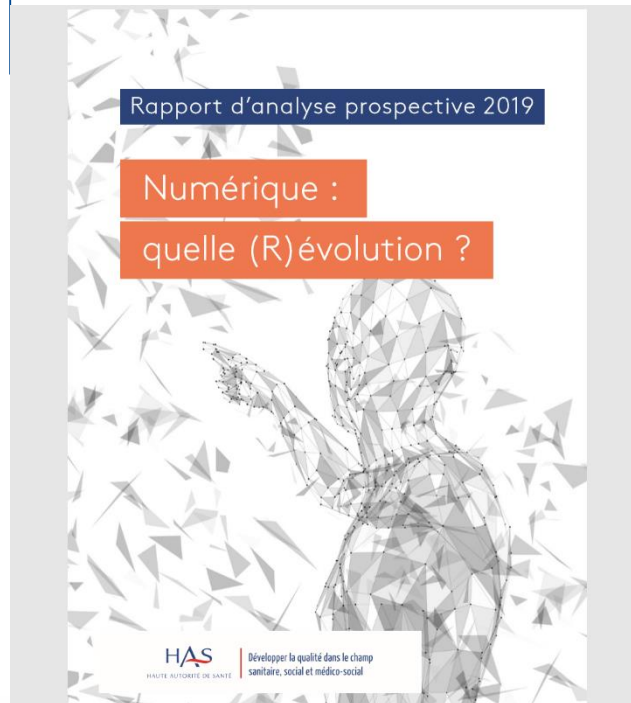


Quality standards for AI in healthcare



Corinne COLLIGNON

French National Authority for Health (HAS)

