



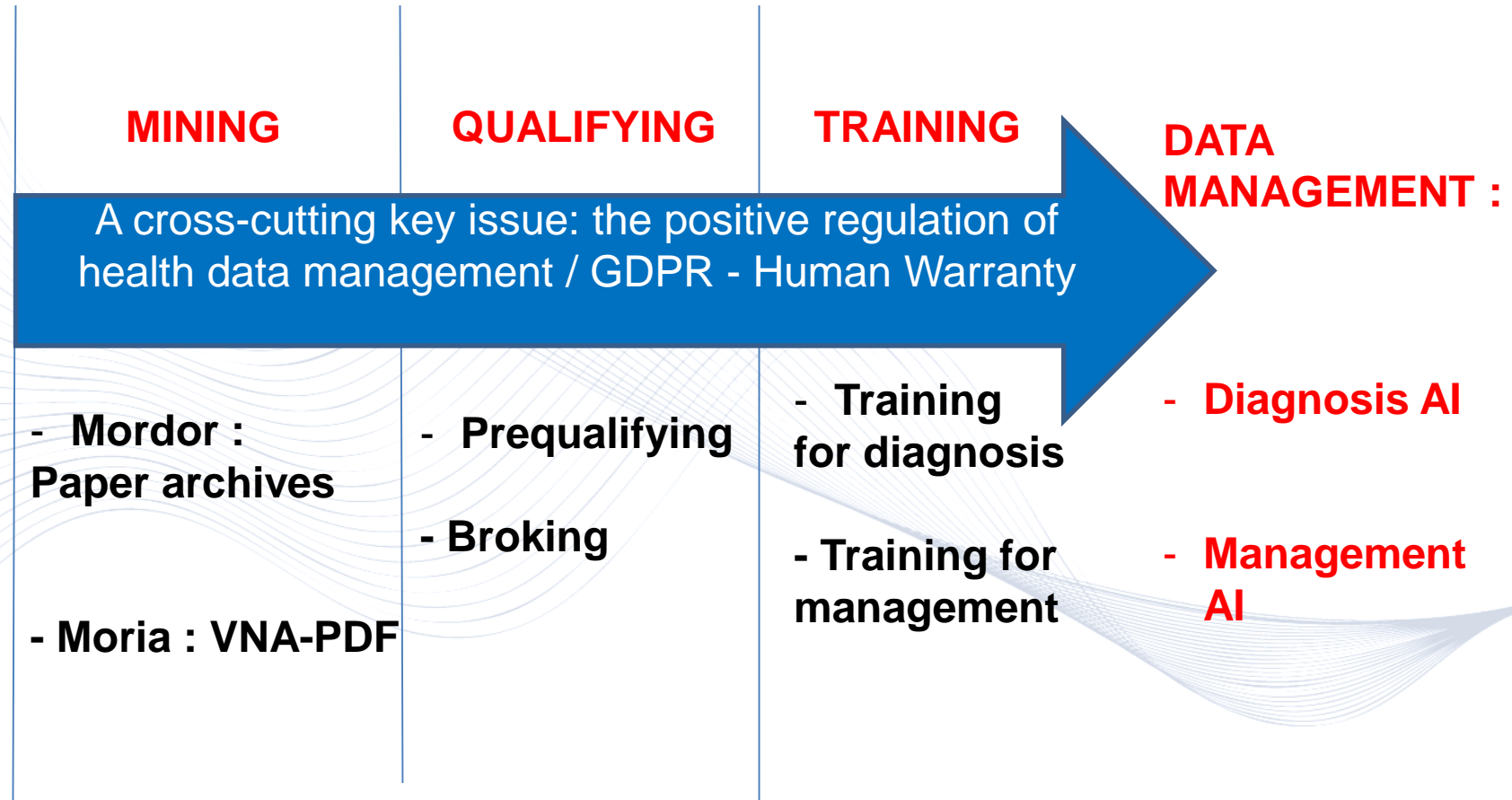
**AI for Healthcare Positive Regulation :
Algorithmic Human Warranty
(ALHUWA) as a standard**

Workshop CEN-CENELEC

Octobre the 27th 2020

Ethik-IA

HUMAN WARRANTY OF AI : ALL ALONG THE HEALTHCARE DATA MANAGEMENT PATHWAY !



