



Ministry of Health Malaysia


# MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT FRAMEWORK

for

# DIGITAL HEALTH TECHNOLOGY



# Preamble



Rapid advancement of digital health technologies (DHTs) — including artificial intelligence (AI)-driven diagnostic tools, robotics, augmented/ virtual reality, mobile health apps, wearable sensors, telemedicine platforms, and electronic health records — is transforming the delivery of healthcare globally. These technologies promise to enhance access, improve patient outcomes, enable personalized care, and increase the efficiency of health systems. However, their integration into routine clinical practice and health policy decision-making poses significant challenges, particularly in evaluating their value, safety, effectiveness, and cost-effectiveness.

Health Technology Assessment (HTA) provides a structured, evidence-based approach to inform policy and reimbursement decisions by assessing the clinical, economic, social, and ethical implications of health interventions. In Malaysia, the HTA framework traditionally applied by the Malaysian Health Technology Assessment Section (MaHTAS), Ministry of Health Malaysia has focused primarily on pharmaceuticals, medical devices, biologics, and clinical procedures. As the digital health landscape evolves and the unique characteristics of digital health technologies — such as rapid iteration cycles, user interactivity, continuous data collection, and dependency on digital infrastructure, there is a pressing need to adapt HTA methodologies to evaluate these emerging technologies in a way that is contextually relevant and methodologically sound.

Recognising this, the HTA Assessment Framework for DHTs is being developed, aligning with the Ministry of Health Malaysia's broader goals of ensuring cost-effective and equitable access to innovative health solutions while maintaining patient safety, data protection, and service quality.

# Background

This document presents a graphical overview of, fit-for-purpose HTA framework that reflects the unique characteristics of DHTs and the local healthcare setting. It aims to provide the outline of the assessment domains to support reviewers, while informing healthcare payers, regulators, policymakers, and developers on the multidimensional value domains included in the assessment.

## **Early Development**

Much of the early development of the framework was based on the project commissioned by The City Cancer Challenge (C/Can), a global initiative supporting cancer care in low- and middle-income cities,. The framework had undergone verification and validation process through the deliberative process and engagement with clinical experts and relevant stakeholders in Malaysia to ensure the framework addressed context-specific challenges, including infrastructure limitations, equity concerns, and local health system readiness.

