HAI Response Public Consultation on EMA AI Reflection Paper

Public Consultation Response | 21 September 2023 | Download response

In July, the EMA released a draft reflection paper on AI as part of the EMA Big Data Steering Group initiatives to develop the European Medicines Regulatory Network's capability in data-driven regulation. The draft paper is open for public consultation.

As part of a wider call to action to other civil society organisations, HAI developed a detailed response to the draft paper, calling on the EMA to take a more proactive role in the use of AI in the medicinal product lifecycle.

Some of HAI's general comments include the need for the EMA to include classification criteria for high-risk AI uses for medicines regulations, the recommendation that the EMA asserts its authority as a regulator, as well as the need for the EMA to develop a roadmap of actions to be taken which enable it to execute its responsibility and safeguard and ensure independent regulatory assessment, among others.

See the full response here.