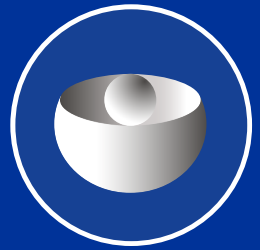

EUROPEAN MEDICINES AGENCY

# Submission of Raw Data to EMA

What Might the Future Landscape of Submitting Data Look Like in 2025

PHUSE EU Connect 2021

Presented by Eftychia-Eirini Psarelli on 15 November 2021
Methodology Workstream, Data Analytics and Methods Task Force, EMA

An agency of the European Union

# Disclaimer

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# Outline

- Introduction to EMA's Lifecycle Regulatory Submissions Raw Data project
  - What, why, how?
- Impact on business processes
  - Proof-of-concept pilots
  - Data access and analysis
  - Interaction with stakeholders
- The way ahead


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# Introduction


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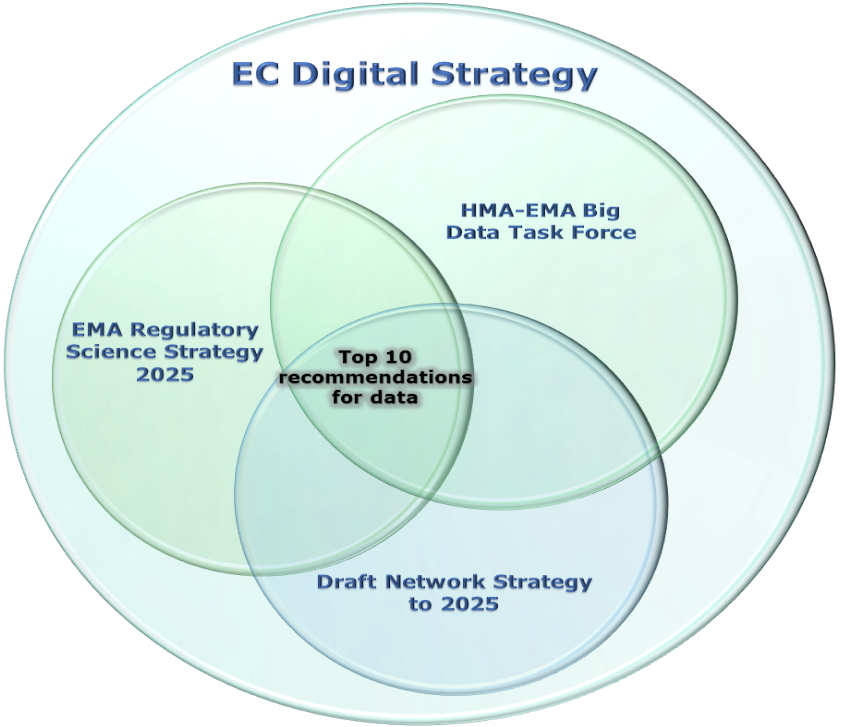
# The timing is now…for raw data

- Commission digital strategy: **"EU health data space"** (EHDS)
- Joint HMA EMA Big Data Task Force **Top-ten data recommendations**
- **EMA Regulatory Science Strategy to 2025**
- **EU Network Strategy to 2025** includes data and digital pillar
- EC **Pharma Strategy** and **Health Union**




Vision: innovate to turn data into decisions on medicines that create a healthier world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# Mandate for investigating access to raw data and design of future pilot

| | |
|---|---|
| 1 | Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network: DARWIN EU) |
| 2 | Establish an EU framework for data quality and representativeness |
| 3 | Enable data discoverability |
| 4 | Develop EU Network skills in Big Data |
| 5 | Strengthen EU Network processes for Big Data submissions |
| 6 | Build EU Network capability to analyse Big Data (technology / analytics) |
| 7 | Modernise the delivery of expert advice |
| 8 | Ensure data are managed and analysed within a secure and ethical governance framework |
| 9 | Engage with international initiatives on Big Data |
| 10 | Establish an EU Big Data 'stakeholder implementation forum' |
| 11 | Veterinary recommendations |

"*To enable analytics of data by the EU Network, technology will need to be delivered and the Big Data Steering Group will be consulted, together with the established EU Network Telematics Governance.* ***Pilots of the analysis of patient level data (PLD) from clinical trials will be initiated so that policy, process and technology choices are informed by evidence.***"


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# Priority Recommendation – 6 – Technology and raw data

## Why

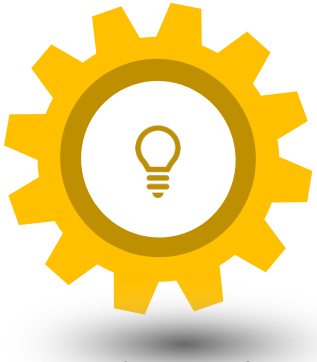
- Currently the Network has limited IT capacity and staff experience to manage and analyse 'raw' data (both patient level data from clinical trials and real world data from health records).

## How

- **Build EU Network capability to analyse Big Data (technology / analytics)**
- Build, step by step, through **pilots**, capacity to analyse Clinical Trials **patient level data**
- Where possible, leverage existing EU technology initiatives.
- Support establishment of **analytics centres** linked to regulatory agencies

## Benefits

- Regulators can receive and analyse 'raw' data to validate claims made by the industry
- Enables better committee decision-making
- Establishment of analytics centres of excellence





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# EMA's Lifecyle Regulatory Submissions Raw Data project (1)

Support better decision-making throughout the product lifecycle of medicines with valid and reliable evidence from clinical trials


- The **purpose** of the project is to **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 the **Network to understand and take informed decisions** on the place of analysis of **raw data for future regulatory submissions.**


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# EMA's Lifecyle Regulatory Submissions Raw Data project (2)


- **Put in place procedures and safeguards to process raw data**, including *clinical* and *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 raw data and to build, step by step, capacity to analyse raw data.
    - To kick-off in 2022
- **Foster stakeholders' engagement** through a communication plan.


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# Impact on business processes


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# Proof-of-concept raw data pilots

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


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# Data access and analysis

- Data access to EMA and National Competent Authorities (NCAs) via Gateway (eCTD)
- Raw data to follow CDISC standards
  - Specific considerations for **non-clinical data** (e.g. SEND format)
- Various **operating models** to be considered for raw data analysis
  - Options being explored including EMA, contractors, NCAs, and hybrids thereof
  - Current review of cluster mechanism via discussion paper on National Centres of Excellence
- Analysis team part of **extended assessment team**

No change


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# Interaction with stakeholders

- **Transparency** is key
  - Interaction with applicant
  - Communication with industry and public
- **Training** and **change management** needs
  - Focus on processes and data standards
  - Guidance will be developed
  - Workshops will be organised
- **Collaboration** with international regulators


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# What lies ahead?


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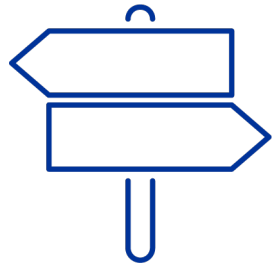
# The way ahead…what the future would look like?

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

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

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

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# Any questions?

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