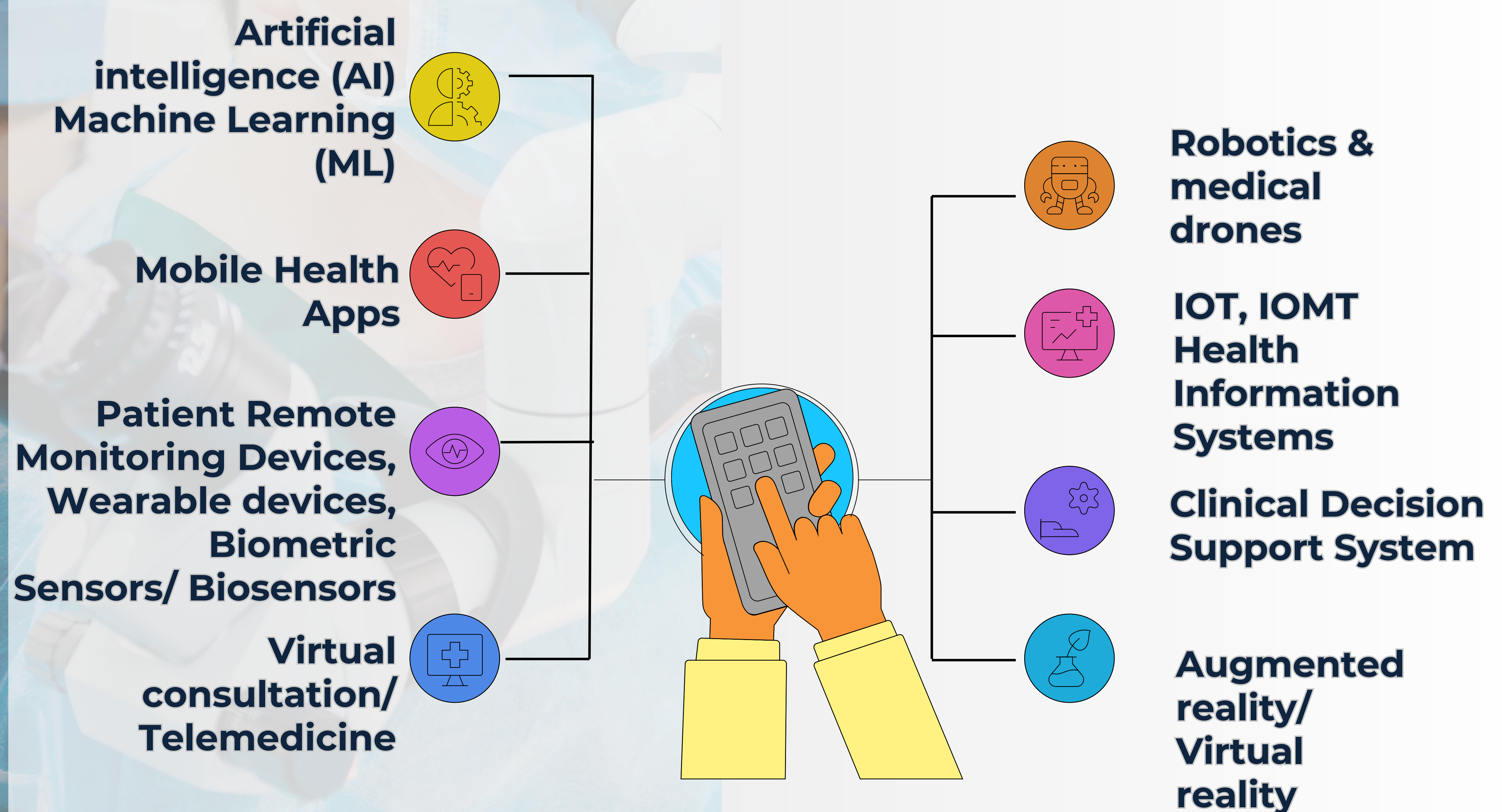
# Definition

For this Framework, we refer to the definition by the US FDA (2023);

- A digital health technology is a system that uses computing platforms, connectivity, software, and/or sensors, for health care and related uses.
- These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics).
- Any tools, systems, software that uses electronic to improve patients' health outcomes, service delivery, monitoring process, or for patient empowerment

# Scope: Types of Digital Health Technology

Aligned with broader MaHTAS responsibilities in providing evidence-based technical input for policy decision-making, the framework includes a wide range of digital health technologies, excluding stand-alone mobile applications and back-end systems as well as enabling infrastructure.



