6. Ethical principles for Digital Health

Supportive document upgraded version
Implementation Plan

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Ethical principles for Digital Health

Adoption by eHealth Network on January 26th, 2022

Digital Health shall be used to well-being for all mankind and biosphere.

Progress towards these goals will benefit from guiding European ethical principles in line with our European humanistic tradition and values. The framework includes European Ethical Principles for Digital Health organized around 4 ethical dimensions.
It is the basis of European citizens' trust in Digital Health. *(…)*

The European Ethical Principles for Digital Health will be reviewed on a regular basis in the coming years. A ***supporting document****, detailing the principles, linking them with the existing and on-going regulations and providing examples from national experiences will be provided.*

European Commission and Member States commit to further explore and discuss actions to respect these European Ethical Principles in their actions on Digital Health, monitor progress and review them jointly in due time.

An initiative of the French Presidency of the Council of the European Union, #PFU2022, driven by the **e-Health networkprotect health and**

Inscrire le numérique en santé dans un cadre de valeurs humanistes ***Base Digital Health on humanistic values***
1. Le numérique en santé complète et optimise les pratiques de santé effectuées en présentiel *Digital Health complements and optimizes face-to-face healthcare*
2. Les personnes sont informées des bénéfices et des limites du numérique en santé *Individuals are informed about the benefits and limits of Digital Health*
3. Les personnes sont informées des modalités de fonctionnement des services numériques en santé et peuvent facilement paramétrer leurs interactions avec ces outils *Individuals are informed about the functioning of Digital Health services and can easily customize interactions with them*
4. Lorsqu'une intelligence artificielle est mise en œuvre, le maximum a été fait pour qu'elle soit explicable et sans biais discriminatoire *When artificial intelligence is used, all reasonable efforts are made to make it explainable and without discriminatory bias*
Donner la main aux personnes sur le numérique et sur leurs données de santé ***Enable Individuals to manage their Digital Health and data***
5. Les personnes ont un rôle actif dans l'élaboration des cadres européens et nationaux du numérique et des données de santé *Individuals are actively involved in shaping the European and national frameworks of Digital Health and data*
6. Les personnes peuvent récupérer facilement et de manière fiable leurs données de santé dans un format couramment utilisé *Individuals can easily and reliably retrieve their health data in a commonly used format*
7. Les personnes peuvent facilement obtenir des informations sur la manière dont leurs données de santé ont été ou peuvent être consultées et dans quel but *Individuals can easily get information on how their health data have been or may be accessed and for which purpose*
8. Les personnes peuvent facilement et de manière fiable donner l'accès à leurs données de santé et exercer leurs droits, y compris leur droit d'opposition quand il est applicable *Individuals can easily and reliably grant access to their health data and exercise their rights, including objection when applicable*
Développer un numérique en santé inclusif ***Make Digital Health inclusive***
9. Les services numériques en santé sont accessibles à tous, y compris aux personnes en situation de handicap ou avec un faible niveau de littéracie *Digital Health services are accessible by all, including by people with disabilities or low levels of literacy*
10. Les services du numérique en santé sont intuitifs et faciles à utiliser *Digital Health services are intuitive and easy to use*
11. Les personnes ont accès à des formations sur le numérique en santé *Individuals have access to Digital Health training*
12. Les services numériques en santé proposent une assistance humaine lorsqu'elle est nécessaire *Digital Health services include support through human communication when needed*
Mettre en œuvre un numérique en santé éco-responsable ***Implement eco-responsible Digital Health***
13. Les impacts environnementaux du numérique en santé sont identifiés et mesurés *Environmental impacts of Digital Health are identified and measured*
14. Les services numériques en santé sont développés dans le respect des bonnes pratiques d'éco-conception *Digital Health services are developed in compliance with eco-design best practices*
15. La réutilisation et le recyclage des équipements informatiques en santé sont prévus *Re-use and recycling of Digital Health equipment is ensured*
16. Les acteurs du numérique en santé s'engagent à réduire leur empreinte écologique *Digital Health stakeholders are committed to reducing their ecological footprint*

European ethical principles for Digital Health Implementation

- **26 January 2022**: **Adoption of the European ethical principles for digital health**
- **March 2022**: **Creation of a dedicated taskforce** to work on an implementation plan
- **01-02 June 2022 eHealth Network Paris**: adoption of the first deliverable, **a supportive document** explaining the ethical principles with more details, as the format of the European ethical principles was a one-pager document.
  - Agreement to submit an upgraded version during upcoming eHealth network meetings
  - The supportive document will keep evolving over time.
- **30 March 2023**: **updated version of the supported document proposed for adoption**

Updated version with upgrades on

- **wording**
- **accuracy of the provided examples**
- **consistency of explanations**

The dedicated task force would like to specifically thank all contributors, and in particular Sarah Murphy for her review of the document.

European ethical principles for Digital Health Implementation Plan update

Implementation of European ethical principles for digital health

Phase 1

Initial preparation

Phase 2

Implementation next steps

Phase 3

Capacity building initiative

23rd eHN Meeting

European ethical principles for Digital Health Implementation Plan update

Implementation phase 1 - Initial preparation : methodology and outcomes

- Build and share a common understanding of the principles
- Collect use cases from all member States
- Propose and perform a preliminary assessment with an assessment grid
- Propose next steps

Approach

"No MS can already claim a full compliance to all 16 ethical principles"

Deliverables Phase 1 –eHN meeting 02.06.22

- Validated Supportive document v0
- Assessment grid v0

Implementation phase 2 - implementation next steps

- **Prepare new version of supportive document**
- Ensure contributions of Member States to assessment grid
- Update Assessment grid
- **Hand over** to Capacity Building driven by EU Commission
- Other tasks initially planned postponed

Approach

"Prepare for hand over to Capacity Building"

Deliverables Phase 2

- **New version of supportive document**
- Update of assessment grid and new contributions
- Transfer of all documents to **Capacity Building Contractor**

23rd eHN Meeting

European ethical principles for Digital Health Implementation Plan update

Implementation phase 3 - Capacity Building

- Capacity building initiative has started for 18 months (contract in August 2022, contractor has started in November)
- First expected outcomes : KPIs, mapping and evaluation of MS compliance (follow up on assessment grid), preparation of a capacity building requirements catalog. This catalog includes requirements to be met when moving to implementation
- Build and share a common sharing of best practices ("best practices compendium": use cases, concrete examples from the ecosystem (industry, patients,..))
- Communication plan to European citizens including a consultation to open discussions and initial EU compliance status
- Draft a white paper on the involvement of end users.

Approach

"Ensure implementation by driving the capacity building initiative and related actions with a close involvement of eHealth Network"

Deliverables Phase 3

- Capacity building plan for European ethical principles, and strong MS involvement and accomplishment rate
- White paper on the involvement of end users
- Requirements Catalog
- Communication plan including outcomes from the consultation of citizens and Initial EU compliance status

23rd eHN Meeting

Thank you

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European Commission