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SCIENCE MEDICINES HEALTH

Training Curriculum on Big Data for regulators

ENCePP Plenary webinar

18th November 2021

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EMA, Healthcare Data – Data Analytics and Methods Task Force

Outline

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2. BDSG Workplan – Recommendation IV
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5. Pharmacoepidemiology curriculum: from RWD to RWE
6. Data Science curriculum
7. Development, implementation and delivery
8. Timeline

BDSG Workplan 2021-2023

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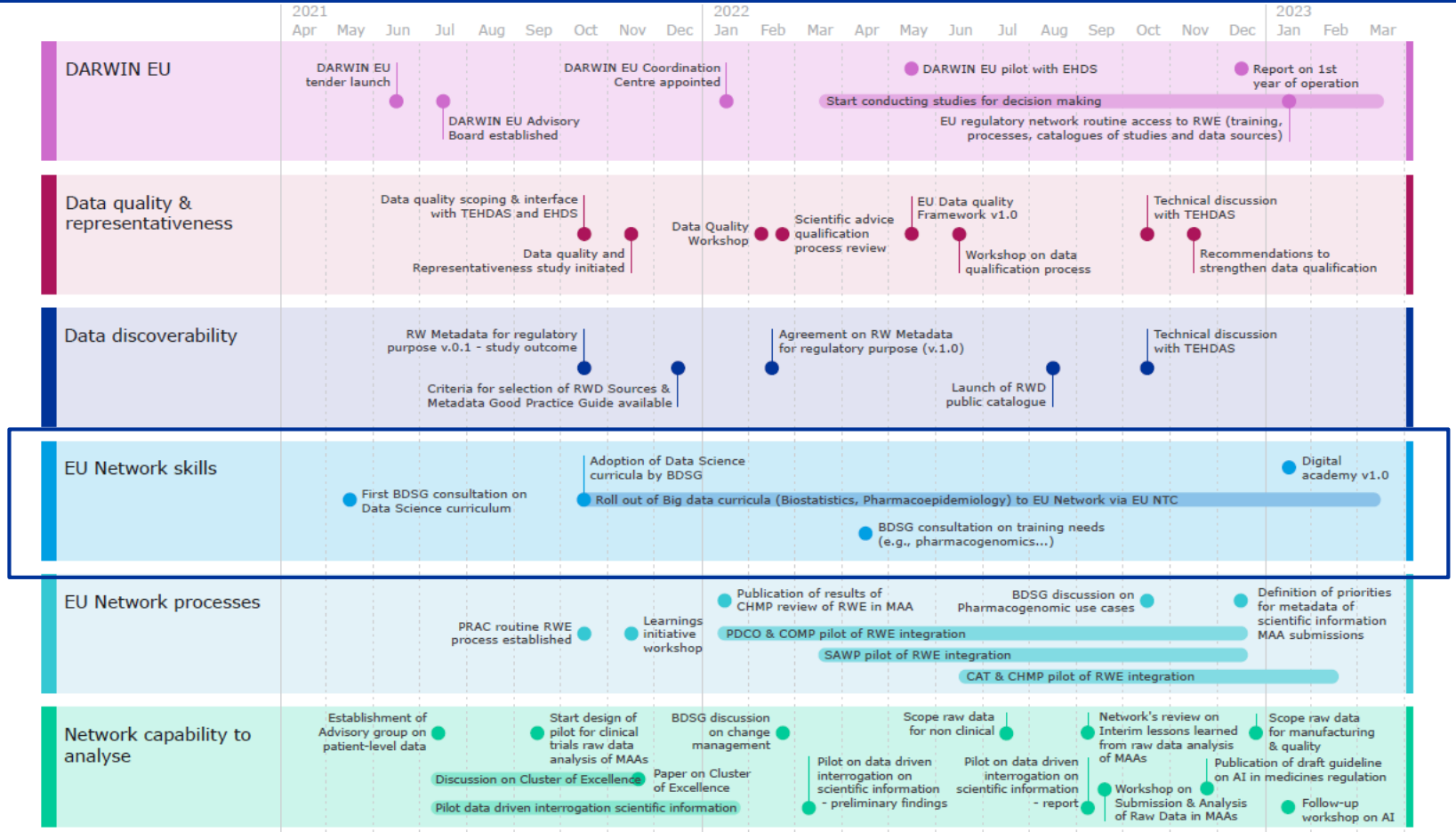