# 6 VALUE DOMAINS



● **Technical Product Information**



● **Effectiveness**



● **Safety**



● **Cost Implication**



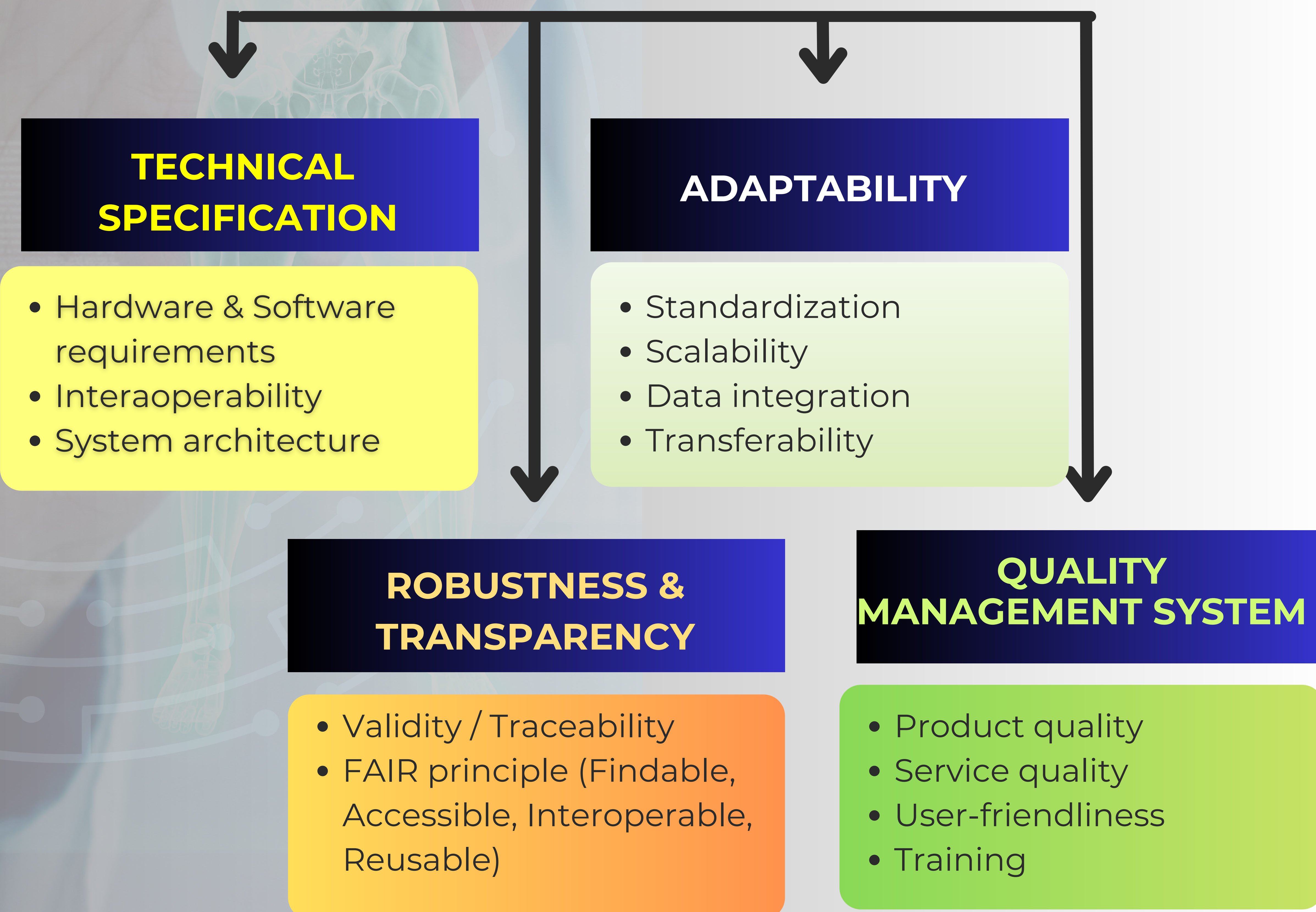
● **Organisational Impact**



● **Ethical, Social, and Legal Considerations**

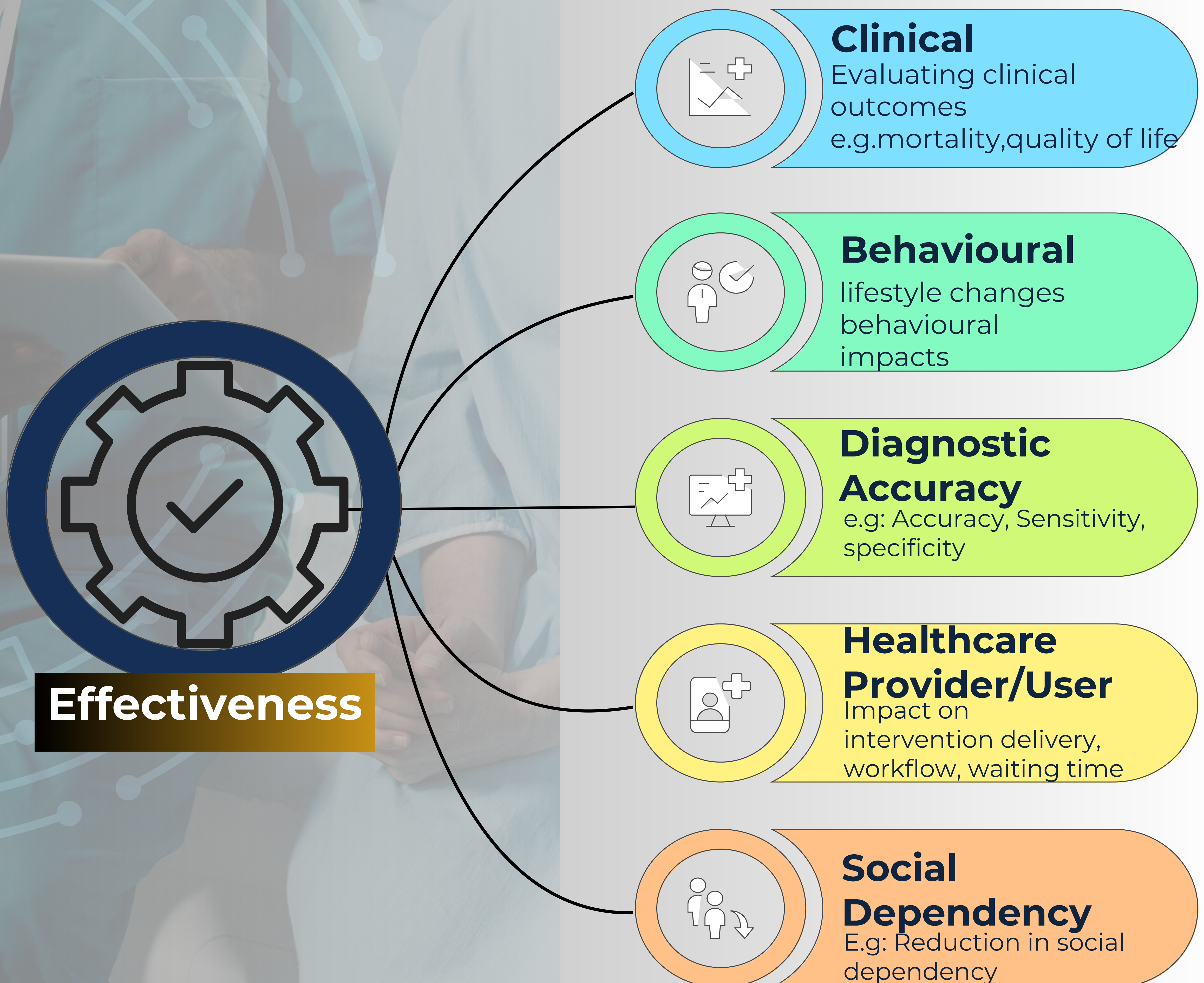
# DOMAIN 1: TECHNICAL PRODUCT INFORMATION

Technical product information domain outlines the essential technical and operational criteria for digital health solutions, focusing on technical specifications such as hardware/software requirements, system architecture, and interoperability. It emphasizes robustness, transparency, and compliance with FAIR principles while addressing adaptability through standardization, scalability, data integration, and transferability. Additionally, it includes quality management aspects like product and service quality, user-friendliness, and training to support reliable and sustainable implementation.



# DOMAIN 2: EFFECTIVENESS

The effectiveness of DHT must be supported by scientific evidence to ascertain its impact on patient outcomes, healthcare provider, and the health system as a whole. It includes dimensions such as clinical effectiveness (e.g: reduction in pain, increase in survival), behavioural impact (e.g: enhances adherence, self-management, or patient empowerment), operational effectiveness (e.g: improves workflow efficiency, resource use, or communication) as well as system effectiveness (e.g: Increases access, continuity, or equity in health service delivery)



