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Meet the Speaker

Eftychia Eirini Psarelli

Title: Seconded National Expert, Methodology, Data Analytics and Methods Task Force

Organisation: European Medicines Agency

Eftychia is statistician on secondment at EMA in the Methodology Workstream of the Data Analytics and Methods Task Force, where she has been managing EMA's Raw Data project, focusing on utilising raw data to generate evidence for better and more efficient regulatory decision making. Prior to joining the EMA in July 2020, she spent 8 years as a Senior Statistician at the Liverpool Clinical Trials Centre within the University of Liverpool, UK, where she has gained strong analytical skills in the area of statistical programming and data curation.

Eftychia fosters EMA activities where data standards can have an added value, particularly for clinical trial data. She is also an observer in Europe's CDISC Coordinating Committee (E3C).

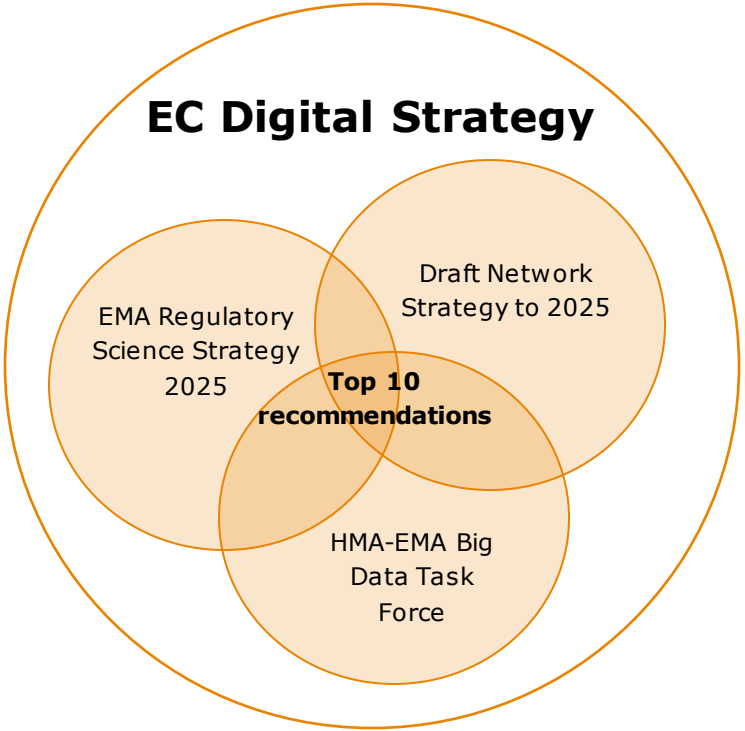
Outline

- Introduction to EMA's Raw Data project
- Planning approach
  - Proof-of-concept pilots
  - Data access and analysis
  - Interaction with stakeholders
- What's next?

Introduction

The timing is now…for raw data

- Key initiatives referred to the Commission digital strategy **"EU health data space"** (EHDS):
  - **EU Network Strategy to 2025** (data & digital pillar)
  - **EMA Regulatory Science Strategy to 2025**
  - **Joint HMA EMA Big Data Task Force;** and
  - the resulting **Top-ten data recommendations**
- Synergic initiatives:
  - **Pharmaceutical strategy for Europe**
  - **European Health Union**



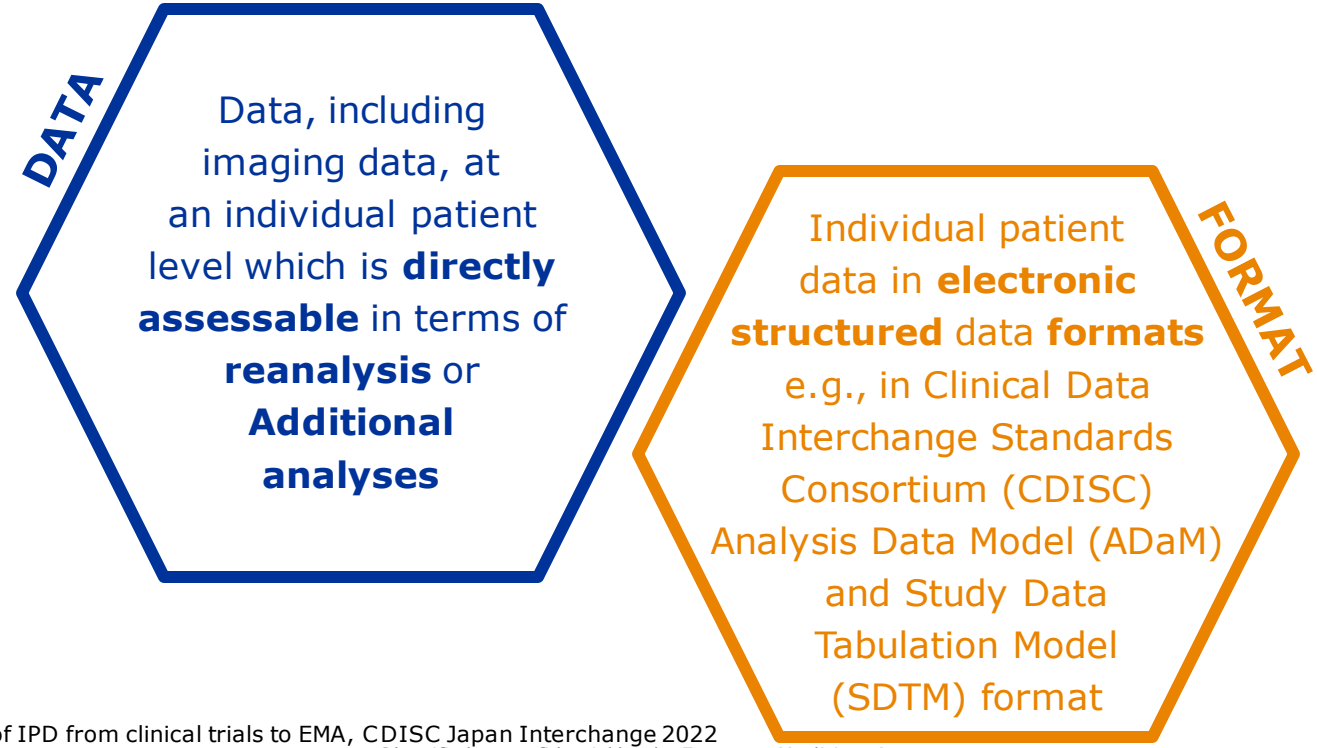
Vision: innovate to turn data into decisions on medicines that create a healthier world

