HAI Response to EMA Real-World Evidence Consultation

Public Consultation Response | 28 September 2023 | Download Response

As more types of data for medicines regulation, so-called real-world data, become available, it is crucial that the EMA governs its use in a way that improves medicine effectiveness and pharmacovigilance insights while protecting standards of evidence, in light of new risks that these data sources bring along. Through this public consultation, we call for transparency, strong safeguards for the quality of evidence, and draw attention to the need to regulate not just real-world data, but also the tools used for analysis of these data, including machine learning.

Download our full response here.