Quality standards for AI applications in healthcare and joint databases for medical data

Isabelle ADENOT
HAS Board Member
President of the Medical Device and Health Technology Evaluation Committee

French National Authority for Health (HAS)

1. **HAS established in January 2005**

2. **Independent public scientific body**

3. **Annual report is submitted to Parliament**

4. **Board of 7 members appointed by the President of the Republic:**
   - Board President nominated by the President of the Republic
   - 3 members nominated by the Ministry of Health
   - 1 member nominated by the President of the Senate
   - 1 member nominated by the President of the National Assembly
   - 1 member nominated by the President of the Economic, Social and Environmental Council

   Members are nominated for a 6-year mandate, renewable once

   Half of the Board is renewed every 3 years

5. **4 operational directions (430 staff members) with 1 General Secretariat under the authority of the General Director**

6. **2500 external experts**

HAS

Three core missions serving a single, overarching goal

Assess and appraise pharmaceuticals, devices and procedures for inclusion on the national list of reimbursed products and services.

Recommend best practices for health care professionals and elaborate public health guidelines.
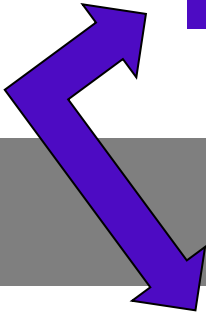
Measure and Improve the quality of care delivered in health and social care organizations.

Advance quality in health and social care to serve both individual and collective interests

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Evaluate health products and procedures

Medical Device and Health Technology Evaluation Committee

Economic Health Evaluation

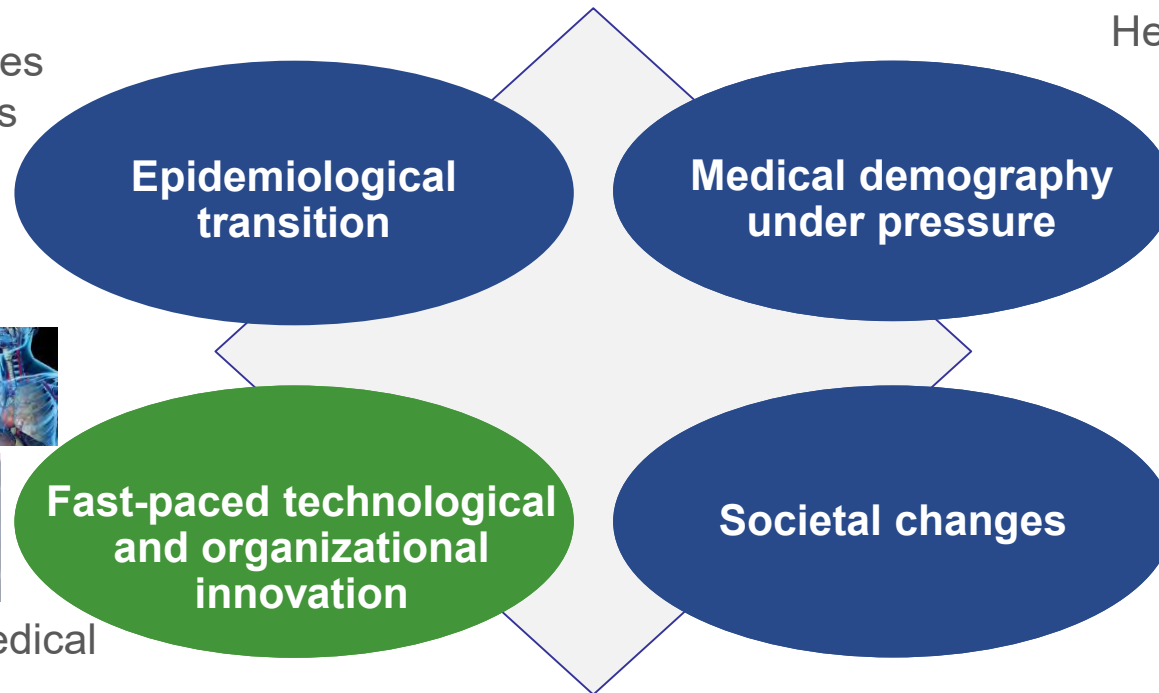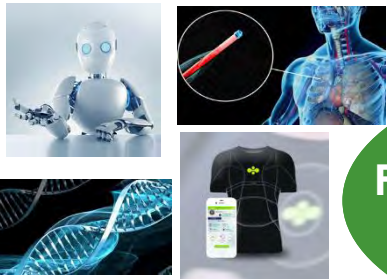| Medications | Medical Devices | Procedures and other health technologies | Public Health Actions and Programs |

objective

Inform health policy decisions (reimbursement and pricing of health technologies and procedures)

