Office of the Principal Scientific Adviser
to the Government of India

RICH
Research and Innovation
Circle of Hyderabad

REPORT ON
HEALTH DATA STANDARDIZATION AND TECHNOLOGY VALIDATION OF HEALTHCARE TECHNOLOGIES

1. EXECUTIVE SUMMARY

This report outlines the existing health data standards and methods for validating healthcare technologies, while also emphasizing the technology readiness levels across various healthcare domains.

The Ayushman Bharat Digital Mission (ABDM) aims to establish a platform for India's integrated digital healthcare infrastructure. The National Health Authority (NHA) is responsible for designing the strategy, building the technological infrastructure, and implementing ABDM. A key aspect of the platform rollout is the adoption of digital solutions to capture patient information, supporting integrated digital healthcare. Healthcare providers, including hospitals, labs, and clinics, will need to implement HMIS, LMIS, and Clinic solutions to prioritize patient safety and healthcare quality based on national and international standards.

The National Biopharma Mission is an Industry-Academia Collaborative Mission of the Department of Biotechnology (DBT) focused on accelerating the early development of biopharmaceuticals. Implemented by the Biotechnology Research Assistance Council (BIRAC), its primary goal is to make India a hub for designing and developing novel, affordable, and effective biopharmaceutical products and solutions. This initiative aims to enhance India's innovation, research, and product development capabilities, particularly in vaccines, biologics, and medical devices to address public health challenges.

BIRAC's Technology Readiness Levels (TRLs) measure the maturity of core technologies within a program from ideation to commercial readiness. The scale consists of nine levels, indicating progress from conceptualization to market introduction, including proof of concepts, prototype development, and regulatory clearances.

Clinical Trial Networks, with Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology (CHOORD) aims to bolster India's capacity to conduct clinical trials for products in these areas, comprising five networks with 36 organizations across 18 states. Each network includes at least six hospital-based investigational sites.

India's government is committed to extending healthcare services to its 1.38 billion population through Universal Health Coverage (UHC). The National Health Policy recommends increasing public spending on healthcare to 2.5 percent of GDP to reduce out-of-pocket expenditures. Transparent and evidence-informed decision-making in healthcare is facilitated by the Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR), evaluating the appropriateness and cost-effectiveness of health technologies.

Health Technology Assessment (HTA) is a widely utilized methodology for optimizing resource allocation in healthcare. It systematically evaluates medical, economic, social, and ethical aspects of health technologies in a transparent and unbiased manner.

2. AYUSHMAN BHARAT DIGITAL MISSION (ABDM)

Reference: https://abdm.gov.in/&https://www.nrces.in/

The Ayushman Bharat Digital Mission (ABDM) aims to develop the backbone necessary to support the integrated digital health infrastructure of the country. It will bridge the existing gap amongst different stakeholders of Healthcare ecosystem through digital highways.

To create a national digital health ecosystem that supports universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, that provides a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensures the security, confidentiality and privacy of health-related personal information.

To strengthen the accessibility and equity of health services, including continuum of care with citizen as the owner of data, in a holistic healthcare programme approach leveraging IT & associated technologies and support the existing health systems in a 'citizen-centric' approach, the Ayushman Bharat Digital Mission (ABDM) envisages establishing state-of-the-art digital health systems. The digital health systems will enable to manage the core digital health data, and the infrastructure required for its seamless exchange by adoption of open standards by all national digital health stakeholders. The system will enable to create personal health records, based on international standards, easily accessible to individuals and healthcare professionals and services providers, based on individual's informed consent.

One of the major requirements for roll-out of the platform is the use of a digital solution to capture the patient information, which can then support integrated digital healthcare. Wherein health-care providers such as hospitals, labs and doctors' clinics will need to implement Hospital Management Information Systems (HMIS), Laboratory Management Information Systems(LMIS) and Clinic solutions respectively to achieve this objective focusing on patients' safety and quality of healthcare based upon national and international standards.

In September 2013 the Ministry of Health & Family Welfare (MoHFW) notified the Electronic Health Record (EHR) Standards for India. The set of standards given therein were chosen from the best available and used standards applicable to Electronic Health Records from around the world keeping in view their suitability to and applicability in India. The Committee constituted to recommend the standards drew from experts, practitioners, government officials, technologists, and industry. The notified standards were not only supported by professional bodies, regulatory bodies, stakeholders, but various technical and social commentators as well, as being a step in the right direction. MoHFW moved ahead with facilitating the adoption, as next steps, and in last two years the Ministry has made available standards like SNOMED CT free-for-use in the country as well as appoint interim National Release Center (NRC) to handle this clinical terminology standard that is fast gaining widespread acceptance amongst the various healthcare IT stakeholder communities worldwide. Table-1 contains the list of EHR standards along with their intended purpose and Table-2 captures the list of supporting / complimenting standards for EHR.

Table-1: List of standards.

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required.

S. No.	Type	Standard Name	Intended Purpose
1	Identification & Demographics	ISO/TS 22220:2011 Health Informatics - Identification of Subjects of Health Care	Basic identity details of patient
2		MDDS - Demographic (Person Identification and Land Region Codification) version 1.1	Complete demographic for interoperability with E-Governance systems
3	Patient Identifiers	UIDAI Aadhaar	Preferable identifier where available
4		Local Identifier	Identifier given within institution / clinic / lab
5		Government Issued Photo Identity Card Number	Identifier used in conjunction with local in absence of Aadhaar
6	Architecture Requirements	ISO 18308:2011 Health Informatics - Requirements for an Electronic Health Record Architecture	System architectural requirements
7	Functional Requirements	ISO/HL7 10781:2015 Health Informatics - HL7 Electronic Health Records-System Functional Model Release 2 (EHR FM)	System functional requirements
8	Reference Model and Composition	ISO 13940 Health informatics - System of Concepts to Support Continuity of Care	Concepts for care, actors, activities, processes, etc.
9		ISO 13606 Health informatics - Electronic Health Record Communication (Part 1 through 3)	Information model architecture and communication
10		OpenEHR Foundation Models Release 1.0.2	Structural definition and composition
11	Terminology	SNOMED Clinical Terms (SNOMED CT)	Primary terminology
12	Coding System	Logical Observation Identifiers Names and Codes (LOINC)	Test, measurement, observations
13		WHO Family of International Classifications (WHOFIC) including ICD, ICF, ICHI, ICD-O	Classification and reporting
14	Imaging	Digital Imaging and Communications in Medicine (DICOM) PS3.0-2015	Image, waveform, audio/video
15	Scanned or Captured Records	JPEG lossy (or lossless) with size and resolution not less than 1024px x 768px at 300dpi	Image capture format
16		ISO/IEC 14496 - Coding of Audio-Visual Objects	Audio/Video capture format
17		ISO 19005-2 Document Management - Electronic Document File Format for Long-Term Preservation - Part 2: Use of ISO 32000-1 (PDF/A-2)	Scanned documents format

S. No.	Type	Standard Name	Intended Purpose
18	Data Exchange	ANSI/HL7 V2.8.2-2015 HL7 Standard Version 2.8.2 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	Event/Message exchange
19		ASTM/HL7 CCD Release 1 (basis standard ISO/HL7 27932:2009)	Summary Records exchange
20		ISO 13606-5:2010 Health informatics - Electronic Health Record Communication - Part 5: Interface Specification	EHR archetypes exchange [Also, refer to openEHR Service Model specification]
21		DICOM PS3.0-2015 (using DIMSE services & Part-10 media/files)	Imaging/Waveform Exchange
22	Other Relevant Standards	Bureau of Indian Standards and its MHD-17 Committee	Standards Development Organizations (SDOs)
23		ISO TC 215 set of standards	
24		IEEE/NEMA/CE standards for physical systems and interfaces	
25	Discharge/ Treatment Summary	Medical Council of India (MCI) under regulation 3.1 of Ethics	Composition as prescribed
26	E-Prescription	Pharmacy Practice Regulations, 2015 Notification No. 14-148/ 2012- PCI as specified by Pharmacy Council of India	Composition as prescribed
27	Personal Healthcare and medical Device Interface	IEEE 11073 health informatics standards and related ISO standards for medical devices	Device interfacing
28	Data Privacy and Security	ISO/TS 14441:2013 Health Informatics - Security & Privacy Requirements of EHR Systems for Use in Conformity Assessment	Basis security and privacy requirements
29	Information Security Management	ISO/DIS 27799 Health informatics - Information Security Management in Health using ISO/IEC 27002	Overall information security management
30	Privilege Management and Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)	Access control
31	Audit Trail and Logs	ISO 27789:2013 Health informatics - Audit trails for Electronic Health Records	Audit trail
32	Data Integrity	Secure Hash Algorithm (SHA) used must be SHA-256 or higher	Data Hashing
33	Data Encryption	Minimum 256-bits key length	Encryption key
34		HTTPS, SSL v3.0, and TLS v1.2	Encrypted connection
35	Digital Certificate	ISO 17090 Health informatics - Public Key Infrastructure (Part 1 through 5)	Digital certificates use and management

Table-2: List of Supporting / Complimenting Standards

The following list is indicative and representative and not comprehensive or definitive. These standards are advised to be used where applicable and as required.

