PD233: Design of Biomedical Devices and Systems

(Lecture-16)

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Course Website:
http://cpdm.iisc.ac.in/utsaah/courses/

- Digital Healthcare
- NDHB
- Ayushman Bharat
  - PM-JAY
  - Wellness Centres

Digital Health

Digital health is the application of **software or hardware**, often using mobile smartphone or sensor technologies to **improve patient or population health and health care delivery**.

Web-based analysis

E-mail

Mobile phones and applications

Text messages

Wearable devices

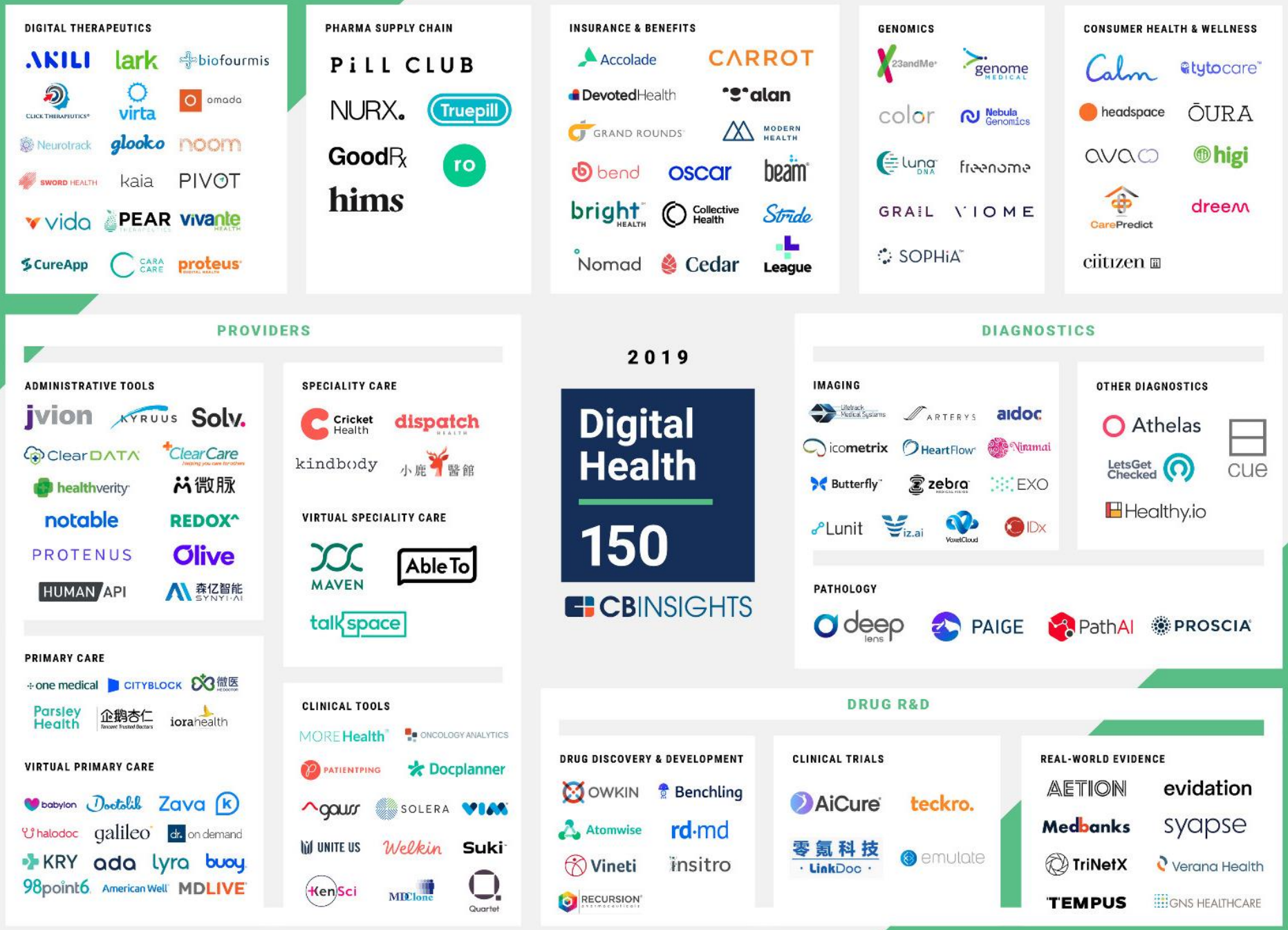
Clinic or remote monitoring sensors

Telemedicine

Electronics Health Records
Clinical Decision Support Systems
Electronic Prescribing Systems