Changing landscape

- Aging
- Chronic diseases
- Polypathologies

- Aging demography
- Demographic Heterogeneity

Epidemiological transition

Medical demography under pressure

Fast-paced technological and organizational innovation

Societal changes

- Drugs, DM, medical progress
- e-Health / Telemedicine
- Organizational changes
- ……

- Demand for greater transparency
- Increased user engagement

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11/28/2019

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Six priorities for 2019-2024

Strategic Plan for HAS   2019-2024

Pillar 1   **Innovation** as a driving force for HAS, supporting its safe access

- *Identify, guide and follow technological innovations*
- *Identify, guide and follow organizational innovations*

Pillar 2   **Public Involvement** as a priority

- *Allow the public to play a role in the quality of care and support systems*
- *Systemize the integration of their view point across all HAS methods and work*

Pillar 3   Promote efficient **health and life pathways**

- *Define efficient strategies for health and life pathways*
- *Contribute to improved coordination amongst players*

Pillar 4   Better integrate **relevance** and **patient-reported outcome measures** in the evaluation process of health care and support services

- *Integrate patient-reported outcomes in HAS evaluations*
- *Strengthen the consideration of relevance in the evaluation of patient-reported outcomes*
- *Encourage further endorsement of the accreditation process of health facilities and the evaluation of social service facilities by professionals and the public*

Pillar 5   Strengthen HAS **efficiency**

- *Define and put into place pluriannual priorities*
- *Reinforce the impact of HAS output*
- *Support HAS and its staff through change*
- *Strengthen transversal working between the health and social sectors*

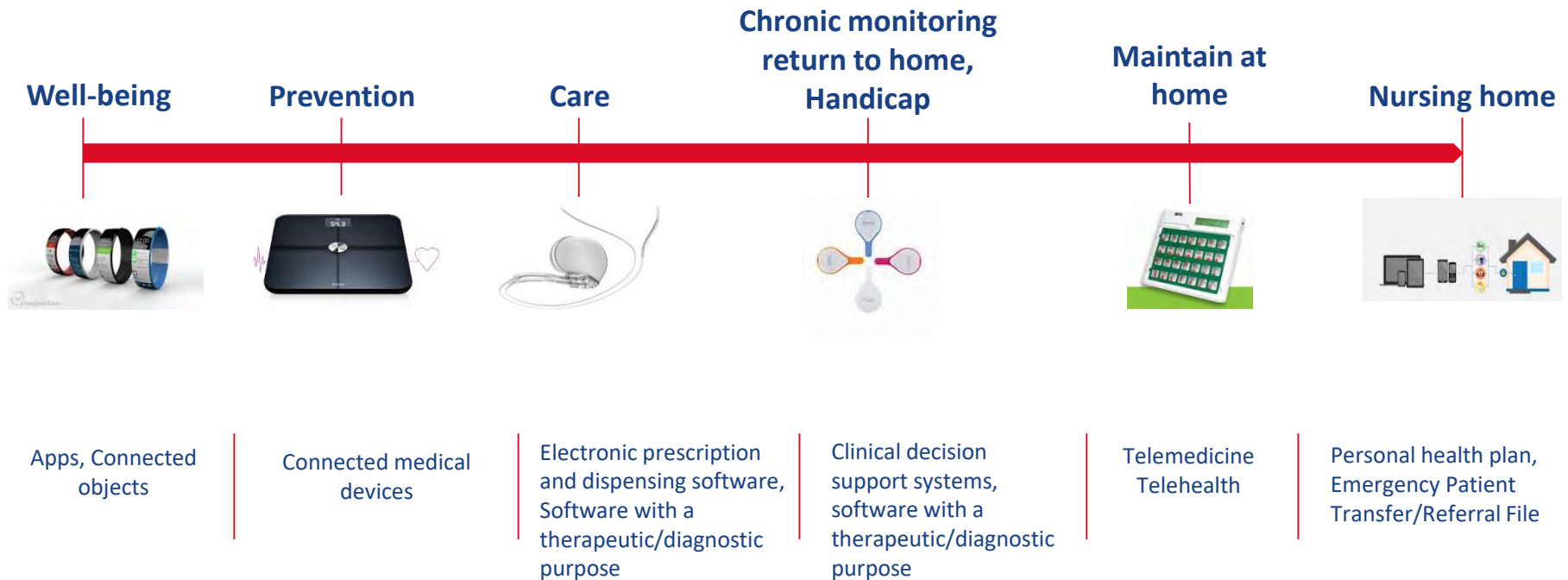**Pillar 6**   Strengthen HAS **international** influence and presence

