EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Breakout session 4
Training and expertise

Workshop on Learnings Initiative for Optimal Use of Big Data for Regulatory Purpose

30th November 2021

Presented by Gianmario Candore and Stefania Simou
EMA, Data Analytics and Methods Task Force

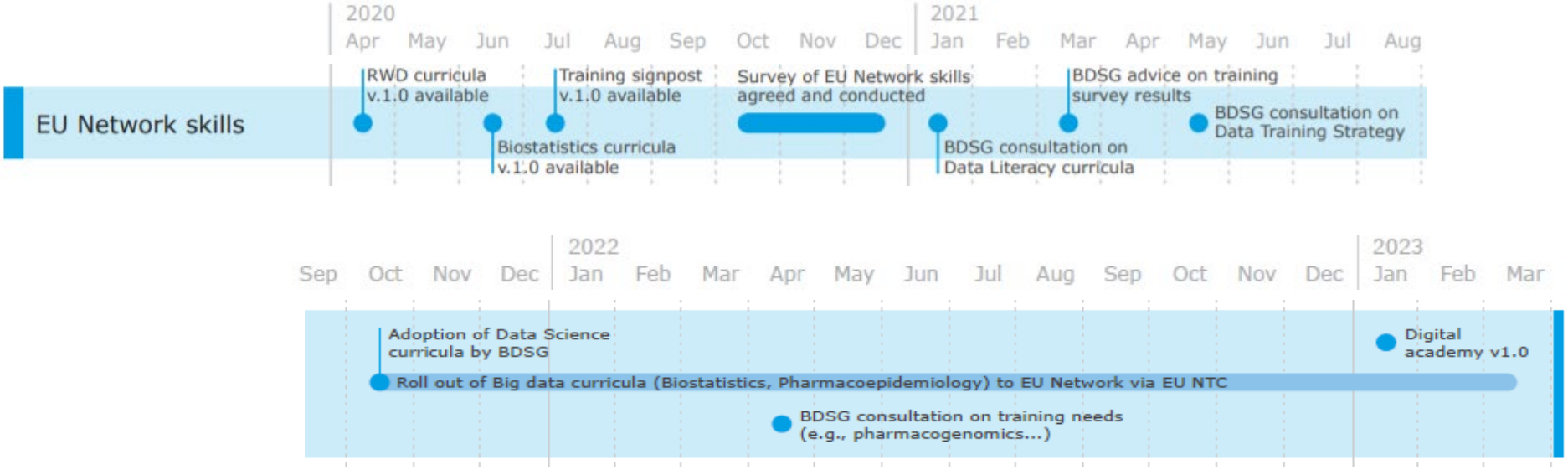
Objective of the session

- Informed by the recommendations from the Artificial Intelligence workshop on need for skills and expertise, and the Big Data Task Force to introduce a training curriculum for big data
  - What additional training and expertise is needed to increase skills in development of study protocols, data analysis and regulatory assessment of protocols and study reports?
  - How to achieve this goal?

- Chair: Marilena Vrana, European Heart Network, Brussels, Belgium
- Rapporteur: Valentijn de Jong, EMA

BDSG Workplan 2021-2023

- The HMA-EMA joint Big Data Task Force introduced **recommendation IV "Develop EU network skills in Big Data"** in its workplan, with the aim to develop a big data training curriculum and strategy based on a skills analysis across the network, roll-out training, targeted recruitment, and collaborate with academia



Background – The need for Big Data curriculum

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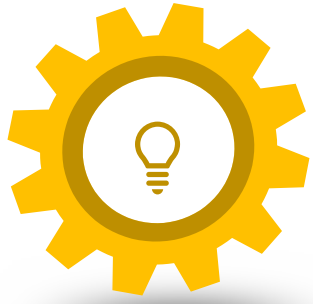
- The increasing volume and complexity of data coupled to rapidly developing technology offers the opportunity to deliver a better characterisation of diseases, treatments and the performance of medicinal products

- Biostatistics, Real-world Evidence (RWE), data management and data analytics are widely used within the regulatory setting and are constantly evolving areas

- Regulatory decisions require specific and top-level expertise, therefore regulators need to keep abreast of new developments

- The 2020 and 2021-2023 BDSG workplans introduced a more data-driven approach (*i.e. raw data, real-world data*) and with that comes a need for training

- Currently limited skills and knowledge in the EU Network in key Big Data areas



AI learning and skills gap recommendations

Aim

- Develop the capability to allow a critical appraisal of studies done with advanced models and/or to perform them

How

- Through curriculum development and initiatives on data science, digital technologies and artificial intelligence-related solutions, and their applications in the regulatory system
- 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
- Collaborate with external experts including academia
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders
- Target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI

Survey on Big Data skills in the EU Regulatory Network

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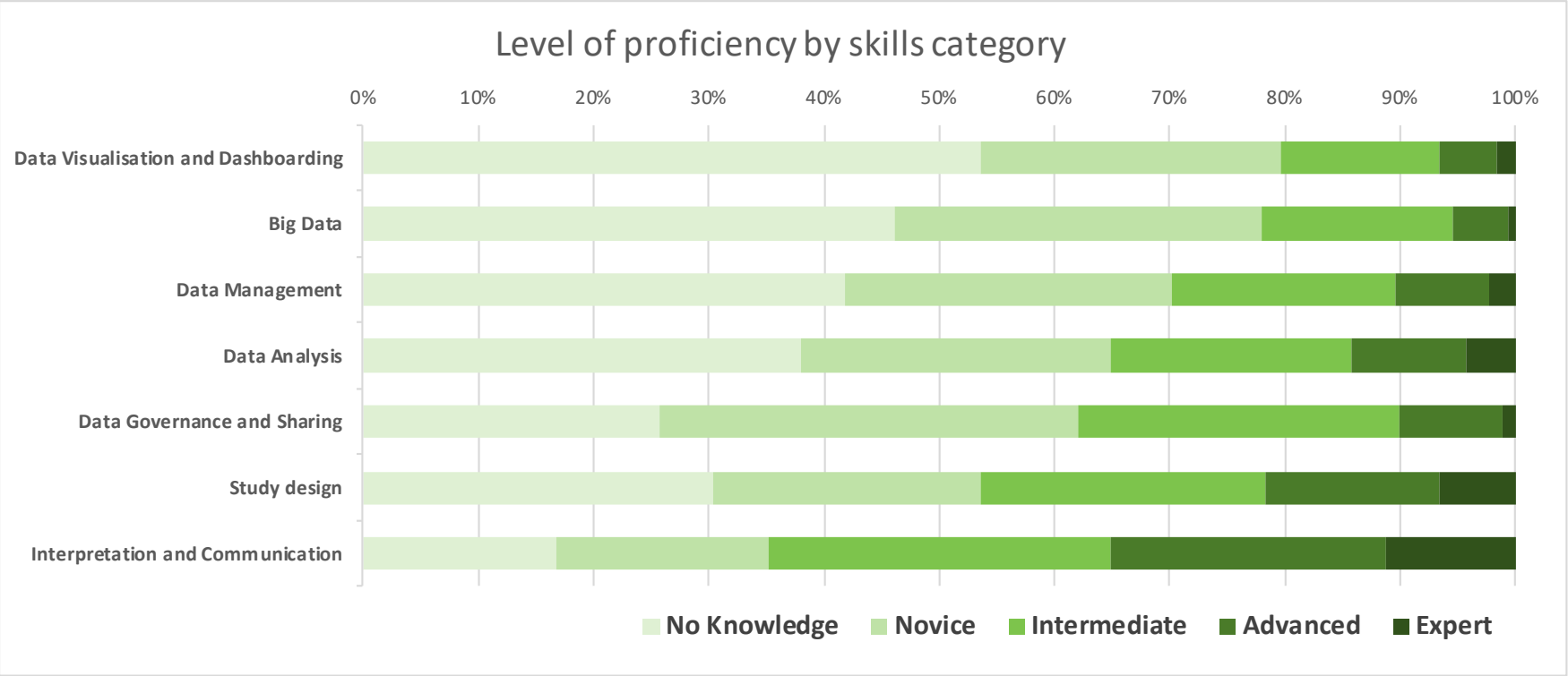
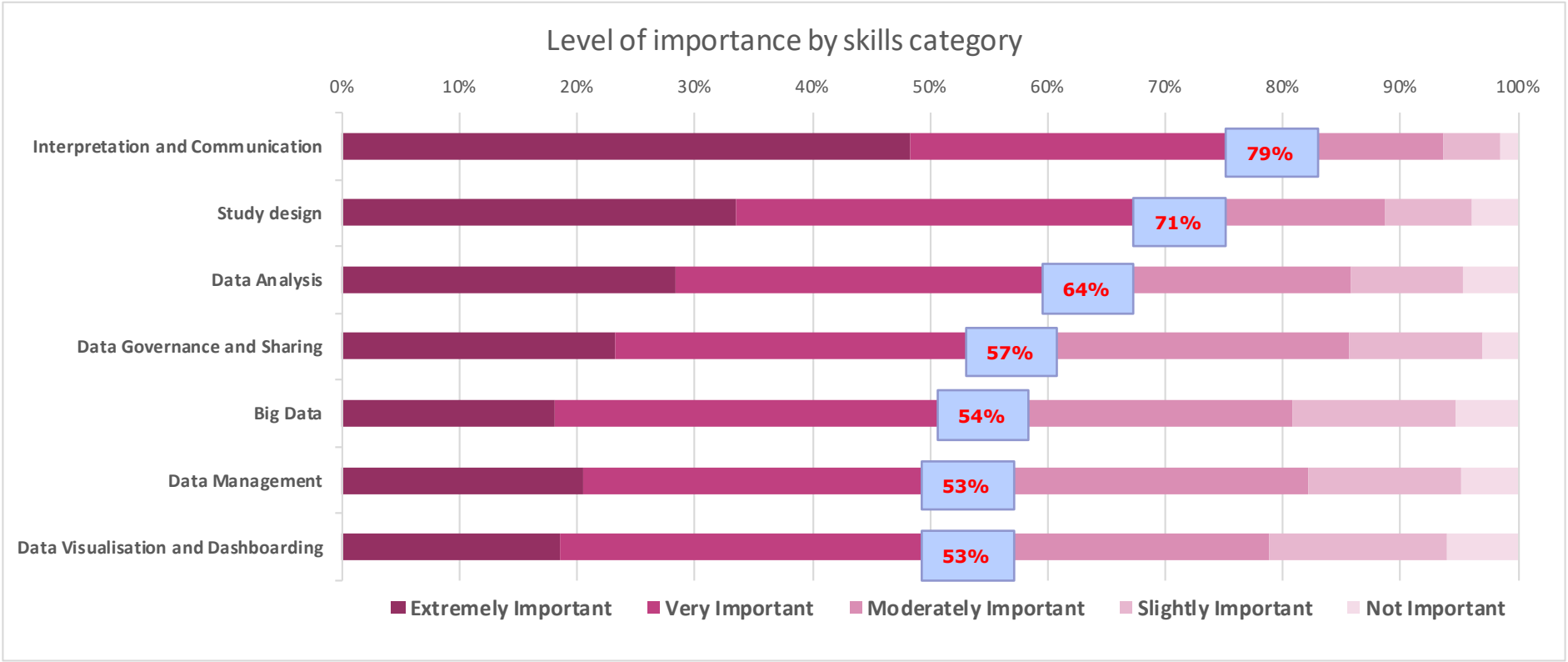
- **Objective**: Identify Big Data **skills gaps** and **training needs** in the EU Network
- **Demographics**: 832 (17,6 %) responses in total, 84% from NCA's, 16% from EMA

Q: Please indicate your current level of proficiency within each skill



Q: Please indicate how important you think it is to develop training modules in each skill



Proposed discussion topics

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1. Which learning and skills gaps should be addressed in priority to develop the capability of different stakeholder groups to use real-world evidence for regulatory purpose, e.g. the EU regulatory network, pharmaceutical companies, patients, health care professionals, academic institutions, other stakeholders

2. Do stakeholders need training from regulators following publication of guidelines published by EMA and the regulatory network for better understanding? Which guidelines would require additional training? What type of training material, for example educational material, training sessions, communications,…

3. Are you producing training material for your own audience? How could collaborations between stakeholders' groups and academic institutions be best established to fulfil training needs? How could knowledge transfer be organised? How could such interactions be supported by the EU regulatory network?

4. Could the training curricula on Data sciences, Pharmacoepidemiology and Biostatistics being developed for the EU regulatory network also address the needs of other stakeholders, and through which mechanisms?

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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