

Development, evaluation and adoption of digital health technologies: how stakeholders need to interact to make this works?

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NICE National Institute for
Health and Care Excellence



Our panel



Felip Miralles, Director of Digital Health Unit at Technology Centre of Catalonia (Eurecat), Spain



Rosa Maria Vivanco Hidalgo, Head of HTA at Agència de Qualitat i Avaluació Sanitàries (AQuAS), Spain



Mark Salmon, Programme Director, Information Resources, NICE, UK



Pilar Pinilla-Dominguez, Associate Director, NICE International, NICE, UK (moderator)
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The digital health context



NICE

Innovation progressing at pace

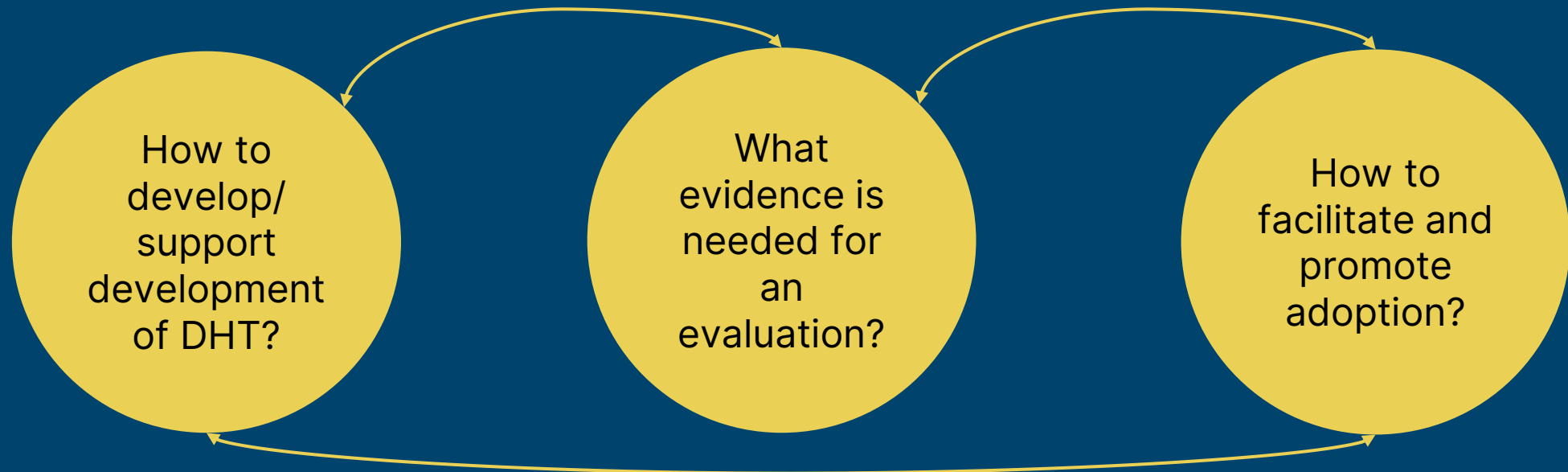
High system demand for digital solutions

Regulation yet to align with speed of change

Economic challenges – pressure to optimise resources

Real world data is driving a revolution in evidence

Development, evaluation and adoption



Poll Question 1



Who are the relevant stakeholders that should interact with each other for the development, evaluation and adoption of digital health technologies?

Poll Question 2

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To what extent do you think that these interactions are currently happening in your jurisdiction?

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"innovating for business"

Development, evaluation and adoption of digital health technologies:
how stakeholders need to interact to make this works?

Felip Miralles - Director Digital Health - Eurecat
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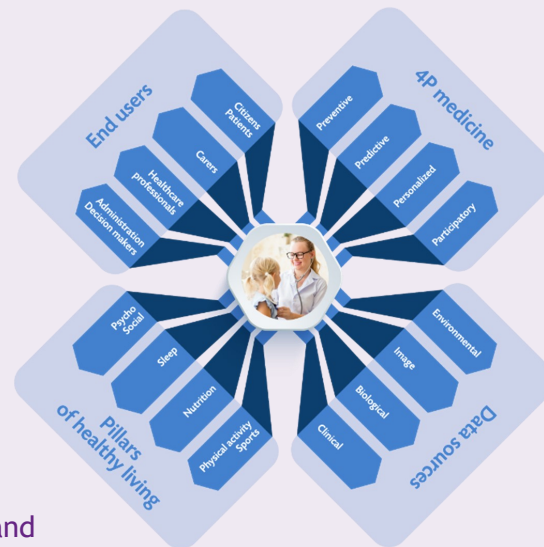


1 Smart hospital of the future - Hospital 4.0

- Planning, optimization and re-engineering of healthcare processes.
- Control center with digital twins, simulation and dashboard tools for smart management of hospitals
- Liquid hospitals, home hospitalization and hyper specialization of intra-hospital services
- Healthcare robotics and Artificial Intelligence for automatization and smart support
- Medical devices to facilitate and standardize diagnosis, intervention and follow-up

3 Clinical Decision Support Systems for evidence-based medicine

- Data analytics in Medicine: analysis and fusion of clinical, epidemiological image, biologic, environmental data
- Application of statistical but specially Artificial Intelligence and Machine Learning techniques
- Predictive and prescriptive models
- Clinical decision support systems for screening, diagnosis, prognosis, therapy management and personalization
- Deployments, evaluation and assessment



