### AI IN HEALTH®



Artificial intelligence in health has adverse effects that cannot be ignored. It's up to us to prevent them! #SoignonsNosAlgos

#### 1. What is AI IN HEALTH and when is it used?

Al IN HEALTH can be defined as a set of devices based on machine learning algorithms.

These algorithms are designed by data scientists and trained using data sets.

Al IN HEALTH is prescribed for the diagnosis and/or treatment of diseases.

It can also be used in precision medicine, to provide personalised care for patients or to anticipate epidemics.

# 2. What information should be known before using AI IN HEALTH?

The use of AI IN HEALTH is regulated in France through several legal texts. The French "loi de bioéthique" (2021) requires healthcare professionals who use AI to inform the people concerned. Developers are also required to ensure that their technologies can be explained to users<sup>1</sup>.

The European General Data Protection Regulation<sup>2</sup> and the "loi informatique et libertés"<sup>3</sup> regulate the use and storage of personal and health data.

The **AI Act** will soon introduce additional rules for highrisk AI, including that embedded in medical devices.

#### 3. How to use AI IN HEALTH?

#### Warnings

Artificial intelligence involves the processing and storage of a large amount of personal and sensitive health data. You should ensure that you **understand** the implications for your privacy and that you **consent** to this processing.

Always use Al IN HEALTH under the supervision of a physician.

Although some of the information in this leaflet also applies to generative AI in healthcare, this leaflet focuses exclusively on AI systems embedded in medical devices.

## 4. What are the possible adverse effects of Al IN HEALTH?

Like all medical products, Al can cause side effects.

#### The following adverse effects have been reported:

- Algorithms used in healthcare are sometimes trained with biased data, where groups are underrepresented:
  - women,
  - ethnic minorities and groups of color,
  - elderly people,
  - people with disabilities.

This can lead to differentiated care for these people, reinforcing discrimination in access to quality healthcare.

- Algorithms are the result of choices made at the design stage. Poorly calibrated or poorly supervised, these devices can lead to errors in diagnosis or medical care, with severe consequences for people's health.
- Mass storage of personal and sensitive health data can undermine data protection and the right to privacy.
- The widespread use of artificial intelligence can contribute to the dehumanisation of care, in particular by altering the doctor-patient relationship and reducing care to a mathematical calculation.
- Digital tools such as Al may be unavailable to certain populations, such as elderly people, who may lack sufficient 'digital literacy'. Al in healthcare can therefore exacerbate inequalities in access to healthcare for these people.

#### 5. Author of this leaflet

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If you have any questions about this leaflet or if you wish to report an adverse reaction, please consult the website <a href="https://www.ghadvocates.eu">www.ghadvocates.eu</a>







<sup>&</sup>lt;sup>1</sup> Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique.

<sup>&</sup>lt;sup>2</sup> Règlement (UE) 2016/679 du Parlement européen et du Conseil du 27 avril 2016 relatif à la protection des personnes physiques à

l'égard du traitement des données à caractère personnel et à la libre circulation de ces données.

<sup>&</sup>lt;sup>3</sup> Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés