



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Raw Data Project Update

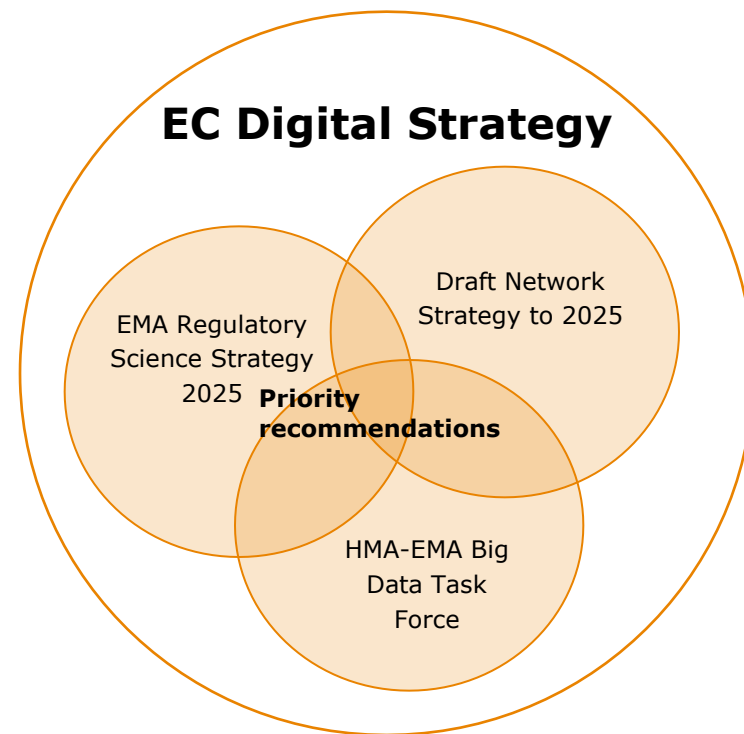
PhUSE/FDA CSS 2022

Presented by Anne-Sophie Henry-Eude, 21 September 2022
Head of Document Access and Publication, European Medicines Agency

