

# The NICE Evidence Standards Framework for Digital Health Technologies

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# NICE evidence standards framework (ESF)

- Commissioned by NHSE in Spring 2018, expanded and updated 2021/22
- Trusted and respected set of standards for evaluating digital health technologies (DHTs).
- Describes the evidence needed for DHTs (including AI that may change over time) to be commissioned in the NHS and care system

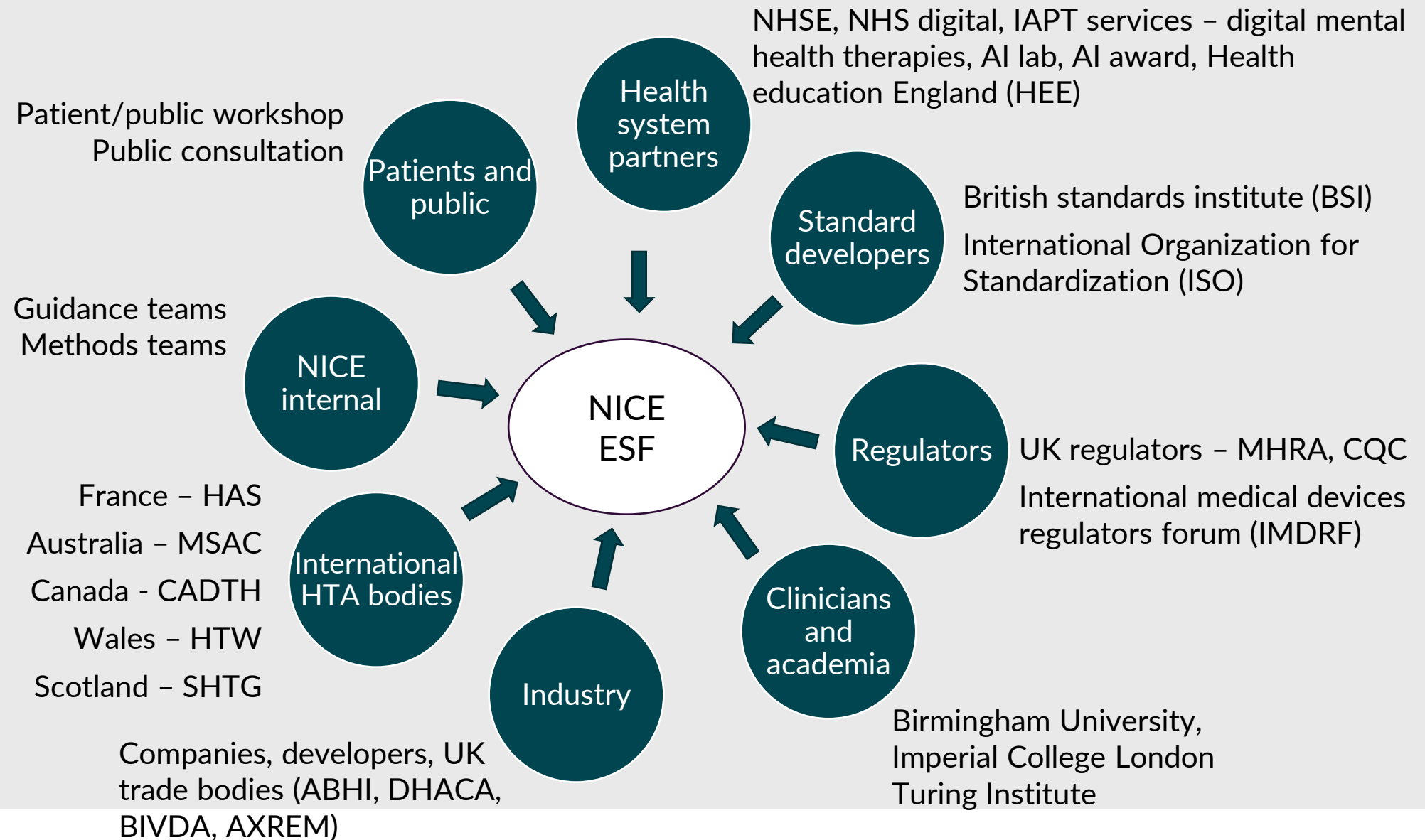


innovators understand the level of evidence they need to produce, so evidence generation plans are faster and more cost-effective.



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

# Working in partnership in digital ecosystem



# ESF Classification of DHTs:

➤ Risk related  
to intended-  
use

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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 citizens 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

# Summary of NICE ESF standards

## Design factors

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

## Describing value

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

## Demonstrating performance

Standard		Applies to DHTs in:		
13	Provide evidence of the DHT's performance to support its claimed benefits			C
14	Additional evidence for critical conditions or functions			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 changes in the DHT's performance over time	A	B	C
17	The DHT should comply with relevant safety and quality standards	A	B	C

## Delivering value

Standard		Applies to DHTs in:		
18	Provide a budget impact analysis	A	B	C
19	Show sensitivity analysis to explore uncertainties	A	B	C
20	For DHTs with higher financial risk: provide a cost-comparison or cost-utility analysis	A	B	C
21	Agree a data collection plan to show value	A	B	C

## Deployment considerations

Standard		Applies to DHTs in:		
22	Ensure transparency about requirements for deployment	A	B	C
23	Describe plans for communication, consent and training processes in place to allow the DHT to be understood by end users	A	B	C
24	Ensure appropriate scalability	A	B	C

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New or amended standards

Relevant to AI risk considerations

Thank you.