Connected Healthcare

*Chen et al., "Characteristics of Digital Health Studies Registered in ClinicalTrials.gov". JAMA Internal Medicine. **179** (6): 838–840.*


DIGITAL THERAPEUTICS
AKILI
lark
biofourmis
CLICK THERAPEUTICS
virta
omada
Neurotrack
glooko
noom
SWORD HEALTH
kaia
PIVOT
vida
PEAR THERAPEUTICS
vivante
CureApp
CARA CARE
proteus
PHARMA SUPPLY CHAIN
PiLL CLUB
NURX.
Truepill
GoodRx
ro
hims
INSURANCE & BENEFITS
Accolade
CARROT
DevotedHealth
alan
GRAND ROUNDS
MODERN HEALTH
bend
oscar
beam
bright HEALTH
Collective Health
Stride
Nomad
Cedar
League
GENOMICS
23andMe
genome MEDICAL
color
Nebula Genomics
luna DNA
freenome
GRAIL
VIOME
SOPHiA
CONSUMER HEALTH & WELLNESS
Calm
tytocare
headspace
ŌURA
ava
higi
CarePredict
dreem
ciitizen
PROVIDERS
ADMINISTRATIVE TOOLS
jvion
KYRUUS
Solv.
ClearDATA
ClearCare
healthverity
微脉
notable
REDOX
PROTENUS
Olive
HUMAN API
森亿智能 SYNYI·AI
SPECIALITY CARE
Cricket Health
dispatch HEALTH
kindbody
小鹿医馆
VIRTUAL SPECIALITY CARE
MAVEN
AbleTo
talkspace
PRIMARY CARE
one medical
CITYBLOCK
微医
Parsley Health
企鹅杏仁
iorahealth
VIRTUAL PRIMARY CARE
babylon
Doctolib
Zava
halodoc
galileo
on demand
KRY
ada
lyra
buoy
98point6
American Well
MDLIVE
CLINICAL TOOLS
MORE Health
ONCOLOGY ANALYTICS
PATIENTPING
Docplanner
gauss
SOLERA
UNITE US
Welkin
Suki
KenSci
MDClone
Quartet
2019
Digital Health
150
CBINSIGHTS
DIAGNOSTICS
IMAGING
Lifetrack Medical Systems
ARTERYS
aidoc
icometrix
HeartFlow
Niramai
Butterfly
zebra
EXO
Lunit
iz.ai
VoxelCloud
IDx
OTHER DIAGNOSTICS
Athelas
LetsGet Checked
cue
Healthy.io
PATHOLOGY
deep lens
PAIGE
PathAI
PROSCIA
DRUG R&D
DRUG DISCOVERY & DEVELOPMENT
OWKIN
Benchling
Atomwise
rd·md
Vineti
insitro
RECURSION
CLINICAL TRIALS
AiCure
teckro.
零氪科技 · LinkDoc ·
emulate
REAL-WORLD EVIDENCE
AETION
evidation
Medbanks
syapse
TriNetX
Verana Health
TEMPUS
GNS HEALTHCARE