An agency of the European Union

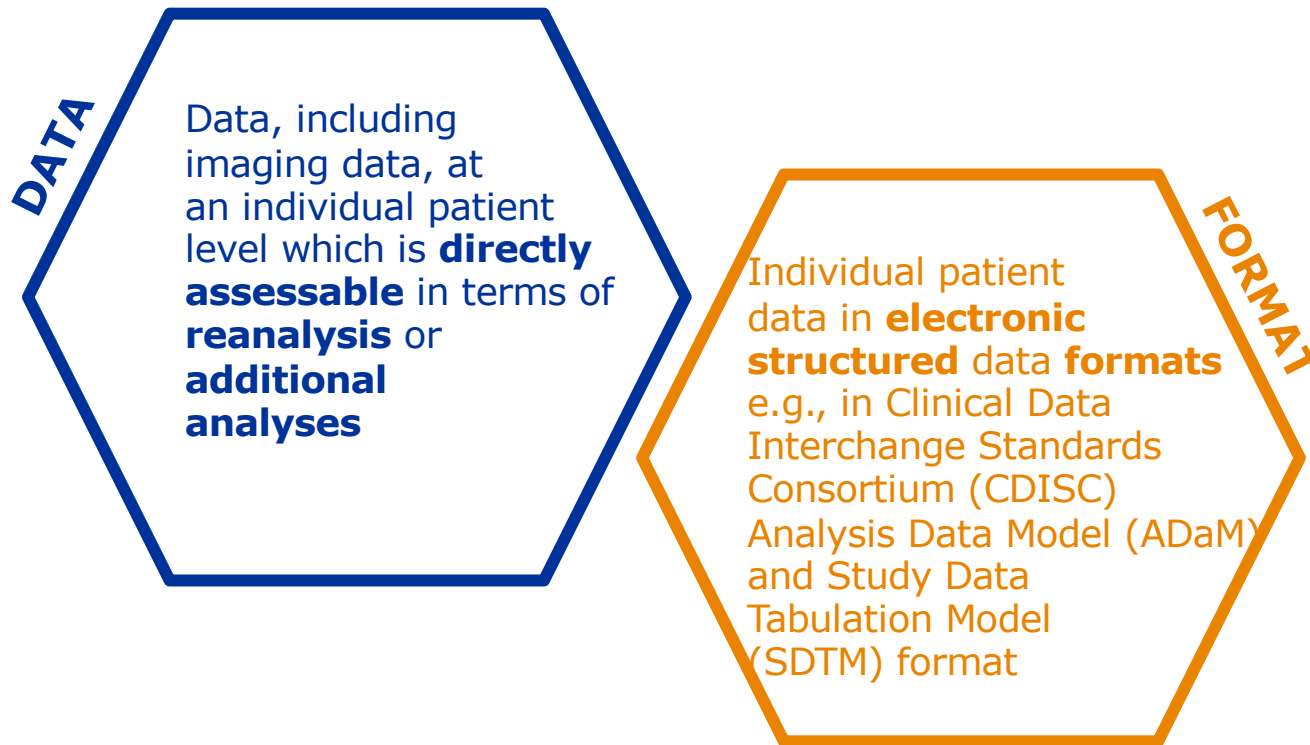


- Key initiatives referred to the Commission digital strategy “**EU health data space**” (EHDS):
 - **EU Network Strategy to 2025** (data & digital pillar)
 - **EMA Regulatory Science Strategy to 2025**
 - **Joint HMA EMA Big Data Task Force;** and
 - the resulting **Top-ten data recommendations**
- Synergic initiatives:
 - **Pharmaceutical strategy for Europe**
 - **European Health Union**
 - **CHMP work plan** 2021 and 2022