2 Integrated care approach for chronic care management

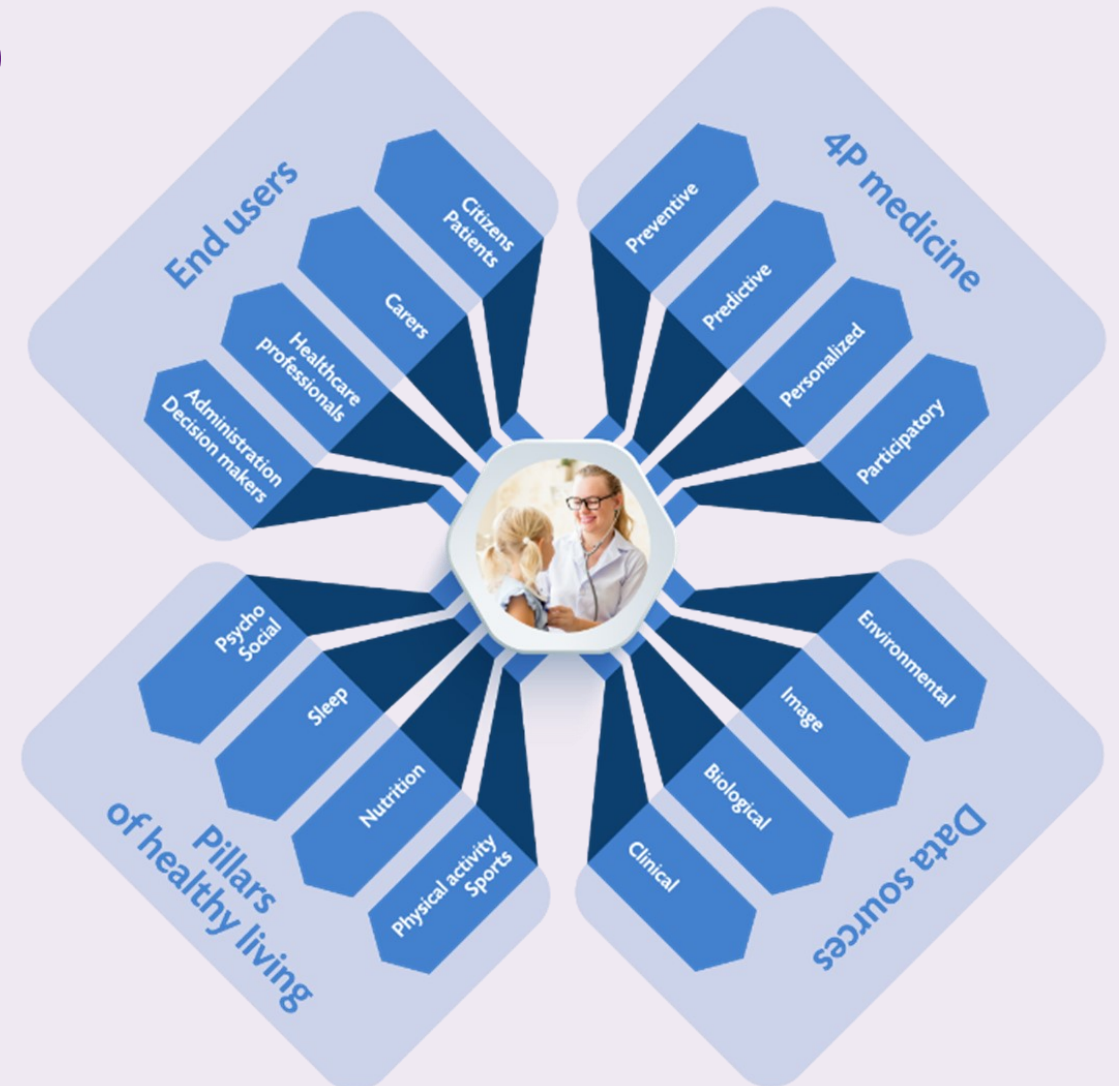
- Self management tools for patients and caregivers
- Collaboration tools for professionals from different health and social tiers
- Advanced services: patient empowerments, training, communication, monitoring, workflow management
- Adaptive and flexible care plan planning and follow up
- Virtual health practice to reduce unnecessary travels and visits and optimize and prioritize added-value face-to-face visits
- Improve adherence to treatments, not only pharmacological

4 Personalized medicine, personalized nutrition

- Holistic and multi-level approach to omic sciences: genomics, transcriptomics, proteomics, metabolomics
- Understanding and interpreting complex diseases mechanisms from a deep biologic perspective
- Personalization of medicine for each individual, based on biology and the interaction with phenotype.
- Personalization of pharmacological and non-pharmacological treatments, therapies, rehabilitation
- Personalization of nutrition with a biological foundation and interaction with life-style

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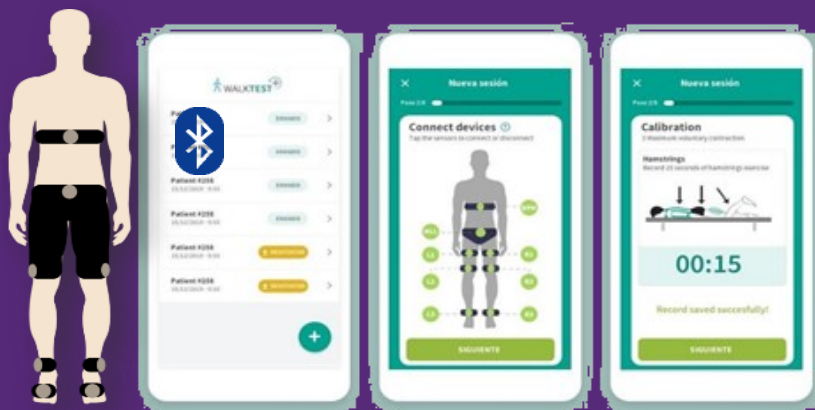
Success stories



Data & Sensorics

Digital transformation of functional assessment protocols

Improvement of diagnosis and follow-up of the Six Minute Walk Test protocol, for instance used in the evolution of chronic neuromuscular diseases, through the integration of biomechanics sensors and data fusion.





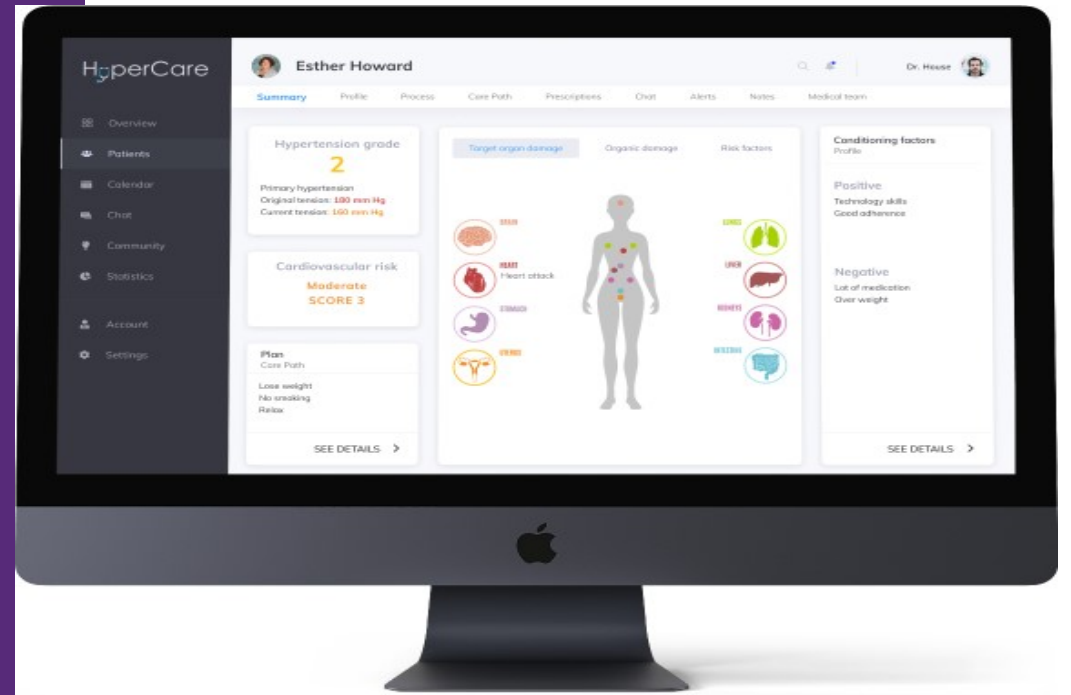
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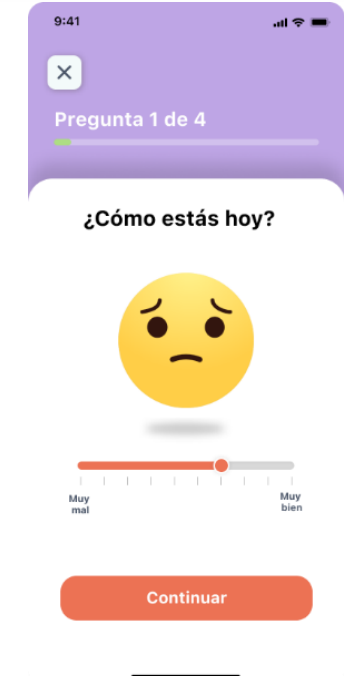
eHealth