Challenges in Digital Healthcare

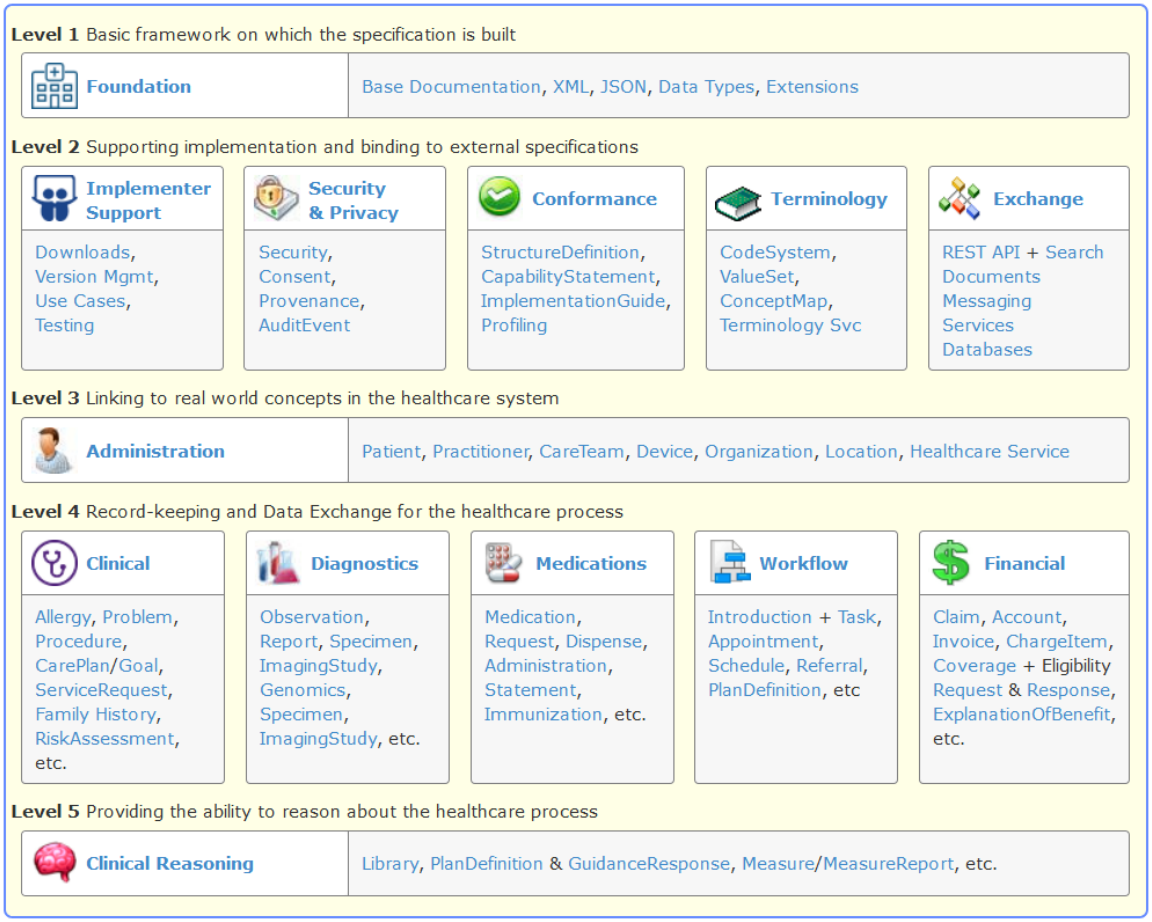
- Technology acceptance by healthcare professionals
- Interoperability and Portability
- Privacy
- Cyber-Security
- Largescale Data Handling & Analysis

Interoperability and Portability

- DICOM [1] – Digital Imaging and Communication is Medicine Standard
  - Started in 1980s for easy exchange of medical images
- HL7- FIHR [2]
  - Build on web-standard technologies (XML,JSON etc.)

(1) https://www.dicomstandard.org/
(2) https://www.hl7.org/fhir/

FIHR – Fast Healthcare Interoperability Resources



FHIR Patient Record Example

```
<Patient xmlns="http://hl7.org/fhir">
  <id value="glossy"/>
  <meta>
    <lastUpdated value="2014-11-13T11:41:00+11:00"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456. Male, 24-Sept 1932</p>
    </div>
  </text>
  <extension url="http://example.org/StructureDefinition/trials">
    <valueCode value="renal"/>
  </extension>
  <identifier>
    <use value="usual"/>
    <type>
      <coding>
        <system value="http://hl7.org/fhir/v2/0203"/>
        <code value="MR"/>
      </coding>
    </type>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <active value="true"/>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender value="male"/>
  <birthDate value="1932-09-24"/>
  <careProvider>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </careProvider>
</Patient>
```

Resource Identity & Metadata

Human Readable Summary

Extension with URL to definition

Standard Data:

