

EU Policy and Regulatory updates by the RPP team

By the RPP Team

European Parliament Approves EHDS

On April 24th, the European Parliament endorsed the provisional agreement on the European Health Data Space (EHDS) reached between the Parliament and the Council. The agreement received 445 votes in favor, 142 against, and 39 abstentions. **The main point of contention during negotiations was the opt-out mechanism for secondary use of health data, particularly for research and development purposes.**



The final text includes the opt-out mechanism with exceptions for data used in the public interest, such as during pandemics. The Council is now expected to approve the provisional agreement, likely after the summer recess. Once approved by the Council, the EHDS will be published in the Official Journal of the EU, becoming legislation.

EFPIA Advocates for Responsible AI Use in Medicine Development

In a [recent statement](#), the European Federation of Pharmaceutical Industries and Associations (EFPIA) underlined the potential benefits of employing Artificial Intelligence (AI) in advancing patient care, fostering innovation, and benefiting society at large. EFPIA emphasized the crucial role AI is playing in revolutionizing the research, development, and manufacturing processes of medicinal products, ultimately **enabling the discovery, development, and delivery of safer and more effective treatments to patients in a quicker timeframe than ever before.**



The statement stressed the **necessity for regulatory frameworks governing the utilization of AI in medicine** development to be both fit-for-purpose and risk-based. Such frameworks should avoid duplication, align globally, and be tailored appropriately to ensure they facilitate rather than hinder the development of safe and effective treatments. EFPIA highlighted that the majority of AI tools used solely for medicinal research and development are exempt from the requirements of the EU AI Act, and those that aren't typically do not fall under high-risk categorization.

Additionally, EFPIA expressed support for the European Medicines Regulatory Network's (EMRN) approach to AI, which integrates AI methodologies into existing practices and standards. The federation anticipates collaborating with EMRN on forthcoming guidance for AI usage in medicine development.

EFPIA outlined five critical considerations for the governance of AI throughout the medicine development lifecycle:

1. The exemption for AI dedicated to scientific research under the EU AI Act.
2. The majority of AI applications in medicine development not qualifying as high-risk under current regulations.

3. The already stringent regulatory environment governing medicine development in Europe.
4. The upcoming guidance from the European Medicines Agency (EMA) on AI use in medicine development.
5. The necessity for adaptable, risk-based governance calibrated to the specific context and intended use of AI systems.

As the AI policy landscape evolves in Europe, including the finalization of the EU AI Act and the ongoing work of EMRN, EFPIA is committed to collaborating with relevant stakeholders to ensure responsible AI implementation while upholding fundamental rights, safety, and ethical principles.

Background:

The final text of the AI Act establishes a comprehensive framework for AI systems in the EU market, categorized by risk. EFPIA's engagement with EMA aims to clarify AI usage and governance in the medicine development lifecycle, aligning with the Act's risk-based approach.

WHO Introduces Cutting-Edge Digital Health Advocate Utilizing Generative AI for Public Health

In anticipation of World Health Day, themed 'My Health, My Right', the [World Health Organization \(WHO\) announced the debut of S.A.R.A.H.](#), a prototype digital health advocate equipped with an enhanced empathetic interface driven by generative artificial intelligence (AI).



S.A.R.A.H., shorthand for *Smart AI Resource Assistant for Health*, represents a significant advancement in AI-driven health information platforms, incorporating state-of-the-art language models and innovative technology. It offers round-the-clock engagement in 8 languages across various health topics, accessible on any device.

This digital health advocate from WHO is trained to disseminate information on a wide array of health subjects, ranging from fostering healthy habits to promoting mental well-being, thereby assisting individuals in optimizing their health journey. Its objective is to furnish an additional resource for individuals to exercise their right to health, regardless of their location.

S.A.R.A.H possesses the capability to aid individuals in comprehending risk factors associated with leading causes of mortality worldwide, such as cancer, heart disease, lung disease, and diabetes. It facilitates access to current information on smoking cessation, physical activity, nutritious eating, stress reduction, and more.