***A New Framework for AI
regulation in France :***

Health Data Hub

***Bioethics Law
Reexamination***

ALHUWA applied cases

**ALHUWA !
ALHUWA !**

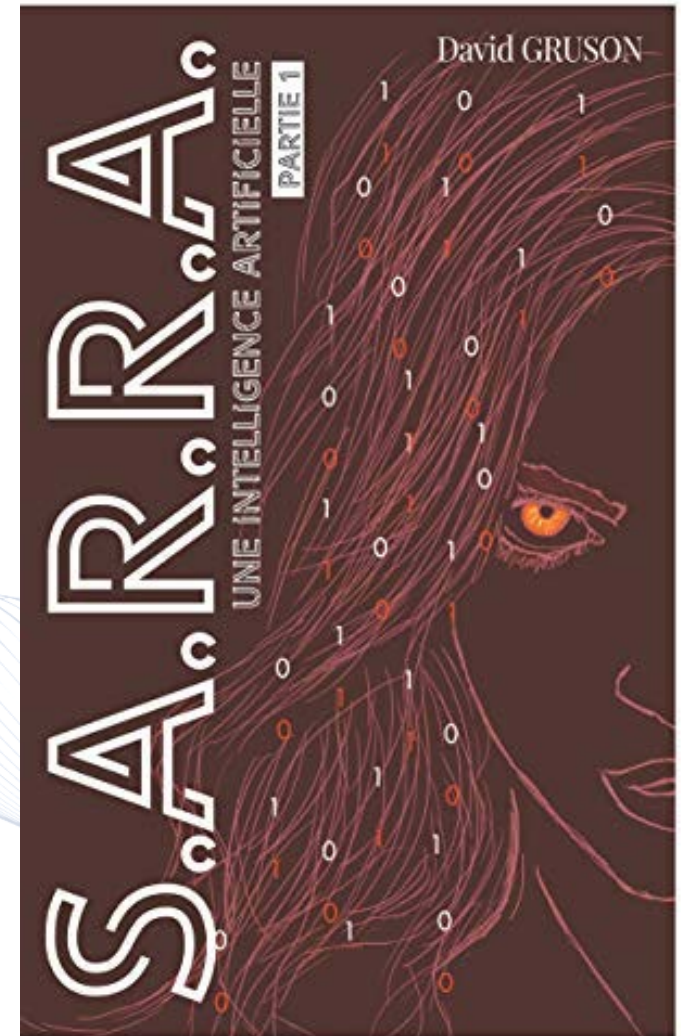


COVID19 context : AI in health and balancing of individual and collective interests

- Delegation of decision / delegation of consent
- A risk of reduced consideration of the person in relation to the collective interest probably reinforced in the context of epidemic crisis management

PANGOLINK

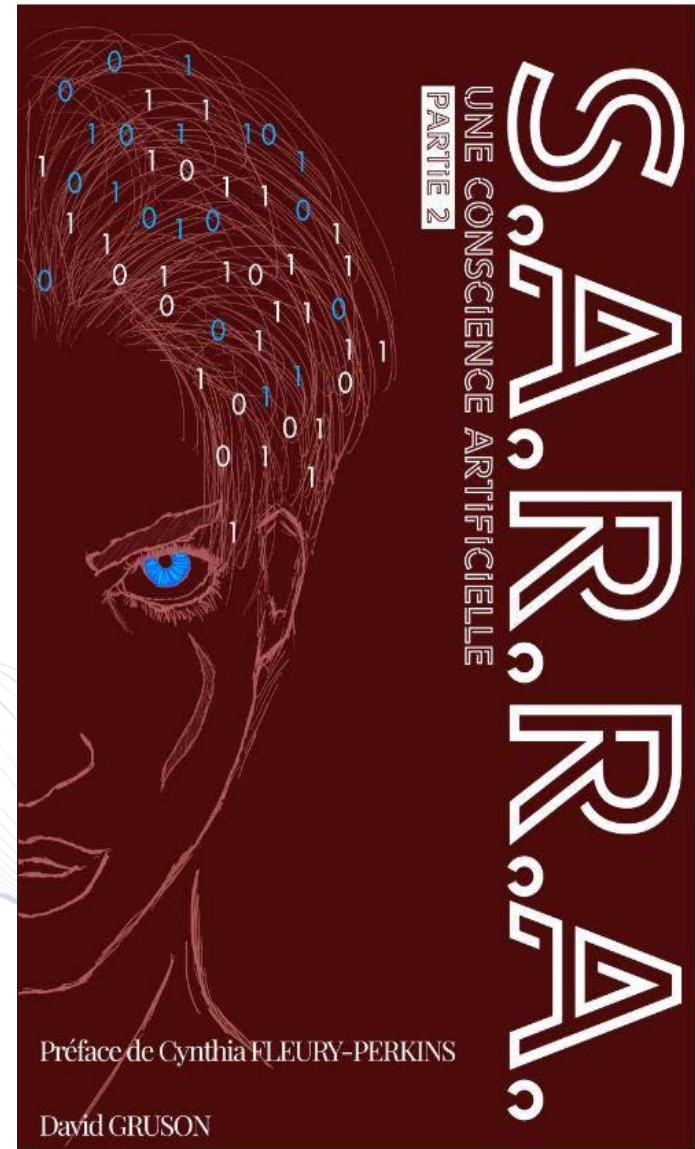
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Ethical questions for tomorrow ... or today?