Integrated Care for the Mental Health (and Cardio Rehab) patient

Multi-use case management and self-management platform for integrated care services.

The main objective is to foster remote monitoring for patients, creating a platform that can absorb the inclusion of future customized clinical cases.





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Success stories



Personalized nutrition

A biomarker and ICT based system that provides personalized dietary and lifestyle advice with behavioral stimuli to engage users to improve their health habits and help them prevent the onset of diet-related diseases

It addresses the exploitation of the potential of omic techniques, especially metabolomics, and behaviour change as drivers of development.

simple
feast



alimentomica
alimentomica

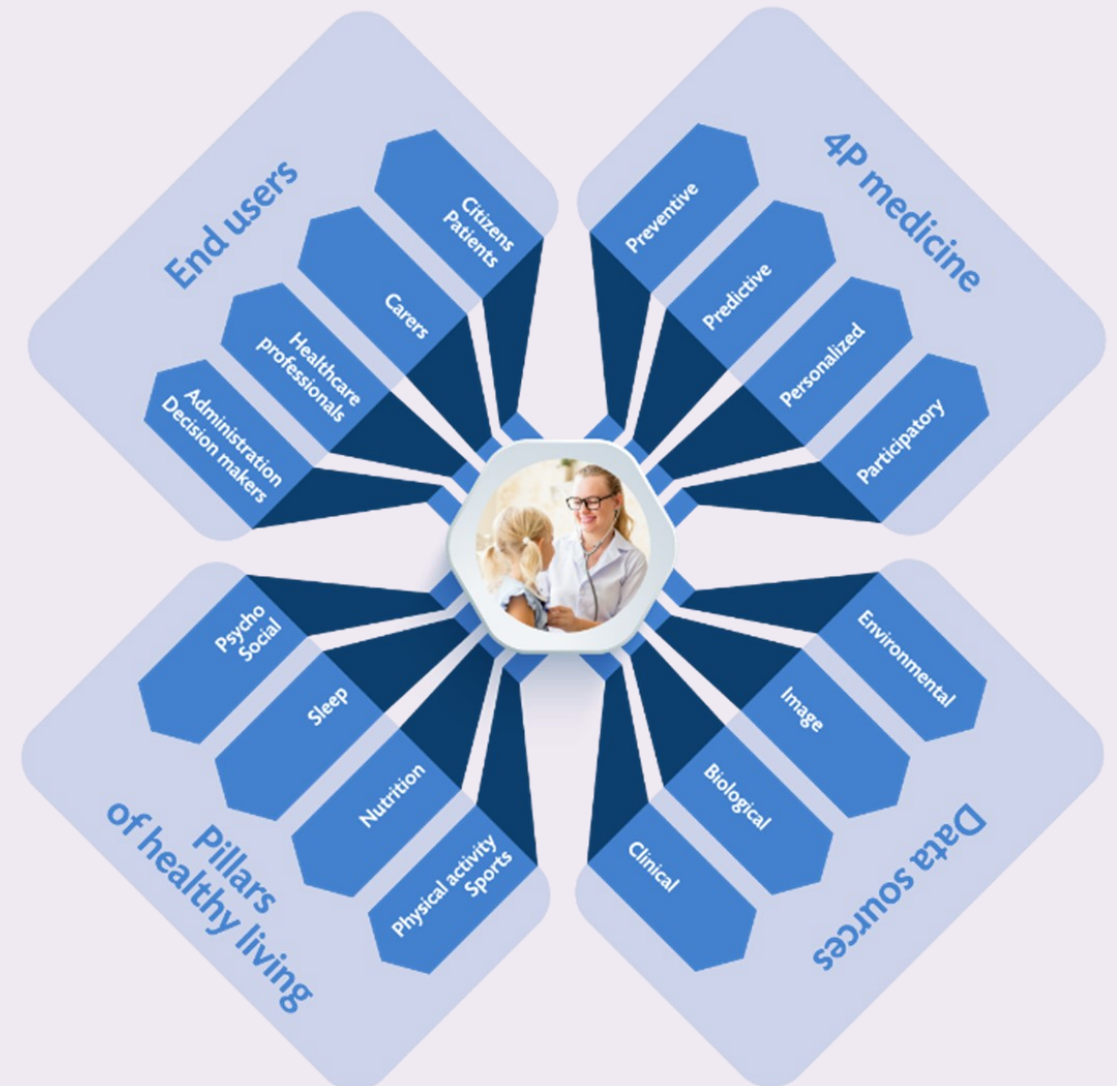


Horizon 2020
European Union funding
for Research & Innovation



3 Clinical Decision Support Systems for evidence-based medicine

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Lung



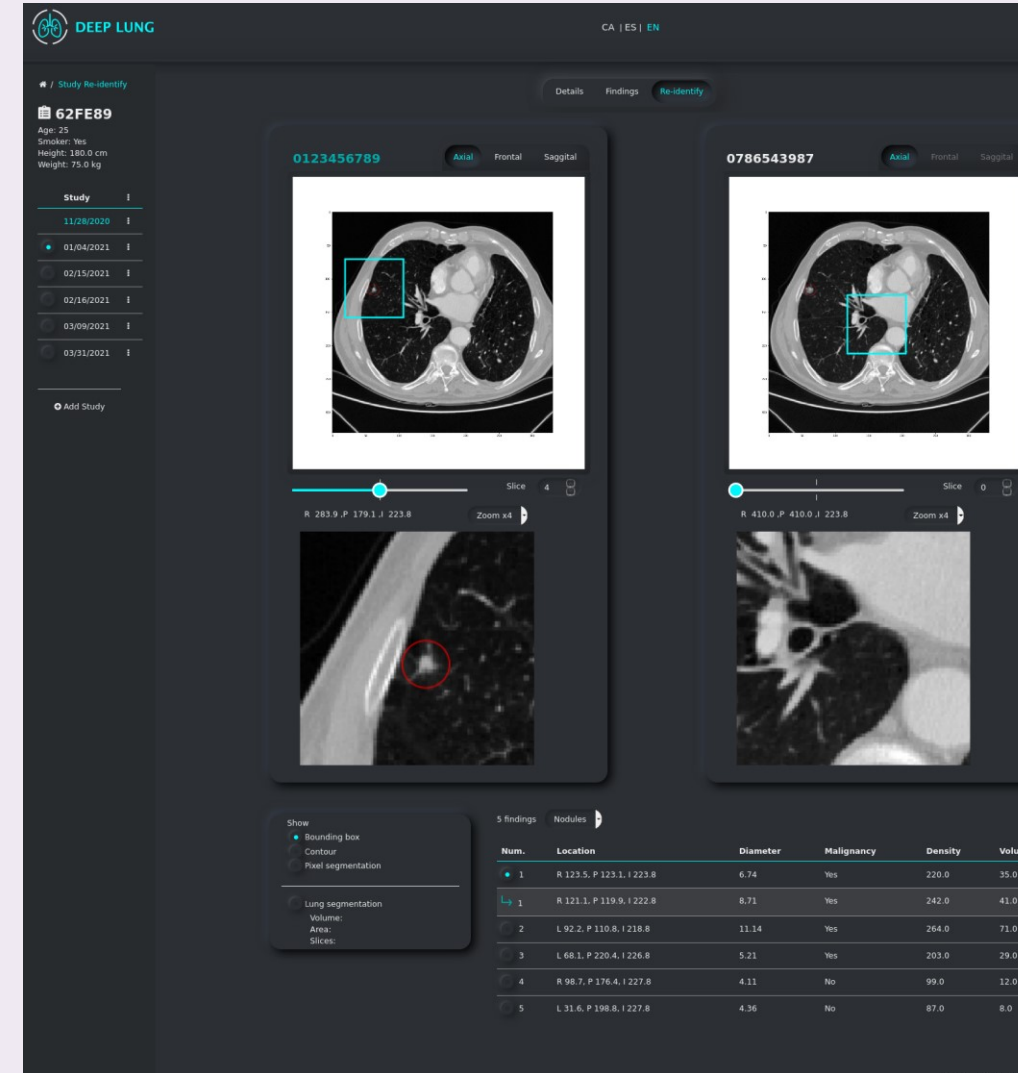
Art systems for screening, early characterization of nodules

Screening of Lung nodules based on non-contrast radiologic images - Success in the management of new cases

Identification, growth quantification and prediction of malignancy. Characterization of nodules, re-identification, growth quantification and prediction of malignancy (CT)

Developed a methodology for the identification of lung nodules to visually assess their characteristics and prognosis.

Developed a user interface for clinical management of the results obtained. Improved efficiency and safety in a clinical setting, assessed by health professionals



Success Stories

Lung

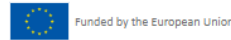


Role/needs/requests/difficulties:

ability, explainability, acceptance
 s: research, clinical validation
 earch, performance validation
 requirements, development, integration, test
 w infrastructure, integration with HIS, PACS
 gers: decision making, processes, sustainability
 ies: HTA, early dialog and advise, standards
 tration: payers, public service catalogue
 ces: payers, private service catalogue
 tees: protocols, clinical trials approval
 lies: MD certification, GDPR assurance
 trials execution, results, costs
 vendors: service provision, business model

Role	Needs	Requests	Difficulties
