

Big Data Training Survey

Preliminary results for AI aspects

Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation

Presented by Jörg Zinserling on 20 April 2021 Federal Institute for Drugs and Medical Devices / BfArM, Germany Prepared with support from Andrea Mattsson (EMA)





Outline

- Background
- Objectives and participants
- Preliminary results
- Conclusions



Background

- **`EU Network skills'**: Recommendation #4 in Big Data Steering Group work plan
- Existing training initiatives in the EU Regulatory Network:
 - 'Biostatistics & Clinical Trial Methodology for regulators' curriculum (*developed*)
 - 'Use of **Real-world evidence** for regulatory purposes' curriculum (*developed*)
 - **`Data Literacy** for regulatory purposes' curriculum (*under development*)
 - Until finalisation of the three curricula, A **Big Data training signpost** is available.
- Questions:
 - Are there any gaps in the training curricula and signpost?
 - Which training modules to prioritise for development and delivery?



Survey overview

Objectives:

- Validate the scope of the three training curricula.
- Identify Big Data skills gaps and training needs in the EU Regulatory Network.
- Obtain feedback on the priority of the delivery and roll-out of trainings on Big Data skills.

Participants:

- 4715 experts in the EU Regulatory Network were invited to participate.
- 832 (17.6 %) responses were received.
- Response distribution by domain:
 - Human: 68 %
 - Veterinary: 18 %
 - Both: 13 %
 - Not defined: 1 %



Preliminary results (1/3)

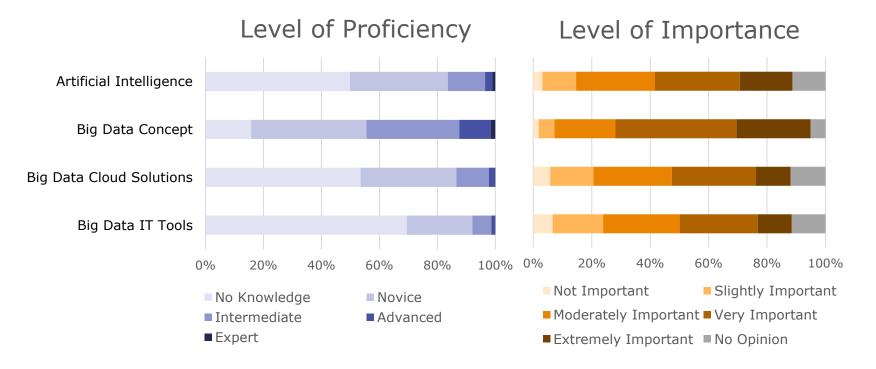
Level of Importance Level of Proficiency Interpretation and Communication Data Visualisation and Dashboarding Data Analysis Data Management Data Governance and Sharing Study design **Big Data** 0% 20% 40% 60% 80% 100%0% 20% 40% 60% 80% 100% Not Important Slightly Important No Knowledge Novice Moderately Important Very Important ■ Intermediate Advanced Expert ■ Extremely Important ■ No Opinion

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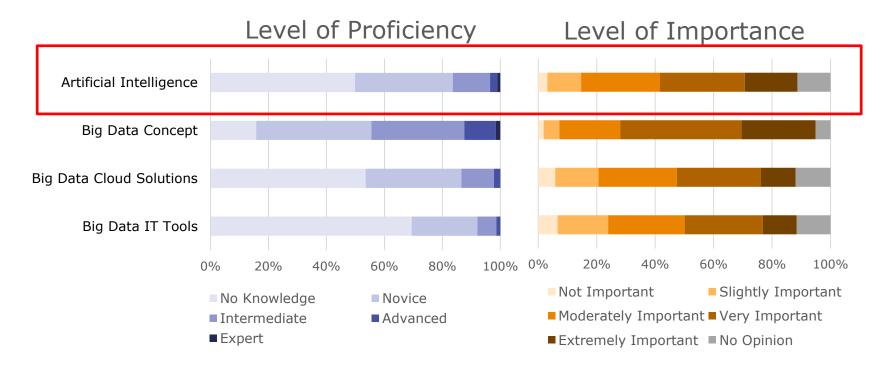


Preliminary results (2/3)





Preliminary results (2/3)





Conclusions

For the **Big Data – Concept**, **IT Tools** and **Cloud Solutions**, and **Artificial Intelligence** skills:

- Majority of the respondents have **no knowledge** or are **novices** with regards to listed skills
- Majority of the respondents consider it at least moderately important to develop training modules in these skills
- Among respondents there is an apparent **discrepancy** between the **reported skills** and the **perceived importance** of Artificial Intelligence as a topic.





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Any questions?

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