EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AI and Digitalisation at EMA

Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation

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AI and digitalisation in EMA

Applications of AI in Medicines and Medicines Regulation

Digital & Analytics Solutions

1

Process (re-) engineering for digital

Mapping of business processes or **re-engineering** of processes to exploit digital technologies, automation and AI

2

Digital solution identification and selection

Selection and **proof of concept** of new digital solutions

3

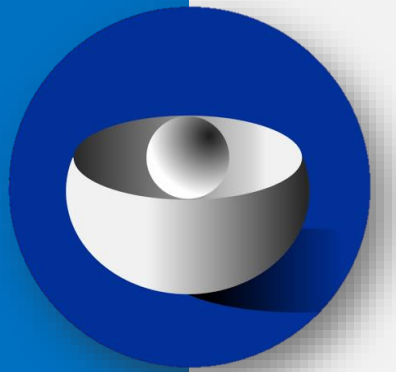
Applying process analytics, AI and automation

Exploitation of process **analytics and Artificial Intelligence** to increase organisational efficiencies

4

Exploitation of novel digital technologies

Scanning for promising **novel digital solutions** on the market and exploring how these could be exploited for EMA business value



Analytics Centre of Excellence (ACE)

ACE explores how **process 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**.

AI for EMA process optimisation

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AI in EMA Processes

Almost all **AI** projects / initiatives for **process improvements** at EMA are related to text analytics, **processing documents**, text and images analysis

Natural Language Processing

EMA applies NLP methodologies to extract content from documents, structure its information, extract entities, categorises and clustering content to be analyses afterwards in our processes

Document processing

EMA has developed processes to analyse the type of documents received and assess its content to notify specific assessors

Image recognition

EMA uses OCR methodologies to read images and charts to analyses the content and extract all needed information

Assisted Validation System

System to support the validation of variations

- Flags missing documents in the application
- Detects dissimilarities between information submitted by applicants and data stored in our databases
- Identifies any change made by applicants in the document submitted (all EU languages)

Document Comparison

System to compare leaflet and labelling documents

- Identifies if content of package leaflet and labelling documents of companies submitted to EMA differs from originator EPAR
- Analyses text and images
- Available for 25 different languages

Personal Data Recognition

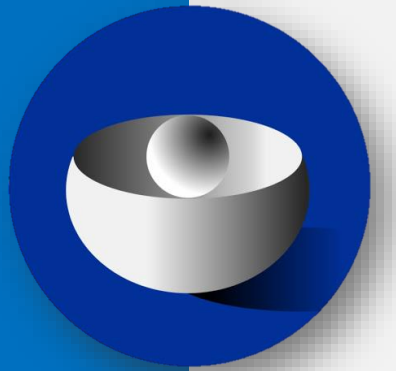
Flags personal data in documents

- It searches for personal data and highlights personal data for human review. By confirming the highlighted data is personal data (or not), PeDaR learns and improves its capability to recognise personal data

And much more to come...

List of other ongoing projects…

- Automatic triage system
- Document package review
- Literature review



Healthcare data analytics

Building capability and capacity in the **analysis of data** and in study methods across the Agency.

A key component is understanding how AI, ML and new digital technologies can be leveraged to **structure and expose messy data** and **achieve deeper insights** into healthcare data.

Healthcare data analytics | Previous work

Activity	Characteristics	Uses & Advantages
Mining unstructured data	Automating the update of the database of ADRs of CAPs and exposing the results	• Decreases manual labour • Improves access to data (structured way to query and analyse)
Duplicate detection	Algorithm to identify duplicated reports in EudraVigilance: 1,082,253 confirmed duplicates identified	• Decreased workload (less signals flagged and less reports to review) • More accurate information (ADR website, request for information)
Characterizing opioid abusers	Analysis of clusters of abuse of prescription opioids	• Characterise who is at risk of abuse and understand effect of covariates
Classifying patients	Predicting genotype using adverse reaction data: PPV >90%; Published paper	• Better estimate of public health impact of ADR

Thank you for your attention

Further information

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Presented by Florence Butlen-Ducuing on 19 April 2021
Senior Scientific Officer, Office of Therapies for Neurological and Psychiatric Disorders

An agency of the European Union

Disclaimer

- No disclosures

OUTLINE

- WHERE ARE WE?
- WHERE ARE WE GOING?
- WHAT IS NEXT?

A definition of AI-High Level Expert Group

"Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions."

AI & HEALTH

- Healthcare Analytics
- Biological Analytics
- Machine learning
- Imaging Analytics
- Big data
- Integrated therapeutic with a device or computerized training
- Wearables dand sensors
- Real World Data
- Digital biomarker/endpoint

- Improving our understanding of disease and
- Identifying patient Population
- Identifying treatment target
- Diagnosis and Earlier disease detection
- Personalised medicine
- Drug design and synthesis
- compliance
- Digital Health Records
- Tele-healthcare

Medical Device Software

- **Software** : a set of instructions that processes input data and creates output data.
- **Medical Device Software (MDSW)** : Software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the Medical Devices Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR)
  - imaging assistance for diagnosis
  - treatment monitoring, adherence
  - ...
- ***Is your software a medical device?***
  - https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

EMA Experience with DHTs - Examples

- ✓ **MAA applications** (eg inhaler with sensor to be used with separate mobile app, tablet with sensor to be connected to a mobile app
- ✓ **Variations** (eg new presentation of a blister that can be connected to a mobile app)
- ✓ **printed QR Code/URL** on Package Leaflets & Outer cartons (Instructions for Use in electronic format.
- ✓ **Qualifications** (eSource qualification, Adherence/Compliance (Ingestible sensor qualification, stride velocity)
- ✓ **ITF meetings**
- ✓ **Participation to IMI initiatives** (e.g. SPRINT-T, PROactive)

AI REGULATORY CHALLENGES (1)

1 June 2020
EMA/219860/2020
Human Medicines Division

Questions and answers: Qualification of digital technology-based methodologies to support approval of medicinal products
Status as of June 2020

"If an applicant is interested in qualifying the use of clinical variables captured by using a wearable device to collect data from clinical studies, which are expected to be evaluated as part of an MAA, aspects on how such data support the benefit-risk assessment (e.g. endpoint outcomes, reliability, accuracy, sensitivity to change, clinical and technical validity aspects, compliance, clinical relevance of data collected, data reflected in the product information) may fall within EMA's remit."

AI REGULATORY CHALLENGES (2)

- Digital Moa? Which duration? Which frequency?
- How can the algorithms be validated and tested : accuracy, reliability and sensitivity to change..?

- How to design a Digital SHAM?
- How to power a study? (endpoint? effect size?)
- How to monitor safety?

- Large volume of data (raw and algorithm-processed data)
  - How much data ? how often?
  - Which statistical methods?

SOME KEY ASPECTS FOR NEXT STEPS

- **Scope** and d**efinitions**
- **Stakeholder** and public engagement
  - Guidance? workshop?
- **Patient**-centered approach,
  - transparency to users, usability, equity, trust, accountability
- **Regulatory science to inform** about IA/ML and applications in Medicines development and evaluation
- **Real-world data feed-back** (for training and evaluation of AI/ML-based tools)

Any questions?

Further information

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