EDiHTA

The first **E**uropean **Di**gital **Health Technology Assessment** framework co-created by all stakeholders along the value chain

EU HORIZON projekt EDiHTA

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O projekcie EDiHTA

EDiHTA to 4-letni projekt w zakresie badań i innowacji w ramach programu ***„Horyzont Europa”*** finansowany w ramach konkursu HORIZON-HLTH-2023-IND-06-07

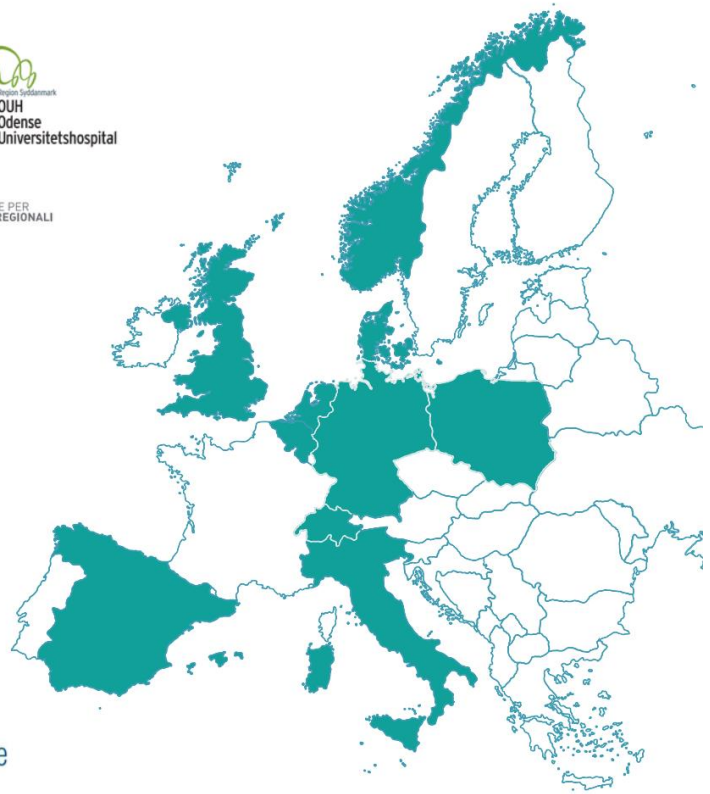
CEL

- **Stworzenie pierwszych, europejskich ram dla oceny cyfrowych technologii medycznych**
  - *(ang. Digital Health Technologies **DHT**),*
- **o poziomie gotowości technologicznej 6-7** (*ang. Technology Rediness Level TRL*),
- umożliwiających ocenę różnych DHTs (DHTs: telemedycyna *z ang. telemediciene*, aplikacje zdrowotne *z ang. Health Apps*, Sztuczna Inteligencja *z ang. Artificial Intelligence AI*)
- na różnych poziomach technologicznych i terytorialnych,
- oraz z różnych perspektyw (płatnik, pacjent, szpital).

Ramy zostaną zweryfikowane **w pilotażach w pięciu dużych europejskich szpitalach** oraz w ramach **otwartego programu pilotażowego z udziałem europejskich deweloperów DHT**.

EDiHTA w liczbach

- 16 partnerów – koordynator: *Universita Cattolica del Sacro Cuore, Włochy*
- 10 krajów, w tym 1 partner z Polski (Instytut Polityki Zdrowotnej NGO)
- 4 lata: 2024-2028
- Budżet 8 milionów EUR
- 5 pilotaży