- *Increase and reinforce HAS visibility and role in Europe and internationally*
- *Strengthen HAS' role in HTA across Europe*
- *Strengthen HAS' network in the area of quality care and safety*

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Le numérique dans les parcours de vie d'un usager/patient

Well-being | **Prevention** | **Care** | **Chronic monitoring return to home, Handicap** | **Maintain at home** | **Nursing home**

Apps, Connected objects | Connected medical devices | Electronic prescription and dispensing software, Software with a therapeutic/diagnostic purpose | Clinical decision support systems, software with a therapeutic/diagnostic purpose | Telemedicine Telehealth | Personal health plan, Emergency Patient Transfer/Referral File

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Patient communities

Online appointment platforms

Electronic patient files – physician files/ hospitals

Imaging

Registries, cohorts, studies

Medical Care Apps, etc.

Connected medical devices

Biological lab results

Connected objects well-being

Smartphones

Genomic data

Social media

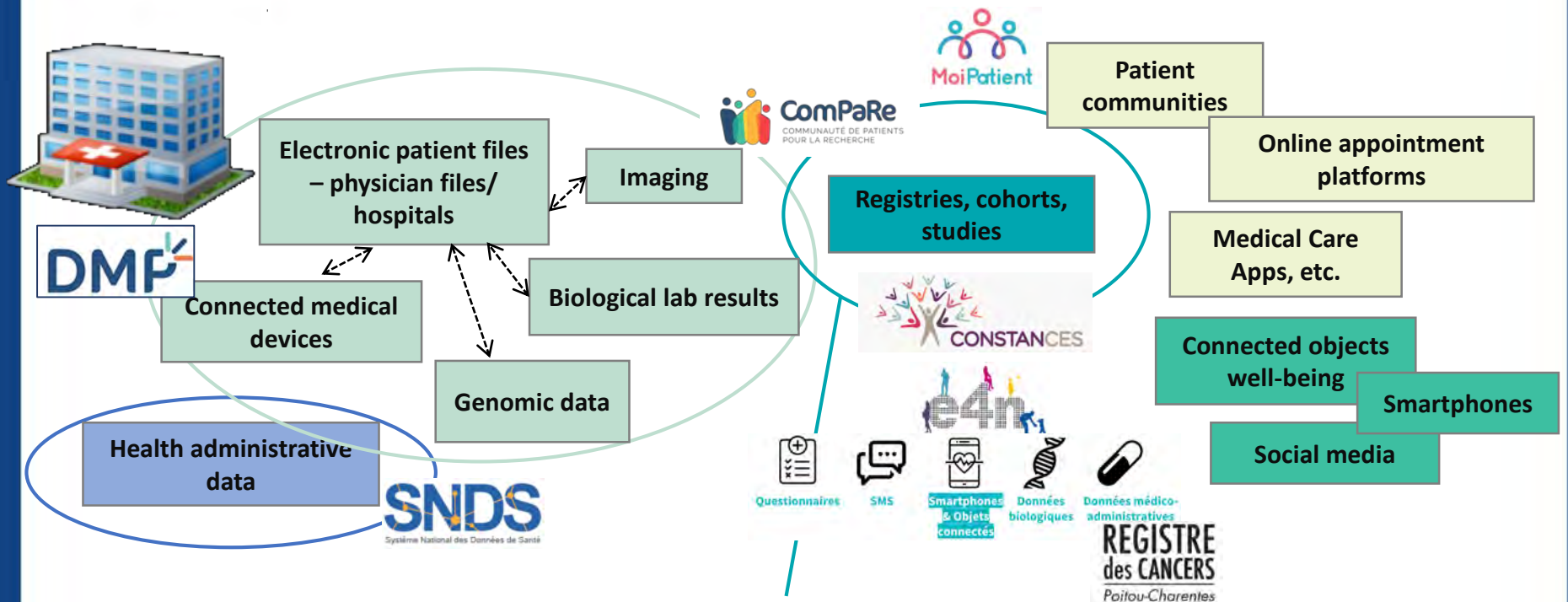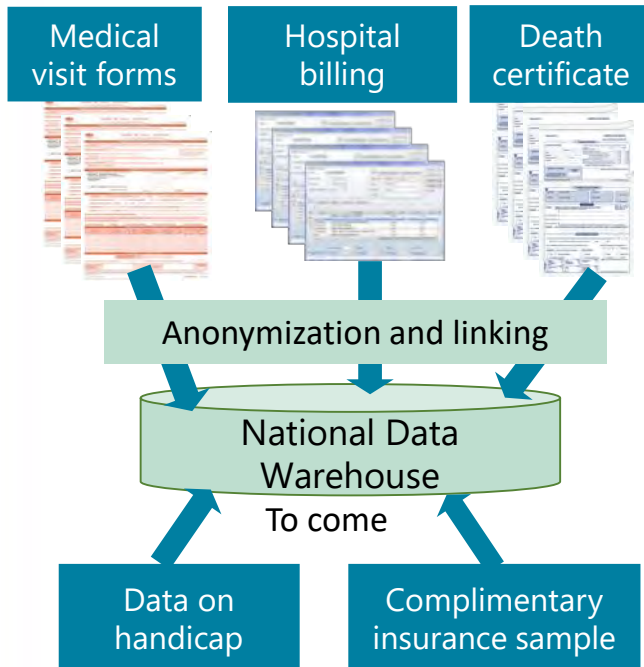Health administrative data

