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Inspections, Human Medicines, Pharmacovigilance and Committees Division

# HMA/EMA Joint Big Data Task Force

## 1. Background

Rapid developments in technology have resulted in the generation of vast volumes of data, creating new evidence which has the potential to add significantly to the way the benefit-risk of medicinal products is assessed over their entire life cycle.

While creating huge opportunities, it is recognised there are also significant challenges in the use of these data. For example there is a fundamental need to establish appropriate access to the data, to understand their strengths and limitations and to apply new analytical methods to integrate and analyse the heterogeneous datasets in order to generate conclusions which contribute to regulatory decision making. Importantly, compliance with data protection legislation ensuring robust mechanisms to protect patient confidentiality is critical for securing patient trust.

It is important for the European Union Medicines Regulatory Network (EMA and HMA) to gather information on the latest developments in the field of big data from the perspective of different stakeholders. This will begin to clarify how and when the multitude of data sources may contribute to medicinal product development, authorisation and surveillance.

## 2. Mandate

The mandate of joint HMA/EMA Task Force on Big Data is to explore a number of issues regarding the emerging challenges presented by big data by:

- Mapping relevant sources of big data and defining the main format, in which they are expected to exist;
- Identifying the usability or application of big data;
- Describing the current state, future state and challenges with regard to
  - regulatory expertise and competences
  - the need to specify legislation and guidelines
  - data analysing tools and systems needed to handle big data
  - regulators' responsibility for raw data analysis vs. sponsor's responsibility
- Designing a big data roadmap;

- Generating a list of recommendations as well as evaluating the usefulness of big data in the regulatory setting;
- Collaborating with FDA, Health Canada and other third country stakeholders, including ICMRA, to ensure bilateral insights on big data initiatives

## 3. Composition/Membership and Secretariat

- The task force is composed of representatives from the NCAs in DE, DK, ES, FI, HU, IE, NL, NO, RO, UK and from EMA
- Chair: Thomas Senderovitz, DKMA, DK
- Co-chair: Alison Cave, EMA
- DKMA provides the secretariat for the task force

## 4. Contact

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