EMA Strategy on digitalisation

6th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

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Digital Business Transformation Task Force

Our vision is to be the accelerating force towards a digital driven world-leading medicines regulator that continuously takes advantage of innovations and emerging technologies for the ultimate benefit of public and animal health in the European Union.

We drive and enable this transformation through services and activities that advance the Agency’s digitalisation:
Transformation / Optimisation of Regulatory Processes
Gaining efficiencies and improving the experience of stakeholders and regulators throughout the regulatory lifecycle

• Investment in integrating and modernising systems and processes supporting the centralised procedure, e.g. IRIS.

• Replacing ageing PDF based forms to enhance structured data capture and integration, through the Digital Application Dataset Integration (DADI) project.
Translation of new regulations / policies into operations
Designing digital native processes to address new needs and challenges

• The implementation of the Medical Device Regulation and In-Vitro Diagnostics Regulation present an opportunity to leverage digitalisation to set up future-proof processes and work towards an integrated regulatory pathway.

• EMA is working to build new ways of working to support these regulations and deliver on the Agency’s extended mandate.
Digital and Analytics Solutions

We are building a Digital Innovation Lab to **discover, experiment** and **develop digital solutions** that support core business and benefit EMA, the Network and our stakeholders.

Our Analytics Centre of Excellence explores how analytics - including Artificial Intelligence, Machine Learning and Robotics – can be used to build pragmatic solutions to existing EMA business needs with the main objective of **gaining efficiency**.
Accelerating digital transformation in the EU Regulatory Network
EMA is boosting its digital and change management capabilities to enhance our ability to meet challenges

1. **Change Management Centre of Expertise**
   We are investing in developing EMA’s change management to ensure the Agency, Network and our stakeholders are fully prepared for changes to ways of working and the tools we use.

2. **Digital Skills Academy**
   EMA recognises the need to future-proof our workforce to fully leverage the opportunities digital transformation brings and is building a Digital Academy to accelerate this journey.

3. **Learning Ecosystem**
   EMA and HMA partner through the EU Network Training Centre to foster collaborative learning. We are investing in deepening knowledge sharing on data and digital.
Data analytics and big data: moving forward based on the Big Data Steering Group workplan

- **Jan. 2020**
  - ‘Ten recommendations to unlock the potential of big data for public health in the EU’

- **May 2020**
  - 1st Big data steering group meeting in May 2020

- **Sep. 2020**
  - Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21

- **May and June 2021**
  - BDSG workplan 2022/2023

- **July 2021**
  - EMA MB and HMA informed of BDGS workplan 2022/2023

- **Sep. 2021**
  - Publication of BDSG workplan 2022/2023
Data quality: procurement launched for a consortium to deliver a data quality framework. Draft data quality framework should be available early 2022.

Data discoverability: workshop on real-world evidence meta data held in April and on track to have agreed meta data by the end of the year. Will support future European inventory of real-world data.

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Network skills: skills survey completed on real-world evidence statistics and data science. 800+ responses. Clear priorities identified for training. EMA exploring outsourcing the delivery of training content to an academic consortium.

Network processes: PRAC pilot of rapid analytics of real-world data completed. Review of 2018 2019 marketing authorisations and real-world evidence completed. Big data topics included in the 2021 work plans of CHMP, PRAC, CAT, COMP, PDCO.

International: a Data Standardisation Strategy for the Network is under development and was the subject of a workshop held in May 2021 with stakeholders. Good progress is being made with the US FDA and Health Canada on developing a Real-World Evidence Collaboration Roadmap.

Veterinary: successful workshop on the Veterinary Data Strategy held on 1/2 June 2021.

Stakeholders: following a successful stakeholder workshop in December 2020, 3 technical workshops have been held so far in 2021 and planning is ongoing for further technical workshops and a multi stakeholder forum on Big Data later in 2021.
Use of Real-World Evidence in Medicines Regulation in Europe

- **Use of RWE** in the development, authorisation and post-marketing surveillance of medicines to facilitate decision-making is increasing.

- Several mechanisms for obtaining Real-World Evidence are available to Scientific Committees. DARWIN EU will provide the breadth in access to data combined with speed of analysis to meet today’s demand and in particular future demand:
  - Requests or obligations to pharmaceutical companies
  - Analysis of public information including public scientific literature
  - Data analyses and studies conducted or initiated by NCAs
  - **EMA studies** on the electronic health databases accessible in-house
  - **Studies procured** through the EMA framework contracts
  - **DARWIN EU** (starting from 2022)
Enabling Technology Capabilities

**Business Objectives**

Enable digital business transformation and data analytics goals

- Interoperability and Data sharing
- Advanced Analytics Capabilities
- Cloud-enabled Architecture

**Transformation**

- Modular platforms
- Data-driven Solutions
- Self-Service/Automation
- Agile ways of working

**Operational Excellence**

- Predictable and stable Operations
- Clear and accessible service levels
- Market conform support
- Portfolio performance

**Business continuity / Information Security / Data protection**

Classified as public by the European Medicines Agency
Thank you for your attention

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