Radiologist	Need to be helped in the process of lung nodule detection and charact. to speed up the process and improve precision	<ul style="list-style-type: none"> - Easy diagnosis - Easy reporting - Easy comparison 	<ul style="list-style-type: none"> - Repetitive Work - Difficult to assess malignancy - Confusion with guidelines - Borderline nodules
Head of Radiology	Need to reduce the manual work that radiologists do, for dedicating extra time to other activities.	<ul style="list-style-type: none"> - Easy management of human resources - Reputation 	<ul style="list-style-type: none"> - Burned-out staff - Long waiting list for CT - Bad performance of circuit
Oncologist	Need to be helped in the follow-up for drug lung cancer treatment	<ul style="list-style-type: none"> - Positive response of the treatment - Short process to treat the patient 	<ul style="list-style-type: none"> - Choosing difficult medication - Report medication - Give bad news
Head of PACS	Need to maintain the PACS in efficient and cheap way	<ul style="list-style-type: none"> - Easy integration - Small legacy of PACS - Happy radiologists 	<ul style="list-style-type: none"> - Collapse of PACS - Extra work for not strategic things
Head of IT	Need to maintain the HIS in efficient and cheap way	<ul style="list-style-type: none"> - Happy professionals with IT 	<ul style="list-style-type: none"> - Collapse of HIS - No human resources for projects - Cibersecurity
Head of Hospital	Need to reduce the value chain expenditure in lung cancer workflow	<ul style="list-style-type: none"> - Increase the revenue - Reduction of CT number - Reduction of waiting list - Reputation 	<ul style="list-style-type: none"> - Strike - Extra cost (of drugs) - Hospitals competition
PUBLIC insurance	Need to reduce expenditure for expensive treatments for lung cancer	<ul style="list-style-type: none"> - Reduction of expenditures - Reputation of Hospitals 	<ul style="list-style-type: none"> - No control on Hospitals' expenses

Optimal Lung



Market and clinical practice:

data collection and processing, Artificial Intelligence, clinical study validation, prototyping, patent, copyright, code registry

Business model: identification of innovation and payer

Business and co-design: functional requirements, user interfaces, APIs, data models, regulatory requirements, design: architecture, Hw infrastructure

Implementation: backends, frontends, integration, user implementation, tutorials, quality management

Evaluation of interventions and consequences

Regulatory: ethical committees' approval, CRO involvement, evaluation of safety and effectiveness

Medical Device class (CE Marking and/or FDA)