S. No.	Type	Standard Name
1	ISO 12967:2009	Health Informatics - Service Architecture (Parts 1 - 3)
2	ISO 13972:2015	Health Informatics - Detailed Clinical Models, Characteristics and Processes
3	ISO 20301:2014	Health Informatics - Health Cards - General Characteristics
4	ISO 21090:2011	Health Informatics - Harmonized Data Types for Information Interchange
5	ISO 8601:2004	Data elements and Interchange Formats - Information Interchange - Representation of Dates and Times
6	ISO 13119:2012	Health Informatics - Clinical Knowledge Resources - Metadata
7	ISO 22857:2013	Health Informatics - Guidelines on Data Protection to Facilitate Trans Border Flows of Personal Health Data
8	ISO 21549-1:2013	Health Informatics - Patient Healthcard Data - Part 1: General Structure
9	ISO TS 14265:2011	Classification of Purposes for Processing Personal Health Information
10	ISO TS 27527:2010	Health Informatics - Provider Identification

A subset of EHR standards is mandated as guidelines for ABDM compliant HMIS/LMIS. Table-3containsthe minimumviablefeaturesandstandards (Column2)ofABDMCompliantHMIS/LMIS. Recommended Features and optional features are provided in Column (3) and Column (4) respectively. Integrated HMIS/LMIS solutions should also have user friendly user interface and functionalities like easy navigation from one page to another,providersfriendly etc.

Table.3: Minimum viable features and standards, Recommended Features and optional features of ABDM Compliant HMIS/LMIS

Features and Standards (1)	Minimum Viable ABDM compliant HMIS (2)	Recommended HMIS (3)	Optional Features in High-end HMIS (4)
Creation and Verification of ABHA (HealthIDs)	Creation: Yes Verification: Yes	Creation: Yes Verification: Yes	
Linking of Health Records	Yes	Yes	
Exchange of Health Records with other HMIS/LMIS/ABDM compliant solutions	Yes	Yes	
Cloud Based Storage	Optional	Yes + Disaster Recovery Plan	Cloud-modeld eployment inprivate/publiccloud infrastructure.
Mobile App for remote access	Optional	Optional	Mobile applications for patients and doctors.
Artificial Intelligence	Optional	Yes	
SpeechtoTextand Text To Speech	Optional	Yes	Novel methods of data entry (smart pen, paper, voice commands,etc.)
Modules: OPDRegistration LaboratoryReports Radiology Billing DischargeSummaries OPConsultation IPD	Yes	Yes	**OptionalModules:** Dietary HR Management
OT Pharmacy Inventory Epidemiology Analysis/Dashboard For public health purposes	Optional Yes Optional	Yes Yes Optional	
Standards for Health Data Coding SNOMEDCT WHO(ICD) LOINC (LIMS)	Yes Optional (MapfromSNOMED may be used forreporting) Yes	Yes Yes (forreporting) Yes	

Features and Standards (1)	Minimum Viable ABDM compliant HMIS (2)	Recommended HMIS (3)	Optional Features in High-end HMIS (4)
Standards for Clinical Information Exchange ABDM supported FHIR R4 Standard and Profiles FHIR R4 Standard Import and export	Yes	Yes	Interface and Exchange of information using relevant exchange standards mentioned in EHRSI-2016
Capturing of Data (Images/Audio/ Videos) Still Image (JPEG) Audio (MP3/ OGG Format) Video (MP4/MOV Format) PDF A2 Format	 Yes Yes Yes Yes	 Yes Yes Yes Yes	
Interface with DICOM Compliant RIS (Radiology Information System) DICOM compliant files/reports DICOM Compliant PACS Interface, if separate RIS	Yes Yes Optional	Yes Yes Optional	
Interface with LOINC Compliant LIS (Laboratory Information System) if separate LIS HL7 v2.x-based order management and reporting LOINC codesfor tests	Yes Optional	Yes Yes	
and observations	Yes	Yes	
Interface with Medical deviceusingstandards	Optional	Yes	TWAIN/DICOM / HL7v2.x/API
Privacy and Security Standards: 1. Alignment with Health Data Management 2. Policy Accesscontrol 3. Transport Encryption 4. Data Encryption(atrest) Audittrail	 Yes Yes Yes Optional - with safe guard Yes	 Yes Yes Yes	

Features and Standards (1)	Minimum Viable ABDM compliant HMIS (2)	Recommended HMIS (3)	Optional Features in High-end HMIS (4)
Compliance with ISO 18308:2011 Standards (Requirements of electronic Health Record Architecture)	Optional	Yes	
Compliance with ISO/ HL710781:2015 Standard (Health Informatics — HL7 Electronic Health Records- System Functional Model, Release 2 (EHRFM)	Optional	Yes	
Compliant with Set of Consent Manager and ABDMAPIs			Compliant with Setof Consent Manager and ABDMAPIs

2.1. Brief overview of Clinical Data Standards of EHR:

a) International Classification of Diseases 10th Revision (ICD-10)

The International Classification of Diseases (ICD) is the classification used to code and classify mortality data from death certificates.

The International Classification of Diseases, Clinical Modification is used to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys.

NCHS serves as the World Health Organization (WHO) Collaborating Center for the Family of International Classifications for North America and in this capacity is responsible for coordination of all official disease classification activities in the United States relating to the ICD and its use, interpretation, and periodic revision.

The Collaborating Center also is responsible in North America for the WHO Family of International Classifications, which includes the International Classification of Functioning, Disability and Health (ICF).World Health Organization (WHO) authorized the publication of the International Classification of Diseases 10th Revision (ICD-10), which was implemented for mortality coding and classification from death certificates in the U.S. in 1999. The U.S. developed a Clinical Modification (ICD-10-CM) for medical diagnoses based on WHO's ICD-10 and CMS developed a new Procedure Coding System (ICD-10-PCS) for inpatient procedures. ICD-10-CM replaces ICD-9-CM, volumes 1 and 2, and ICD-10-PCS replaces ICD-9-CM, volume 3.

ICD-10-CM/PCS code sets will enhance the quality of data for:

- Tracking public health conditions (complications, anatomical location)
- Improved data for epidemiological research (severity of illness, co-morbidities)
- Measuring outcomes and care provided to patients
- Making clinical decisions
- Identifying fraud and abuse
- Designing payment systems/processing claims.

b) LOINC

LOINC is a set of identifiers, names and codes for identifying health measurements, observations and documents. It is owned, maintained and distributed by Regenstrief Institute, Inc USA.

A universal code system will enable facilities and departments across the world to receive and send results from their areas for comparison and consultation and may contribute toward a larger public health initiative of improving clinical outcomes and quality of care.

A formal, distinct, and unique 6-part name is given to each term for test or observation identity. The database currently has 84868 terms that can be accessed and understood universally. LOINC has two main parts: laboratory LOINC and clinical LOINC. Each database record includes six fields for the unique specification of each identified single test, observation, or measurement.

c) SNOMED CT

SNOMED CT is the most comprehensive, multilingual clinical healthcare terminology in the world. It is owned, maintained, and distributed by the SNOMED International, United Kingdom. It is a widely used terminology and contains comprehensive active concepts with unique meanings and formal logic-based definitions organized into hierarchies.

Incorporation of such a comprehensive terminology in EHR requires understanding of the underlying concept model, various levels at which clinical information can be effectively represented, and cross-mapping to other international vocabulary standards.

SNOMED International is an international not-for-profit organization based in London, United Kingdom. SNOMED International is a product and service organization. It owns and administers the rights to SNOMED CT and related terminology standards.

SNOMED CT is a clinically validated, semantically rich, multilingual, comprehensive clinical terminology that can be used to represent clinically relevant information consistently and reliably in an electronic health record. It provides a standardized way to represent clinical phrases captured by the clinician. SNOMED CT based clinical information benefits individual patients and clinicians as well as populations and also supports evidence based care.

3. BIRAC's TECHNOLOGY READINESS LEVELS (TRLs)

Reference: https://birac.nic.in/desc_new.php?id=443

Technology readiness levels (TRLs) is a measure of estimating technology maturity of core technologies in a program during the selection process and in subsequent monitoring and evaluation phases until these technologies, or products utilizing them, attain market readiness. Originally introduced by NASA, the TRL scale is a metric with nine technology readiness levels for describing the maturity of a technology from ideation stage (TRL-1) to highest degree of application/ commercial readiness (TRL-9). Levels in between covers establishment of proof of concepts, prototype developments, functional validations from models to real operational environments and clearances of mandatory regulatory barriers between levels towards market introduction of these technologies/products.

