

Training Curriculum on Big Data for regulators

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Outline



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- 6. Data Science curriculum
- 7. Development, implementation and delivery
- 8. Timeline

BDSG Workplan 2021-2023



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BDSG Workplan 2021-2023

EUROPEAN MEDICINES AGENCY Jun Jul Jan Feb May Jan Feb Mar Apr Mav Aug Oct Nov Dec Aua Nov Dec Roadmap for RWE Delivery of expert Publication of ENCePP guidance agreed methods guide advice Establishment of strengthened methods expert advice Fully strengthened Publication of methods expert advice registries guidance Governance framework EMA draft Q&A on secondary use of Strengthen BDSG BDSG mandate review and benefits assessment health care data and data protection ethics expertise EHDS legal proposal and impact Data protection training Technical discussion with assessment study discussion through EU NTC TEHDAS on data dovernance International initiatives International regulators Draft Data Standardisation strategy summit on data/ RWE International collaboration on framework for RWE Publish Data Review of Data Standardisation Strategy Standardisation Strategy FU BD stakeholder implementation forum Stakeholder Stakeholder forum forum Stakeholder Veterinary data strategy Follow-up Veterinary Stakeholder forum workshop discussion at BDSG recommendations Stakeholder International cooperation forum workshop feedback and the Vet Data Hub established

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Background – The need for Big Data curriculum



- 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



BDSG Workplan – Recommendation IV

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.

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- Key milestones achieved according to 2020 workplan:
 - ✓ Training signpost
 - ✓ Survey of EU network skills
 - ✓ Big Data curriculum table of contents developed
- Upcoming milestones according to 2021-2023 workplan:
 - Ø Development of training content
 - Roll out of trainings to EU Network via EU NTC
 - Integration with Digital academy, a place where digital awareness and upskilling content can be found

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Benefits

By increasing the level of expertise within the EU regulatory network, it is expected that:

- There will be more contribution from regulators to the definition of research questions, study
 protocols and interpretation of study results, as well as informed advice on strengths and
 weaknesses of using certain types of data sources for post-authorisation studies (both safety
 and effectiveness)
- The general level of expertise on pharmacoepidemiological methods will be increased throughout Europe
- The EU Network will act as a reference for data-driven regulation





What?

The Big Data curriculum includes 3 curricula:

- Biostatistics & Clinical trial methodology
- Pharmacoepidemiology/RWE
- Data Science

Who?

- Audience
 - $\circ \ \ \mathsf{EU} \ \mathsf{Network}$
 - o EMA staff

Proficiency levels

- o Beginner
- Competent
- \circ Advanced



• **Objective**: enhance understanding of basic methodology and statistical concepts of assessors in the network (e.g. clinical or quality assessors)

Training topics:

- Basic statistical principles
- EMA Biostatistics guidelines
- Clinical trial design
- Specific topics for individual therapeutic areas
- o Estimands
- Real World Data / Pharmacoepidemiology
- Safety analyses
- Bayesian methods

Pharmacoepidemiology curriculum: from RWD to RWE

• **Objective:** provide knowledge on core principles of pharmacoepidemiology to increase EU regulatory network's capacity in the use of RWD to generate real-world (observational) evidence for regulatory purposes.

Training topics:

 landscape of RW data sources, their characteristics, strengths and weaknesses, conditions of access and utilisation

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- requirements for generating reliable evidence from RWD
- o formulating research questions for RWD-based studies and assessing study protocols
- assessing and interpreting results of observational studies



• **Objective**: enhance understanding and expertise of data management, analytical concepts and skills related, but not limited, to big data

Training topics:

- Introduction to Data Science
- o Data Governance
- o Data Standardisation
- o Data Management
- o Master Data Management
- Data Quality
- o Big Data
- Performing data analysis and interpretation of results
- o Data Visualisation and Dashboarding
- Artificial Intelligence
- o Omics Data
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How the curriculum will be delivered?

- EMA is considering having a tender for helping in the development of training material. Existing trainings from NCAs might also be used.
- □ A market survey was launched to identify market capacity and interest
- □ The trainings will be accessible through the EU NTC platform & Digital Academy
- □ Possible training formats:
 - Material and resources for self-learning
 - E-learning: asynchronous learning consisting of narrated slides where a presenter takes the audience through the content
 - Face-to-face training and webinars
 - Blended learning programmes consisting of a combination of the above formats
 - Assignments and assessments

Timeline past & going forward



April 2020 Table of contents of Pharmacoepidemiology curriculum developed & adopted by EMA scientific committees and working parties June 2020 — Table of contents of **Biostatistics curriculum developed and adopted** EU skills survey launch and results presented to BDSG 01-02 2021 Table of contents of Data Science curriculum developed and adopted 03 2021 Launch of market survey ٠ Q4 2021 Analysis of survey results and exploration of options for content development Additional BDSG consultation on training needs (e.g. pharmacogenomics) 02 2022 2022 - 2023 **Content development** Trainings to be made available in EU NTC & Digital Academy

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 At a later stage, there will be discussions on whether the training curriculum can be made available more widely, e.g. to ENCePP, but many aspects will need to be considered

• EMA will inform the ENCePP centres when the tender is published as proposals may be a joint effort of academic institutions



Any questions?

Further information

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