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Note on European Medicines Agency's involvement in HORIZON-HLTH-2023-TOOL-05-09: Developing a Data Quality and Utility Label for the European Health Data Space

On 12 January 2023, the European Commission opened a Call for Proposals for Topic ID HORIZON-HLTH-2023-TOOL-05-09 titled "Developing a Data Quality and Utility Label for the European Health Data Space". The Topic description includes: "The European Health Data Space (EHDS) will provide a common EU framework for secondary use of health data such as research, innovation, regulatory purposes, policymaking and personalised medicine. […] Several initiatives have developed or are developing guidelines and recommendations for health data quality, however, these typically focus on specific data types (i.e. 1+ Million Genome Initiative) or areas of applications (i.e. European Medicines Agency – EMA and Heads of Medicines Agencies' Big Data Steering Group activities to support medicines regulation). […] The proposed framework should take into account the various needs of data users whilst at the same time avoid becoming an excessive burden on data holders which will need to produce the data quality and utility label."

This document provides applicants planning to submit a proposal to the HORIZON-HLTH-2023-TOOL-05-09 call with information to be considered for proposing the European Medicines Agency (EMA)'s involvement in their proposal.

Given EMA's coordinating role in the Big Data Steering Group and DARWIN EU and the need to cover the needs of these initiatives, the EMA considers that it might decide to participate to applicants' or funded consortias' decisions regarding the orientation of the work programme, the development of research protocols, and the discussion and dissemination of the results. This may require EMA involvement in an Advisory Board, in a Steering Committee or, exceptionally depending on the workload involved, in a relevant work package(s). In this context, the EMA will not lead, manage or coordinate a work package or part of the work programme, but may provide expertise where appropriate. Please consult the works of EMA related the topic including:

- Draft Data Quality Framework for EU medicines regulation (public consultation version)
- Draft Good practice guide for the use of the Metadata Catalogue of Real-World Data Sources (public consultation version)
- European Medicines Regulatory Network Data Standardisation Strategy

After applicants are awarded the grant, EMA will take a decision on its involvement in line with the 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 explains that areas of regulatory science to which the EMA might contribute must be closely related to

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its role and responsibilities and aligned with its strategic priorities. Please consult the EMA services to support externally funded research and projects and the EMA Regulatory Science Research Needs (EMA/705364/2021) document in these regards.

Intentions to propose EMA's involvement in a project should be communicated to Regulatory.Science@ema.europa.eu. Where relevant, EMA provides feedback on the preferred type and level of involvement for consideration of the applicants.