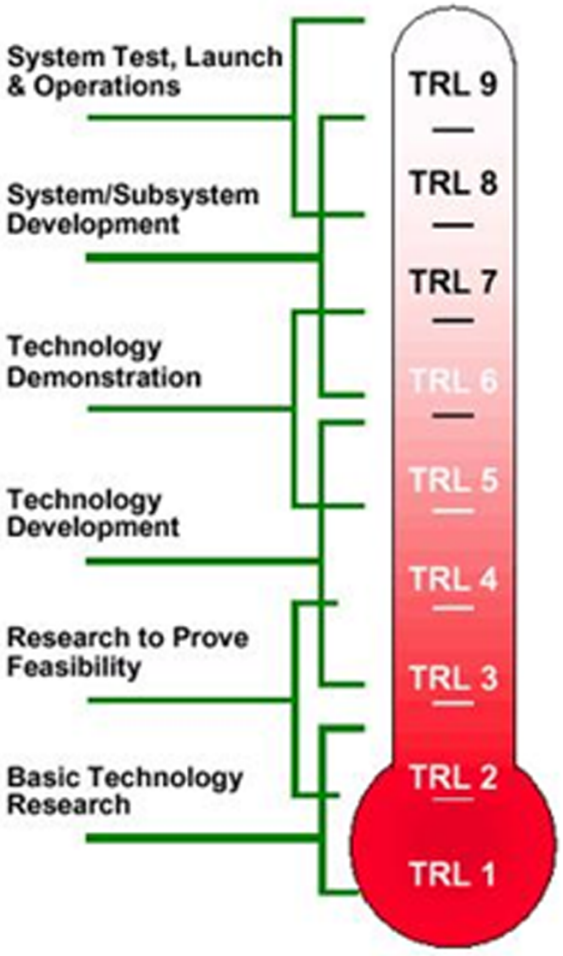


Figure-1: NASA Technology Readiness levels

BIRAC has an inherent system of distributing the projects into different thematic areas for effective selection process, efficient project monitoring for technology maturation and for tracking investments against outputs in each sector. Broadly, the following thematic areas cover projects supported under BIRAC mandate:

Healthcare:

a. Drugs (including drug delivery)

b. Biosimilars

c. Regenerative Medicine

d. Vaccines

e. Devices and Diagnostics

f. Bioinformatics & software (Including Artificial intelligence, Big Data Analysis, IoT's, software development etc.

Technology readiness levels of MedicalDevicesandDiagnosis and Bioinformatics & software are captured as an example in this report.

Table-4: Technology Readiness levels of Medical Devices and Diagnosis

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)	Need identified, Basic principles observed and reported (Scientific research begins which can be translated into applied research and development)
Proof of Principle	TRL-2	Market surveillance data and competitor analysis available to support the idea. Basic device design ready and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured. Development of individual components initiated.	Hypothesis formulated and protocols developed. Market surveillance data and competitor analysis available to support idea. Individual core components of kit/reagents (Antibodies/ Antigens/Aptamers/ Nano particles) finalized, developed/procured for testing	Market surveillance data and competitor analysis available to support the idea. Basic implant design ready, candidate materials shortlisted, and product specifications defined based on the competitor analysis and patent landscaping. FTO ensured
Proof of Concept demonstrated	TRL-3	Individual modules/ Components/PCBs/ Software s/Systems developed and tested separately for its functionality on a breadboard/laboratory level. Material safety, electrical safety & biocompatibility of the systems demonstrated	Individual core components optimized at lab scale. Demonstrated the limit of detection/Sensitivity with metabolite serial dilution or ELISA or spiked biological sample studies.	Material research completed and material properties of the finalized material/composites compared against benchmarks. Relevant ASTM standard tests (strength, ductility, corrosion, surface properties, antimicrobial activity, usability, shelf life etc.) on the material performed successfully. Material sterilization method finalized. Biocompatibility (ISO 10993) proven in in-vitro cytotoxicity assays.

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Proof of concept established	TRL-4	Functional Prototype developed by integration of different modules and safety, efficacy and performance of candidate device or system demonstrated in a defined laboratory, Simulated Environment, or animal model (with Institutional Animal Ethics Committee approvals)	Optimized core components integrated into the kit or platform (Microfluidics/ filter paper/ LFA etc) along with the reagents to come up with a functional prototype of the kit. Integrated system tested in house with metabolite serial dilution or ELISA or spiked biological sample studies.	Material safety and or imaging compatibility proven in in vivo small animal model study (with Institutional Animal Ethics Committee approvals). Functional Prototype implant device developed as per the design in a near GMP condition. Sterilization and packaging established.
Early-stage validation	TRL-5	Relevant IEC & ISO tests (Electromagenetic interference, Electromagnetic compatibility, Electrical safety, Biocompatibility, software test, radiation safety test drop test, packaging test, transportation test, physico –chemical and mechanical testing etc.) of the device performed and safety proven. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	Integrated system tested in-house extensively with clinical samples (Blood, Urine, Sputum etc.) before taking it for clinical validation. Analytical validation of the kit completed. Shelf life, stability data of the kit reagents available. Quality management certification (ISO13485) in place Clinical study plan approved by Institutional Ethical Committee and/or CDSCO	In vivo pre-clinical studies performed (with Institutional Animal Ethics Committee approvals) using functional prototype implant device on the relevant small or big animal (disease) models to establish its safety (tissue reactivity/ allergy/degradability, Histopathology) and efficacy (. Quality management certification (ISO13485) in place. Design iterated prototype ready to go for clinical validation. Clinical study plan approved by Institutional Ethical Committee and/or CDSCO
	TRL-6	Fully functional clinical grade device ready with regulatory dossier for use on human subjects/ patients. Quality assurance certification (like CE) applied. Pilot clinical study/ trials on limited number of subjects/patients to prove safety and substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval	Clinical study performed on statistically significant number of samples at one or two centres to define the specificity and sensitivity of the Assay/kit. Quality assurance certification for the product applied/obtained	Clinical level implant device fabricated using clinical grade material in GMP facility with safety dossier for use on human subjects/ patients. Quality assurance certification (like CE) applied. Pilot clinical trials performed on statistically significant number of patients against the predicate implant device to prove safety, substantial equivalence/efficacy. Data submitted to CDSCO for Pivotal study approval.

Stage	Technology Readiness Level	Definition (Medical Devices including diagnostic devices)	Definition (In vitro Diagnostic Kits & reagents)	Definition (Biomedical implants)
Late-stage Validation	TRL-7	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/ trials completed, and clinical performance data submitted to CDSCO for manufacturing license	Multi-Centric Trials completed at NABL accredited centres and performance evaluation report submitted to CDSCO for Commercial license. Performance evaluation report of notified products (IVD for HIV, HCV, HBV and Blood grouping sera) obtained from NIB, Noida.	Manufacturing lines established. Design for manufacture (DFM) finalised and devices manufactured. Documentation on design history file (DHF) ready. Pivotal clinical study/ trials completed, and clinical performance data submitted to CDSCO for manufacturing license
Pre-commercialization	TRL-8	Manufacturing license obtained from CDSCO, and commercial batch manufacturing initiated	Manufacturing license obtained and commercial scale manufacturing set up/ Packing/labelling etc. Commercial batch manufacturing initiated	Manufacturing license obtained from CDSCO, and commercial batch manufacturing initiated
Commercialization and post market studies	TRL-9	Commercial launch of the new device, Post marketing studies and surveillance	Commercial launch of in vitro diagnostic kit or reagents and Post marketing studies and surveillance	Commercial launch of the implant, Post marketing studies and surveillance

Table-5: Technology Readiness levels of Medical Devices and Diagnosis of Artificial intelligence, Big Data Analysis, IoT's, software development & Bioinformatics

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	• Neededentified, • Development of basic use, basic properties of software architecture, Mathematical formulations,and general algorithms.
Proof of Principle	TRL-2	• Research ideas developed • Technology concept or application formulated. • To carry out analytics studies and coding starts & comparing competing technologies
Proof of concept demonstrated	TRL-3	• Concept / Pre-alpha script is ready and working draft is created.
Proof of concept established	TRL-4	• Development of limited functionality environments to validate critical properties and analytical prediction using non integrated software components and partially representative data • Laboratory Results Showing Validation Of Critical properties.

Stage	Technology Readiness Level	Definition
Early-stagevalidation	TRL-5	• Developed Software technologies to integrate with different aspects of existing system • Developed Software technologies implementations conform to target environment /interfaces. Experiments with realistic problems • Rigorous Alpha testing
	TRL-6	• Feasibility Of The Software Technology Is Demonstrated on full-scale realistic problems • Technology Validated In Relevant End To- End environment. • Rigorous Beta testing
Late-stageValidation	TRL-7	• Rigorous Testing & Validation By Third Parties
Pre-commercialization	TRL-8	• ISO/IEC 9126 software quality as per the international standards • Data Privacy & Protection as per international standards(may be complied as per HIPAA Norms) • Launch of The Software
Commercialization and Post market studies	TRL-9	• Continuous Improvement (New Version)asperuser demand and feedbacks. • Continuous Incorporation of new features as per user demand and feedbacks.

4. CLINICAL TRIAL NETWORK

Reference:https://www.birac.nic.in/nbm/cms/page/clinical-trial-network

National Biopharma Mission is An Industry-Academia Collaborative Mission of Department of Biotechnology (DBT) for Accelerating Early Development for Biopharmaceuticals; implemented by Biotechnology Research Assistance Council (BIRAC).

The Mission Programme is a Pan-India Programme with the main aim of making India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions. This Program would aid in enhancing India's innovation research and product development capabilities, especially by focusing on development of vaccines, biologics and medical devices for combating public health concerns.

Clinical trial is an important step in the product development path requiring multiple trial sites. Indian Biotech companies face numerous challenges in identifying trial sites which have the required infrastructure, capacity, trained manpower, harmonized processes and background data on disease incidence at institutional, local, regional/state, and national levels. The delay in conduct of clinical trials can impact the development timelines of biologics and drugs and thereby delaying the launch of affordable biosimilars for Indian population.

