12 February 2024
EMA/65720/2024

Note on the HORIZON-JU-IHI-2024-06-two-stage funding call: Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence

On 16th January 2024, the Innovative Health Initiative (IHI) published a Call for Proposals for Topic ID HORIZON-JU-IHI-2024-06-two-stage, with the title "Development of evidence based practical guidance for sponsors on the use of real-world data / real-world evidence." The expected outcome is, "Industry, sponsors, and other stakeholders have access to structured, evidence-based and practical guidance and recommendations on the use of real-world data / real world evidence (RWD/RWE) that could be followed to support the development, and regulatory, health technologies assessment (HTA), and payer decision-making of innovative medicines and health technologies with a focus on medicinal products, medical devices, and therapeutic products that combine a medicinal product with a medical device (drug-device combinations); Regulators, HTA bodies and payers will receive more structured and consistent RWD/RWE submissions to inform their decision making."

This note provides organisations planning to submit a proposal to the HORIZON-JU-IHI-2024-06-two-stage call with information to be considered concerning a potential involvement of the European Medicines Agency (EMA)'s in their proposal and consortium.

The EMA and the European Medicines Regulatory network, overseen by the EMA-HMA Big Data Steering Group, are working towards a sustainable framework that enables the use and establishes the value of RWE in decision-making across the entire medicinal product lifecycle. Therefore, the EMA considers that it might participate in decisions on the orientation of the proposed work programme, development of research protocols, discussion and dissemination of results. This role would go beyond participation in an advisory board and may require membership in the steering group(s) or in relevant work package(s), depending on the proposal and workload. The EMA will however not lead, manage or coordinate a work package, but may provide expertise where appropriate.

Applicants can propose EMA's involvement in their documentation submitted with their proposal. For the applicant consortium invited to the second stage, EMA can be requested to be involved and will take a decision in line with the provisions described in European Medicines Agency process for engaging in externally funded regulatory sciences and process improvement research activities for public and animal health (EMA/158095/2019) and EMA's support for regulatory science research. Areas of regulatory science research to which the EMA might contribute must be closely related to its role and responsibilities as well as aligned with its strategic priorities. In this context, applicants should consult the EMA's Regulatory Science Research Needs (EMA/705364/2021), the HMA-EMA Big Data Steering Group's Workplan 2023-2025 and the Report on the experience gained with regulator-led studies (EMA/289699/2023). Information on engaging with regulators published by the IHI should also be considered.

Applicants should communicate proposals for EMA's involvement to Regulatory.Science@ema.europa.eu.

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