HARMONISATION OF EVALUATION STANDARDS FOR DIGITAL MEDICAL DEVICES IN EUROPE

Marco Marchetti, MD

Director HTA Departement, Agenzia Nazionale per i Servizi Sanitari Regionali (Agenas), Italy

Co-Chair, HTA Member State Coordination Group (HTACG), EU

agenas AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI

HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Luxemburg, May 14th 2024

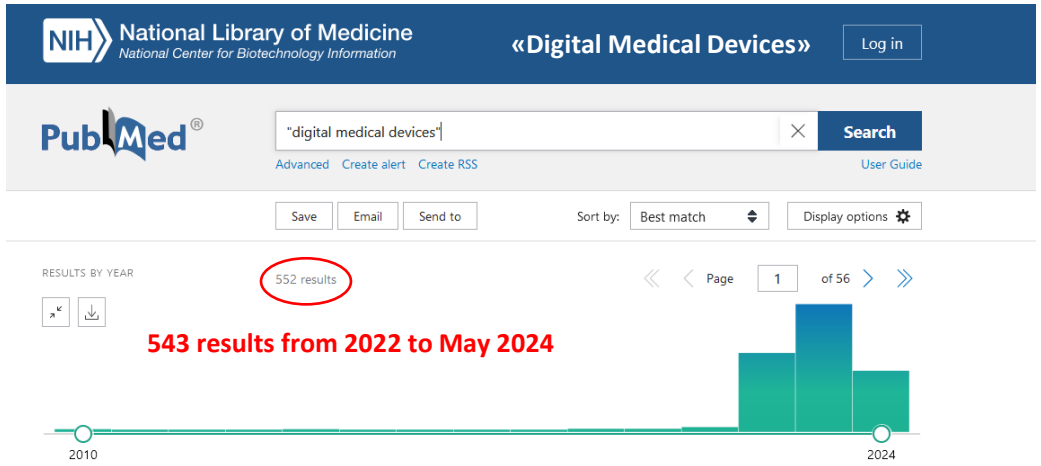
European Digital HealthTech Conference 2024

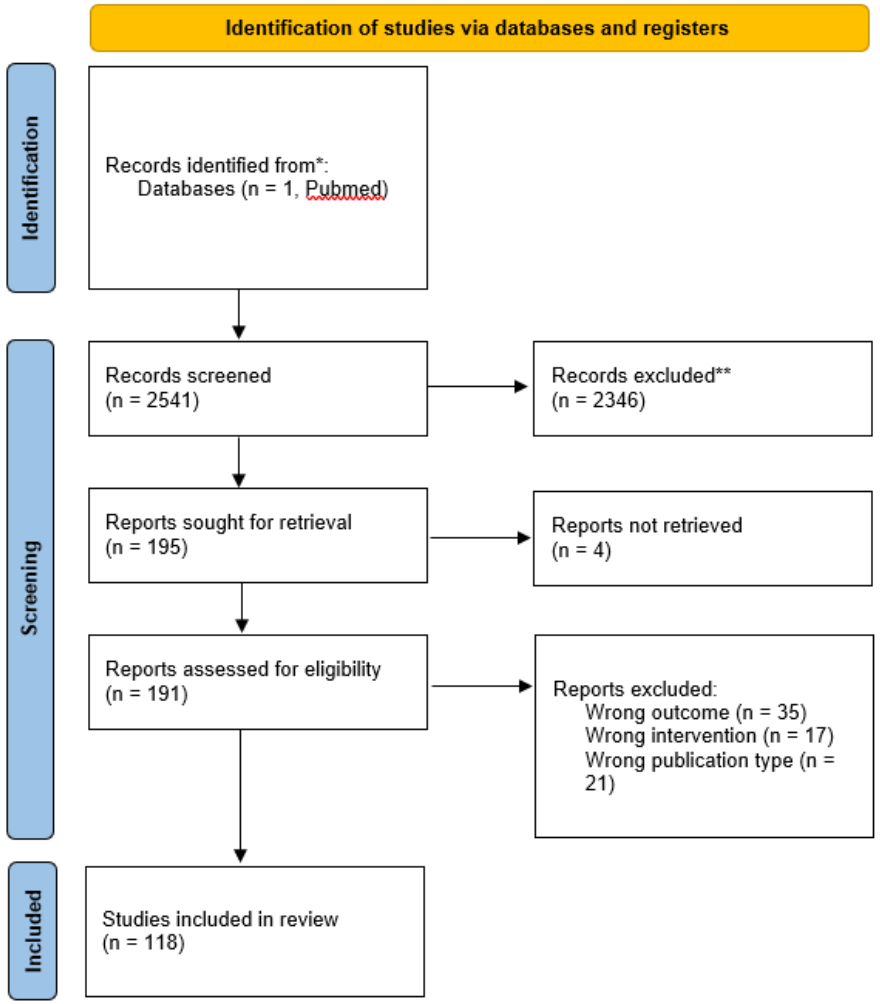
Supporting digital medical technologies from incubation to market access