Transition towards healthcare service provision

Business development, service deployment, internationalization

Future releases, improvements and new uses



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"innovating for business"

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How AQuAS is responding to these requirements and different stakeholders' needs



- I declare no conflict of interest
- Rosa Maria Vivanco Hidalgo, MD PhD MPH Head of HTA and Quality at AQuAS
- Contact details:

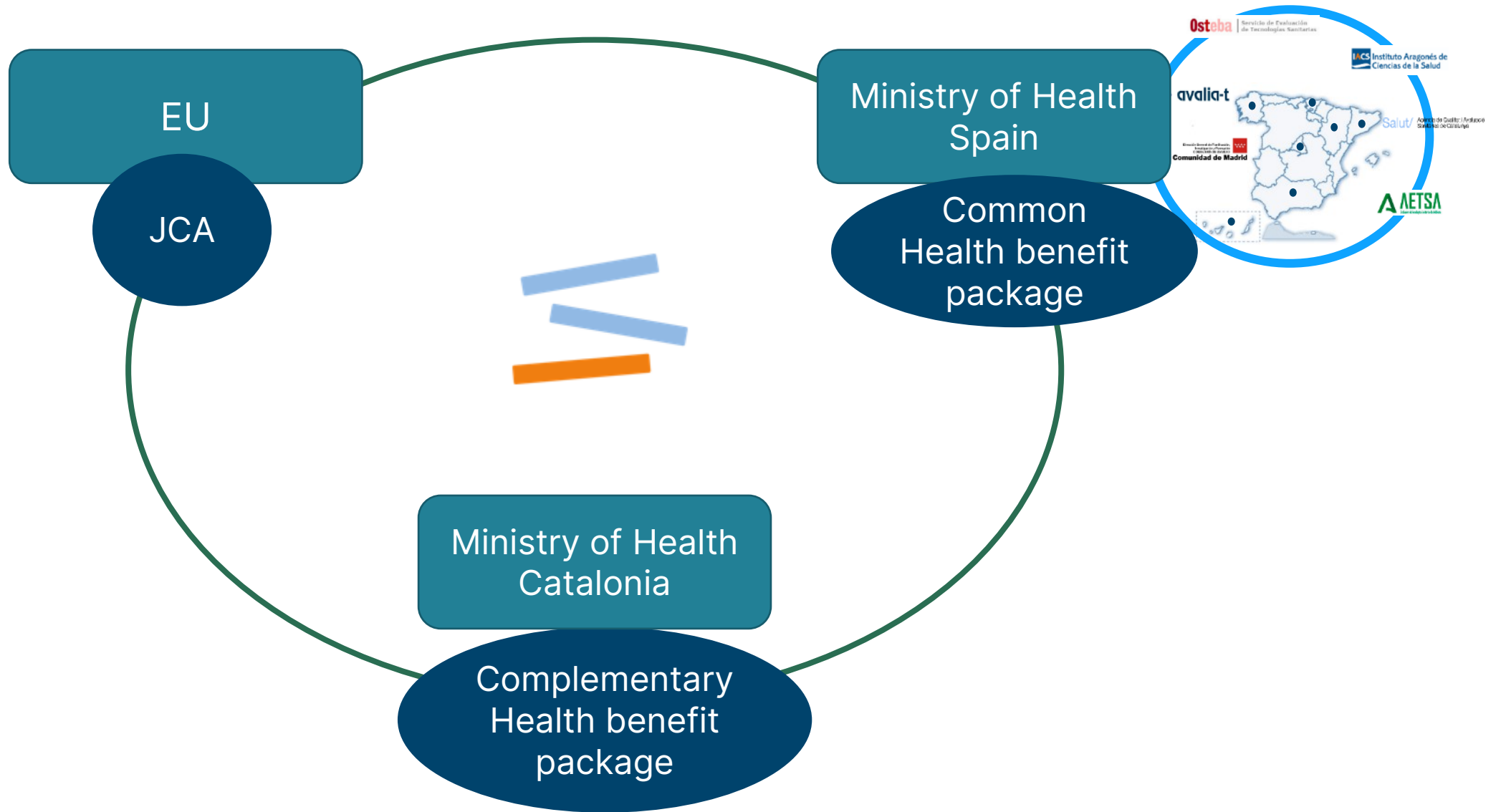
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RedETS



RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN DE TECNOLOGÍAS Y PRESTACIONES DEL SISTEMA NACIONAL DE SALUD



Safety, Effectiveness, Quality, Equity and Efficiency

Evaluations to help in decision-making for the adequacy of the common health benefit package