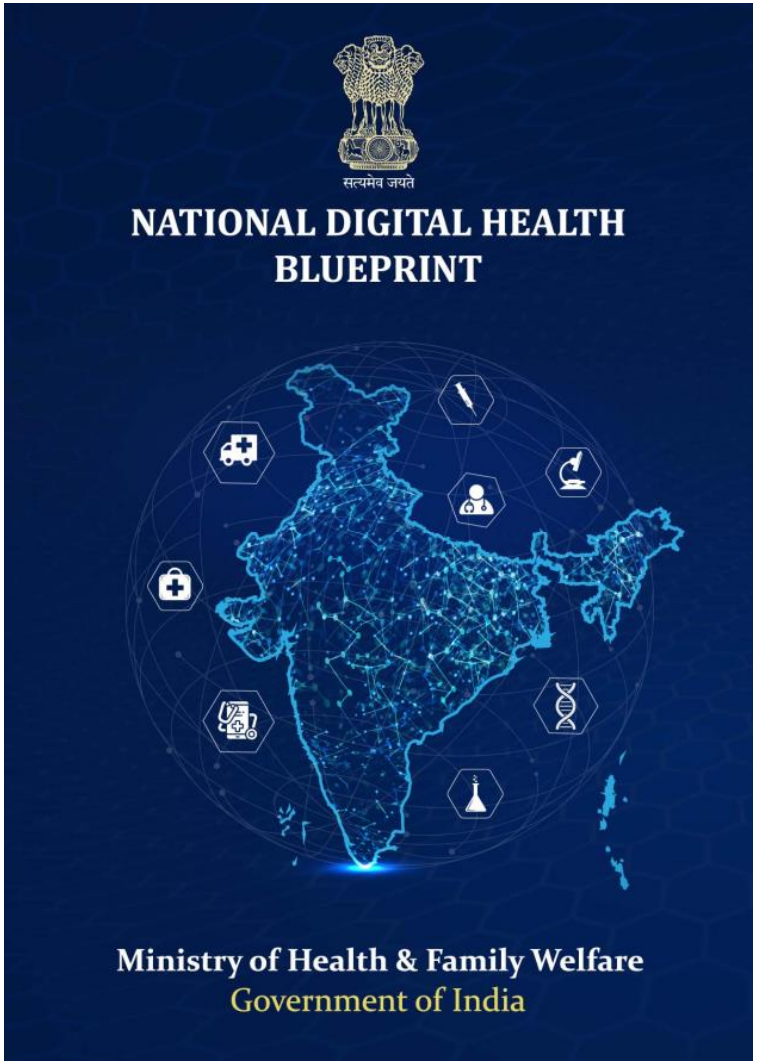
- MRN
- Name
- Gender
- Birth Date
- Provider