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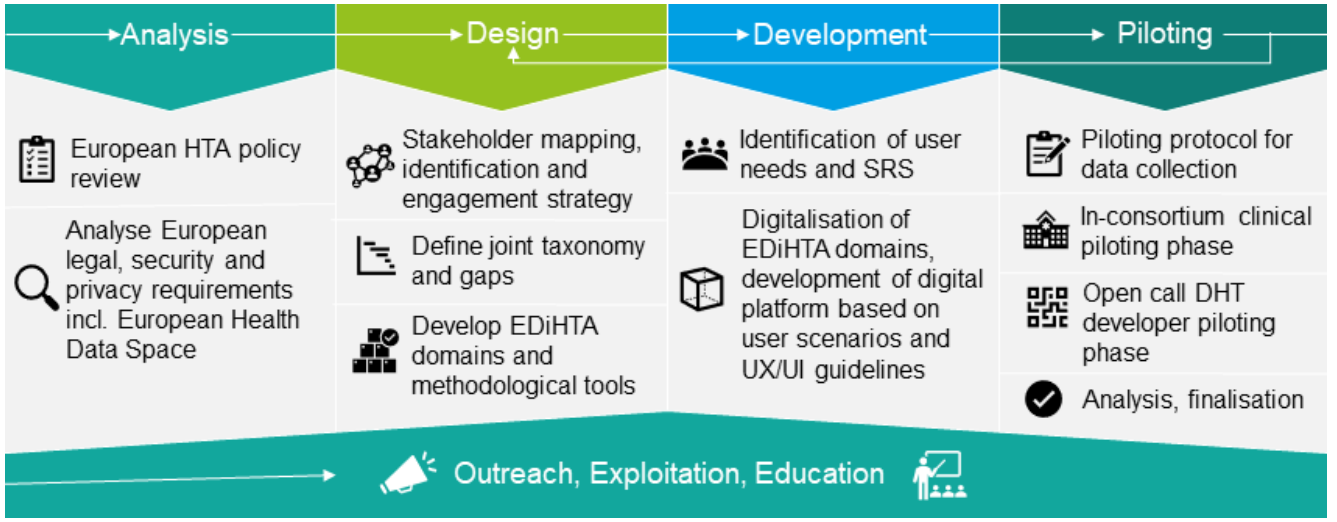
Innowacyjność

EDiHTA obejmuje pełen łańcuch innowacji: od analizy po walidację stworzonych ram **Oceny (Cyfrowych) Technologii Medycznych**. Ramy te zostaną zdefiniowane dla wszystkich aspektów **Oceny Technologii Medycznych (z ang. Health Technology Assessment HTA)** oraz udostępnione do wykorzystywania za pośrednictwem iteracyjnej platformy cyfrowej, która będzie zgodna z potrzebami zainteresowanych stron, zapewniając wskazówki i wsparcie metodologiczne.



Plan pracy 2024-2028

8 ściśle powiązanych ze sobą pakietów roboczych (WPs):

- **WP1 - Zarządzanie i koordynacja projektu**
- **WP2 - Ocena i analiza aspektów etycznych, prawnych i społeczno-ekonomicznych**
- **WP3 - Prace koncepcyjne, projektowanie ram EDiHTA**
- **WP4 - Stworzenie ram dla EDiHTA**
- **WP5 - Digitalizacja**
- **WP6 - Pilotaże**
- **WP7 i WP8 – Rozpowszechnianie i wykorzystanie rezultatów projektu**