# DOMAIN 3: SAFETY

The clinical safety of digital health technology (DHT) is critical, as it directly affects patient health outcomes. Scientific evidence is required to assess the safety of DHT, particularly regarding its clinical use and technical performance. Key risks include the potential for side effects and adverse events, misuse or misinterpretation of DHT-generated outputs, and issues related to diagnostic sensitivity and specificity. Safety considerations also towards technical aspects, such as data protection, cybersecurity, and the interoperability of DHT systems with existing healthcare information infrastructure. A comprehensive evaluation of both clinical and technical safety dimensions is necessary to support the safe integration of DHT into routine healthcare practice.

## Safe Data Exchange & Integration

Any protocols for safe data exchange and integration with existing patient information



## Clinical Safety

Adverse events to patients  
e.g. physical, mental harm  
-Incident reporting, post-market surveillance  
-potential algorithm biases, hallucination and discrimination



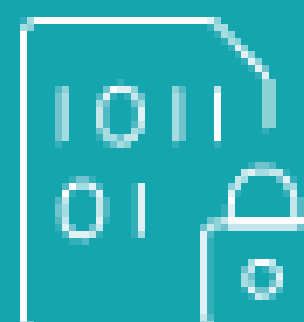
## Technical Security

- Involves cybersecurity measures to protect against breaches
- Any established procedures for incident reporting or technical failures
- Adhere to national/local regulatory framework
  - Follow guidelines in developing the AI/digital system