Big Data Task Force Priority Recommendations

- Data quality & representativeness
- Data discoverability
- EU Network skills
- EU Network processes
- Network capability to analyse
- Delivery of expert advice
- Governance framework
- International initiatives
- EU stakeholder implementation forum

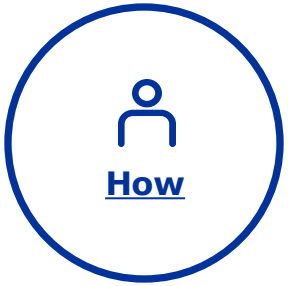
Definition and legal background

Raw data / Individual Patient Data (IPD) / Patient Level Data (PLD) / is **defined** as:



EMA's Raw Data project

- **Determine the regulatory benefit of access to raw data** via **pilots of analysis of raw data** from clinical trials, before coming back with **recommendations to the Committee for Medicinal Products for Human Use** (CHMP).
- Ultimate aim is for **Network to understand and take informed decisions** on the place of analysis of **raw data for future regulatory submissions.**



- **Put in place procedures and safeguards to process clinical trial raw data**, also considering non-clinical data, in accordance with data protection legislation.
- **Establish an Advisory Group on Raw Data** identified in HMA-EMA Joint Big Data Taskforce Phase II report (multidisciplinary group consisting of CHMP and EMA Working Party members; cross-NCAs set-up)
- **Perform a proof-of-concept pilot** in order establish the value of IPD and to build, step by step, capacity to analyse raw data.
- **Foster stakeholders' engagement** through a communication plan.

Planning approach

Proof-of-concept raw data pilots

- **Design phase** ongoing; pilot to kick-off Q3 2022
- **Selection** of procedures
  - Raw data analysis for approximately 10 Marketing Authorisation Applications
  - Clinical (including modelling & simulation, Good Clinical Practice data); non-clinical data to be considered
  - Different types of applicants (large pharmaceutical companies, small/medium-size enterprises)
  - Parallel submission to FDA or PMDA can be considered

Data access and analysis

- Submission of data to EMA and National Competent Authorities (NCAs) via Gateway (eCTD); no change
  - Data submission meeting to take place
- Raw data to follow **CDISC standards** (SDTM, ADaM)
  - Specific considerations for non-clinical data (e.g. SEND format)
- Various **operating models** to be considered for raw data analysis
  - Analyses will not impact assessment timelines
- **Software** to be explored
  - SAS and R for statistical analysis
  - JMP (clinical) for visualisation

Interaction with stakeholders

- **Transparency** is key
  - Interaction with Applicant
  - Communication with industry and public
- **Training** and **change management** needs
  - Practical learnings on operational, resource, technological, change management and data standard needs will be collected as part of the pilot
  - Focus on processes and **data standards**
  - Guidance will be developed
  - Workshops will be organised
- **Collaboration** with international regulators (FDA, PMDA)

What’s next?

The way ahead…

- **Data landscape**
  - Quality and manufacturing structured data
  - Veterinary data
  - Combine submission data with external RWE data

- **Data standards** and **analytical software**
  - Beyond CDISC data format (e.g. CDASH, HL7 FHIR)
  - Beyond SAS (e.g. R-shiny)
  - Visualisation software

- **EMA: Working for every patient in Europe** → working for every agency in Europe
  - **Business and IT solution** should be working for all 27 EU Member states providing fair access to raw data

Any questions?

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