EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Big Data Taskforce and Regulatory Science Strategy Recommendations on AI

Joint HMA/EMA workshop on artificial intelligence in medicines regulation

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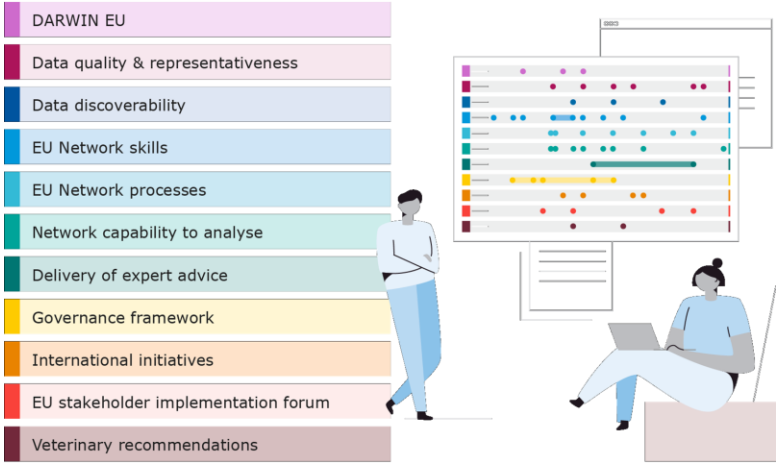
An agency of the European Union

Content

- Setting the scene
  - HMA/EMA Joint Taskforce on Big Data
  - Regulatory Science Strategy to 2025
- How recommendations were developed
- Main recommendations

HMA/EMA Joint Taskforce on Big Data

- Initiative to explore the challenges and opportunities posed by big data in medicines regulation
  - Broad look at Big Data, including analytical techniques
- Two reports
  - Phase I reviewed the landscape of big data from a regulatory perspective and identified opportunities for improvements
  - Phase II made practical recommendations to inform strategic decision-making and planning
  - Both reports include recommendations on AI
- Main output - Ten priority actions for the regulatory network to evolve its approach to data use and evidence generation



https://www.ema.europa.eu/en/about-us/how-we-work/big-data

Regulatory Science Strategy to 2025

- Plan for advancing EMA's engagement with regulatory science, published in 31 March 2020
- The five key goals of the strategy include
  - Catalysing the integration of science and technology in medicine development
  - Driving collaborative evidence generation to improve the scientific quality of evaluations
  - Advancing patient-centred access to medicines in partnership with healthcare systems (for human medicines only)
  - Addressing emerging health threats
  - Enabling and leveraging research and innovation in regulatory science

https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy

How recommendations were developed

- Aim of using AI within the regulatory network
  - Improve efficiency through process automation
  - Inform decision making supporting the evidence generation
- Key areas where AI impacts the regulator network

Drivers	AI activities	Examples
External	Legislation and external collaboration	Collaboration with EC and the EU Agencies Network to provide input to AI legislation and policy aspects
	Regulatory submissions	Regulatory and scientific support to developers of medicines and devices utilising an AI component
Internal	Digitalisation / process automation	AI as part of the digital business transformation aiming at process efficiency
	Healthcare data analytics	AI to interrogate healthcare data to gain insights to support regulatory assessment and decision-making

How recommendations were developed

- What are the key evidentiary needs to enable it
  - Meaningful evidence: data that needs to contain relevant information of adequate quality and representativeness
  - Valid evidence: methodology that meets scientific standards
  - Expedited evidence: synchronised with the decision making and processes
  - Transparent evidence: auditable, reproducible, with human oversight (if needed), and ultimately trusted by decision makers

Foreword on the recommendations on AI

- Both initiatives addressed broader topics than AI, but AI specific recommendations were issued
  - On occasion, the same or similar recommendations, with only slightly different wordings were made. This presentation paraphrases those recommendations to avoid repetition
- Some non-AI-specific recommendations can have a significant impact on AI
  - e.g. access to data, data discoverability, data representativeness, data quality, FAIR principle
  - Those are considered fundamental building blocks for AI but have been treated more extensively in the HMA-EMA top priorities recommendations

AI recommendations

- Promote experimentation
- Learning and skills gap
- Partners and collaboration
- Methods and guidelines
- Initiatives
- Governance

Promote (a culture of) experimentation

Experimentation with AI / Sandbox

- Establish a digital innovation lab to explore, pilot and develop solutions and processes, across the drug regulation spectrum, that leverage novel digital technology and AI to support increase in efficiency and regulatory decision-making

Make regulatory data open

- Open regulatory data sets which are non-sensitive to provide opportunities for researchers to develop novel and possibly disruptive analytical approaches
  - Data security and privacy of such data sets must be implemented by design

Learning and skills gap

Develop capability

- Establish the capability to validate AI algorithms within the EU regulatory network
- Develop the capability to allow a critical appraisal of studies done with advanced models and/or to perform these studies

Upskill EMA and EU Regulatory Network

- Develop capability and expertise across the regulatory network through curriculum development and knowledge-sharing initiatives on data science, digital technologies and artificial intelligence-related solutions, products and endpoints, and their applications in the regulatory system
- Collaborate with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI

Learning and skills gap

Engage with experts

- Identify and enable access to the best expertise across Europe and internationally
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

EMA Expert Group on AI

- Create an EMA Expert Working Group on methods and analytics by combining the existing biostatistics, modelling and simulation, extrapolation and pharmacokinetics groups and enriching with real world data and advanced analytics expertise

Partnership and collaboration

International collaborations

- Engage in efforts (e.g. via standardisation activities) for achieving greater global alignment with other regulators (e.g. FDA) on these topics
- Develop or achieve alignment on guidelines

Build partnerships with academic and research centers

- Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

Initiatives

Influence research priorities for funders

- Propose regulatory research priorities for funders in the Big Data area
  - Ensuring alignment with the regulatory science strategy and wider public health and stakeholders' needs

Create and maintain a multi-stakeholder forum

- Create and maintain a Health Data Science and AI forum to engage with a diverse set of stakeholders in novel digital technologies and AI
  - This will include the technical, ethical, legal, regulatory and scientific perspectives of the use of digital technologies, and AI-powered applications
- Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs and research/academic groups

Methods and guidelines

Build a framework that supports the development of guidelines

- Establish a dedicated framework for the development of guidelines and recommendations
  - The framework should include a gap analysis of guidelines, address which are a priority, how the guidelines should be developed, and which areas might be impacted, as well as the acceptability metrics or success factors

Develop a framework to assess and validate AI

- Develop a validation framework for AI used in relation to medicinal products
  - E.g. AI-based digital endpoints utilised in clinical trials

Establish framework for early engagement with potential end-users of AI

- E.g. health professionals should be involved early and fully informed about AI

Governance to address ethics and trust

Address ethical aspects of AI

- Ensure that data security and ethical considerations are embedded in the governance of data within the Network

Promote transparent and auditable AI

- Promote transparency and auditability of machine learning algorithms
  - Appropriate governance in the production and handling of the evidence generated should be established

Overview

Promote experimentation

Experimentation with AI / Sandbox
Make regulatory data open

Learning and skills gap

Develop capability
Upskill EMA and EU Regulatory Network
EMA Expert Group on AI

Partners and collaboration

Build partnerships with academic and research centers
International collaborations

Methods and guidelines

Build a framework that supports the development of guidelines
Develop a framework to assess and validate AI
Early engagement with potential end-users

Initiatives

Influence research priorities for funders
Create and maintain a multi-stakeholder forum

Governance

Address ethical aspects of AI
Promote transparent and auditable AI

Any questions?

Further information

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Mapping of the AI recommendations