- When the Real exceeds Fiction: AI in the response to COVID19; first AI vaccine and antibiotic production
- Public health in a pandemic context in the digital age: democracy or authoritarianism?
- To avoid guardianship: anticipation of the application of article 11 of the P JL Bioethics and the principle of an AI Human Warranty



Bioethics Law Reexamination

- The impact study explains the **draft article 11** by the Human Warranty principle.
- Explanatory memorandum of the Bill : "Article 11 aims to secure the correct information of the patient when an algorithmic processing of big data (" artificial intelligence ") is used during a treatment. It also declines the warranty of human intervention. "
- Principle of patient information on the use of AI
- Implementation of a Human Warranty principle notably in the form of **Human Warranty Colleges associating professionals, patients and innovators in AI**

Bioethics Law Reexamination

- **The patient's information on the use of AI is very clearly reaffirmed.**
- There are two useful exceptions to this information: "urgency" and "impossibility" to inform. These derogations should, it is easy to understand, be concretely defined in practice.

Bioethics Law Reexamination

Common criterion : ***“algorithmic treatment”***

Three operational levers of **ALHUWA traceability** :

- **A Human Warranty standard in the operational supply of the algorithm for a specific patient:** the capture of information relating to the patient in the algorithmic treatment is done under the control of the healthcare professional who uses this treatment;
- **A Human Warranty in the decision itself:** "no medical decision can be made on the sole basis of an algorithmic treatment;

Bioethics Law Reexamination

- **A Human Warranty in the form of quality control of the algorithm in real life.** This quality control integrates the designers and users of the algorithm: the designers of an algorithmic processing ensure the transparency of the operation of the tool for its users.

Applied ALHUWA : Applied case 1 / AI applied to dental care

- Article 51 UFSBD experiment carried for 48 elderly caring hospitals
- Deployment of an automatic image recognition solution on dental panoramics with the start-up Dental Monitoring
- The Human Warranty on two levels:
 - Human Warranty integrated into AI;
 - External supervision by a **Human Warranty College** associating professionals and patient representatives

Applied ALHUWA : case 2 / The draft AI good practice standard applied to genomic data

- Imagine's desire to develop its action in the field of artificial intelligence in health
- The observation shared by professionals of significant ethical issues in the application of AI - and more specifically Machine Learning - to genomic data
- The practical awareness, in the projects already carried out, of a certain number of brakes and blockages in the development of innovation and health research
- The choice to be part of the logic of "learning health system"

Applied ALHUWA : case 2 / The draft AI good practice standard applied to genomic data

- A variation of "key n 3" in the 5 keys for regulating AI and health robotization developed by Ethik-IA: graduation of the level of protection of health data according to their sensitivity
- In practice: the identification of a **perimeter of sensitivity** within which are allowed deeper AI treatments applied to precisely identified genomic and phenotypic data.
- Secure exchange mechanisms with more generalist AI operating beyond the scope: anonymization, pseudonymization, blockchain

Applied ALHUWA : case 2 / The draft AI good practice standard applied to genomic data

- An example of R&D on the production of benchmarks for good practices based on use cases constructed with the teams
- A function likely to be developed upstream of the intervention of the regulatory authority
- A complementary role for Ethik-IA and Imagine within the framework of **Project 3 IA “Prairie”**

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Applied ALHUWA : case 3 / Human Warranty under the aegis of representatives of a medical profession

- The origins of the DRIM France IA Radiology project
- The positive regulation component of the project
- Possible variations in emergency medicine, biology and dental

DRIM FRANCE IA



Conseil professionnel
de la radiologie française

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Take-Home Messages

- **AI standardization : striking a balance between regulating and nurturing innovation.**
- **Some reasons to be optimistic : Positive Regulation and ALHUWA tend to become trendy !**
- **No time to waste...**



Thanks for your attention !

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