Privacy and Cyber-Security

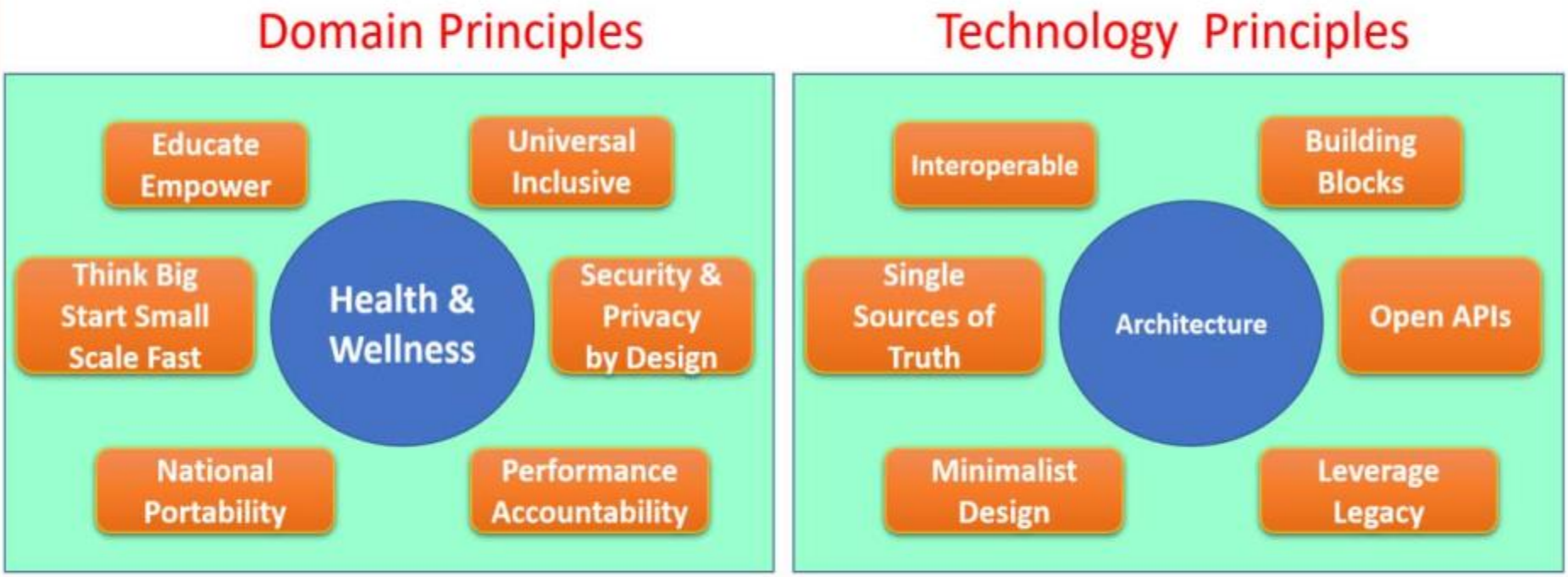
National Digital Health Blueprint

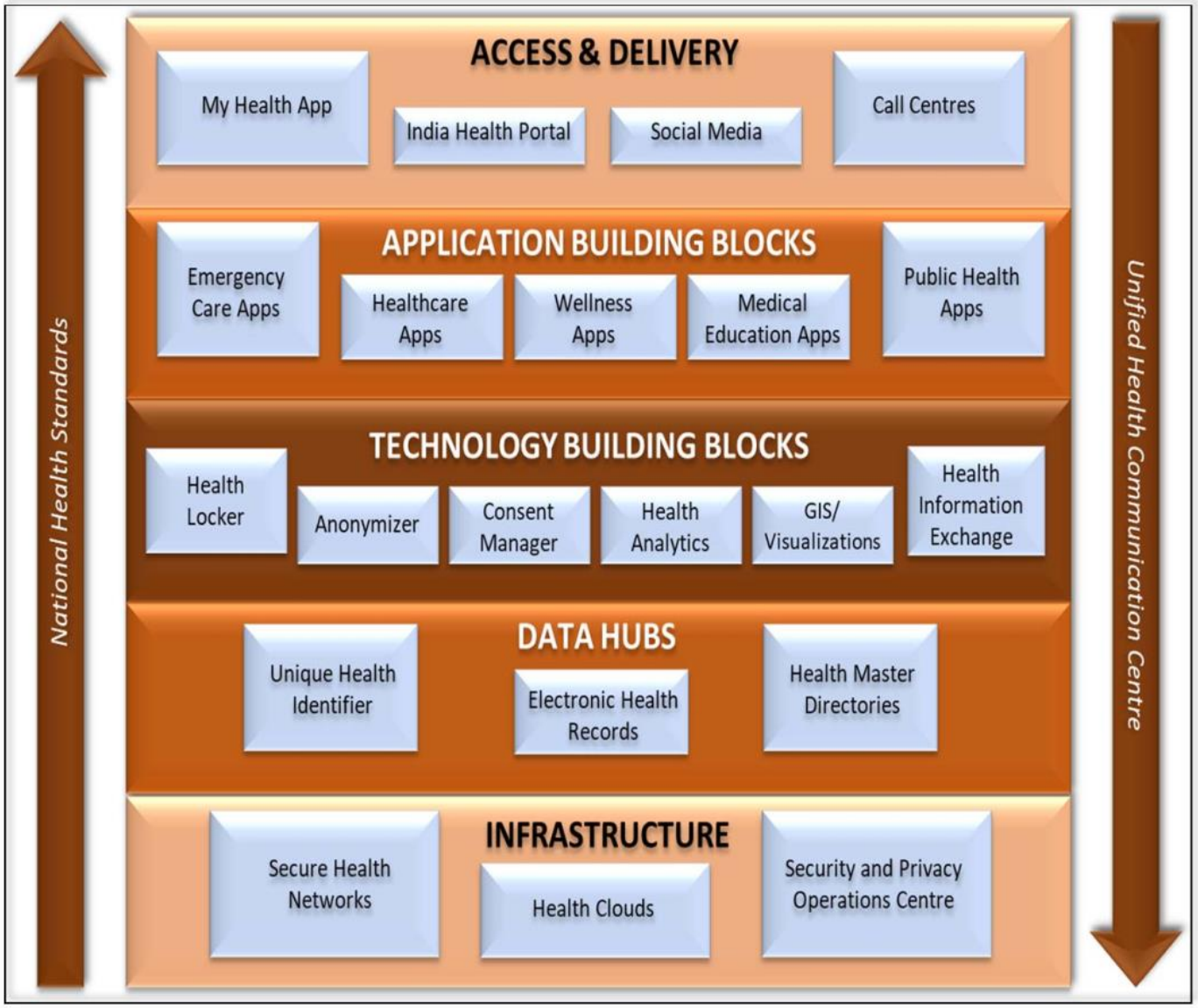
- Final Version Release on 9th Nov 2019
- Framework created to allow implementation of National Health Stack proposed by NITI Aayog

Eco-system not a system



Principles of NDHM





Building Blocks of NDHB

Recommended Standards by NDHB

- Consent Management

Purpose	Recommended Standard
Consent Management	ISO/TS 17975:2015 Health Informatics - Principles and data requirements for consent in the collection, Use or Disclosure of personal health information
Consent Framework	Electronic Consent Framework (Technology Specifications v1.1) with its subsequent revision(s) published by MeitY.