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HEALTH PROGRAMME PROCESSES

Step 1
Indentifying target health programmes

1.1 Planning & Implementation charter
1.2 Health system organogram
1.3 User personas

Step 2
Assessing current state and country readiness

2.1 Process matrix
2.2 Current state workflow diagram

DIGITAL CONTEXT

Step 3
Designing digital health interventions

3.1 Digital health interventions
3.2 Future state user journey
3.3 Landscape analysis

Step 4
Defining capabilities and functionalities

4.1 Functional requirements to summarize end-user needs

Step 5
Linking to national enterprise architecture

5.1 Interoperability standards, applications and data sources

FINANCIAL & OPERATIONAL CONSIDER-ATIONS

Step 6
Monitoring and evaluation of implementation

6.1 Adaptive management checklist
6.2 Logic model
6.3 Key metrics for monitoring and evaluation (M&E)

Step 7
Costing for implementation, maintenance and scale

7.1 Cost drivers across phases

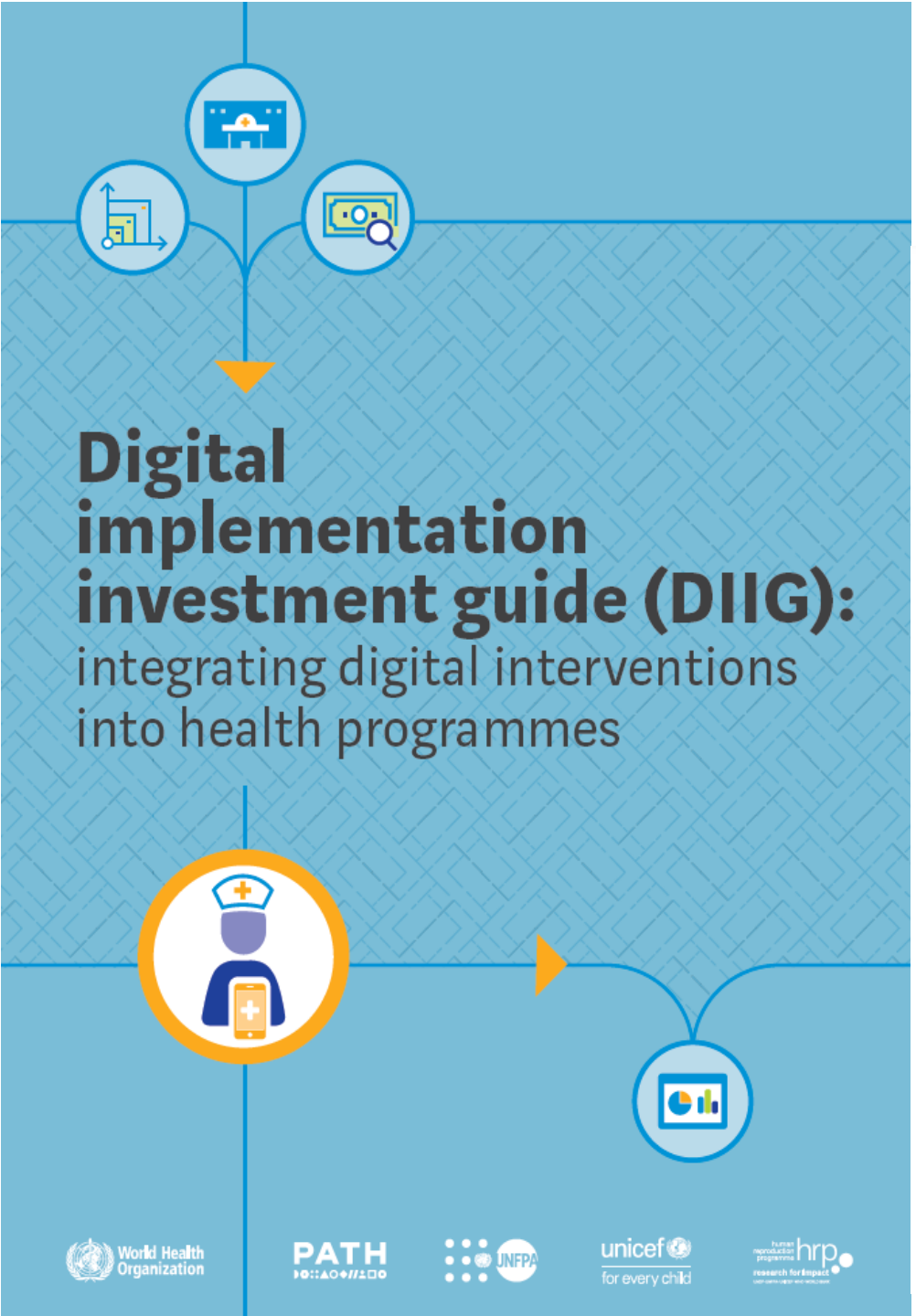

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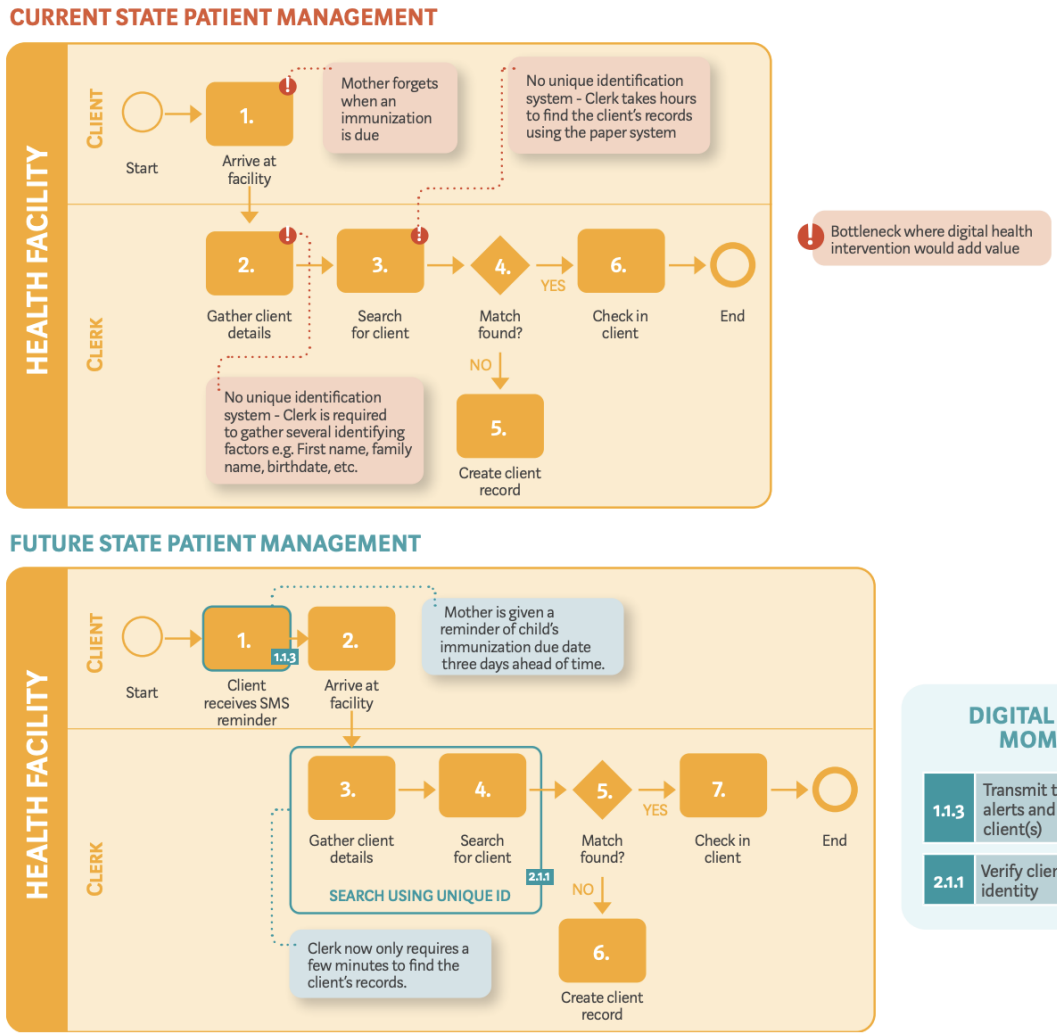
Fig. 4.3.3.1. Bottleneck and future-state workflow diagrams.



WHO compendium of innovative health technologies for low-resource settings

2022

World Health Organization

COMMERCIALLY AVAILABLE

2022

Fetal monitor - wireless, mobile

Country of origin | Japan
Primary function | Monitoring
Category | Medical device

Commercial information

List price (USD): 8000
Year of commercialization: 2019
Number of units distributed: 101-1,000
Currently marketed in: South East Asia Region
Brand: Melody International Ltd.

Product description

The fetal monitor iCTG ensures proper care of pregnant women and their fetuses. iCTG graphically displays the fetal heart rate and uterine contractions in 20 minutes to several hours. The iCTG is comparable in performance to conventional CTGs but is ultra-compact, completely wireless, and mobile. The widespread use of this device will enable the early transfer of pregnant women to secondary or tertiary hospitals in areas where there is a shortage of doctors or poor access to medical care.

Product details

Consumables: Ultrasound gel, 2 x CTG belts
Warranty duration: 5 year
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, AC, 110V, 220V,1-hour battery recharge cycle, 6-hour battery life
Facility requirements: Access to a cellular phone network, Storage temperature -10 to 45°C, relative humidity 10-90%, atmospheric pressure 700-1060hPA

Contact: Emi Sogo | Email: sogo@melody.international | Phone: +81 87 813 7362 | Web: www.melodyi.net

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In 2017, around 295,000 women died during and after pregnancy and delivery, with the vast majority of deaths (94%) occurring in low-resource settings. In 2019, an estimated 1.9 million babies were stillborn at 28 weeks or later, with three-quarters of all cases occurring in Sub-Saharan Africa and South Asia. With better monitoring and availability of emergency obstetric care, a large proportion of these deaths could be avoided.