Luxembourg, 14 -15 May 2024

Health Care and Digital Medical Devices Revolution

- The medical and healthcare field has seen tremendous changes and advances as a direct result of **Digital Transformation.**
- **Digital Transformation is revolutionizing the healthcare field**, with machine learning-driven artificial intelligence (AI) driving rapid advances in all areas of the industry.
- Scientific Evidence is growing rapidly





Digital Therapeuthics (Dtx)

Research question: clinical efficacy and safety of different digital therapeutics (last 5 years) - (systematic literature review- may 2024)
"digital therapeutic*" OR "dtx" OR "digital medical devices" OR "software as medical devic*"

Evaluation of Digital Medical Devices and Digital Therapeutics Frameowork

European Union Countries

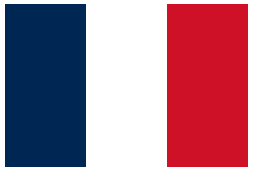
Belgium

- mHealthBELGIUM
- https://mhealthbelgium.be/

Germany

- Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG)* Vom 22. März 2024
  - https://www.recht.bund.de/bgbl/1/2024/101/VO.html
- Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG) Vom 9. Dezember 2019
  - https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=%2F%2F%2A%5B%40attr_id=%27bgbl119s2562.pdf%27%5D#__bgbl__%2F%2F*%5B%40attr_id%3D%27bgbl119s2562.pdf%27%5D__1715545227236
- DiGA
  - https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/dipa_leitfaden.pdf?__blob=publicationFile
- DiPA
  - https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/dipa_leitfaden.pdf?__blob=publicationFile

France



- Décret n° 2023-232 du 30 mars 2023 relatif à la prise en charge anticipée des dispositifs médicaux numériques à visée thérapeutique et des activités de télésurveillance médicale par l'assurance maladie au titre de l'article L. 162-1-23 du code de la sécurité sociale
  - https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000047377863
- PECAN
  - https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/early-access-reimbursement-digital-devices-pecan

Extra European Union Countries

United Kingdom

- Digital Technology Assessment Criteria (DTAC)
  - https://transform.england.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/
- Evidence standards framework (ESF) for digital health technologies
  - https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

U.S.A

- S.723 - Access to Prescription Digital Therapeutics Act of 2023
  - https://www.congress.gov/bill/118th-congress/senate-bill/723
- Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial

Other less structured framework are also existing….