Medical Devices Assessment department

HTA division

HAS & Medical devices

1. Commercialisation : CE requirements

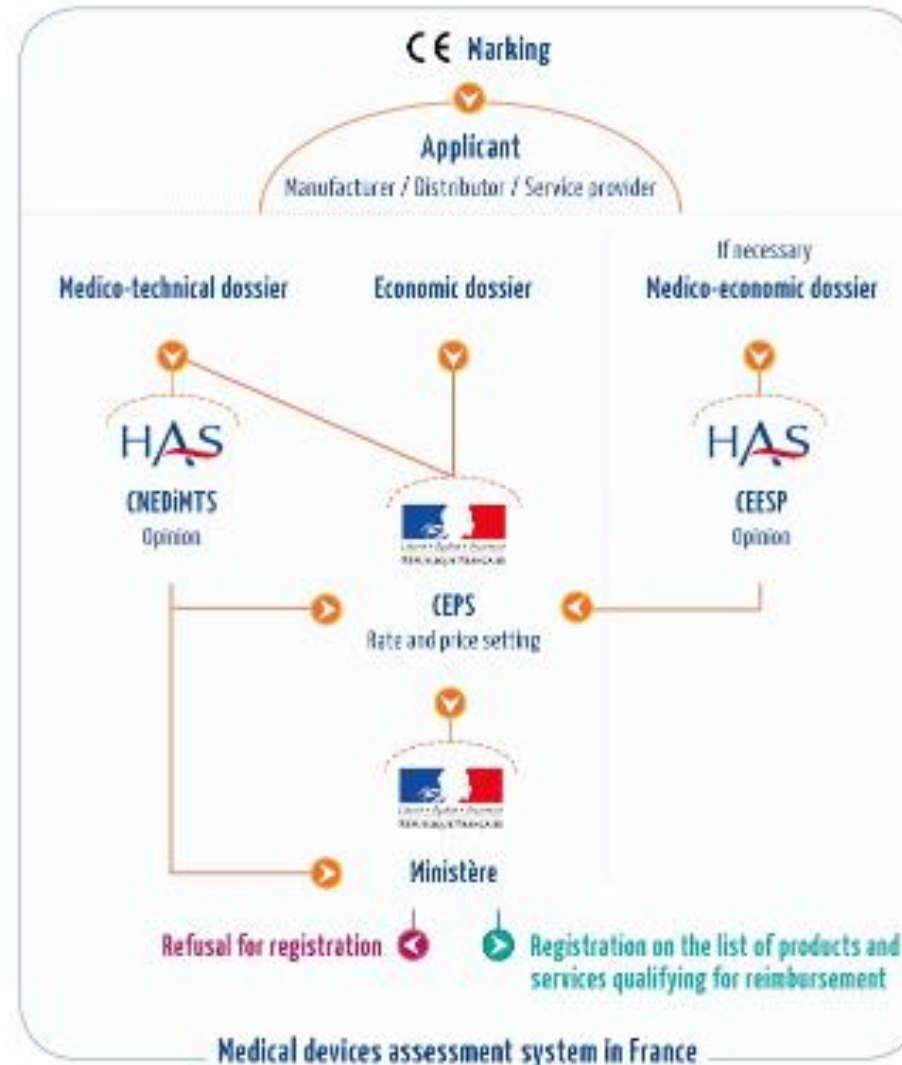


2. Access to reimbursement: specific evaluation

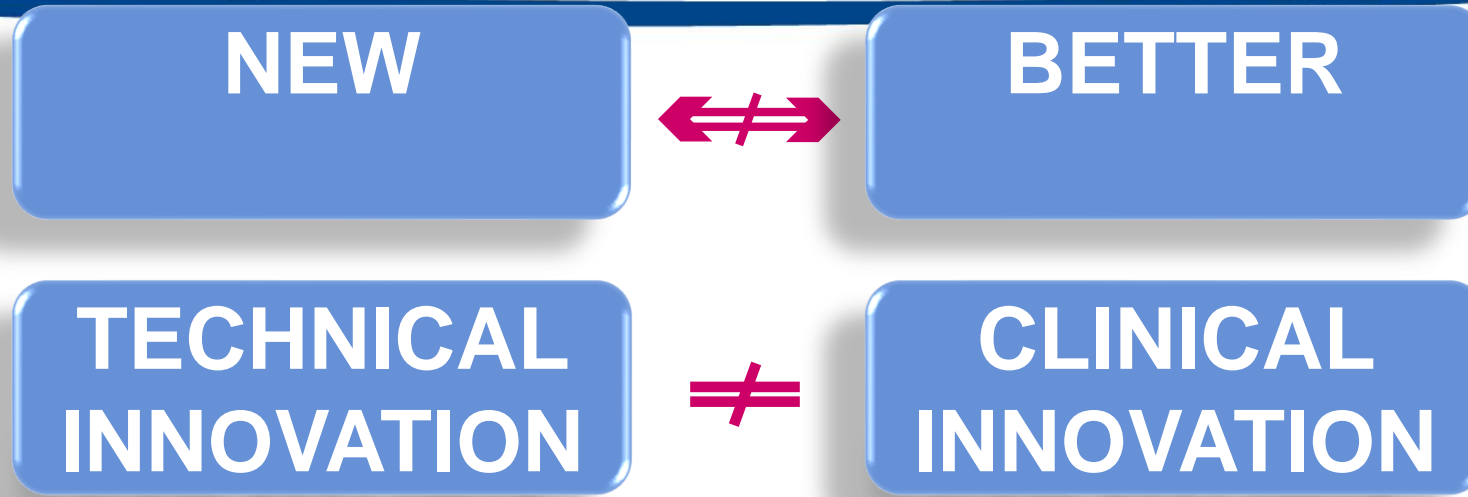
- **Purpose: MD coverage**
- **2-steps Process: Assessment then Appraisal**
- **Parameters taken into account:**
 - Clinical benefit for the patient
 - General context:
 - Existing arsenal
 - Severity of the disease
 - Public health interest



Process of access to reimbursement in France



Our task on MDs: scientific guidance for reimbursement



- Should this MD be paid for by the taxpayer?
- What is its added value for the patient?
- What is the size of the population for which reimbursement is justified and in which the MD has an added value?
- What is its impact on public health?

The same criteria whatever the MD is

Assessed by the HAS' committee based on clinical data

Do we need adaptative methods for AI-based MDs?