NHS

Digital health strategic line

2021 Annual Planning RedETS AQuAS: HTA framework for digital Health technologies


Block A:
Domains and dimensions



Block B:
Evidence Standard
framework



Sistema de Salut de Catalunya

/Salut

esade  

 TIC Salut Social  eurecat
Centre Tecnològic de Catalunya

 CIDAI Centre of Innovation for Data tech and Artificial Intelligence



Block A:
Domains and dimensions





ISPOR Europe 2022
 6-9 November 2022
 Vienna, Austria and Virtual
 #ISPOREurope



>3000 documents

Thematic analysis to identify domains

Focal groups

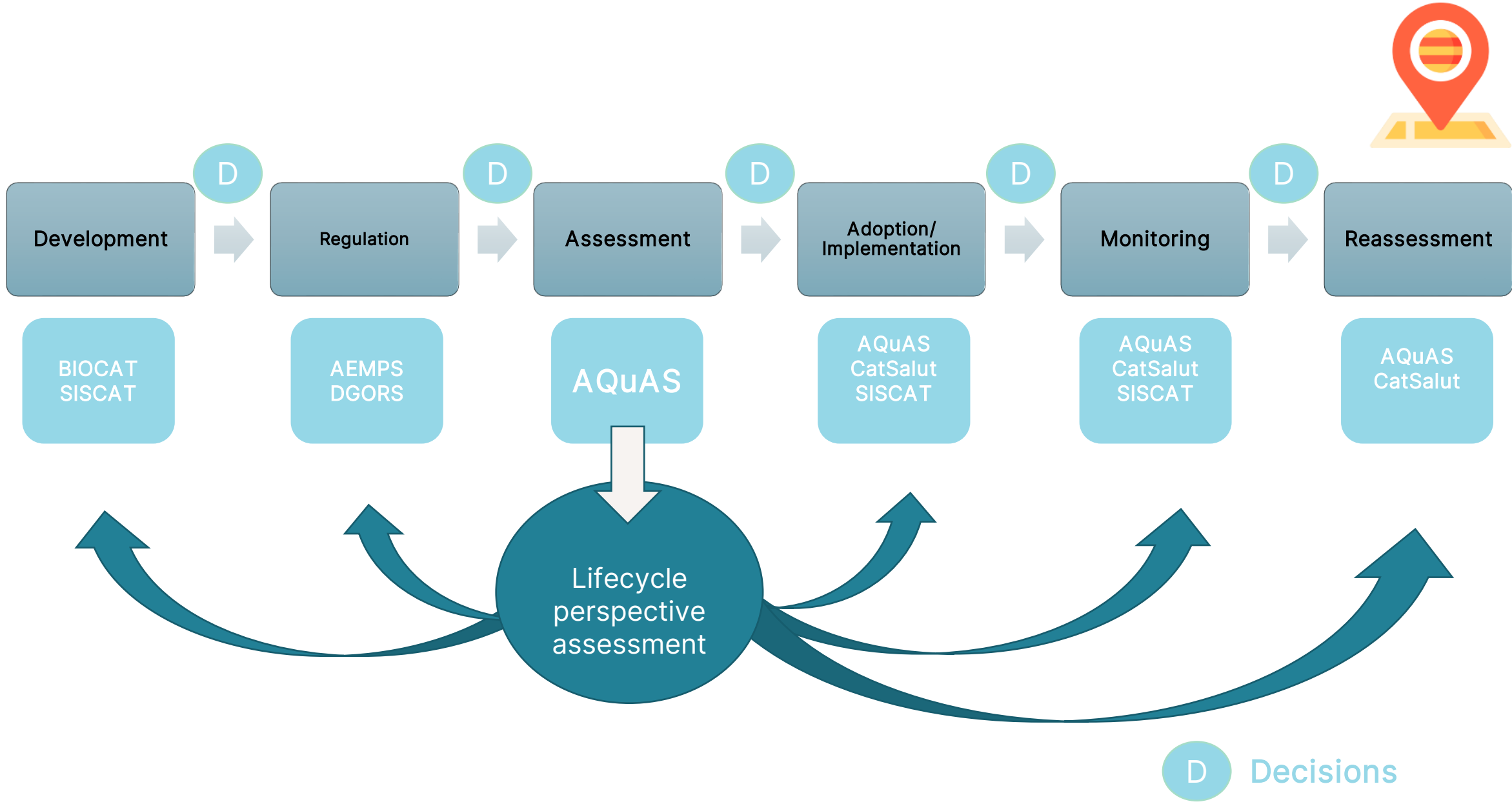
Block B:
Evidence Standard
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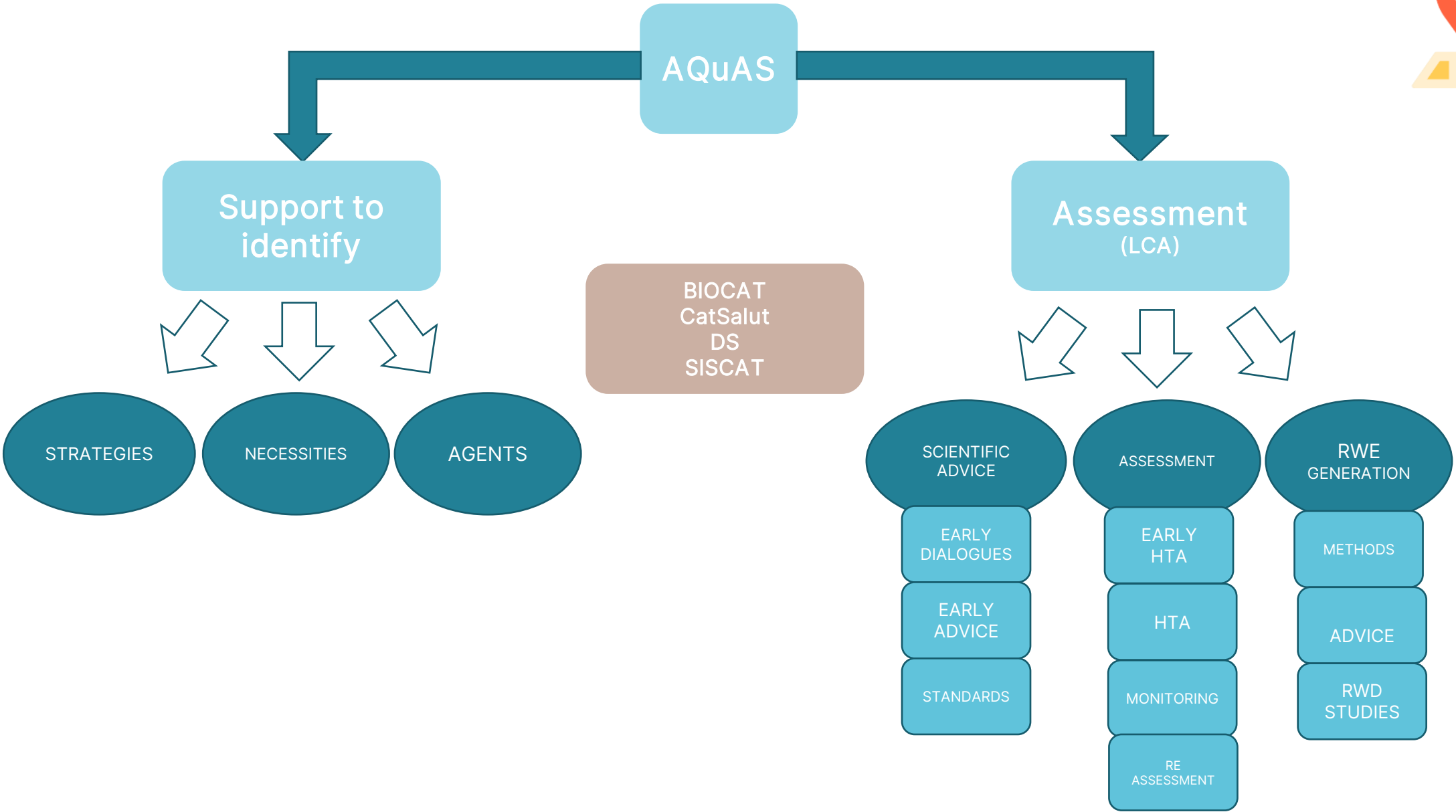


**2nd version
AUGUST 2022**



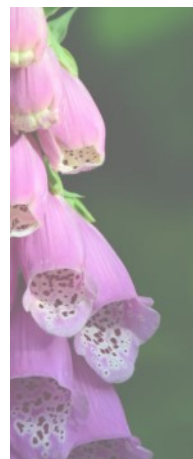
Adaptation (WIP)