The European strategies on Health

A path towards harmonization

An integrated strategy with a complete redesign of the EU Health Care Governance

MD and IVD Regulation

HTA Regulation

European Health Data Space

New Pharmaceutical Legislation

AI Regulation

HTA CG

MEMBER STATE COORDINATION GROUP
ON HEALTH TECHNOLOGY ASSESSMENT

Towards Integrated HTA for Improved Decision-Making

Regulation (Eu) 2021/2282 On Health Technology Assessment (HTAR)

HTAR governance structures

Member State Coordination Group

Joint configuration (medicinal products and medical devices) until the date of application of the Regulation

HTACG Chair
Rosin Adams, NCP,*Ireland*

HTACG Co-Chair
Expertise on medicinal products
Niklas Hedberg,TLV Sweden

HTACG Co-Chair
Expertise on Medical Devices
Marco Marchetti,Agenas, Italy

Chair
Paul de Boissieu
HAS, France

Co-Chair
Anne Willemsen ,
ZIN, Netherland

Joint Clinical Assessment (JCA)

M P M P

Chair
Stephanie Said
G-BA, Germany

Co-Chair
AEMPS, Spain

Joint Scientific Consultation (JSA)

M P M P

Chair
Kim Helleberg Madsen *Danish Medicines Agency, Denmark*

Co-Chair
Jelena Ivanovic
AIFA, Italy

Identification of Emerging Technologies

M P M P

Chair
Beate Wieseler
IQWiG, Germany

Co-Chair
Sara Couto
INFARMED, Portugal

Methodology

M P M P

MP-Medicinal Product ! MD – Medical Devices

SECRETARIAT BY THE EUROPEAN COMMISSION

Administrative Support | Technical Support | IT Support

HTA IT PLATFORM

Public Website | Secure workspace for the Coordination Group and its SubGroups | Secure workspace Manufactures and HTA Coordination Group

HTA Stakeholder Network

Include patients associations, non governmental organization in the filed of health, health technology developers and health professional.

Facilities dialogues between stakeholder oerganizations and the HTA Coordination Group

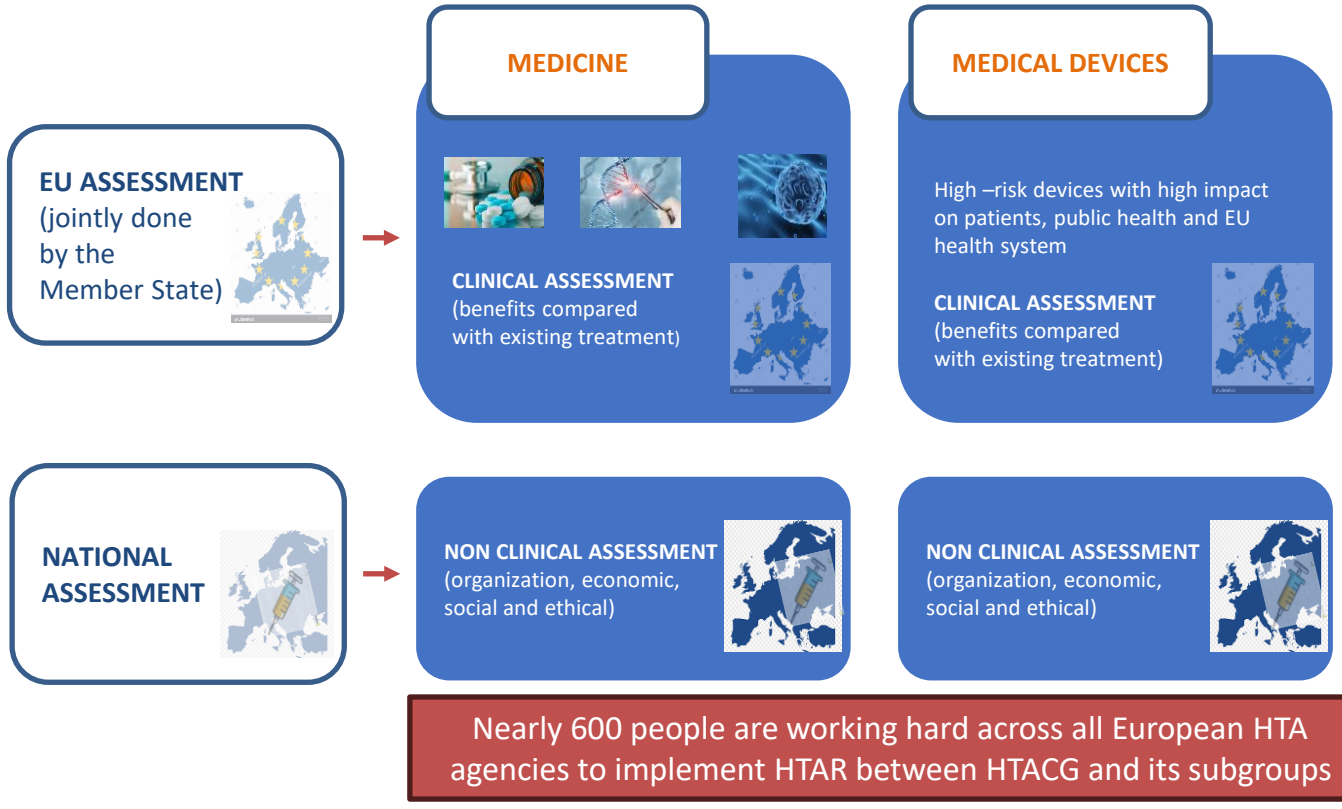
Members are umbrela organizations with geoghrapical coverage of several EU/EEA Member States