BDSG Workplan 2021-2023

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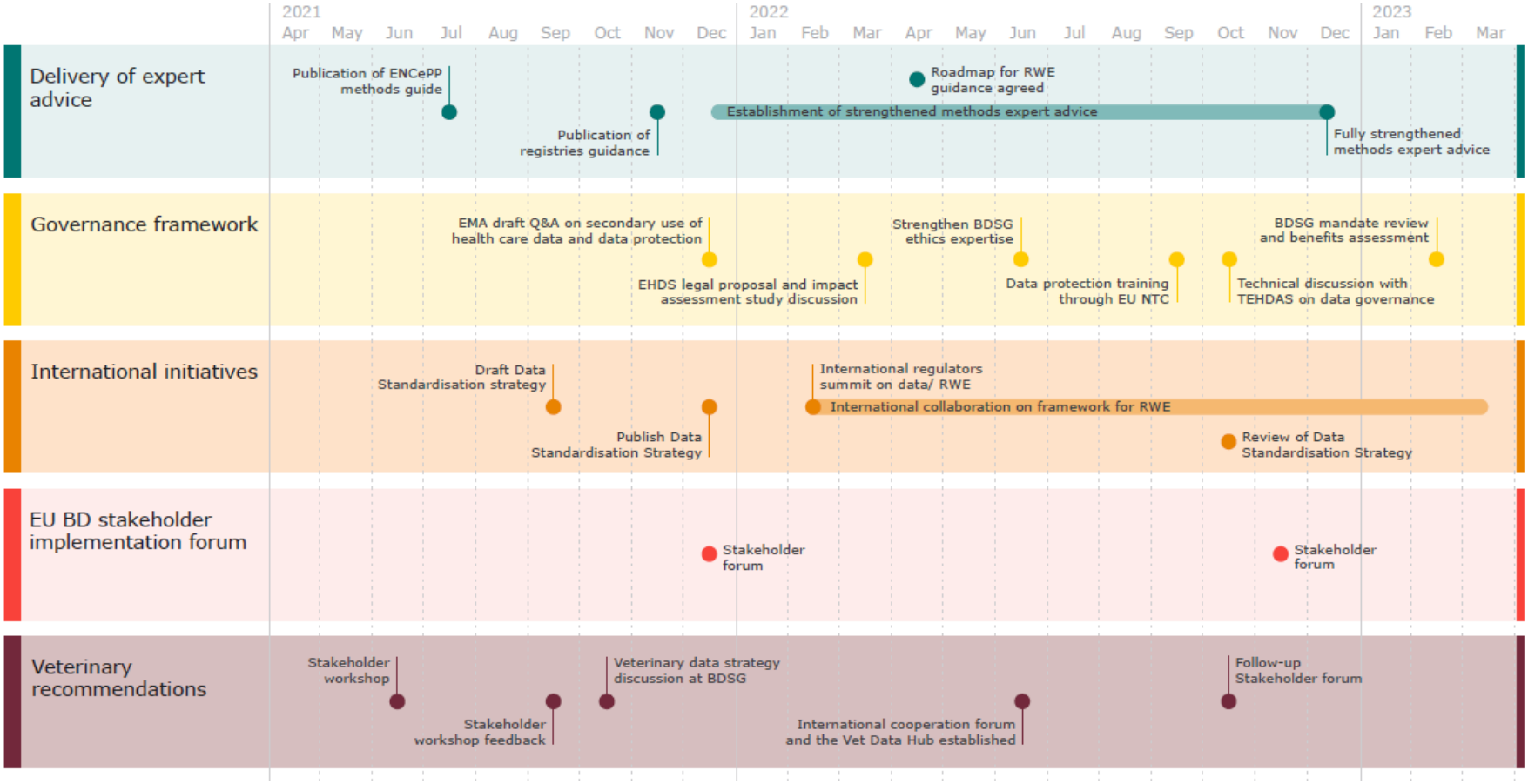