PLA D'ACCIÓ DEPARTAMENTAL DS XIV LEGISLATURA

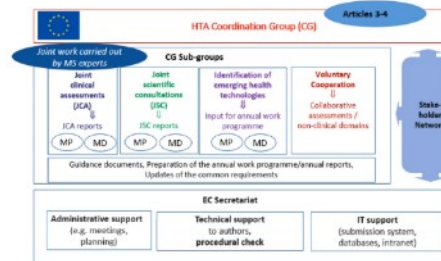


ESTRATEGIA DE SALUD DIGITAL
SISTEMA NACIONAL DE SALUD

Secretaría General de Salud Digital,
Información e innovación para el SNS
2 de diciembre de 2021



HTA Regulation Governance



MP = medicinal products, MD = medical devices



European Region

Regional digital health action plan for the WHO European Region 2023–2030

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Mark Salmon
Programme Director – NICE,
UK

NICE National Institute for
Health and Care Excellence



**Three
examples of
collaborative
working in
Digital Health**

NICE



1. NICE Evidence Standards Framework for Digital Health Technologies

2. NICE Early Value Assessment Programme for MedTech

3. Multi Agency Advice Service for AI



[Home](#) > [About](#) > [What we do](#) > [Our programmes](#)

Evidence standards framework (ESF) for digital health technologies

As digital health technologies (DHTs) develop at an increasing pace, we've worked with stakeholders, system partners and thought leaders to develop standards that ensure new DHTs are clinically effective and offer value to the health and care system:

On this page

- [What is the evidence standards framework?](#)

NICE evidence standards framework (ESF)

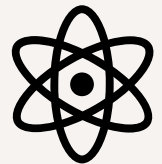
- First Commissioned by NHS England in Spring 2018
- Trusted and respected set of standards describing evidence needed for different types of digital health technologies (DHTs), for commissioning in the NHS and care system



innovators understand the level of evidence they need to produce, so evidence generation plans are faster and more cost-effective.



NHS can commission, deploy and scale clinically and cost-effective digital health tools that meet demand.



Sits alongside other system standards such as CE/CA marking for clinical safety, technical stability, interoperability, info governance etc

AI-ESF: 2022 Update and expansion of NICE ESF

- NHS England commissioned an update and expansion to the ESF
- Project commenced summer 2021, public consultation March 2022
- Published July 2022

Goals for the update were to:

- Align classification with regulatory requirements
- Use stakeholder workshops with industry, commissioners/payers and patient panels to help improve content and usability

Goals for the AI expansion were to:

- Specify evidence requirements for AI and data-driven technologies with adaptive algorithms
- Include AI and data-driven DHTs with adaptive algorithms in functional classification

Imperial College
London



UNIVERSITY OF
BIRMINGHAM

The
Alan Turing
Institute

- Working with



MHRA



Technoleg Iechyd Cymru
Health Technology Wales

SHTG
Advice on health
technologies

- Consulting with national and international stakeholders - academics, HTA bodies, developers

NICE

Digital and AI technologies in healthcare



Clinician-facing software...



...or patient-facing health and wellness apps



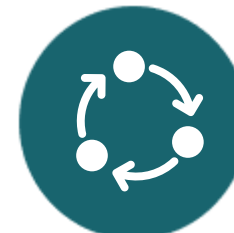
Measurable health outcomes...



...or system efficiencies and cost savings



DHTs can be static...



...or may change over time

ESF Classification of DHTs:

➤ Risk related
to intended-
use

NICE

Tier C

DHTs for treating and diagnosing medical conditions, or guiding care choices

Includes DHTs with direct health outcomes, and those that are likely to be regulated medical devices

Inform clinical management

Does not trigger an immediate or near term action

Drive clinical management

Aids, guides and triages for treatment or diagnosis

Treat specific condition

Provides treatment for a specific condition

Diagnose a specific condition

Provides diagnoses for a specific condition

Tier B

DHTs for helping people and patients to manage their own health and wellness

Communicating about health and care

Allows 2-way communication between citizens, patients or healthcare professionals.

Health and care diaries

Includes lifestyle improvement and general health monitoring using fitness wearables and health diaries. Data stays on device.

Promoting good health

Population level information to maintain healthy lifestyle and manage conditions

Tier A

DHTs intended to save costs or release staff time, no direct patient, health or care outcomes

System services

provide services to health and social care system

Mapping from IMDRF classification to anticipated MHRA classification

NICE

ESF classification group	Description	Healthcare situation or condition	Medical device class name (MHRA)
Inform clinical management	DHTs that record and transmit data to a professional, carer or third-party organisation to inform clinical management in the future.	Non-serious	Class 1
		Serious	Class 1
		Critical	Class 2a
Drive clinical management	Information provided by the DHT will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions	Non-serious	Class 1
		Serious	Class 2a
		Critical	Class 2b
Diagnose a condition	Information provided by the DHT will be used to take an immediate or near-term action to diagnose/screen/detect a disease or condition.	Non-serious	Class 2a
		Serious	Class 2b
		Critical	Class 3
Treat a condition	Information provided by the DHT will be used to take an immediate or near-term action to treat/prevent or mitigate by means of providing therapy to a human body.	Non-serious	Class 2a
		Serious	Class 2b
		Critical	Class 3

Challenges of creating evidence standards

Setting high evidence levels helps ensure effectiveness...



...but creates barriers to innovation

Creating very technical standards allows precision...



...but can't be understood by commissioners

Summary of NICE ESF standards

Design factors

Standard		Applies to DHTs in:		
1	The DHT should comply with relevant safety and quality standards	A	B	C
2	Incorporate intended user group acceptability in the design of the DHT	A	B	C
3	Consider environmental sustainability	A	B	C
4	Consider health and care inequalities and bias mitigation	A	B	C
5	Embed good data practices in the design of the DHT	A	B	C
6	Define the level of professional oversight	A	B	C
7	Show processes for creating reliable health information		B	C
8	Show that the DHT is credible with UK professionals		B	C
9	Provide safeguarding assurances for DHTs where users are considered to be in vulnerable groups, or where peer-peer interaction is enabled		B	C

Describing value

Standard		Applies to DHTs in:		
10	Describe the intended purpose and target population or user group	A	B	C
11	Describe the current pathway or system process	A	B	C
12	Describe the proposed pathway or system process using the DHT	A	B	C
13	Describe the expected health, cost and resource impacts compared with current care	A	B	C

Demonstrating performance

Standard		Applies to DHTs in:		
14	Provide evidence of the DHT's performance to support its claimed benefits			C
15	Show real-world evidence that the claimed benefits can be realised in practice	A	B	C
16	The company and evaluator should agree a plan for measuring usage and changes in the DHT's performance over time	A	B	C