Cardiotocography enables the evaluation of fetal health during pregnancy by examining fetal heart rate patterns. The primary goal of antepartum and intrapartum fetal monitoring is to identify fetuses at risk of hypoxia and allow for a timely intervention to lower the risk of hypoxic injury or death while also avoiding unneeded interventions in well-oxygenated fetuses.

The manufacturer's iCTG offers a paperless, wireless, portable solution for both antepartum and intrapartum monitoring, which should only be used by a trained healthcare provider. It is intended to enable real-time visualization of relevant clinical data and facilitate remote diagnosis. The device does not support fetal heart rate measurement in multiple pregnancies, despite of the possibility of monitoring more than one foetus, caution must be exercised in the use of this device in low-resource settings, as it is not clear how it behaves in unidentified multiple pregnancies.

WHO specification comparison

The Melody International CTGi – Cardiotocograph MI1001A device is claimed to be a "Foetal heart detector" and not a "Monitor". Consequently, at the time of report creation, WHO technical specifications are not available to perform a compliance evaluation with this type of technology.

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Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	⚠	Ease of cleaning	→
Ease of Use	→	Ease of maintenance	⚠
Positive impact on clinical outcomes	→	Infrastructure requirements	⚠
Affordability	✗	Local access to sales support	⚠
Engineering resources minimization	→	Local access to technical support	✗
Cultural and social acceptability	N/A	Local access to training	⚠
Environmental conditions	→	Local access to spare parts	⚠
Aesthetics	→	Locations of use within target setting	→

Target settings: Primary, Secondary & Tertiary level, Ambulance

This product, available commercially, offers added observation of expecting mother and their baby condition while away from the hospital. Although it is not a replacement for a clinically acceptable fetal monitoring system, it delivers information that can help manage mother and baby vital conditions during pregnancy. The sensors, to be placed on the mother's abdomen, detect the baby's heart movement using ultrasound detectors (doppler effect) and convert the information into a heart rate while a second force-based sensor detects the mother's contractions. Since the baby heartbeat sensing sensor uses quartz substance to create and sense changes in the ultrasound wave pitch - the handling of the iCTG must be gentle in order to prevent damage to the quartz (i.e. from dropping).

The product is powered by a rechargeable Lithium battery that must be charged after 6 hours of operation. The charging time is an hour. This condition may require patients to obtain an additional backup unit for use during the battery depletion or charging period, which may increase the cost of the overall product. Additionally, the submission notes that an iPhone or iPad is required, while the Android devices have not yet been tested for connectivity.

Intellectual property and local production

Technology transferability	✗
Openly access intellectual property	✗
Local production	✗

Intellectual property – It is patent-protected and the design is registered. There are registered trademarks for the device. Clearance to use this technology is required.

Local production – Innovator does not want to consider producing locally. There is also a high dependency on imports for local production.

WHO related guidance material

- Maternal mortality: evidence brief - https://apps.who.int/iris/handle/10665/329886
- Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division - https://apps.who.int/iris/handle/10665/327595
- Managing complications in pregnancy and childbirth: a guide for midwives and doctors – 2nd ed. - https://apps.who.int/iris/handle/10665/255760
- WHO recommendations on antenatal care for a positive pregnancy experience - https://apps.who.int/iris/handle/10665/250796
- WHO recommendations on maternal health: guidelines approved by the WHO Guidelines Review Committee - https://apps.who.int/iris/handle/10665/259268
- Recurrence of adverse perinatal outcomes in developing countries - https://dx.doi.org/10.2471/BLT.12.111021

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WHO compendium of innovative health technologies for low-resource settings - 2022 — COMMERCIALLY AVAILABLE

Fetal monitor - wireless, mobile

Regulatory assessment

Pre-market assessment	⚠ Proceed with caution
Post-market assessment	✗ Not acceptable
Quality system assessment	→ Proceed

Pre-maket - A safety and EMC report, as well as a usability assessment based on IEC 60601-1-6/IEC 62366, was provided, but no protocol or test report was submitted. Report on biocompatibility and clinical performance or ultrasound testing and wireless and alarm validation were not included. The software validation is based on JIS T 2304:2017 certificate.

Post-maket - Documents were not provided. The ISO 13485 certificate expires in 2023. It has a MHLW manufacturing certificate.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	→	→
Safety	→	→
Economy	✗	✗
Organizational	→	→
Legal	⚠	⚠
Social	→	→
Ethical	→	→
Green environment	→	→

Melody-i is already commercially available as a cardiotocography device that detects fetal heart rate using an ultrasound Doppler method and uterine contraction using a strain gauge from mid-pregnancy to birth. The device can be used in areas with unstable power supplies since it has a built-in battery that provides 6-10 hours of usage. The battery can be charged using a small solar charger. It is durable, easy to produce and maintain. There is a high medical need. High implementation costs prevent the device from being affordable for low-resource settings. If the costs cannot be reduced significantly, the device is not recommendable.

Summary

Innovation

Technology evidence assessment Not recommended

Technology readiness level 9

FINCCHTA

Digi-HTA

EDiHTA

TOTAL SCORE		DEFINITION
10		**THE PRODUCT MEETS THE ASSESSMENT CRITERIA** There is strong evidence of the effectiveness of production. Safety, data security and protection, and usability and accessibility of the product are at an adequate level. The cost of using the product is reasonable.
9		**THE PRODUCT MEETS THE ASSESSMENT CRITERIA MAINLY** An organization considering the deployment of the product should note that **in one key area there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
7–8		**THE PRODUCT MEETS THE ASSESSMENT CRITERIA PARTIALLY** An organization considering the deployment of the product should note that **in two or three key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
5–6		**THE PRODUCT MEETS THE ASSESSMENT CRITERIA ADEQUATELY** An organization considering the deployment of the product should note that **in four or five key areas there are things to consider**. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
≤4		**THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT** An organization considering the deployment of the product should note that **there are shortcomings in one or more key areas**. Information about the effectiveness of the product is untrustworthy or of low quality. There may be shortcomings in the product's safety, or information related to it may be unreliable or of low quality. Product costs may be prohibitively high. There could be shortcomings in the product's data security and protection or in usability and accessibility.

Assessment fields

- **Effectiveness:** Sufficient
- **Safety:** Sufficient
- **Costs:** Reasonable
- **Data security and data protection:** Sufficient
- **Usability and accessibility:** Sufficient

Other things to consider when using the product:

References:

Assessment team:

Key Assessment Domains

POINTS	EFFECTIVENESS	SAFETY	COST	DATA SECURITY AND PROTECTION	USABILITY AND ACCESSIBILITY
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but more evidence is needed	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

eHealth Tools Assessment

A Practical Toolbox
ehealth-criteria-toolbox.net

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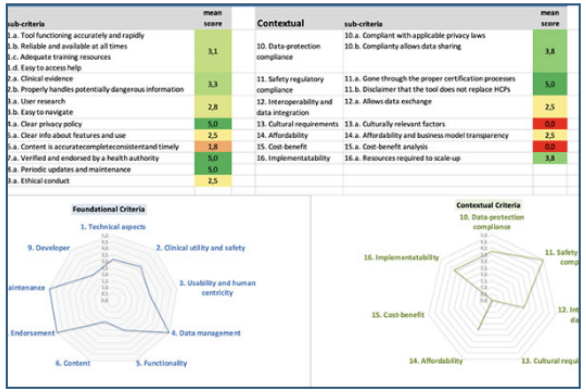
Assessment Instrument