More than 600 people are working hard across all European HTA agencies, HTACG and its subgroups EMA and EU Commission to implement HTAR between

First Release October 2023- (3 releases is foresee in august 2024)

HTA Joint Work at EU level

What will be assessed at EU and at national level?



Nearly 600 people are working hard across all European HTA agencies to implement HTAR between HTACG and its subgroups

Article 7

Health technologies subject to joint clinical assessments

1. The following health technologies shall be subject to joint clinical assessments:

(a) medicinal products as referred to in Article 3(1) and Article 3(2), point (a), of Regulation (EC) No 726/2004, for which the application for a marketing authorisation is submitted in accordance with that Regulation after the relevant dates set out in paragraph 2 of this Article, and for which that application is in compliance with Article 8(3) of Directive 2001/83/EC;

(b) medicinal products authorised in the Union for which a joint clinical assessment report has been published, in cases where an authorisation is granted pursuant to the second subparagraph of Article 6(1) of Directive 2001/83/EC for a variation to an existing marketing authorisation which corresponds to a new therapeutic indication;

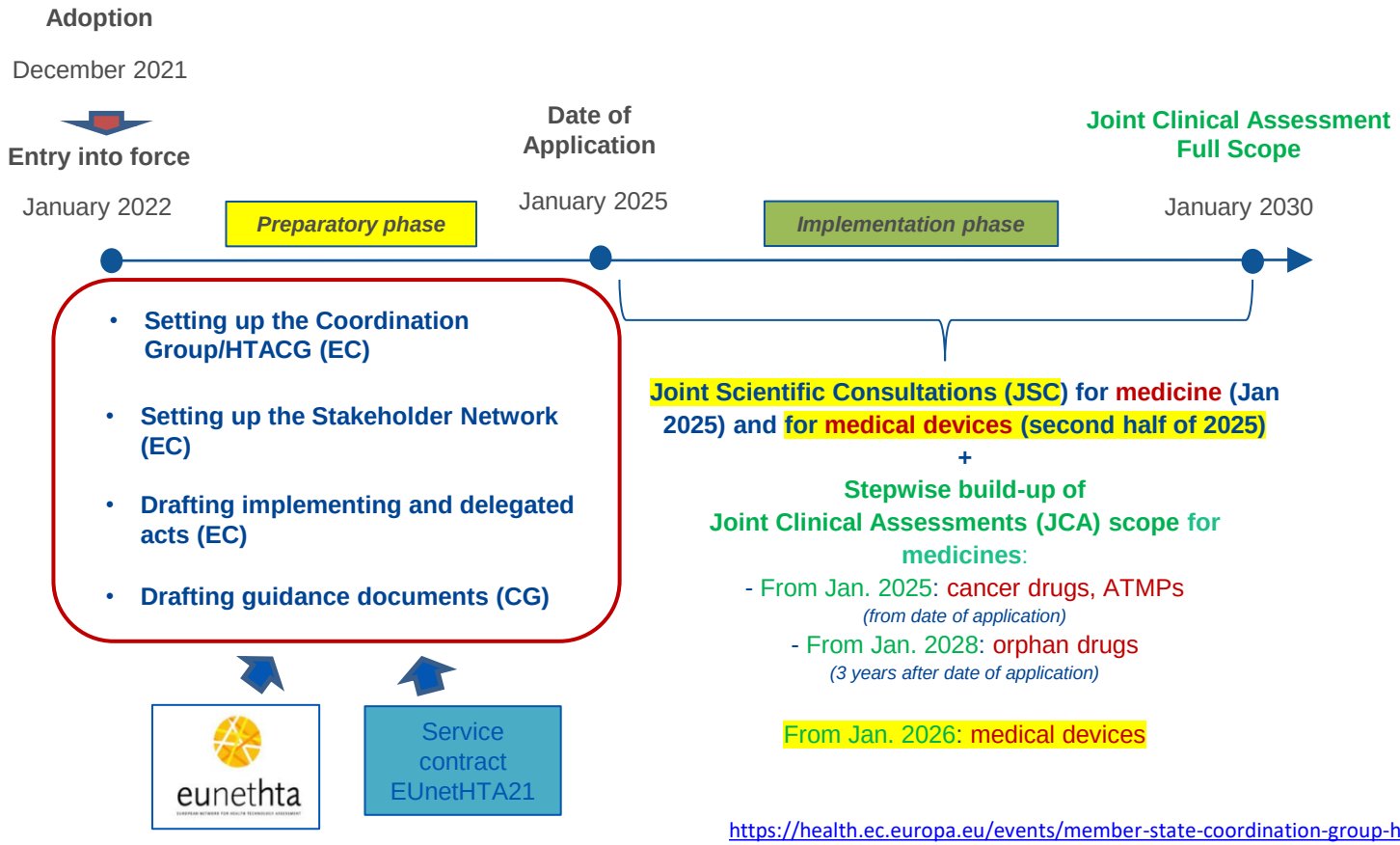
(c) **medical devices classified as class IIb or III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion** in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, and subject to selection pursuant to paragraph 4 of this Article;

(d) ***in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views** in the framework of the procedure pursuant to Article 48(6) of that Regulation, and subject to selection pursuant to paragraph 4 of this Article