To address the above, Department of Biotechnology and National Biopharma Mission's initiative, Clinical Trial Networks, with Consortia of Hospitals in the areas of Oncology, Ophthalmology, Rheumatology and Diabetology, CHOORD aims to strengthen thecapacity to conduct clinical trials in India for products developed in these areas. It comprises of 5 networks of 36 organizations, public and private hospitals, clinics, reputed academic institutions, spread across 18 states of India.Each specialty network comprises of at least 6 hospital-based investigational sites (public and private hospital sites) across different geographical regions of the country.

Table-6: Clinical Trial Network Field Sites

S. No.	Name of Sites	Location
DHS sites		
1	Society for Health Allied Research and Education INDIA	Hyderabad, Andhra Pradesh
2	Christian Medical College Vellore Association	Vellore, Tamil Nadu
3	ICMR- National Institute of Epidemiology	Tiruvenelveli, Tamil Nadu
4	The INCLEN Trust International	Palwal, Haryana
5	KEM Hospital Research Centre	Vadu, Maharashtra
6	Pondicherry Institute of Medical Sciences	Pondicherry, Tamil Nadu
7	Maulana Azad Medical College	New Delhi
8	Society for Applied Studies	New Delhi
9	ICMR-Regional Medical Research Center	Bhubaneshwar, Odisha
10	Andhra Medical College	Vishakhapatnam, Andhra Pradesh
11	The INCLEN Trust International	Shillong, Meghalaya
Data Management Platform		
1	The INCLEN Trust International	New Delhi

Table-7: Environmental and Health Risk Management Plan (EHRMP) Sites

S. No.	Name of Lead sites	Clinical Trail Network
1	Amrita Institute of Medical Sciences, Kochi, Kerala	Ophthalmology
2	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry	Oncology
3	Gokula Education Foundation-M.S. Ramaiah Medical College and Hospitals, Bangalore	Diabetology
4	Tata Memorial Hospital, Mumbai	Oncology
5	Medanta Institute of Education and Research, Haryana	Rheumatology

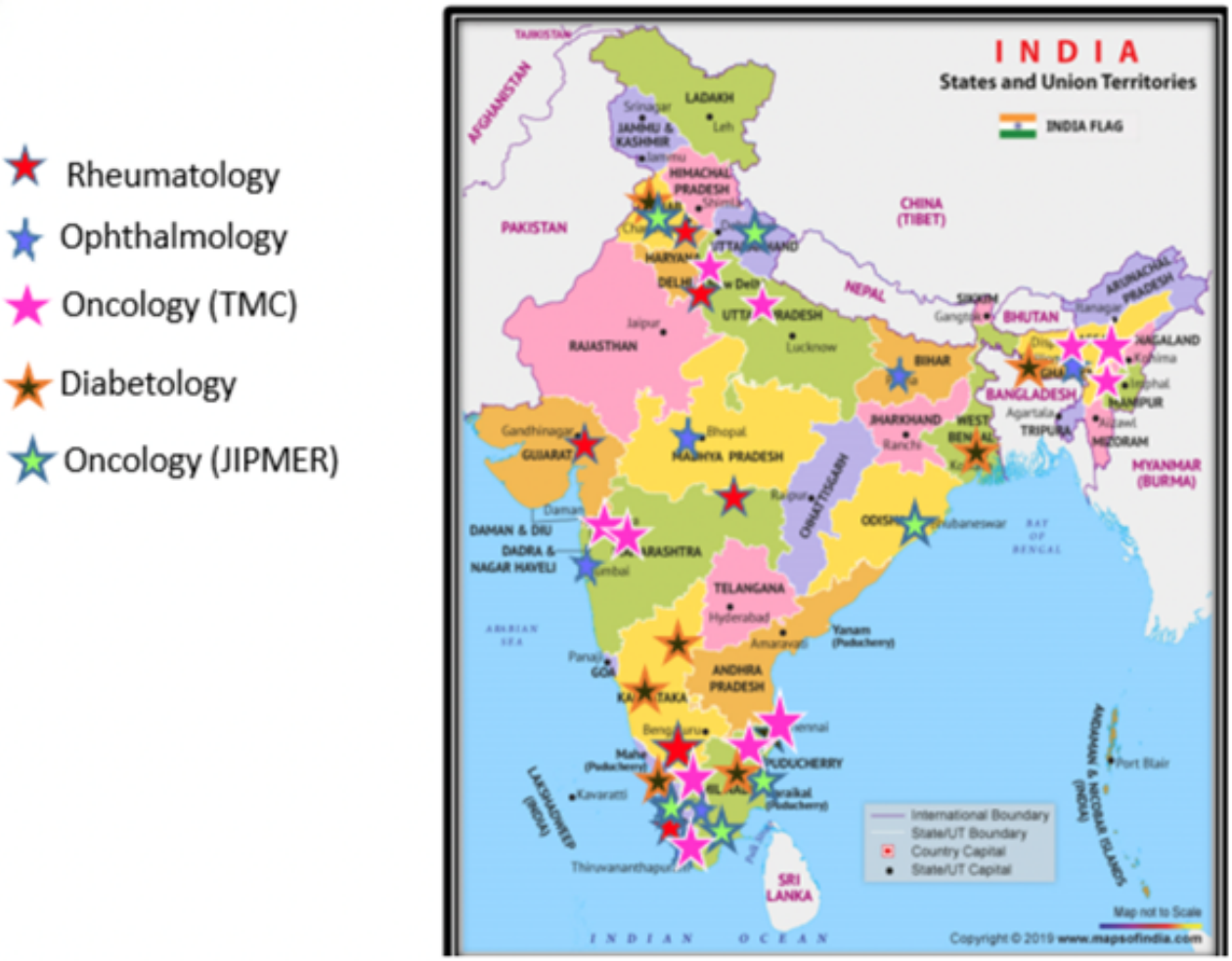


Figure-2: India map showing Clinical Trial Network Field Sites

4.1. Ophthalmology:

The aim is to develop a network of clinical trial centres across Indian both in government and private sector providing high volume tertiary care services in Ophthalmology through the multi central collaboration of academic institutions with Indian industry, to handhold them and bring out some very high quality, innovative Biologicalsinto the market. The network is a right mix of innovator institutions, high volume centres, rural and backward areas of India and collaborators with immense experience. The Pan India presence includes: the South in Kerala, the health hub of India with two centres, one in government and one in private side. Chitrakootis one of the highest volume centres in India. Regional Institute of Ophthalmology, Patna and Sri Sankaradeva Netralaya, Guwahati, are the best hospitals in rural and backward part of India. The lead site of the Ophthalmology network is Amrita Institute of Medical Sciences, Kochi, Kerala. For the first time in India, a solitary Patient Registry “A Hospital-Based Multicentre Registry for common medical retinal diseases” for four diseases (diabetic retinopathy, Age related macular degeneration, retinal vein occlusion and CNVM) is being developed under the clinical trial network collaborated with six other hospitals/institutions which are excellence in the field of Ophthalmology.

