EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

5.2 Pilot on raw data analysis – an update

PCWP/HCPWP joint meeting, 1 & 2 June 2022

Presented by Angela Bradshaw (Alzheimer Europe) and Eftychia-Eirini Psarelli (TDA-MET, EMA)

Outline of presentation

Refresher about Raw Data project

- definition
- mandate
- scope
- benefits for EU patients and healthcare professionals

Update on upcoming proof-of-concept pilot

- objective
- progress made
- next steps

Definition and legal background

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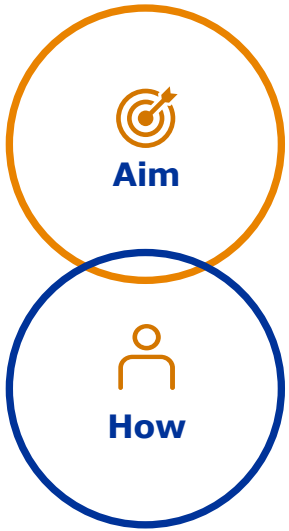
- Raw data / Individual Patient Data (IPD) / Patient Level Data (PLD) / is **defined** as:
  - 'data, including imaging data, at an individual patient level which is directly assessable in terms of reanalysis or additional analyses'
  - 'individual patient data can be structured in various electronic formats, e.g. in Clinical Data Interchange Standards Consortium (CDISC) or Data Analysis Model (ADaM)

- Clinical trial data **already provided by marketing authorisation applicants and sponsors** in modules 4 and 5 of all MAA dossiers
  - EMA currently receives this data in the form of PDF listings; in a format that does not support or even hinders data analysis
  - In contrast to PDF listings raw data is directly assessable in terms of reanalysis, additional analyses or visualisation

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

Raw Data Project – Scope



- **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 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 WP members; cross-NCA 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.
- **Foster stakeholder engagement** through a communication plan.

Expected Benefits for patients and HCPs (this list is not exhaustive)

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1. **Improved confidence in regulatory decision-making;** through access to raw data and better understanding of clinical study results, reassurance that medicines continue to be authorised based on robust evidence

2. **Faster patient access to innovative medicines and optimisation of safe and effective use**; through better understanding of clinical study results and fewer complex questions to the applicants (shorter clock-stops)

3. **Improved stratification of patient groups and populations;** identification of better-defined patient groups and populations for indications via processing of raw data (e.g. subgroup analysis) will support better greater therapeutic benefit

4. **Refined product labelling;** better targeting of subgroups with the recommended indications will support refinement of product labelling

Mandate for exploring raw data analysis and PoC pilot

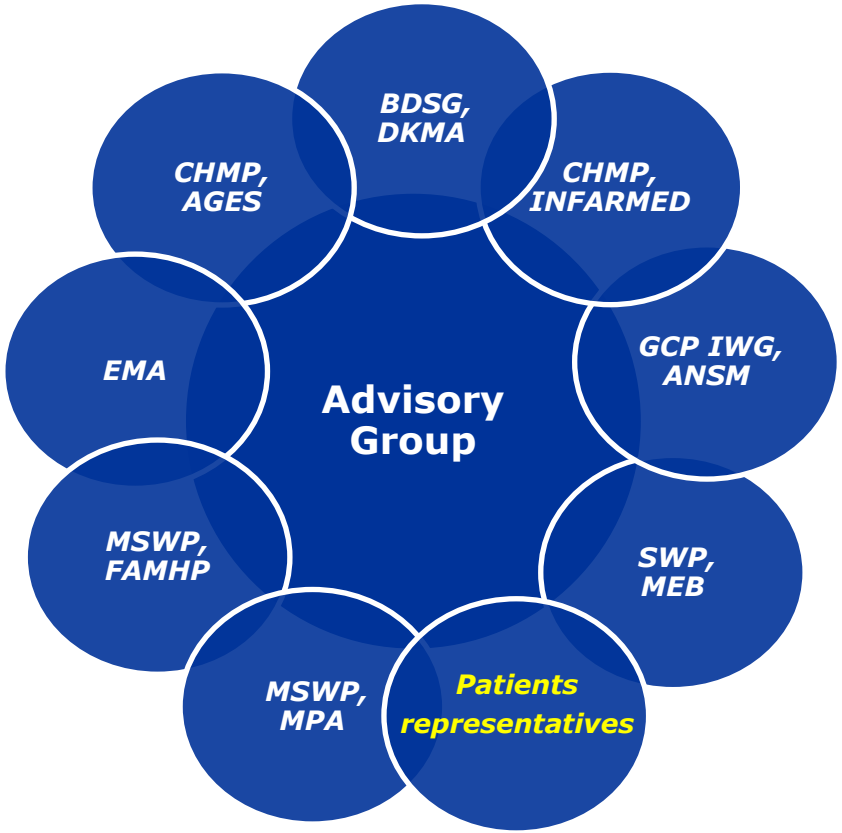
Key objective

Explore the analysis of raw data *from Marketing Authorisation (MA) dossiers to support assessment of initial MA applications.*

Activities in 2022

Proceed with proof-of-concept pilots of analysis and visualisation of raw data from MA dossiers to support the assessment and learn of the practicalities and benefits of such an approach.

Network – Advisory Group on Raw Data



Progress made – key considerations

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Design & preparatory work (ongoing)

- Patient representatives in Advisory Group on Raw Data already supporting
- Public communication about pilot planned for June 2022
- Data Protection Impact Assessment ongoing
  - To be finalised in Q2/Q3 2022
  - Data Protection Notice and Records of Data Processing to be made publicly available

Next steps

- Procedures submitted from September 2022
- Feedback to inform learnings from pilot to be collected via surveys or interviews (Industry, EMA, NCAs)
- Interim lessons learned from pilot to be available in 2023
- Final lessons learned to be available and published in 2024
- Targeted communication to patients will be developed once learnings from pilot are available

Thank you

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