Digital Medical Devices and Digital Therapeutics generally are not in class 2B and 3 but they are expected to have a huge potential impact on patients, public health or healthcare systems

The Regulation (EU) 2021/2282 on health technology assessment (HTAR)

Implementation timeline



https://health.ec.europa.eu/events/member-state-coordination-group-hta-htacg-2023-11-16_en

HTAR and Voluntary Cooperation

Art. 23 HTAR

22.12.2021 EN Official Journal of the European Union L 458/1

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(Legislative acts)

REGULATIONS

REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 December 2021
on health technology assessment and amending Directive 2011/24/EU

(Text with EEA relevance)

SECTION 4
Voluntary cooperation on health technology assessment
Article 23
Voluntary cooperation

1. The Commission shall support the cooperation and the exchange of scientific information among Member States on:
(a) non-clinical assessments on health technologies;
(b) **collaborative assessments on medical devices and in vitro diagnostic medical devices**;
(c) HTAs on health technologies other than medicinal products, medical devices or in vitro diagnostic medical devices;
(d) the provision of additional evidence necessary to support HTAs, in particular in relation to health technologies for compassionate use and obsolete health technologies;
(e) **clinical assessments of health technologies referred to in Article 7** for which a joint clinical assessment **is not yet initiated and of health technologies not referred to in that Article, in particular health technologies** for which the report on emerging health technologies referred to in Article 22 has concluded that **they are expected to have a major impact on patients, public health or healthcare systems.**

