Artificial Intelligence in Medicines Regulation

Taking stock of initiatives following the AI workshop

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Overview

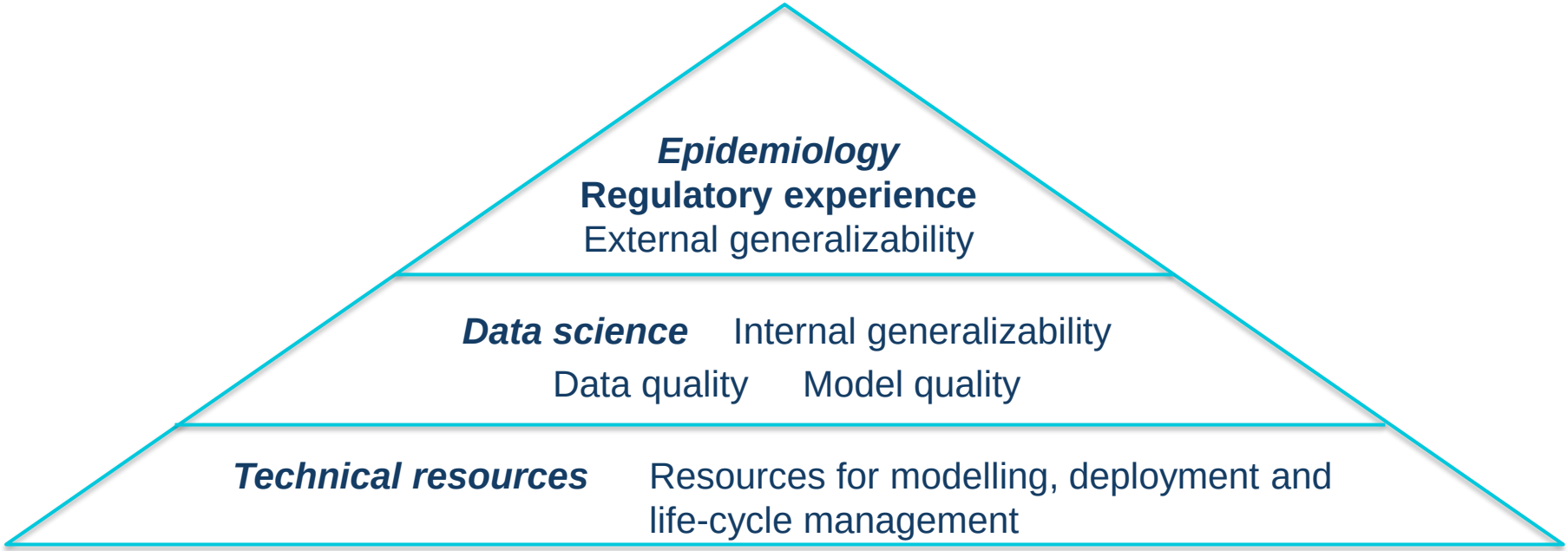
- Conclusions from the 2021 Joint HMA/EMA Workshop on AI in Medicines Regulation
- Ongoing follow-up activities
- Planned future activities

Conclusions from the Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation (April 2021)

Top stakeholder priorities

1. Develop a framework to assess and validate AI
2. Build a framework that supports the development of guidelines
3. Build partnerships with academic and research centres and collaborate with international partners
4. Upskilling EMA and EU regulatory network

The regulatory AI success pyramid



EU framework for AI in medicines regulation

Innovation task force (ITF)

Committee for medicinal products for human use (CHMP)