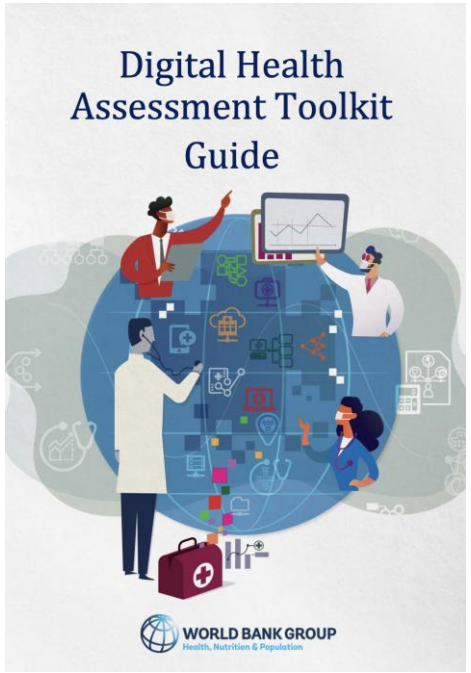


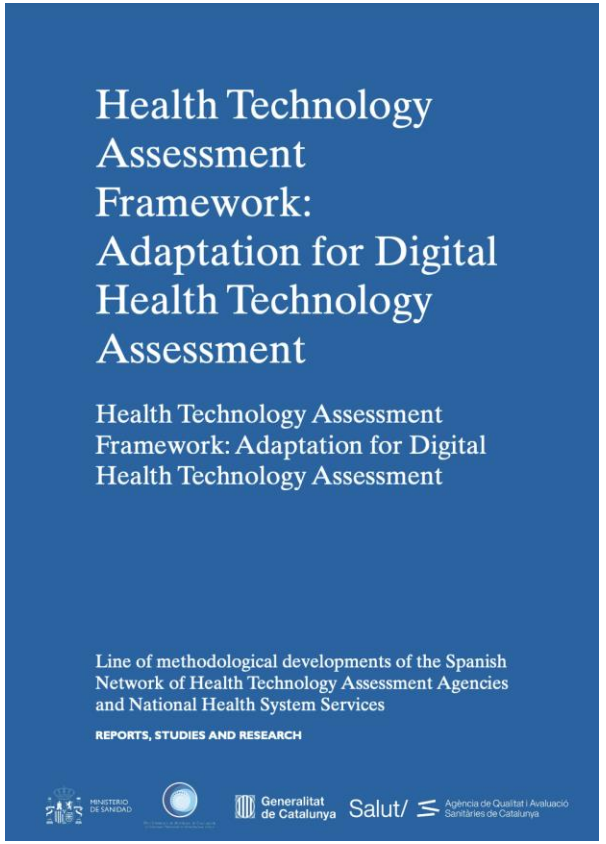
Downloadable assessment sheet and interactive dashboards