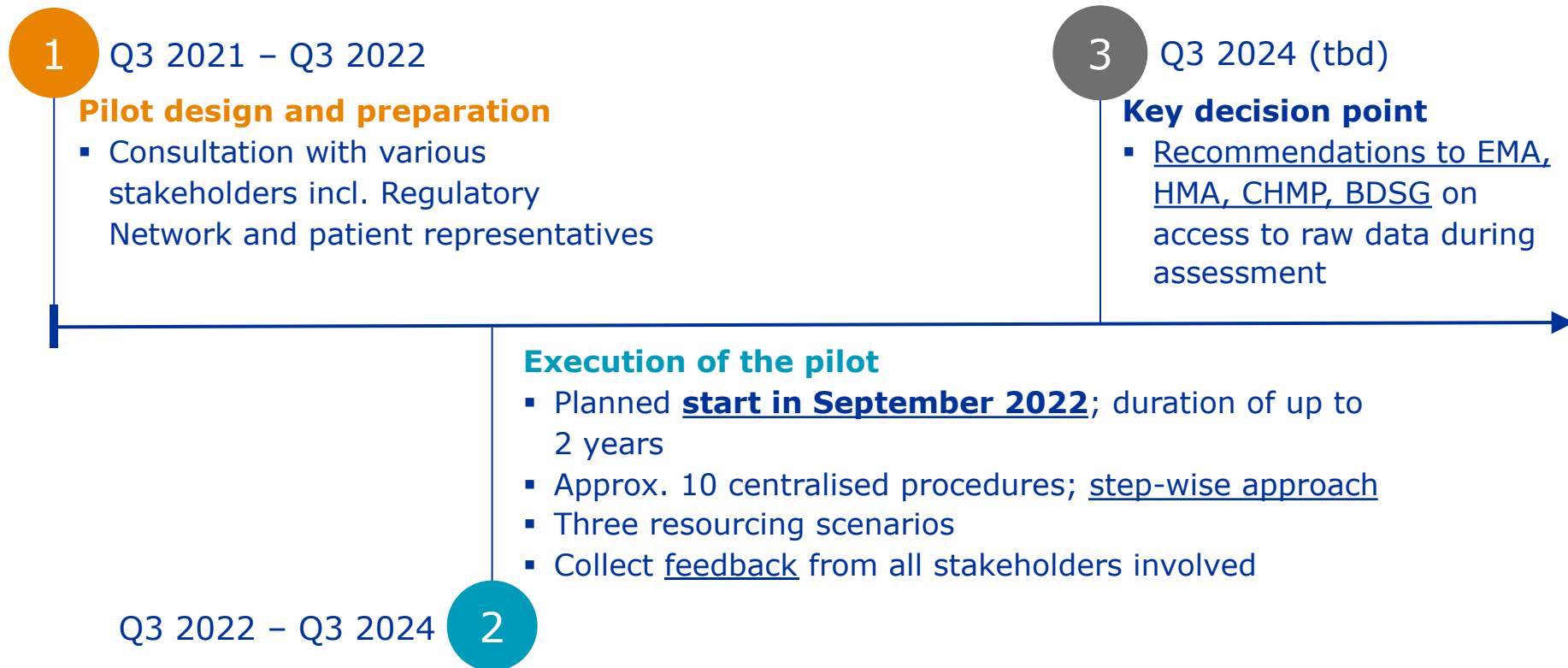


Vision: innovate to turn data into decisions on medicines that create a healthier world

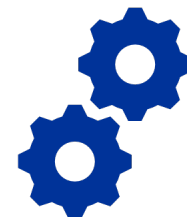
Raw data / Individual Patient Data (IPD) / Patient Level Data (PLD) / is **defined** as:

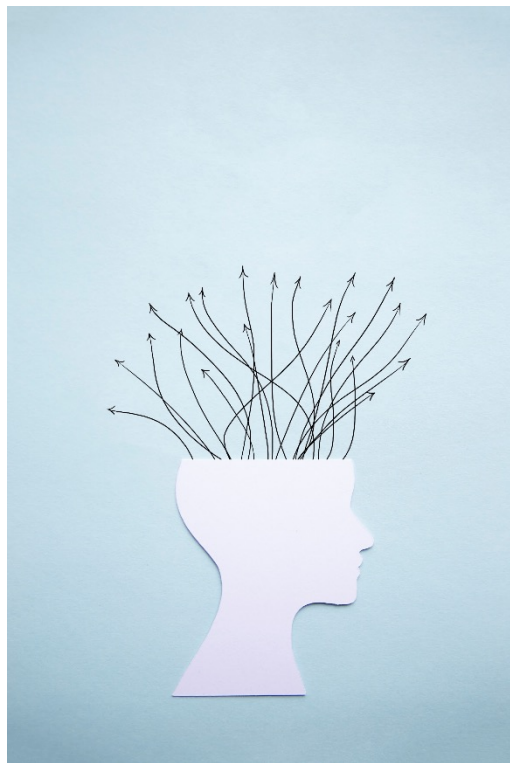


- Clinical trial data **already provided by marketing authorisation applicants and sponsors** in modules 5 of MAA dossiers
 - as Patients line listings [annexed](#) to the Clinical Study Report
 - in the form of [PDF listings](#)
- In contrast to PDF listings, IPD / raw data is [directly assessable in terms of reanalysis, additional analyses or visualisation](#)



- For procedures chosen for PoC pilot, applicants/Marketing Authorisation Holders [submit raw data in addition to regular dossier](#) (how: Q&A will follow)
- During assessment, [questions](#) may arise which [Rapporteurs want to answer via raw data analysis](#)
- Raw data analysis happens [during assessment phases](#), e.g. btw. Day 1 to Day 80 for iMAAs
- Rapporteurs [include description of results in assessment report \(AR\)](#)
- CHMP requests [replication of analysis results](#) from applicant e.g. via LoQ/LoOI/RSI





Voluntary participation by Rapporteurs & Applicant/MAH

Analyses to support assessment of dossier, no analyses across dossiers

Pilot participation will not cause delay to CHMP opinion

Procedures and safeguards are being implemented in accordance with personal data protection legislation

Transparent communication with Applicant (AR and LoQ/LoOI/RSI)



Any questions?

Further information

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