EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Note on European Medicines Agency's involvement in HORIZON-HLTH-2022-TOOL-11-02: New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment

On 6 October 2021, the European Commission published a Call for Proposals for Topic ID HORIZON-HLTH-2022-TOOL-11-02 titled "New methods for the effective use of real-world data and/or synthetic data in regulatory decision-making and/or in health technology assessment." The principal aim of this topic is to address the data needs of health regulatory bodies and HTA bodies across the EU, as outlined in the recently published HMA-EMA Joint Big Data Taskforce (BDTF) Phase II report: 'Evolving Data-Driven Regulation" and its associated Data Analysis and Real World Interrogation Network (DARWIN EU) project. In addition to national competent authorities, proposals could consider the involvement of the European Medicines Agency (EMA) for an added value in order to provide an effective interface between the research activities and regulatory aspects and/or to translate the research results into validated test methods and strategies that would be fit for regulatory purposes.

This document provides organisations planning to submit an offer to the HORIZON-HLTH-2022-TOOL-11-02 call with information to be considered for proposing European Medicines Agency (EMA)'s involvement in their proposal.

Given the coordinating role that EMA has in the BDTF and DARWIN EU and the need to cover the needs of these initiatives, the EMA considers that it might participate to decisions regarding the orientation of the work programme, the development of research protocols, and the discussion and dissemination of the results. This role would require going beyond participation in an Advisory Board and would require membership in the Steering Committee or, exceptionally depending on the workload involved, relevant work package(s). The EMA will not lead, manage or coordinate a work package or part of the research programme, but could provide adequate expertise to the project if appropriate.

EMA's involvement in the project Steering group can be proposed by tenderers in the documentation submitted to the Call. For the applications accepted, EMA will take a decision on its level of involvement 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). This document stresses that areas of regulatory science to which the EMA might contribute must be closely related to its role and responsibilities and aligned with its strategic priorities. Tenderers may consult the EMA Regulatory Science Research Needs (EMA/705364/2021) document in this regard.

Intentions to propose EMA's involvement in a project should be communicated to Regulatory.Science@ema.europa.eu.

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