Dr Tedros Adhanom Ghebreyesus, WHO Director-General, remarked, "The future of healthcare lies in digital innovation, and enabling nations to leverage digital technologies for healthcare is a key priority for WHO." He added, "S.A.R.A.H. offers a glimpse into how artificial intelligence can revolutionize access to health information in a more interactive manner. I urge the research community to further explore how this technology can address disparities and provide people with reliable, up-to-date health information."

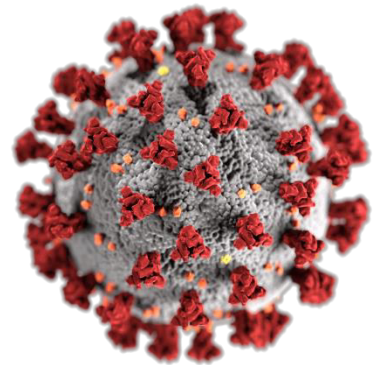
Powered by generative AI, S.A.R.A.H. now delivers more precise real-time responses, engages in dynamic personalized conversations that closely resemble human interactions, and furnishes nuanced, empathetic responses in a non-judgmental environment. This technology is bolstered by Soul Machines Biological AI.

WHO advocates for ongoing research into this innovative technology to uncover its potential advantages for public health and to address potential challenges. While AI holds immense promise in fortifying public health efforts, it also poses significant ethical considerations, including equitable access, privacy, safety, accuracy, data protection, and bias.

Through continuous evaluation and refinement, WHO underscores its commitment to delivering health information to individuals while upholding the highest ethical standards and evidence-based content. Stakeholders, including developers, policymakers, and healthcare providers, must address these ethical and human rights concerns when developing and deploying AI to ensure universal benefits.

The S.A.R.A.H. initiative strives for perpetual learning and advance meant of a prototype that offers reliable, responsible, and accessible information. Previously, iterations of S.A.R.A.H., known as Florence, were instrumental in disseminating critical public health messages during the COVID-19 pandemic, covering topics such as the virus, vaccines, tobacco use, healthy eating, and physical activity.

WHO continues to leverage various digital tools and channels, including social media, chatbots, channels, and text messaging, to amplify health information dissemination efforts.



Council releases Draft Conclusions on Horizon 2020 evaluation



The Council of the European Union highlighted the significance of [Horizon 2020](#) in bolstering the EU's competitiveness in its [Draft Conclusions](#) regarding the [ex-post evaluation](#) of the research and innovation funding program. Recognizing Horizon Europe as pivotal to enhancing Europe's competitiveness, the Council underscores its role as the primary EU instrument for supporting research endeavours and facilitating collaborative research efforts beyond other available means or funding channels.

In pursuit of this objective, the Council emphasizes the importance of securing an adequate and consistent budget for Horizon 2020, along with fostering a robust European Research and Innovation (R&I) ecosystem. Additionally, it advocates for enhanced stakeholder engagement, promotion of private investments, support for breakthrough technologies, and greater involvement of SMEs. Furthermore, the Conclusions underscore the necessity of aligning Horizon 2020 with the [European Research Area](#) (ERA), improving access to research infrastructure, and promoting effective data management.

The Council anticipates the Commission's report on the Horizon Europe Interim Evaluation and plans to further deliberate the draft document during the [Working Party on Research](#) meeting on April 9th.

In-depth discussions reveal that Member States recognize the shortfall of an additional EUR 159 billion required to fund all high-quality proposals submitted to Horizon 2020, highlighting the ongoing challenge in achieving the EU-level target of investing 3% of GDP annually in R&D. The conclusions stress the importance of supporting diverse forms of innovation, especially those with transformative potential, and facilitating SME participation in research and innovation endeavours. Additionally, there's an emphasis on promoting private investments to stimulate employment, economic growth, and productivity.

Moreover, the Council advocates for a balanced approach in funding opportunities to bridge fundamental research with the economic or societal valorisation of research outcomes. It's noted that Horizon 2020 fell short of its budgetary target for climate-specific topics.