Two types of use

Care / services for an identified patient

Masked data (de-identification)

Highly-Fragmented Data Collection

Pros : Complete perspective on the patient health pathway, **67 millions individuals**, no selection bias, no lost to follow-up, **13-year experience**, good coding homogeneity

Cons : limited data (no clinical/para-clinical data, medical history, risk factors, demographic data, etc.)

✓ Sufficient for a certain number of analysis

✓ Base for pairings with more specific data

2016 : unification of governance and access rules, open principle under conditions

Conditions for making best use of available data for the benefit of all?

1. Necessary to be able to **access data** quite easily (not the case today for a majority of the data)

2. Importance of **quality and exploitable data**

3. Necessary to be able to **match different databases** and to create multi-source systems, sustainably or with respect to a given project

4. Importance of increasing exploitability *intelligently*

April 2019: Ethics guidelines for trustworthy AI
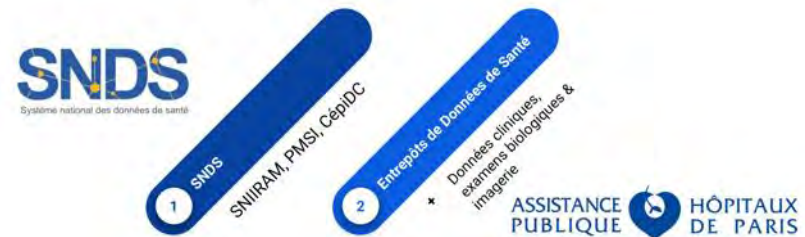
1. **Human agency and oversight (fundamental rights)**

1. **Technical robustness and safety :**
   1. *Resilience to attack and security*
   2. *Fallback plan and general safety*
   3. *Accuracy*
   4. *Reliability and reproducibility*

2. **Privacy and data governance**
   1. *Respect for privacy and data Protection*
   2. *Quality and integrity of data*
   3. *Access to data*

3. **Transparency (*Including traceability*)**
   1. *Traceability*
   2. *Explainability*
   3. *Communication*

4. **Accountability through auditing**

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In France: implementation at a sustainable pace, milestone examples

2 major challenges 07/2018
- « How to improve medical diagnostics through IA »
- « How to secure, certify and render reliable systems that use IA?»