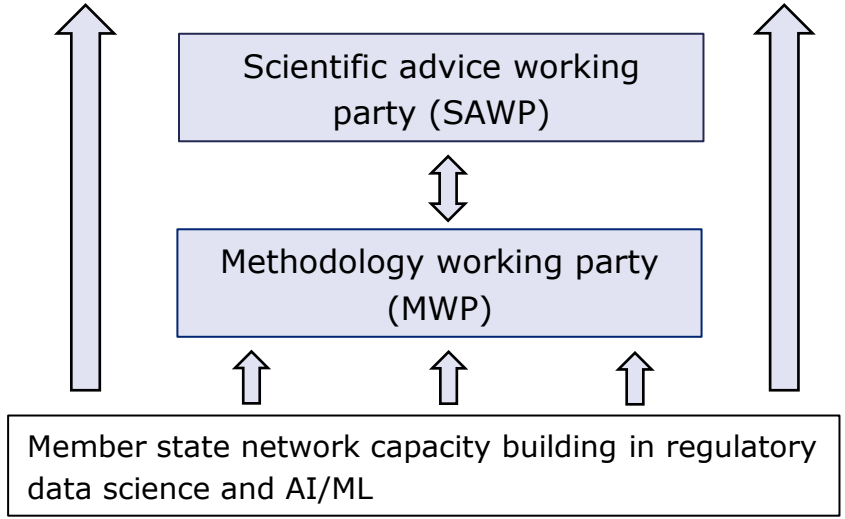
Pharmacovigilance risk assessment committee (PRAC)

Big data steering group (BGSD)

ICMRA

ICH

EU MDCG



Product specific advice on data science applications within medicines development

AI guideline development, supported by the European specialised expert community (ESEC)

HMA/EMA cluster of excellence BDSG data science training curriculum

Reflection paper on AI in medicines regulation

- High-level document covering regulatory aspects of AI/ML tools, to support a future EMA guideline
- Need identified by BDSG
- Presentation to **CHMP**, **GCP IWG**, **SAWP** in 2021 to obtain mandate and to invite volunteers
- EMA's AI Coordination group overseeing initiation of the process – planned hand-over to newly formed EMA Methodology Working Party (MWP)
- Drafting group kick-off May 2022

AI reflection paper – primary drafting group composition

Network members

- Gabriel Westman (MPA, MWP, BDSG)
- Jesper Kjær (DKMA, BDSG)
- Jörg Zinserling (BfArM, SAWP, MWP, BDSG)
- Liam Childs (PEI)

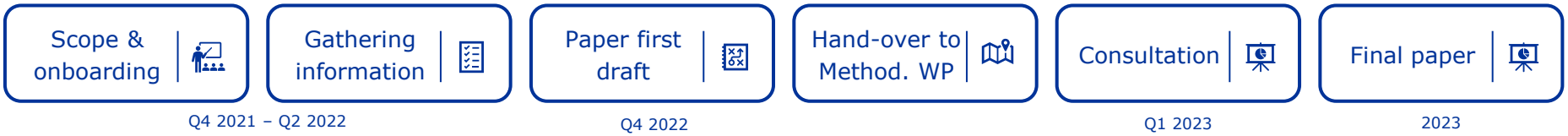
EMA members

- Fia Westerholm, Laurent Brassart (DG coordinators)
- Luis Pinheiro, Florian Lasch (TDA); Ralf Herold (TRS); Francesca Cerreta, Thorsten Vetter, Lorenzo Guizzaro, Claudia Vincenzi (H Div)
- Orsolya Eotvos (DPO); regulatory, legal, scientific, technical support, incl. from V Div, as necessary

AI reflection paper - proposed subtopics for drafting

- Impact on assessing the B/R in medicine development and authorization in relation to GxP standards
- Impact on post-marketing use, PhV surveillance and drug effectiveness studies
- Model development and deployment
- Risks exploration
- Data privacy, legal and ethical recommendations
- Regulatory interactions

AI reflection paper – work process and progress



Drafting group kick-off in May 2022

First collation of subtopic content 25 November 2022

Partnerships with academic centres and international partners

- Academic partners are welcome to approach the EU regulatory network for collaboration
- Cooperation on (market neutral) grant proposals is possible
- Examples of AI/ML regulatory science already exist