From a larger range of MDs called connected MDs



Used for medical telemonitoring purposes

e.g. implantable cardiac defibrillator and remote medical monitoring



- **Prompting action from the patient for self-treatment or self-monitoring purposes**

e.g. nerve stimulators to treat pain connected to a smartphone application allowing patients to manage their treatment themselves



- **Producing or receiving information in view of treatment optimisation**

e.g. an insulin pump combined with a sensor for the continuous measurement of interstitial glucose using the patient's electronic diary to optimise their treatment



to date: A few of MDs with AI assessed

Do we need adaptative methods for AI-based MDs?

- **Various types of algorithms suitable to our evaluation**

- Until 2019: numerous CMDs with deterministic algorithms
- 2019: the first CMDs with AI in 2019



- **AI-based technologies are spreading in the field of MDs**

- A huge potential into the healthcare field
 - Research
 - Prevention
 - Diagnosis
 - Personalisation of care etc...
- As in other areas (transport, finance.....)

Do we need adaptative methods for AI-based MDs?

- **No specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement**

2019

- Specific guide published to help companies to build their clinical development plan

- Work in progress on the specific topic of the organizational impact:

- What dimensions can be taken into account?
- Which criteria can be use to measure the impact on it?



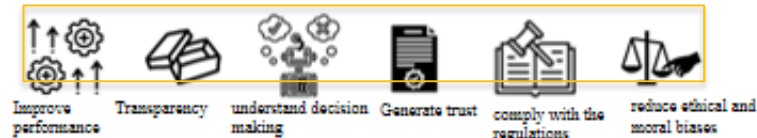
