

Artificial intelligence at EMA

Use cases

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The promise of AI AI promise across the medicine lifecycle

Greater efficiency/productivity

- Automate processes
- Address scalability issues
- Leverage personal assistants (chatbots)

Do more things, faster

Reduce error

- Facilitate access to information
- Reduce human cognitive load

Provide information at the fingertip

Expose data

- Transform text data into structured data
- Reduce dimensionality of data
- Imputation of missing data
 - Structure and summarise information

Expand insights

- Probabilistic phenotyping
- Synthetic control arms
- Clinical prediction modelling
- Confounding adjustment
- Digital endpoints
- Heterogeneity of treatment effects

Predict probability of events



AI in healthcare Regulatory drivers







Structure information and increase insights into data to inform decision-making



AI at EMA Set up

Digital Innovation Lab (DigiLab)

Established 2021 to accelerate digital innovation and experimentation

Analytics Centre of Excellence

Explore analytics, AI, ML and robotics to build pragmatic solutions and experiment with new technology

-- Process analytics --

Health Data Lab (pilot)

Develop innovative analytics to **extract insights from healthcare data**, to provide answers/recommendations and maximise intelligence -- Healthcare data analytics --

Infrastructure

Information Processing and Analytics

Improve the organisation's performance through streamlining information processing across the regulatory lifecycle. -- Data analytics tools and platforms --



AI at the health data lab Examples

Literature screening

Use of large language models (LLMs) to identify abstracts with information on the occurrence of adverse reactions

Extraction of ADRs from SPCs

(semi) automated extraction of ADRs from product information

Automated adjudication of ADRs

Automated adjudication of ADRs

Improve signal detection with previous reviews

Using signal reviews to improve signal detection



Maximising value from innovation

Start from ideas not from technology

- AI is not the solution for everything.
- Sometimes yesterday's technology is better.
- HDL's approach: *simplest solution with greatest impact.*

Have a development framework

- Follow the same technical and ethical requirements we expect from applicants.
- AI system is not the same as a method; bridge the two.
 - (if it's nice but you don't know what it's for, go back to ideation)

Bring everyone along

- Great methods are worthless if they are not used or understood.
- Communicate, train, engage – share knowledge and foster trust.

Collaborate

- Shorten uncertainty by engaging in safe fora.
- Learn from others, share
 with others, go longer
 together rather than
 faster alone.





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AI in the veterinary domain

Use case approach

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AI in the veterinary domain From business need to use case

Is artificial intelligence always the solution?



9 Artificial intelligence in the veterinary domain

Union Product Database Quick overview

 Single source of information on all authorised veterinary medicines, homeopathic and other assorted vet products, and their availability in the EU/EEA.



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Currently



Data is manually inputted by NCAs.





Union Product Database data entry

SPC reader



Data key points extracted from SPC.

Converted into structured, standardised and machine-readable format.



How does it work







- Select the document to be analysed.
- Verify the type of document.
- Confirm if documents are stored in the right place.
- Have a clear understanding of the structure of the document.
 - Instruct the algorithm on what to search for in the document.

- Align data found in the document with the structure that is expected from the EU Implementation Guide.
- Understand the relevance of the extracted data.
- Some data structure from the document might need additional modifications.



- Free text data must be converted into a suitable format.
- Format can be specified and changed to fit the requirements.
 - For the current use case, data is converted into JSON format to align with the format from the UPD system.





SPC reader potential advantages

Increased data quality and reliability

Eliminates the risk of discrepancies between SPCs and UPD.

Efficient and scalable data extraction

Automatises the otherwise time consuming and error prone manual process.

Language agnostic

Seamlessly handles SPCs in any language, and outputs doc in English. Customizable output structure

Output document tailored to our specific needs.





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