Delivering value

Standard		Applies to DHTs in:		
17	Provide a budget impact analysis	A	B	C
18	For DHTs with higher financial risk, provide a cost-comparison or cost-utility analysis	A	B	C

Deployment considerations

Standard		Applies to DHTs in:		
19	Ensure transparency about requirements for deployment	A	B	C
20	Describe strategies for communication, consent and training processes to allow the DHT to be understood by end users	A	B	C
21	Ensure appropriate scalability	A	B	C

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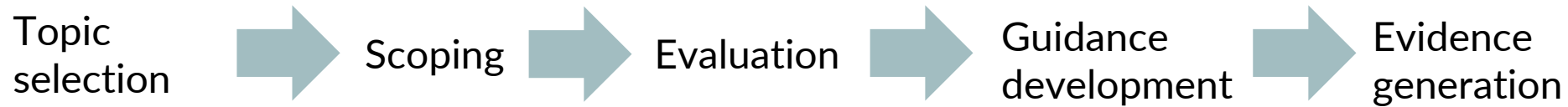
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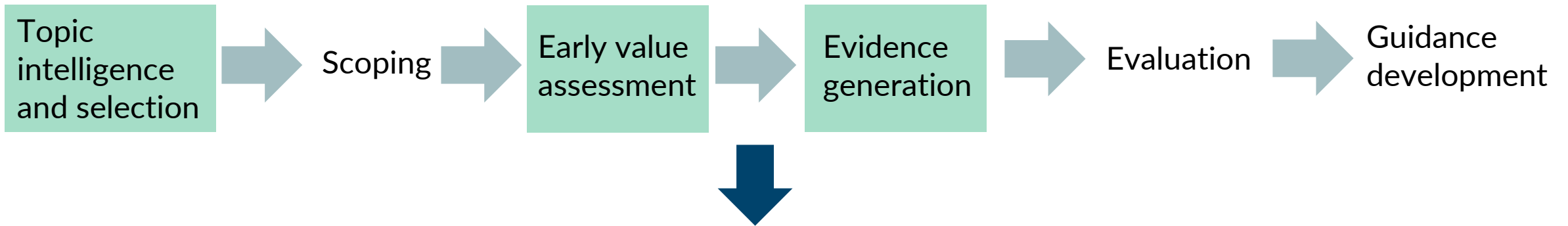
3. Multi Agency Advice Service for AI

Current approach versus new approach

Current approach



New approach



- Recommendations – use while collecting real world evidence.
- Evidence generation plan.

**Three
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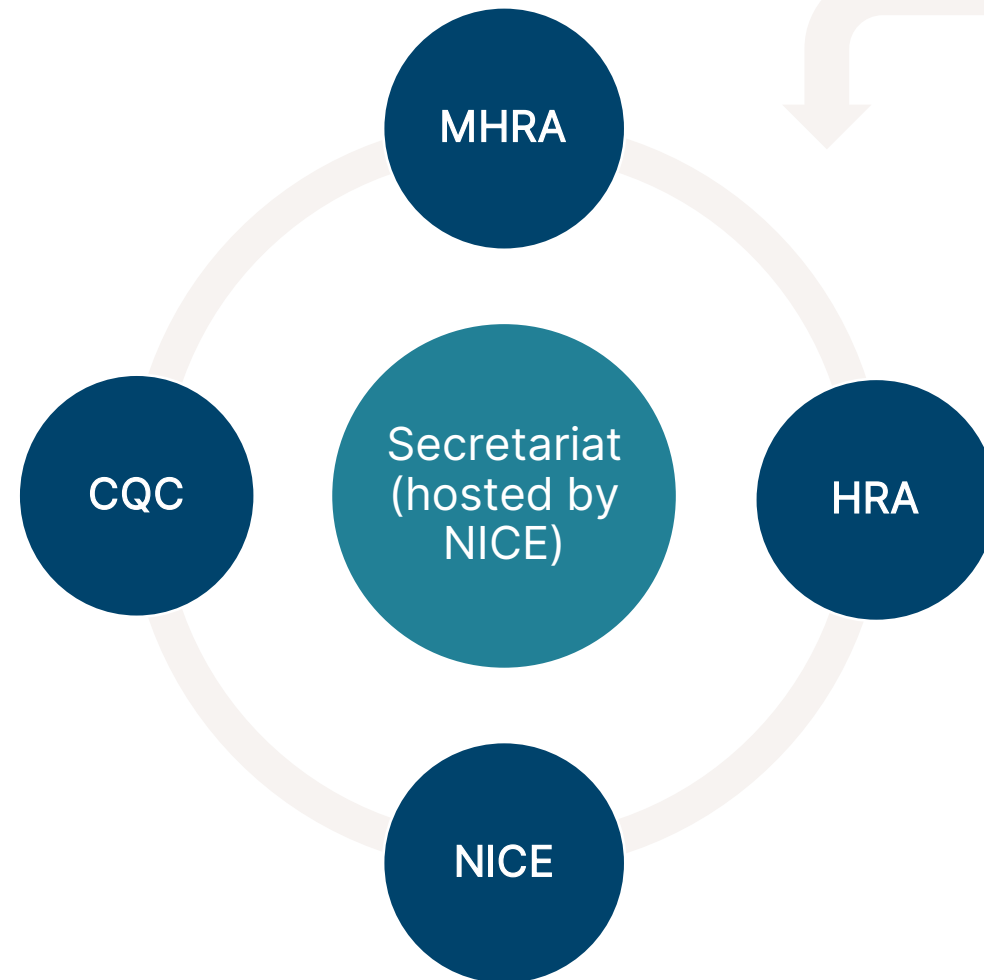
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3. Multi Agency Advice Service for AI

A Regulatory Partnership on AI...

The service will be developed and delivered by four organisations.



Other agencies that may contribute to the advice service include:

- NHSE project sponsor
- ICO
- NHS Digital
- AAC
- NHS providers

NICE

AAC, Accelerated Access Collaborative; CQC, Care Quality Commission; HRA, Health Research Authority; ICO, Information Commissioner's Office; MHRA, Medicines and Healthcare products Regulatory Agency; NICE, National Institute for Health and Care Excellence (NICE)

Project aim

The project aims to collaboratively research, develop and test a multi-agency advice service, offering:



On the regulation and health technology assessment pathways for artificial intelligence (AI) in health and care, and potentially other data-driven technologies.

NICE

The service will provide easy access to comprehensive information and support so that:



innovators can meet robust measures of assurance in safety and quality.



health and care providers have the knowledge and tools to help them adopt and deploy the best AI technologies.

Thank you.

digitalhealth@nice.org.uk



Q&A