Research

IA National Research Program, **11/ 2018**, Inria

Strategy AI for Humanity, **03/2018**

Bioethics law Art.11 **2019/2020**

Health sector contracts 02/2019

10/2018

Economics

Economic aspect of the IA strategy, **07/ 2019**,

Health Data Hub
- 80 M€
- IA data pairing
- Technical platform and simplified access
- Catalogues and projects databases

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Real life data for regulators

▶ **Monitoring and health surveillance**

▶ **Evaluation** of medicines, medical devices, procedures (increasing uncertainties with pre-inscription, need to validate in real life)

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▶ **Pharmaco-surveillance** / health product safety

▶ **Monitoring system performance**, gaps, areas **HAS** for improvement

▶ **Efficiency gains** (average adjustments, freeing **HAS** up medical/physician time,…)

Risques associés au dispositif de stérilisation définitive « Essure» en comparaison à la stérilisation cœlioscopique (ligature) à partir des données du SNIIRAM

Etude ANSM, JAMA 2018

Research

JAMA | Original Investigation

Association of Hysteroscopic vs Laparoscopic Sterilization With Procedural, Gynecological, and Medical Outcomes

Kim Bouillon, MD, PhD; Marion Bertrand, MSc; Georges Bader, MD; Jean-Philippe Lucot, MD; Rosemary Dray-Spira, MD, PhD; Mahmoud Zureik, MD, PhD

Low dose oestrogen combined oral con pulmonary embolism, stroke, and myoc million French women: cohort study

Drug Saf
https://doi.org/10.1007/s40264-019-00880-9

ORIGINAL RESEARCH ARTICLE

Non-bleeding Adverse Events with the U Anticoagulants: A Sequence Symmetry

Géric Maura[1,2] · Cécile Billionnet[1] · Joël Coste[1] · Alain Weill[1] Anke Neumann[1] · Antoine Pariente[2,4]

Risque accru de lymphome chez les patients traités par anti TNFα utilisés dans la prise en charge des maladies inflammatoires chroniques intestinales (MICI), à partir des données du SNIIRAM

Etude ANSM, JAMA 2017

Research

JAMA | Original Investigation

Association Between Use of Thiopurines or Tumor Necrosis Factor Antagonists Alone or in Combination and Risk of Lymphoma in Patients With Inflammatory Bowel Disease

Magali Lemaitre, PhD; Julien Kirchgesner, MD, MSc; Anne Rudnichi, MD; Fabrice Carrat, MD, PhD; Mahmoud Zureik, MD, PhD; Franck Carbonnel, MD, PhD; Rosemary Dray-Spira, MD, PhD

Circulation: Cardiovascular Quality and Outcomes

ORIGINAL ARTICLE

Clinical Events After Discontinuation of β-Blockers in Patients Without Heart Failure Optimally Treated After Acute Myocardial Infarction
A Cohort Study on the French Healthcare Databases

See Editorial by Ko and Jackevicius

BACKGROUND: β-blockers have been among the first medication shown to improve outcomes after acute myocardial infarction (AMI). With the advent of reperfusion therapy and other secondary-prevention medications,

Anke Neumann, PhD
Géric Maura, PharmD
Alain Weill, MD
François Alla, MD, PhD
Nicolas Danchin, MD, PhD

D'après planche de Mme Polton, colloque HAS

HAS
HAUTE AUTORITÉ DE SANTÉ

Développer la qualité dans le champ sanitaire, social et médico-social

Evaluation by HAS/ CNEDiMTS

Connected objects
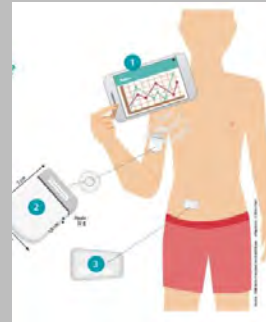
Without an intended medical use declared

Medical Devices CE

Individual Use

Use reserved for health professionals

Evaluation HAS/CNEDiMTS

2017

Elaboration of a manual to submit specific Connected Medical Devices (CMD)

=> allows applicants to provide a legible CMD-description

2018

Elaboration of a manual relative to methodological specificities to evaluate CMD

=> Anticipate clinical standards and requirements requested by the committee (CNEDiMTS)

2019-2020

Work related to organizational impact

2019-2020

Elaboration of a project « evaluation scale » for IA placed under public consult

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Artificial Intelligence:
a challenge for society….

1. **Data governance**

2. **Bias, inequalities**

3. **Cybersecurity and protection of sensitive information**

4. **Trust (transparence, reliability, explainability, evidence, certification, evaluation …)**

   – In its prospective report, HAS encouraged the use of an evaluation scale for software designed for therapeutic/diagnostic use.

   – Article 55 (last Health Reform) requested a report for parliament on this topic

5. **Decision-delegation to machines?**

6. **Human guaranty in health**

7. **Future of work and employment**

New	≠	Better

Technological Innovation	≠	Clinical Innovation

MERCI!
THANK YOU!

HAS