- **Rapidity of technological development;**
 - New product or new version



- **Interaction with other devices/objects/platforms**
 - Medical device ?
 - Distant connection ?
 - Data collection/transfer/analysis



- **Existence of expert data processing systems**
⇒ intelligible and interpretable algorithms



- **But technical specificities**

No standards for AI

What are we talking about?

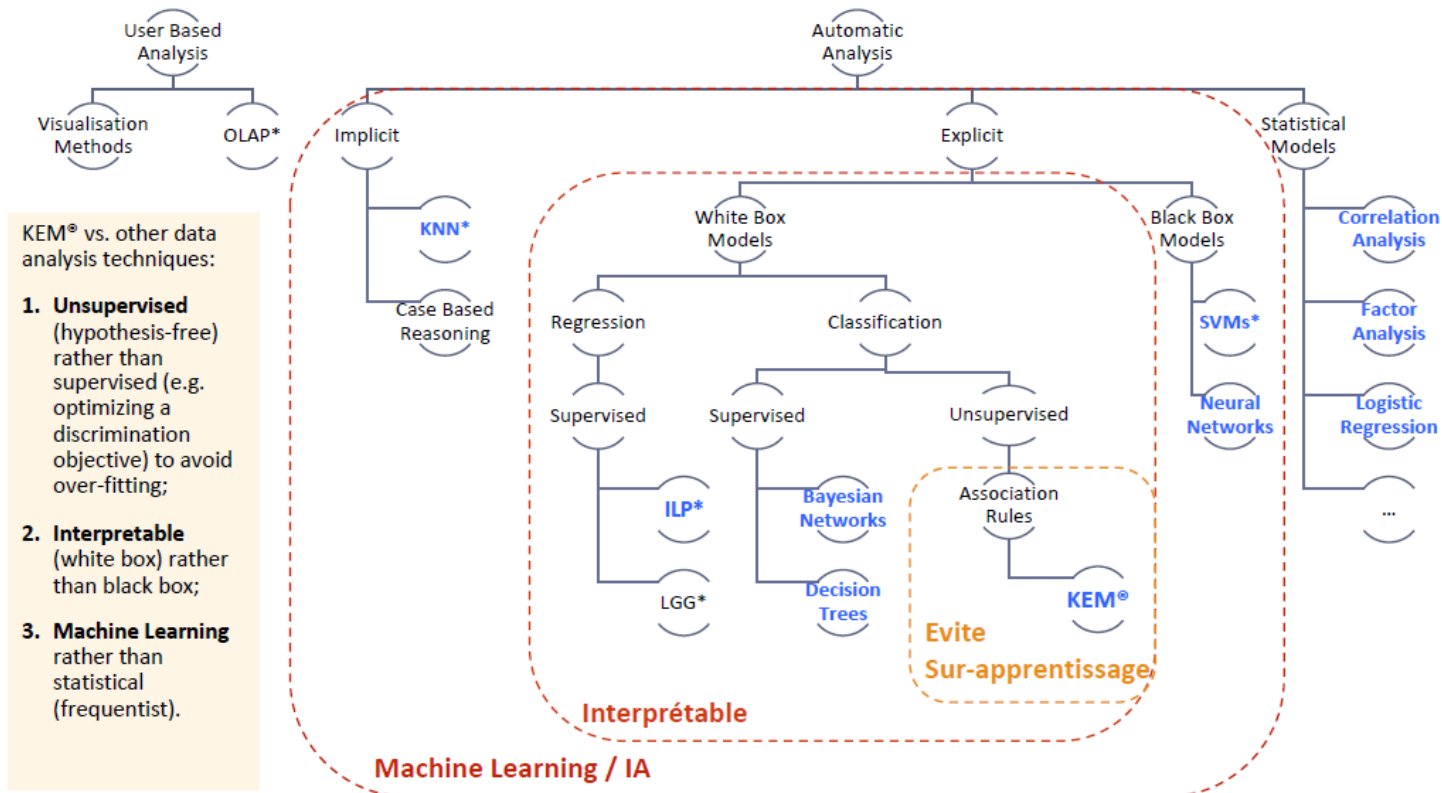
Examples of definition of AI	Organisations
Technology for the realization of intelligent functions, such as learning, inference, and judgment , by artificial means, and utilization of the relevant functions realized by artificial means.	Ministère japonais de la santé
Science and engineering of creating machines or computer programs that can sense, reason, act, and adapt to come up with solutions for problems	Philips
AI is a branch of computer science concerned with the development of systems that can perform tasks that would usually require human intelligence, such as problem-solving, reasoning, and recognition	Xavier Health Organization
A machine's ability to make decisions and perform tasks that simulate human intelligence and behavior	Agence canadienne des médicaments
The capability of a machine to imitate intelligent human behavior	Ministère allemand de la santé
A branch of computer science dealing with the simulation of intelligent behavior in computers	Ministère allemand de la santé
AI as the science and engineering of making intelligent machines, especially intelligent computer programs	Federal Drug Agency

A key point = the learning capability

AI technologies

Ariana

Positionnement des méthodes statistiques et les différentes familles de méthodes d'IA



* OLAP – OnLine Analytic Processing // KNN – k-nearest neighbor algorithm // ILP – Inductive Logic Programming // LGG – Least General Generalizations // SVMs – Support Vector Machines

A grid projet to drive the analysis of the AI part of a MD



2019 - 2020

- **A set of informations crucial to understand the key points of the algorithm(s) with IA in the MD**
- **Built through our experience on the first dossiers we received with AI**
- **Our objective:**
 - To help companies to describe the algorithm (s)
 - To limit the duration of our assessment
 - To make clinical innovations available for patients

A framework at least for:

- MDs manufacturers
- committee members

Also useful for other stakeholders? (patients , caregivers...)

A grid projet to drive the analysis of the AI part of a MD



36 items structured in 8 categories

- **purpose of use**
- **learning**
- **initial learning or re-learning input data**
- **input data involved in the decision**
- **performance**
- **validation**
- **system resilience**
- **explicability / explainability**

2019 - 2020

A framework for AI part of a MD: HAS' grid projet

■ A public consultation launched

2019 - 2020

● Nov. 2019
Public consultation

To come: the english version

○ 15/01/2020
Deadline to contribute

● April 2020
Final grid

The screenshot shows the HAS website interface. At the top, there is a navigation bar with the HAS logo and several menu items: 'Medicament', 'Dispositif', 'Moyens d'information', 'Évaluation médico-économique', and 'Agenda'. Below the navigation bar, there are two main columns. The left column contains a 'Contexte' section with the following text: 'Objet de la consultation publique', 'Objectifs de la consultation', 'Participer à la consultation publique', 'À qui s'adresse la consultation publique?', 'Jusqu'à quelle date pouvez-vous participer?', 'Comment soumettre vos commentaires?', 'Comment seront prises en compte vos contributions?', and 'Que deviennent les données personnelles collectées?'. Below this is a 'Voir aussi' link. The right column features the title 'Projet de grille d'analyse pour l'évaluation de dispositifs médicaux avec intelligence artificielle' and the date 'Clôture de la consultation le 15 janvier 2020'. Below the title, there is a summary: 'Ce projet de grille d'analyse est destinée à être utilisée par la CNEDiMITS pour contribuer à son évaluation de dispositifs médicaux embarquant des systèmes décisionnels s'appuyant sur des procédés construits par apprentissage automatique ou auto-apprenants (« Intelligence artificielle »)'. A 'Contexte' section follows, explaining the role of the HAS and the CNEDiMITS in evaluating medical devices. The 'Objet de la consultation publique' section describes the background of the project and the need for a public consultation. At the bottom, there is a note: 'In fine, l'évaluation permettra de renforcer la confiance nécessaire à l'utilisation de ces nouveaux DM et d'en favoriser l'appropriation par les professionnels et les usagers.'

A grid projet to drive the analysis of the AI part of a MD

2019 - 2020

- **Expected answers on 3 level for each criteria:**
 - Is the wording explicit?
 - Are the criteria appropriate?
 - Are they
 - Essentiel?
 - Useful?
 - Informative ?
- **Should we add other criteria?**

The screenshot shows the HAS website interface. At the top, there is a navigation bar with the HAS logo and menu items: 'Medicament', 'Dispositif', and 'Moyens'. Below the navigation bar, there are buttons for 'ÉCOUTER' and 'AJOUTER À MA SÉLECTION'. The main content area is titled 'Projet de grille d'analyse pour l'évaluation de dispositifs médicaux avec intelligence artificielle'. It includes a sub-header 'Clôture de la consultation le 15 janvier 2020' and 'CONSULTATION PUBLIQUE - Mise en ligne le 20 nov. 2019'. A summary paragraph states: 'Ce projet de grille d'analyse est destinée à être utilisée par la CNEDiMTS pour contribuer à son évaluation de dispositifs médicaux embarquant des systèmes décisionnels s'appuyant sur des procédés construits par apprentissage automatique ou auto-apprenants (« Intelligence artificielle »)'. Below this, there are sections for 'Contexte' and 'Objet de la consultation publique'. The 'Contexte' section explains the role of the HAS and the CNEDiMTS in evaluating medical devices. The 'Objet de la consultation publique' section details the project's goals and the need for a grid analysis to evaluate AI-based decision-making systems.

https://www.has-sante.fr/jcms/p_3118247/fr/projet-de-grille-d-analyse-pour-l-evaluation-de-dispositifs-medicaux-avec-intelligence-artificielle



A next step?

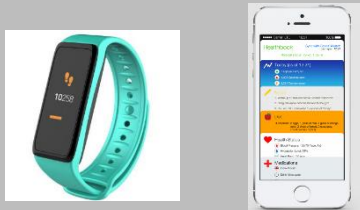
What has to be specifically assessed?

Current French framework for digital technologies

Guidelines for Quality standards

No specific assessment

Digital technologies without any medical purpose declared



Specific assessment

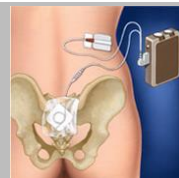
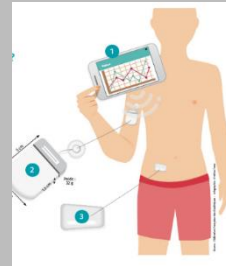
No specific assessment

Dispositifs médicaux



Used by patients

Used by professionals



Should this framework evolve?

A matrix for evaluation ?

2020?

Graduated requirements

- Intended use? Administrative, therapeutic, diagnosis...
- Level of risk for patients?

- **Guidelines for Quality standards for mHealth app etc...**

- **For innovative technologies?**
 - Faisability of such quality framework?
 - Accuracy vs specificity?
 - Relevance?
 - Clinical data requirements?



To discuss: A matrix ?

- ⇒ cartography of the type of digital technologies
- ⇒ level of evaluation graduated according to the purpose of use and the risks

Thank you!



Questions ?