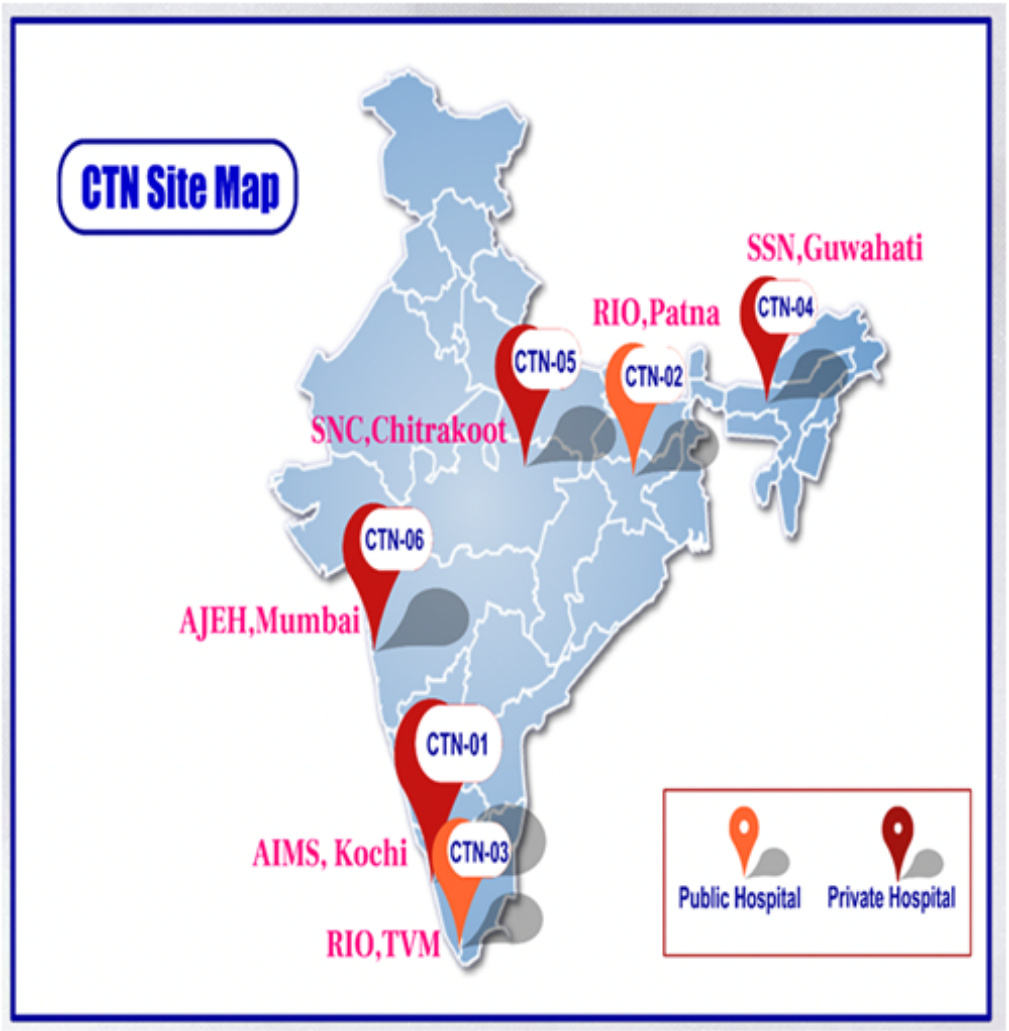


Figure-3: India map showing Clinical Trial Network Field Sites in Ophthalmology

4.2. Oncology-1 - Tata Memorial Centre (Lead Site)

The aim is to build and strengthen a network of clinical trial units within the National Cancer Grid (NCG) to promote multicentric high-quality clinical trials for affordable therapy in oncology, which will enhance the capability for conduct of Industry sponsored trials of new cancer drugs and biosimilars by: Manpower training and infrastructure development, process harmonization between centres and to conduct collaborative investigator-initiated research. There are 11 sites (7 public and 4 private) in the consortia from different regions under PAN India. Tata Memorial Hospital, Mumbai is Lead site of the multicentric Clinical Trial Network (CTN). Prospective Registry database in Lymphomas, Chronic Myelogenous Leukemia, Colorectal Cancer, Lung Cancer, Gall Bladder Cancer is being created across sites of the network.

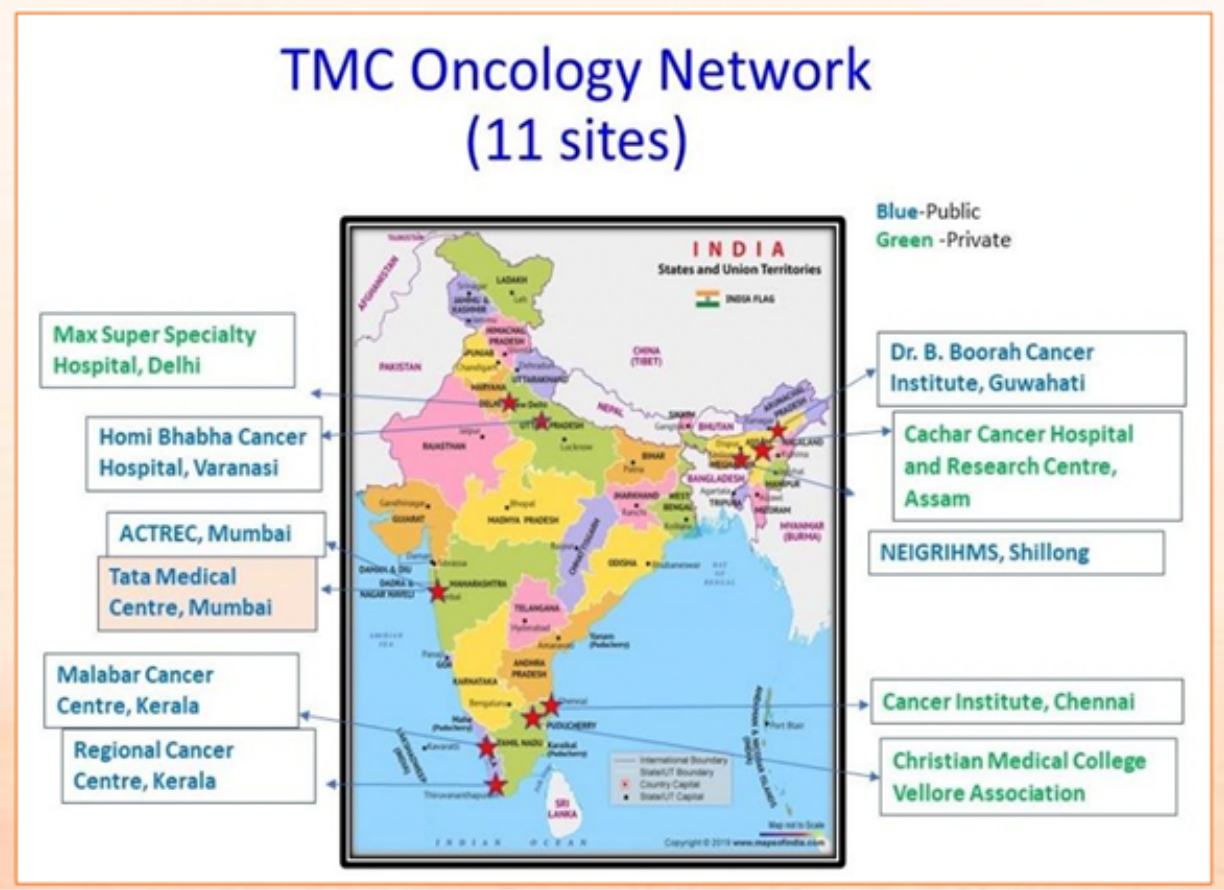


Figure-4: India map showing Clinical Trial Network Field Sites in Oncology with Tata Memorial Centre as Lead Site

4.3. Oncology-2 JIPMER (Lead Site)

The aim is to establish Network of Oncology Clinical Trials in India (NOCI), which will enhance the capability for conduct of Industry-sponsored trials of new cancer drugs and biosimilarsby: Manpower training and infrastructure development, process harmonization between centres and to conduct collaborative investigator -initiated research. The purpose is to strengthen Clinical Trial capacity and to create a registry of common cancers which gives backgrounddata on outcomes. The network brings 6 large oncology centres representing different regions of India (North 2, South 3 & East 1) with access to large patient pool andincrease their clinical trial capabilities. Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherryis lead site of the network. An individual patient data registry of cancer care and outcomes being developed in collaboration with six other centres across India. A common protocol for establishing the database has been established among all centres and approved by Institutional Ethics Committee. Site started creating database for 06 common cancers (Lung, Head and neck Cervix, Ovary, Breast and Brain cancers) where data of patients are captured to a software aiming to aid in real-world evidence of disease manifestation and treatments.

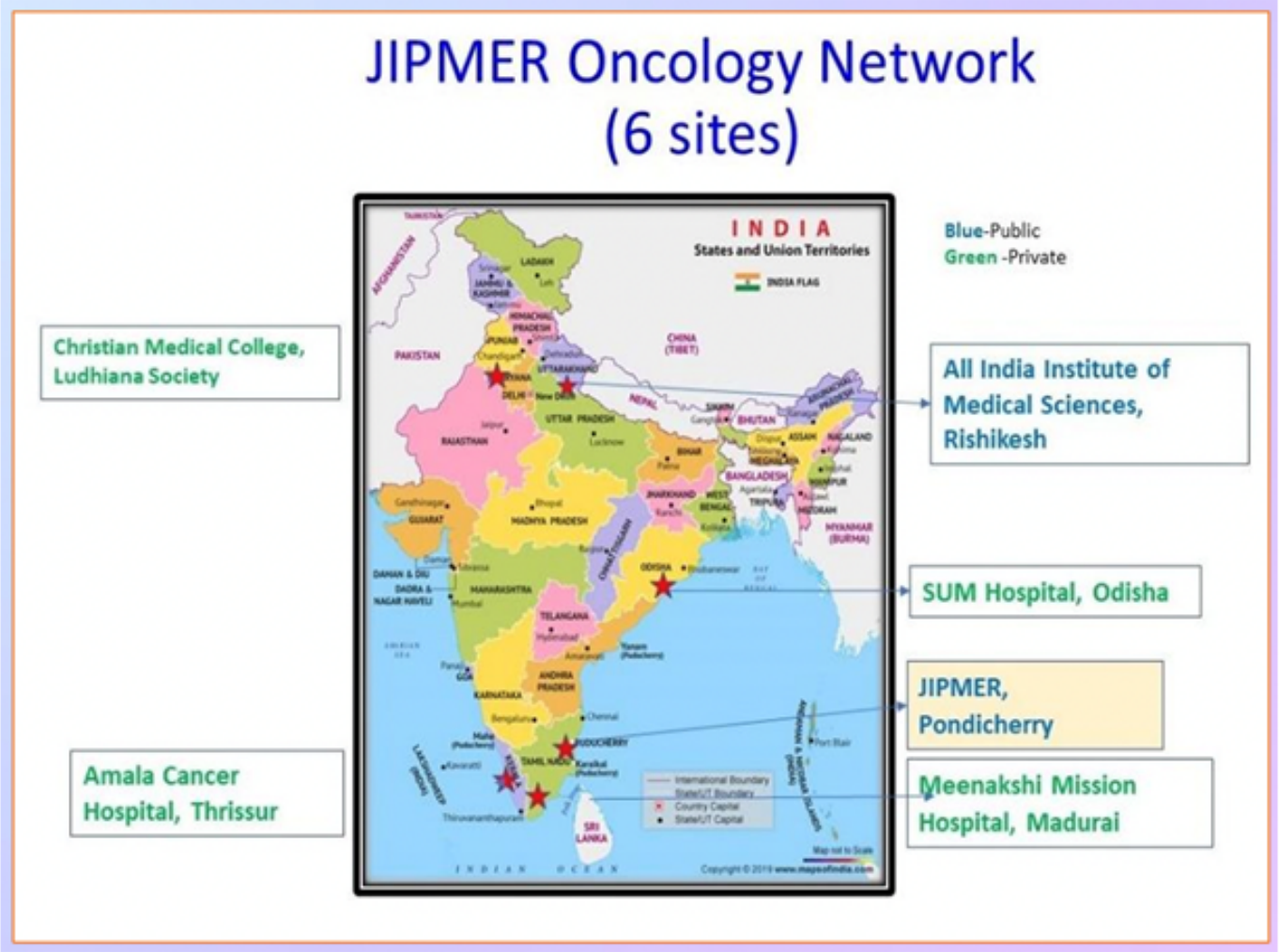


Figure-5: India map showing Clinical Trial Network Field Sites in Oncology with JIPMER as Lead Site

4.4. Diabetology

To establish pan Indian network of clinical trial sites with expertise in handling diabetes trials and to ensure uniformity in training, SOPs, access to technology, regulatory & GCP compliance in network collaboration. The aim is to make all the network centers world class stature in terms of research and training. To ensure representation of all geographical parts of the country, the sites are chosen in such a way that there is a right blend of experienced and inexperienced sites, as well as representation of both government and private organizations. 4 Public hospitals (Victoria Hospital, Bangalore Medical College & Research Institute, Bengaluru, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, NIMS Medicity, Aralumoodu& Institute of Post Graduate Medical Education and Research SSKM hospital, Kolkata) and 3 private centers (Sri Guru Ram Das University of Health Sciences, Amritsar, SRM Institutes for Medical Science, Chennai & M.S. Ramaiah Medical College and Hospitals, Bangalore) are part of Diabetology network. The lead site of the Diabetology network is M.S. Ramaiah Medical College and Hospitals, Bangalore. Through this initiative the plan is to strengthen Clinical trial capacity across different sites of the CTN and to develop registry of diabetic population available for Clinical Trials. The site is creating Type 1 & Type 2 Diabetes Mellitus Registry is which patient data is collected from 7 centers in the network across India. A common IT platform for collecting Registry database has been developed, the database can be used to get the pool of eligible patients for future clinical trials in Diabetology.

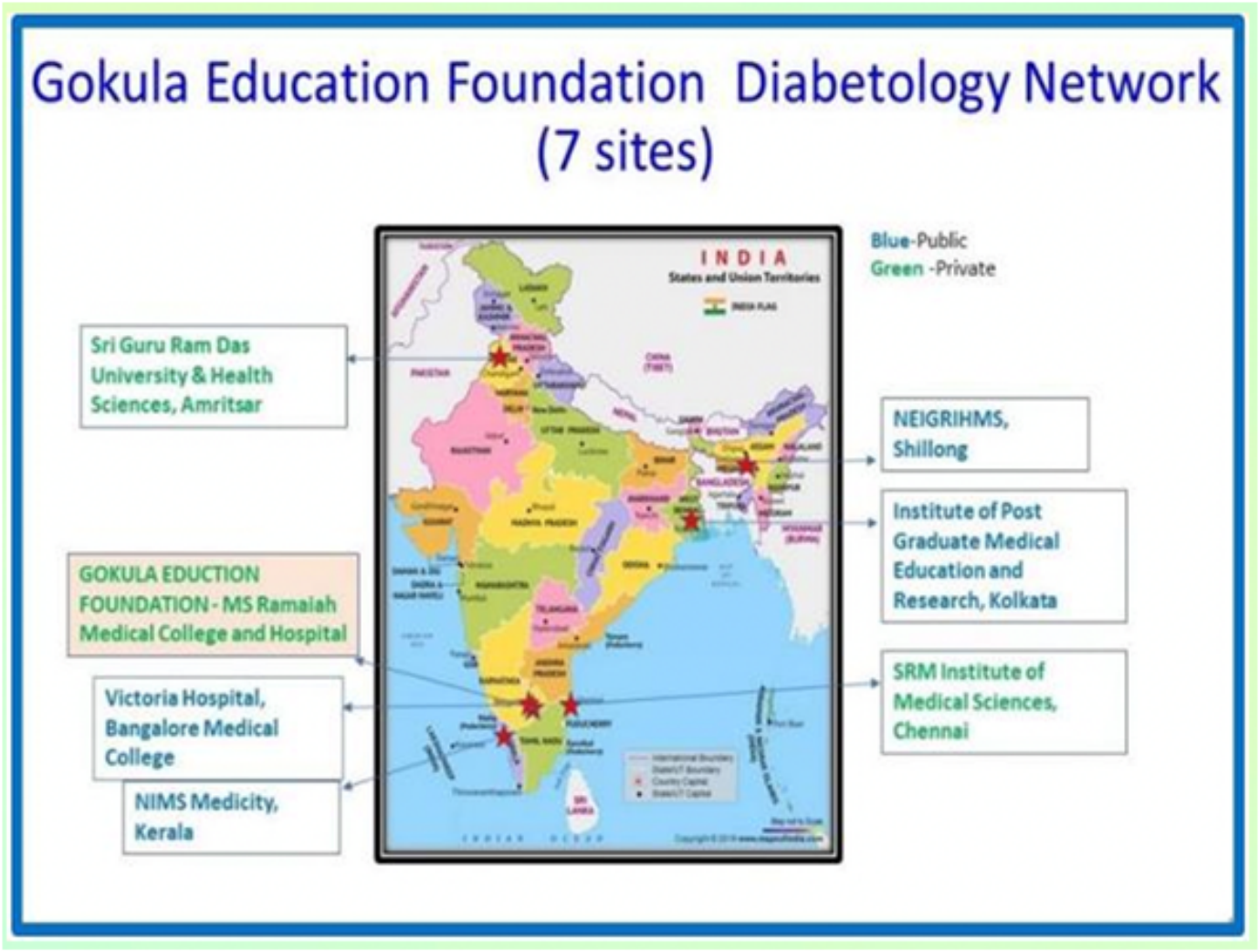


Figure-6: India map showing Clinical Trial Network Field Sites in Diabetology

4.5. Rheumatology

The aim is to create a network of Rheumatology centres and research institutes across India with the mandate of establishing uniform research standards in compliance with best practices to ensure faster, cost-effective drug development in Rheumatology. Under BIRAC NBM grant, GCP compliant network is being established by utilising trained manpower, procurement of equipment's, establishment of common software for Rheumatology database. Medanta Institute of Education and Research is leading the network with 5 other collaborators (3 private sites-Centre for Arthritis & Rheumatism Excellence, Kerala, St Johns National Academy of Health Sciences Bangalore & Kusum Dhirajlal Hospital Ahmedabad, Gujarat and 2 public hospitals-Post Graduate Institute of Medical Education & Research, Chandigarh & Mahatma Gandhi Institute of Medical Sciences, Seva gram, Maharashtra). The aim is to develop harmonised research processes in compliance with GCP for faster and cost effective conduct of clinical trials. Electronic database for registry of various Rheumatology diseases such as Rheumatoid Arthritis, Psoriatic Arthritis, Spondylo arthritis, Myositis, Sjogren's syndrome, Systemic lupus erythematosus, Systemic scleriosis, ANCA associated vasculitis, Aorto arteritisis being created on a common IT platform to support GCP compliant clinical trials in Rheumatology. Common protocol for establishing database has been established among all centres and approved by Institutional Ethics Committee.