## Data Protection, Storage & Privacy

Ensures compliance with data protection/privacy laws and secure data handling



# DOMAIN 4: COST IMPLICATION

## Categories of Cost

### System-level Costs



#### Start-up Costs

Equipment, infrastructure/network, software licenses, implementation, initial training

#### Operational Costs

Recurring costs, maintenance, software updates, cloud hosting, license renewals

### Service Delivery Costs



#### HCP-related costs

Human resources, workflow changes, consumables, utilities

### Individual-Level Costs



#### Out-of-pocket expenses

Digital access burden (mobile data, internet)

Time and travel

Training effort for patients



### Direct Cost

- Labour/HR cost
- Production cost
- Material cost (components)
- Manufacturing and supply cost
- Development and implementation costs
- Maintenance and support costs
- Training costs
- Operational costs
- Direct and indirect medical costs
- Out-of-pocket expenses
- Capital and non-capital costs
- Health expenditure
- Cost of storage
- Cost of device and delivery
- Transport cost
- Marketing cost
- Uptake cost
- Maintenance cost
- Packaging cost
- Research & development (R&D) cost



### Indirect Cost

- Loss of productivity absenteeism
- Caregiver costs
- Loss of income,
- Accessibility cost
- Equity cost
- Annual maintenance
- Insurance
- Cost of patent (intellectual property rights)
- Technology failures
- Maintaining web, portals/apps
- Time and travel costs
- Intangible costs
- Environmental costs
- Administration and support
- Office and equipment rental costs
- Investment write-offs

The cost assessment of digital health technologies encompasses a broad range of financial considerations, including start-up, operational, and system-level expenses, as well as costs borne by healthcare providers and patients. A structured evaluation helps determine the economic feasibility, sustainability, and value of implementing DHT within the health system.

# DOMAIN 4: COST IMPLICATION

## Cost Assessment



### Economic Evaluation

- Cost-Effectiveness Analysis (CEA)
- Cost-Consequence Analysis (CCA)
- Cost-Utility Analysis (CUA) - if applicable



### Budget Impact

**Return of Investment (ROI) - if needed**

# DOMAIN 5: ORGANISATIONAL IMPACT

This domain focuses on the practical and inclusive use of digital health solutions across user groups—healthcare professionals, patients, and other users. It addresses user readiness, digital literacy, engagement, and compliance with accessibility standards such as WCAG 2.2. Key considerations include integration into clinical workflows, ease of use across devices and connectivity levels, user training and support, and ongoing feedback to improve design, experience, and equitable access.

## Accessibility

Adhering to WCAG 2.2 guidelines for accessibility

## Compatibility

Ensuring functionality across multi-devices and internet settings

## Training and Support

Necessary training and support for sustainability



## Integration and Interoperability

Ensuring seamless integration with current care pathways, workflows and existing systems  
-System interoperability  
-Policy interoperability

## User Acceptance

Evaluating user readiness, feasibility and satisfaction

## Healthcare Professional Involvement

Engaging professionals in design and testing

# DOMAIN 6: ETHICAL/LEGAL/SOCIAL CONSIDERATION



## Data Privacy & Security

- Data protection laws (PDPA, HIPAA)
- Security standards (COPPA, GDPR, etc.)
- Cloud data storage, breach response plan
- Data security, privacy, ownership and compatibility with multiple devices and low/no internet settings

## Autonomy & Consent

- Clear consent for data use
- Awareness of data collection
- Right to withdraw consent (highlight any limitations)



## Equity & Justice

- Non-discrimination and non-stigmatization
- Education, training, and awareness to enhance eHealth literacy
- Compliance with WCAG 2.2 guidelines for accessibility
- Patient feedback & Patient-Reported Experience Measures (PREMs) for continuous improvement
- Social dependency, social functioning



## Transparency & Accountability

- Clear process flows
- Open-source/IP issues
- Regular audits and public trust in providers



Ethical assessment addresses critical issues, including data privacy, informed consent, equity of access, and accountability. Integrating these considerations helps ensure that digital technologies are implemented in a manner that respects individual rights and promotes public trust.

# References

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3. John D, Dutta Majumdar A, Pillai RN, et al. Health technology assessment for digital health Technologies in India: a framework for action. *Int J Technol Assess Health Care*. 2024;40(1):e70
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**THE END**

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