Background – The need for Big Data curriculum

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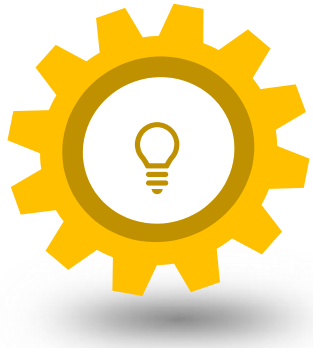
- The increasing volume and complexity of data coupled to rapidly developing technology offers the opportunity to deliver a better characterisation of diseases, treatments and the performance of medicinal products

- 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

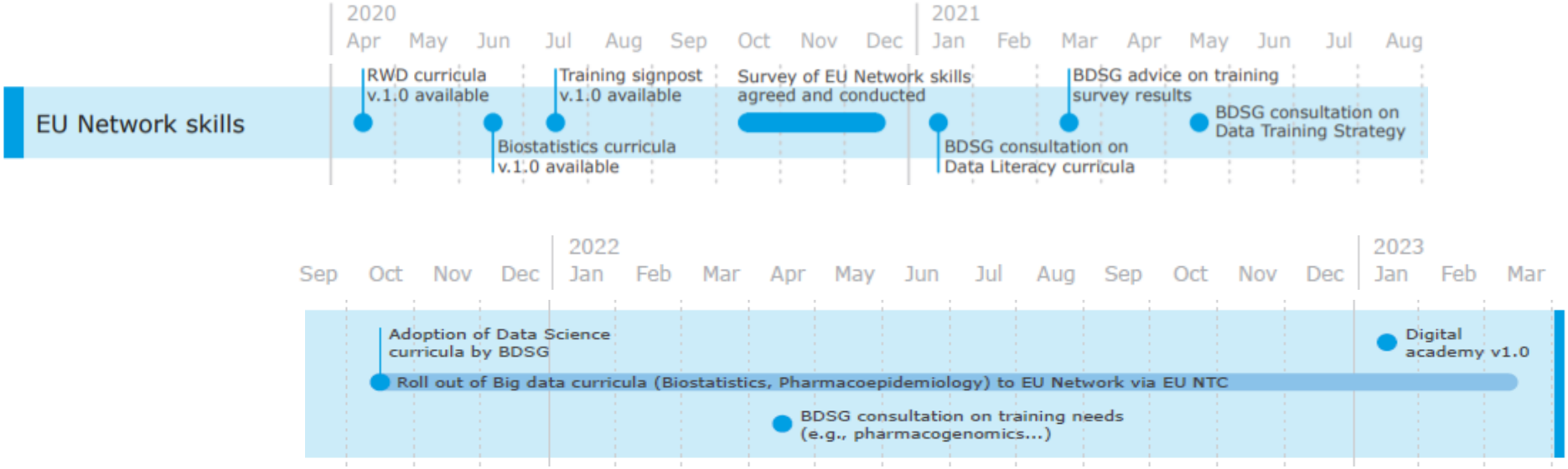
- The 2020 and 2021-2023 BDSG workplans introduced a more data-driven approach (*i.e. raw data, real-world data*) and with that comes a need for training

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



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.



BDSG Workplan – Recommendation IV

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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:
  - 🎯 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*

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

Big Data curriculum

❑ What?

The Big Data curriculum includes 3 curricula:

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

❑ Who?