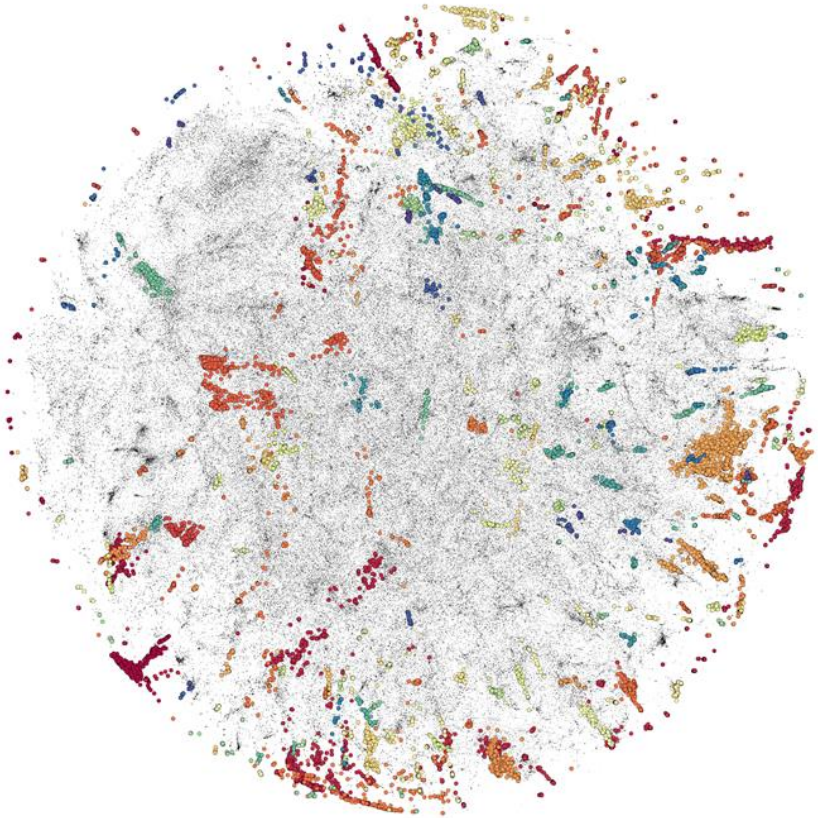
A natural language processing approach towards harmonisation of European medicinal product information

- Aim – to identify semantically similar sentences in the corpus of European medicinal product information documents
- Cooperation between Swedish Medical Products Agency, Uppsala University and EMA
- >400 semantic clusters identified using NLP and clustering techniques
- All data and results openly accessible (https://doi.org/10.57804/ggrw-hr06)

Results

Cluster id	Spread	Number of sentences	Number of unique sentences
10	0,46	1316	425

(n=281) Do not take a double dose to make up for a forgotten dose.
(n=89) Do not take a double dose to make up for a forgotten tablet.
(n=34) Do not use a double dose to make up for a forgotten dose.
(n=24) If you miss a dose, take it as soon as you remember.
(n=18) If you forget to take a dose, take it as soon as you remember.
(n=17) Do not inject a double dose to make up for a forgotten dose.
(n=16) Then take your next dose at the usual time.
(n=15) Do not take a double dose to make up for forgotten individual doses.
(n=15) Then take the next dose as usual.
(n=15) If you forget for more than 12 hours, simply take the next single dose at the usual time.



Upskilling EMA and EU regulatory network

- BDSG training curriculum
  - Data Science curriculum adopted Sep 2021
  - Training module development starting in 2023
  - Roll-out TBD

Future activites and remaining issues

- Follow-up AI workshop – tentatively Q2 2023
- Developing the ERN cluster of excellence for regulatory data science – what is the next step?
- BDSG data science curriculum - evaluate impact of training modules
- Academic partnerships – how to initiate/strengthen these and what output is expected?
- Adoption of ICH and ICMRA standards and guidance for AI within the ERN
- AI/ML in medical devices – coordination with the EU MDCG?
- Regulatory open model/data repositories for common use?

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union