2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.
3. The cooperation referred to in paragraph 1, points (b) and (c), of this Article may be carried out using the procedural rules established in accordance with Article 3(7) and Articles 15 and 25 and using the format and templates established in accordance with Article 26.
4. The cooperation referred to in paragraph 1 of this Article shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and on the IT platform referred to in Article 30.
5. Member States, through their designated member in the Coordination Group, may share national assessment reports on a health technology not referred to in Article 7, in particular on health technologies for which the report on emerging health technologies referred to in Article 22 has concluded that they are expected to have a major impact on patients, public health or healthcare systems, to the Coordination Group through the IT platform referred to in Article 30.
6. **Member States may use methodological guidance developed pursuant to Article 3(7), point (d), for the purpose of national assessments.**

HTA and Voluntary Cooperation

HTACG, Minutes of the 6th meeting – November 16th 2023

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Digital, EU4Health and Health systems modernisation
Health technology assessment

Sixth Meeting of the Member State Coordination Group on Health Technology Assessment

16 November 2023, Brussels

Summary Minutes

- **Point 1: Priorities for voluntary cooperation**
  - **Several Member States signalled their interest in voluntary cooperation**. Topics ranging from cost-effectiveness, **digital medical devices**, Post Licensing Evidence Generation (PLEG) to collaboration on procedures and other types of health interventions, screening programs and vaccinations, unmet medical needs, registries on rare and ultrarare pathologies as well as real world evidence, artificial intelligence, evidence synthesis for medical exposure to ionising radiation, etc. were raised as possible areas for further work.
  - It was suggested that not all Member States would need to always be included in all areas of voluntary cooperation, but topics and lessons learnt could benefit every member in the HTACG. There was consensus, though, to focus on the mandatory work for the time being. The HTACG will form an interest group …to come up with recommendations on the way forward and set priorities for the future.
  - The methods and procedures in which this voluntary cooperation will take place must also be defined and the possible connection with the work done by the current subgroups currently in place. Further whether the IT platform could be used as a working platform for voluntary work and what operational support would be available for such work. The work should also include an analysis of possible connections to the existing regional HTA initiatives in EU (e.g. BENELUXA and FINOSE).

https://health.ec.europa.eu/document/download/e0f5ded4-231c-4d1e-896d-f8c24f39e126_en?filename=hta_20231116_mi_en.pdf (access May 15° 2024)

Horizon Europe Program, Innovative Health Initiative *(Research and Innovation Actions)* **and other EU Initiative on Digital Medical Devices**

- The first European Digital Health Technology Assessment framework co-created by all stakeholders along the value chain (EDIHTA) - Call HORIZON-HLTH-2023-IND-06.
- Support Utilisation of Sustainable and Tailored Innovative methods for HTA (SUSTAIN HTA) – Call HORIZON-HLTH-2023-IND-06.
- Harmonised approach to early feasibility studies for medical devices in the european union (HEU-EFS) – Call HORIZON-JU-IHI-2022-02-two-stage
- Development & harmonisation of methodologies for assessing digital health technologies in Europe (ASSESS-DHT)
- European Taskforce for Harmonised Evaluations of Digital Medical Devices (DMDs)

The HTA Agencies group and the process to develop a common HTA framework for DMD

- In the last Head of Agencies Group (HAG) (April 16th -17th 2024) EDIHTA and The objective of the presentation was to involve other EU HTA Agencies in consultation activities to create and develop a shared Digital Medical Devices framework
- ASSESS-DHT project were presented from AGENAS and AIHTA
- This is an iterative process which aims to capture in the most accurate way the needs and requirements of HTA agencies across Europe
- A group of people participating will be set up
- People will be enrolled in this group should be involved in HTA evaluation processes in their countries, especially the ones more relevant to Digital Health Technologies

A harmonization process is necessary, but now there are all the conditions to achieve it

Grazie per l’attenzione

Marco Marchetti

marchetti@agenas.it
hta@agenas.it

agenas AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI