

CPME/AD/EC/07082020/065_Final/EN

On 7 August 2020, the CPME Executive Committee adopted the 'CPME Response to the eHealth Stakeholders Group on First Year Priorities' (CPME 2020/065 FINAL).

CPME Response to the eHealth Stakeholders Group on First Year Priorities

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME welcomes the relaunch of the eHealth Stakeholders Group and its renewed membership to represent the physicians' (and end-users') perspective in the Group.

CPME advises caution on the setting-up of sub-groups to examine specific questions on the basis of terms of reference defined by the European Commission, as they can jeopardise the legitimate and balanced representation of members in each topic. At least during the first year, CPME strongly discourages the creation of sub-groups to test and understand the Group's dynamics as well as its level of contribution to the field.

CPME recognises how digital transformation is changing medical practice. We believe that the benefit of digital tools in healthcare depends on its appropriate design, validation, and implementation. CPME's objective is to ensure that new technologies can be trustworthy for patients and health professionals and healthcare data is duly safeguarded.

CPME calls on the eHealth Stakeholders Group to focus on the following during its first year:

I - Ethical aspects

• Develop and propose ethical rules on artificial intelligence in healthcare.

II – Legal aspects

 Encourage or contribute to the development of a common model for obtaining consent for research purposes (secondary use) according to the Declarations of Helsinki,¹ Taipei² and the General Data Protection Regulation;

¹ WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and as amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

² WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.

• Explore the need of a robust legal protection for human genetic data and make appropriate recommendations to policy makers.

III – Technical aspects

- In addition to the legal aspects of consent for research purposes, encourage or contribute to an interoperable technical framework for consent documents, which include policies on processing patients' data, to be technically processed throughout the Union;
- Encourage or contribute to the development of practical recommendations (such as pseudonymisation and anonymisation techniques, and risk assessment tools) for exporting clinical data into a research database for secondary use;
- Explore the possibilities of developing common information security guidelines and standards for the protection of healthcare data for exchanging health information and secondary use;
- Recommend the usage of semantic standards such as the SNOMED CT as well as of interoperable document standards such as the International Patient Summary for unplanned cross-border healthcare delivery, as well as within healthcare systems of Member States;
- Encourage the transition of IHE-Profiles from HL7v2 and HL7v3 to HL7-FHIR. Develop recommendations for coping with different generations of HL7-Standards (v2, v3, FHIR).

Concerning the support CPME could provide to the Group, CPME can join a drafting group for a report, disseminate and carry out surveys among its members. CPME is also interested in participating in the work of the European Electronic Health Record Exchange Format (EEHRXF).