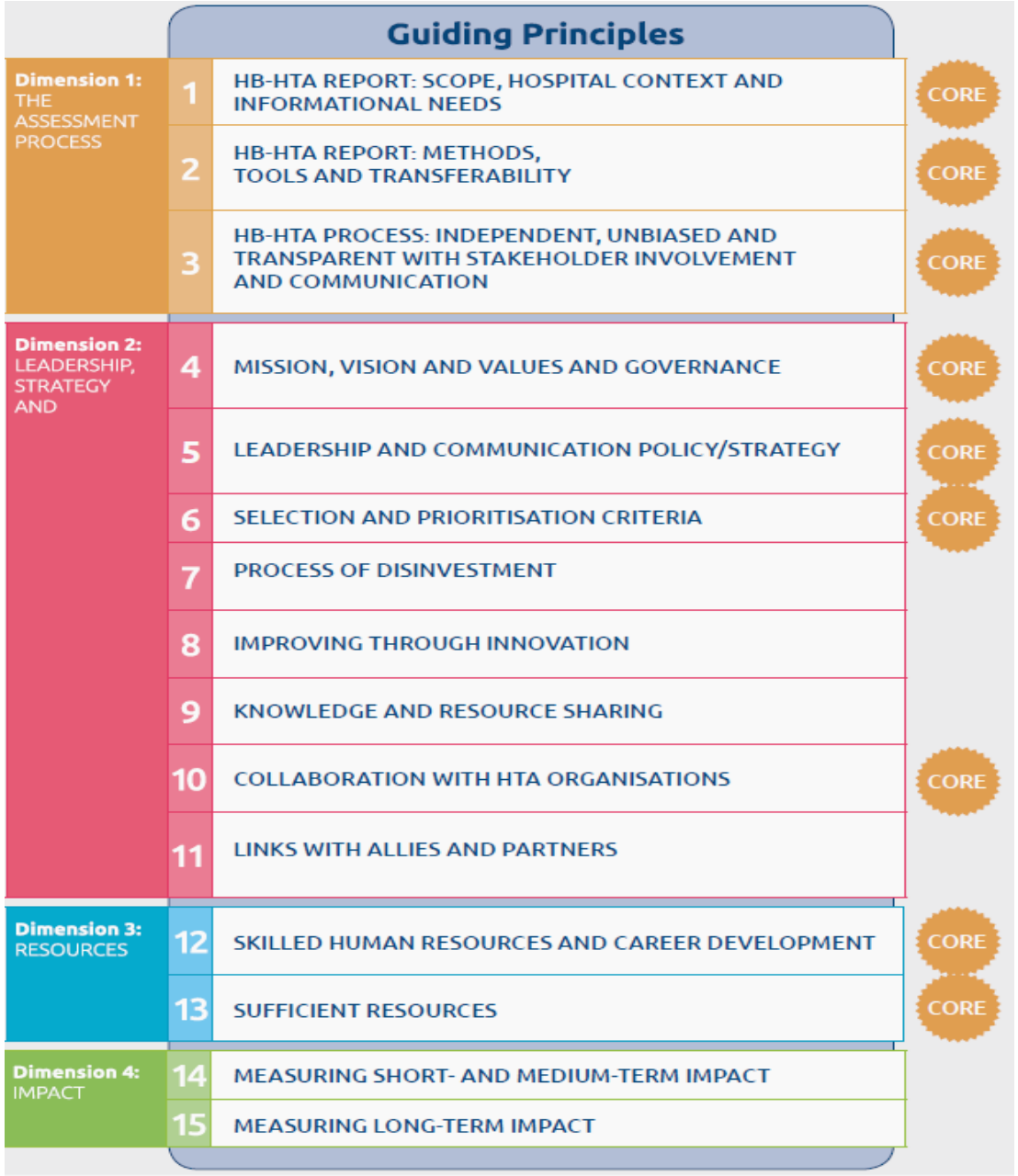
→ Download Beta Version

Web-based assessment instrument

→ Access here






Guiding Principles
Dimension 1: THE ASSESSMENT PROCESS
1 HB-HTA REPORT: SCOPE, HOSPITAL CONTEXT AND INFORMATIONAL NEEDS
CORE
2 HB-HTA REPORT: METHODS, TOOLS AND TRANSFERABILITY
CORE
3 HB-HTA PROCESS: INDEPENDENT, UNBIASED AND TRANSPARENT WITH STAKEHOLDER INVOLVEMENT AND COMMUNICATION
CORE
Dimension 2: LEADERSHIP, STRATEGY AND
4 MISSION, VISION AND VALUES AND GOVERNANCE
CORE
5 LEADERSHIP AND COMMUNICATION POLICY/STRATEGY
CORE
6 SELECTION AND PRIORITISATION CRITERIA
CORE
7 PROCESS OF DISINVESTMENT
8 IMPROVING THROUGH INNOVATION
9 KNOWLEDGE AND RESOURCE SHARING
10 COLLABORATION WITH HTA ORGANISATIONS
CORE
11 LINKS WITH ALLIES AND PARTNERS
Dimension 3: RESOURCES
12 SKILLED HUMAN RESOURCES AND CAREER DEVELOPMENT
CORE
13 SUFFICIENT RESOURCES
CORE
Dimension 4: IMPACT
14 MEASURING SHORT- AND MEDIUM-TERM IMPACT
15 MEASURING LONG-TERM IMPACT


THE AdHopHTA HANDBOOK
A HANDBOOK OF HOSPITAL-BASED HEALTH TECHNOLOGY ASSESSMENT
Information and knowledge for decision-making on managing technology at hospital level through the use of hospital-based Health Technology Assessment
AdHopHTA
Adopting Hospital Based Health Technology Assessment

EDiHTA

HBHTA w Polsce już jest!

HARMONOGRAM PROJEKTU

HOSPITAL-BASED HTA (HB-HTA)

PROJEKT WDROŻENIA SYSTEMU SZPITALNEJ OCENY INNOWACYJNYCH TECHNOLOGII MEDYCZNYCH

Ocena technologii medycznych (Health Technology Assessment - HTA) służy zwiększeniu możliwości zarządzania systemem opieki zdrowotnej w Polsce, poprzez dostarczanie systematycznej i przejrzystej oceny innowacyjnych, nielekowych technologii medycznych.

Kompleksowo, funkcjonalnie, adekwatnie, szybko.

Jak efektywnie oceniać nowe technologie medyczne?

Contact

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