- **Audience**
  - EU Network
  - EMA staff
- **Proficiency levels**
  - Beginner
  - Competent
  - Advanced

Biostatistics and Clinical Trial Methodology curriculum

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- **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
  - Estimands
  - Real World Data / Pharmacoepidemiology
  - Safety analyses
  - Bayesian methods

Pharmacoepidemiology curriculum: *from RWD to RWE*

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

Data Science curriculum

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- **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
  - Data Governance
  - Data Standardisation
  - Data Management
  - Master Data Management
  - Data Quality
  - Big Data
  - Performing data analysis and interpretation of results
  - Data Visualisation and Dashboarding
  - Artificial Intelligence
  - 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

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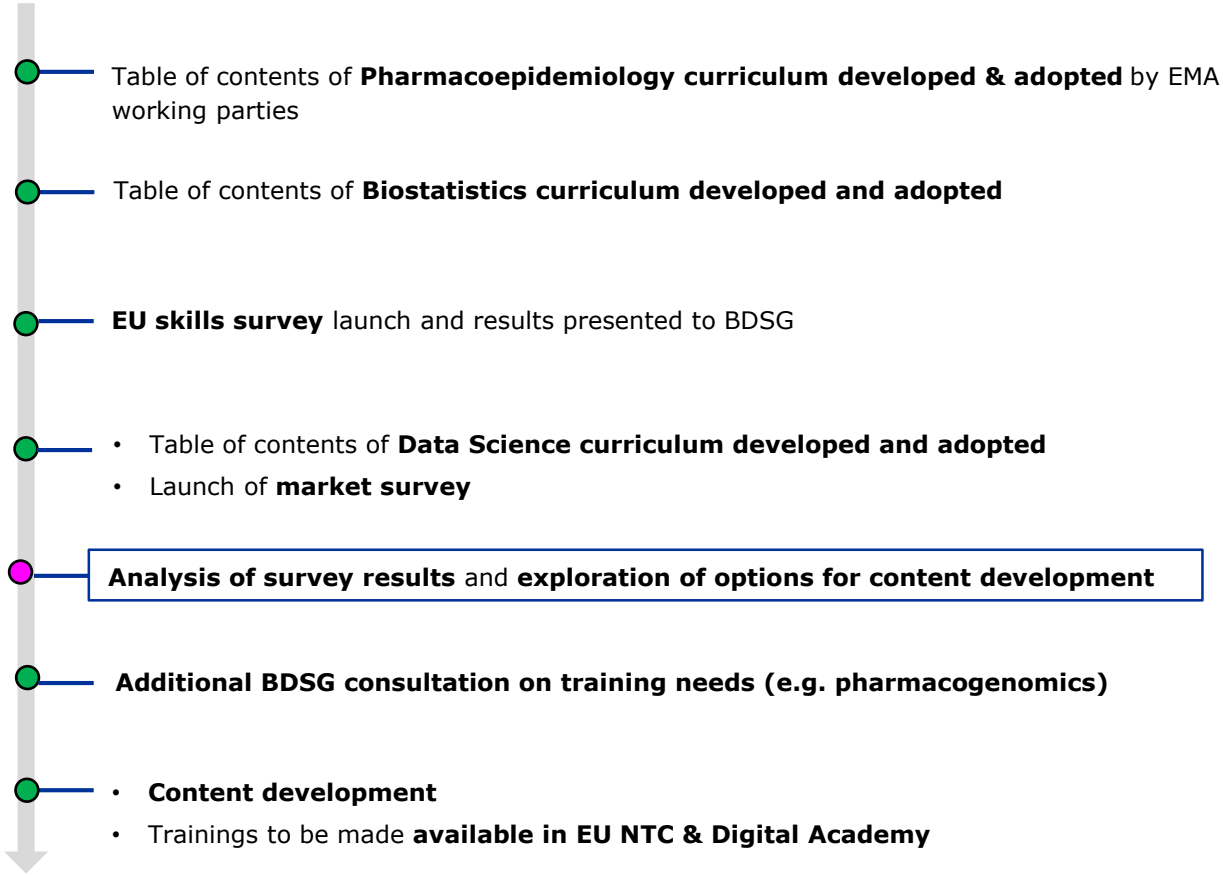

Points for ENCePP

- 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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