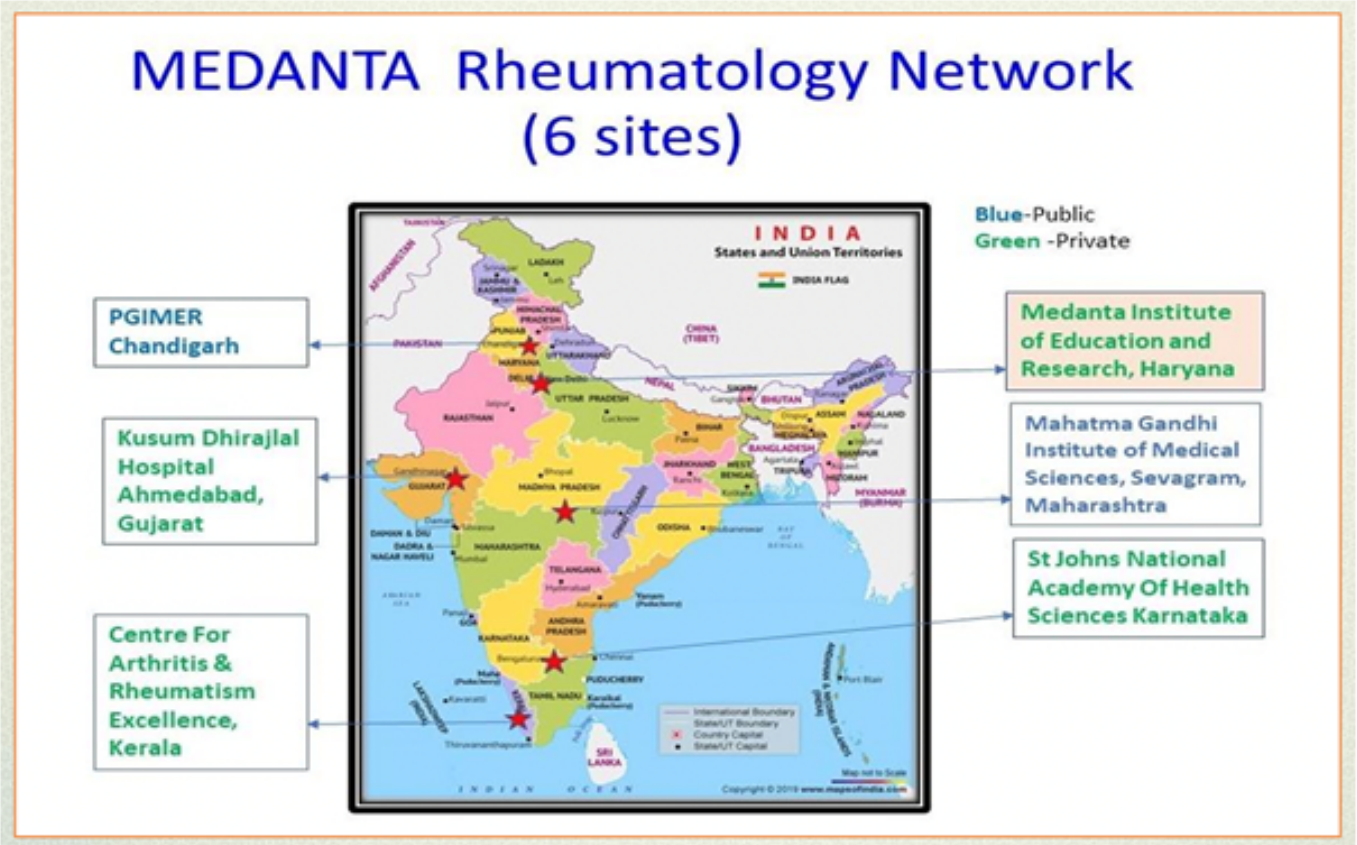


Figure-7: India map showing Clinical Trial Network Field Sites in Rheumatology

5. HEALTH TECHNOLOGIES ASSESSMENT (HTAIN) - DHR-HTA

Reference: https://dhr.gov.in/health-technology-assessment-india-htain

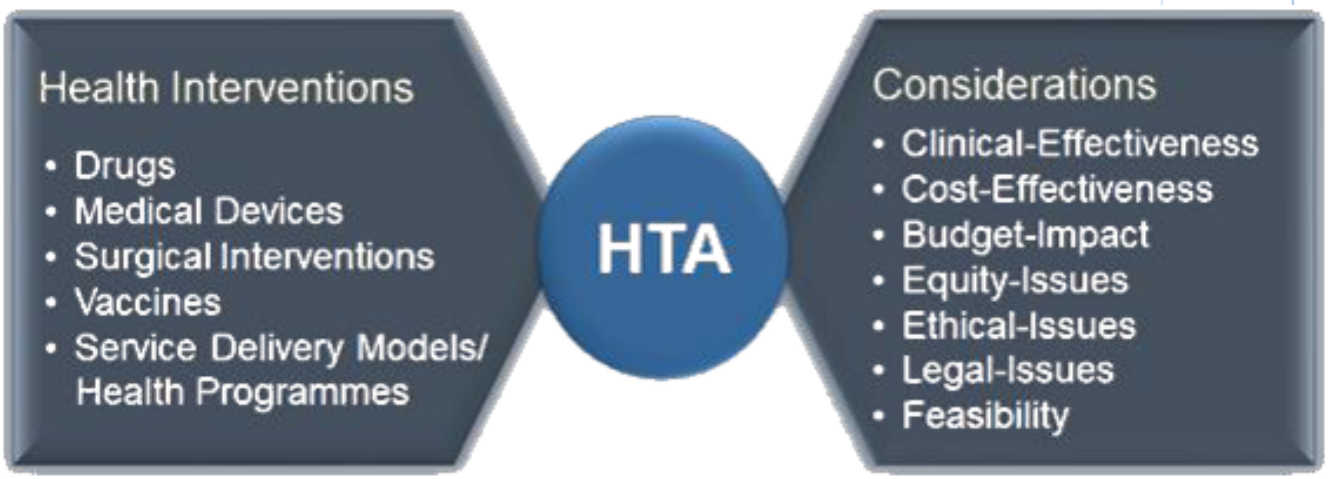
The Government of India is committed to extend healthcare services to its 1.38 billion population as part of India's Universal Health Coverage (UHC) agenda. The National Health Policy has recommended an increase in public spending on healthcare services from existing 1.15 percent to 2.5 percent of GDP. It notes that this can significantly reduce the out-of-pocket-expenditure of the overall healthcare spending. With such a challenge, it is essential for the government to ensure optimal utilization of existing resources to ensure that the greatest amount of health is generated for every rupee spent. To facilitate the process of transparent and evidence informed decision making in the field of health, Government of India has created an institutional arrangement called the Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR) for evaluation of appropriateness and cost effectiveness of available and new health technologies in the country as part of research governance mandate of the Department.

HTA is a widely used methodology for optimization of resource allocation in Health. It is a multidisciplinary process that summarizes evidence and information on medical (clinical effectiveness), economic (cost effectiveness), social and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.

5.1. Health Technology Assessment in India (HTAIn)

Health Technology Assessment in India (HTAIn) is a sub-scheme under the umbrella scheme Human Resource and Capacity Building in the 15th Financial Commission approved for year 2021-22 to 2025-26 under the Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW), Government of India to facilitate the process of transparent and evidence-informed decision making in the field of healthcare. HTAIn is entrusted with the responsibility to analyses health technologies viz. medicines, devices and health programmes for its cost-effectiveness, clinical-effectiveness and equity issues by means of Health Technology Assessment (HTA), and in turn help in decision making for an efficient use of the limited health budget and provide people access to the quality health care reducing their out of pocket expenditures (OOPs) on health.

Health technology assessment is intended to provide a bridge between the worldof research and the worldof decision-making. HTA inform Government agencies while drafting policy recommendations in the field of health, health care professionals in drafting Standard Treatment Guidelines, hospitals and healthcare administrationregardingtheuseofahealthintervention,insurancecompanies while deciding their premium and reimbursement rate, manufactures during deviceordrugproduction,patientcaresandadvocacygroupsregardingtheethical and legal issues of a health intervention. We can say, HTA is a multidisciplinary process and together it has the potential to help the country in its global commitment of Universal Health Coverage (UHC).



5.2. Objectives and Significance of HTAIn

- To undertake HTA studies aiming at maximising health in the population, reducing out of pocket expenditure (OOP) and reducing inequity.
- To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.
- Develop systems and mechanisms to assess new and existing health technologies by a transparent and inclusive process.
- To appraise health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety.

» To collect and analyse evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy.

» Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health.

5.3. Structure of HTAIn

Health Technology Assessment in India (HTAIn) consists of an in-house HTAIn Secretariat, Board, Technical Appraisal Committee (TAC) and Regional Resource Centres (RRCs).

5.4. Resource Centres (RRCs)

Resource Centres have been established in Government research institutes to conduct HTA and other multi-centric studies allocated by HTAIn Secretariat.

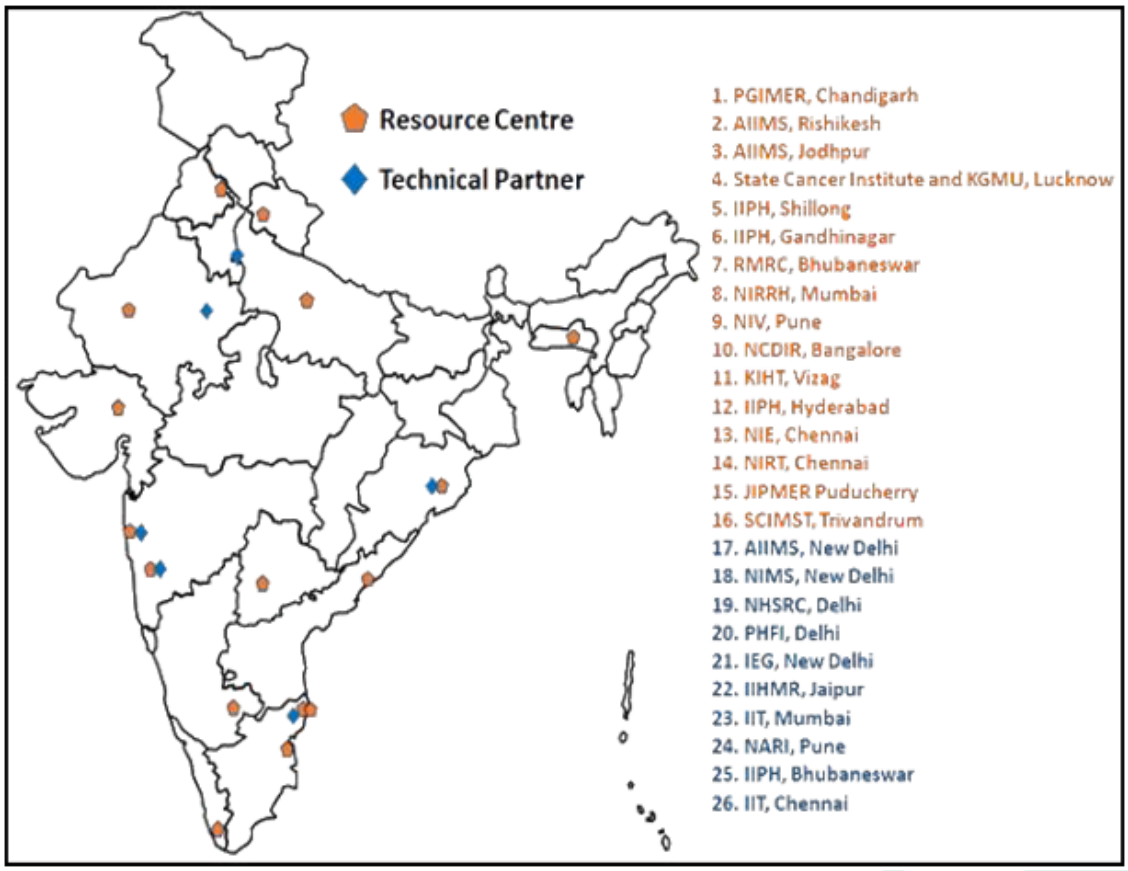


Figure-8: India map showing Resource Centres and Technical Partners of HTA

a) List of Resource Centres:

1. Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh.
2. Indian Institute of Technology-Delhi
3. All India Institute of Medical Sciences, Jodhpur
4. Indian Institute of Public Health (IIPH), Gandhinagar
5. National Institute of Virology, Pune
6. National Institute for Research in Reproductive Health (NIRRH), Mumbai
7. National Centre for Disease Informatics and Research, Karnataka
8. Indian Institute of Science (IISc.) Bengaluru
9. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum
10. Jawaharlal Institute of Postgraduate Medical Education and Research,Puducherry.
11. National Institute for Research in Tuberculosis (NIRT), Chennai
12. National Institute of Epidemiology, Chennai
13. Indian Institute of Public Health, Hyderabad
14. Kalam Institute of Technology (KIT), Hyderabad
15. Regional Medical Research Center (RMRC), Bhubaneswar
16. Indian Institute of Public Health (IIPH), Shillong
17. State Cancer Institute and King George Medical University, Lucknow
18. All India Institute of Medical Sciences, Rishikesh
19. Institute of Medical Sciences, Banaras Hindu University (BHU), Varanasi
20. Dr Rajendra Prasad Government Medical College, Kangra

5.5. Type of HTA Projects, Funding Mechanism, Progress and Monitoring

a) Types of projects HTAIn may undertake following type of Research studies/ projects related to HTA:

i. Monocentric Studies (HTA)

ii. Multi-centric Project (HTA/ Validation study/Operational study etc.)

iii. Any other project/ study requested by the Central and the State Government.

b) Funding Mechanism

i. The budget for a multicentric study may vary between Rs.1-15 crores based on the proposal submitted by the PI of the study.
ii. The budget proposal will be recommended by the TAC to DHR, which will be approved by the Secretary, DHR.
iii. The approved budget for each year will be released from the budgetary provision of DHR under the scheme.
iv. The funds will be released on yearly basis till the project is completed. For the subsequent years, the funds will be released only after receipt of the annual progress report of the previous year along with Chartered Accountant (CA) or standard auditor certified utilization certificate (UC) and statement of expenditure (SOE).
v. Expenditure should not ordinarily exceed the prescribed budget. Any inter-se variations under various components will be permissible only with the specific recommendation of TAC and approval of Secretary, DHR.
vi. Contingency grant is restricted below 5% of the budget proposed. The contingency grant can be utilized for purposes it was sanctioned but not limited to – Stationary, Printing, Computer Utilities, Official Travels etc.
vii. Overhead charges should be between 3-5% of the proposed budget. viii. The budget will cover, Manpower, recurring, travel, contingency and overhead.

Note: The studies will be undertaken within the allocated budget. However, in exceptional cases where additional budget is will be decided on case to case basis with the recommendations of TAC and approval of Secretary DHR in consultation with AS & FA.

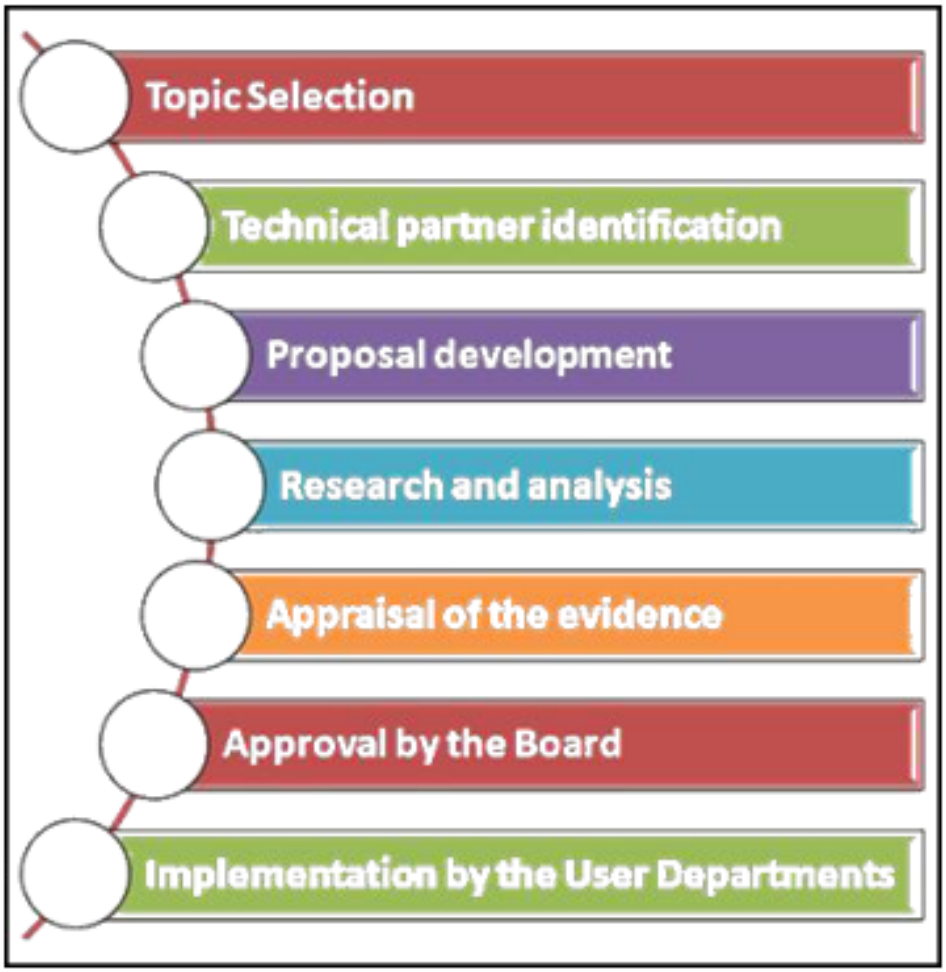
c) Progress

i. The Principle Investigator (PI) will provide updates regarding the progress of the study on quarterly/ half-yearly basis.
ii. PI may respond to all inquiry/ update from the Secretariat.
iii. The PI/ research team may visit HTAIn Secretariat if there is a need of further clarification regarding the research question or methodology.

d) Monitoring

i. The resource Centres or technical partner undertaking the study may be called to the Technical Appraisal Committee meeting at DHR headquarters for a review presentation or update quarterly. ii. Officials from DHR may also visit the respective institute for monitoring purpose.

5.6. Process of HTAIn



i. The User Department will send their topic(s) to the Secretariat for assessment.
ii. The topic will be prioritized by the Programme Division. I
iii. Approved topics are then allocated to suitable Technical Partner/ Resource Centres to conduct the study.
iv. The respective TP/ Resource Centres then will submit the study proposal that contains the policy question(s), research question(s), objective(s), methodology, timeline, manpower required and the estimated budget.
v. The proposal will be presented to the TAC for approval.
vi. After the approval the TP/ Resource Centres will be allowed to conduct the HTA study and after completion of the study submit the Outcome Report to the Secretariat for TAC approval.
vii. The report is also uploaded in the website to get comments from Stakeholders or a meeting conducted with stakeholders to get their comments.
viii. The recommendations will be presented to the HTAIn Board for final approval and subsequently sent to the User Department for implementation.

6. CONCLUSION

In conclusion, this brief report sheds light on the diverse landscape of healthcare technologies, emphasizing the importance of standardized health data and robust validation processes.

The initiatives such as Ayushman Bharat Digital Mission and the National Biopharma Mission underscore India's commitment to advancing its healthcare infrastructure and fostering innovation in biopharmaceuticals, medical devices, diagnostics and other sub-domains of Life Sciences.

The delineation of Technology Readiness Levels (TRLs) by BIRAC provides a structured approach to assess the maturity of core technologies, crucial for effective decision-making and market readiness. Additionally, the establishment of Clinical Trial Networks like CHOORD signifies a concerted effort to bolster India's capacity in conducting clinical trials across various medical domains.

India's pursuit of Universal Health Coverage (UHC) is commendable, with the National Health Policy advocating for increased public spending on healthcare services. The emphasis on optimizing resource allocation through Health Technology Assessment (HTA) reflects a strategic approach towards evidence-based decision-making and cost-effectiveness in healthcare.

Overall, this report underscores the importance of collaborative efforts, technological readiness and validations, and evidence-informed policies in driving India towards a more inclusive and efficient healthcare system that meets the needs of its vast population while ensuring the highest standards of quality and affordability.

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