- Content and Interoperability
  - Technical interoperability
  - Semantic and syntactic interoperability

Content and Interoperability Standards

Purpose	Recommended Standard
Structured Clinical Information Exchange	FHIR Release 4 (subject to section 3.4.2) (with any future errata(s))
Still Images / Documents Audio / Video	Still Image: JPEG Document/ Scan: PDF A-2 Audio: MP3 / OGG Video: MP4 / MOV (embedded as binary content in relevant FHIR resource)
Diagnostic Images (Radiology including CT, MRI, PET, Nuclear Medicine / US / Pathology), Waveforms (e.g. ECG)	DICOM PS3.0-2015c (embedded as binary content in relevant FHIR resource)
Terminology/ Vocabulary	SNOMED CT (for all clinical terminology requirements in health records)
Coding System	WHO ICD-10 (for statistical classification of diseases and related health problems) LOINC (for observation, measurement, test-panels, test items and units)

Recommended Standards by NDHB

- Privacy and Security

Purpose	Recommended Standards
Security	Digital Certificate, TLS / SSL, SHA-256, AES-256
Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

- Additional requirements

Immutability	Record once created cannot be deleted or modified without follow due process.
Versioning	Any record created may be 'amended' with new version numbe same records with any changes (previous records to be mar inactive) with only highest version considered active.
Non-Repudiation	All created records must be traceable to its creator unambiguously
Audit Log	All creation, amendments, access of records should be audit logge manner that it is verifiable and reliable
Patient Control	Patient should be able to access/view own health records anyt and control access by others.

EHR Standards for India 2016 should be incorporated.

Recommended Standards by NDHB

- Patient Safety and Data Quality
- Quality in healthcare services and safety of electrical-medical equipment are of utmost importance in the NDHB.
- Electrical-medical equipment used in the NDHE should be safe for the patient and para-medical personnel and against safety hazards like electric shock,harmful radiation, excessive temperature, implosion, mechanical instability and fire.
- Bureau of Indian Standard has published 38 standards in this area. These standards are either an adoption or technical equivalent of the related IEC standard. The work on some additional standards is ongoing in IEC/TC 62.

NDHB Action Plan:

Year 1 (Planning & stabilizing NDHM)	Year 2 (Pre-requisite infrastructure)	Year 3 (Execution)	Year 4 (Analytics & Innovation)	Year 5 (Sustenance & Research)
▯ Approval of National Digital Health Mission (NDHM) and its operationalization. ▯ Design and development of federated enterprise architecture, adopting Agile IndEA Framework. ▯ Design of core building blocks of NDHB (to be identified) and defining the standard interfaces ▯ Assessment of legacy systems for conformity with NDHB. ▯ Design and notification of NDHM Security & Privacy Policies ▯ Design and development of consent management framework	▯ Designing and establishing Unique Health Identifier(UHID) , directories of health professionals & health institutions ▯ Design and implement federated health cloud & secure network infrastructure. ▯ Enhancing of legacy systems to conform to NDHB Principles, and interoperable ▯ Implementation of a plan for adoption of health informatics standards including Electronic Health Record (EHR) for citizen with family folders	▯ Establishing Health Information Exchange (HIE) ▯ Design, develop and launch Common Applications ▯ Establish health app store ▯ Design and implement it building plan ▯ Establish the repository of standards, API's, metadata and data dictionaries	▯ Implementation of artificial intelligence enabled clinical decision support systems ▯ Designing and developing health analytics platform ▯ Design and develop anonymization methodology for health data analytics Establish Security and Privacy Operations Centre (SOC), Network Operations Centre (NOC) and Privacy Operations Centre (POC) ▯ Design and notification of Framework for value-added services	▯ Ensuring continuum of care ▯ Continued Research ▯ Sustenance of operations