various laws that do not directly seek to regulate AI, but may affect the development or use of AI in India. A non-exhaustive list of key examples includes:

- The Information Technology Act 2000,[4] together with the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules 2011. This is set to be replaced by the Digital India Act 2023 (currently in draft form).
- The Digital Personal Data Protection Act 2023 which, at the time of publication, is yet to come into force.[5]

These laws are designed to be technology-agnostic (i.e., the principles in these laws are intended to apply, regardless of which technologies are in use).

Intellectual property laws may affect several aspects of AI development and use.

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Key compliance requirements

As noted above, there are currently no specific laws or regulations in India that directly regulate AI.

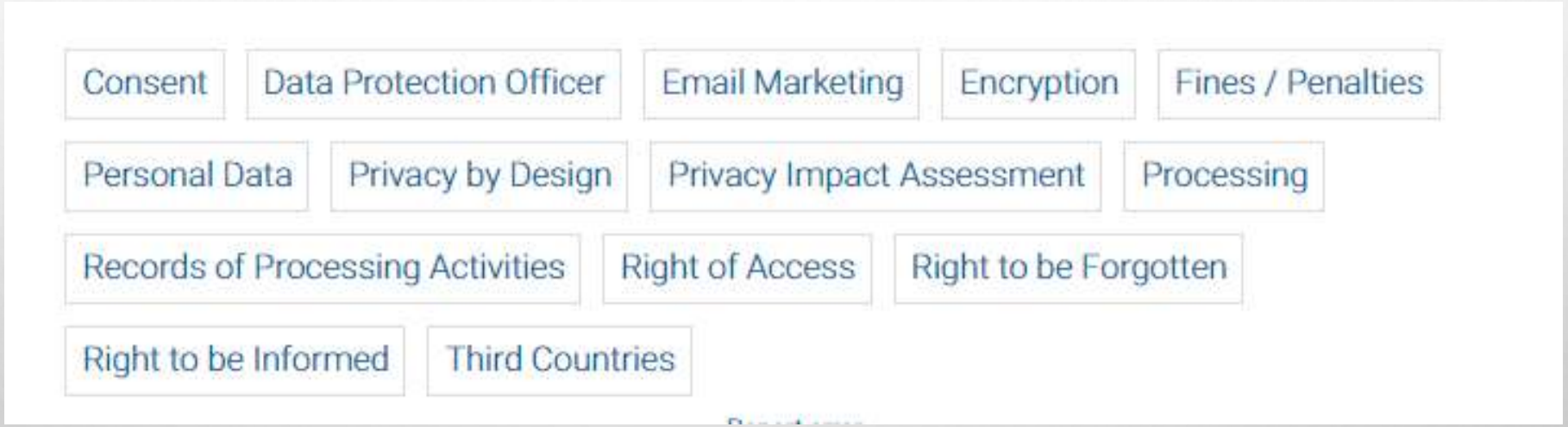
Nevertheless, the Principles for Responsible AI[11] identify the following broad principles for responsible management of AI, which can be leveraged by relevant stakeholders in India:

- The principle of safety and reliability
- The principle of equality
- The principle of inclusivity and non-discrimination
- The principle of privacy and security
- The principle of transparency
- The principle of accountability
- The principle of protection and reinforcement of positive human values

- **"SOFTWARE INTENDED TO BE USED FOR ONE OR MORE MEDICAL PURPOSES THAT PERFORM THESE PURPOSES WITHOUT BEING PART OF A HARDWARE MEDICAL DEVICE."**

General Data Protection Regulation

GDPR



THANK YOU