EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic Health Record: Access, Share, Expand Project

Project objectives

Joint PCWP and HCPWP virtual meeting, 2 June 2020

Sabine Brosch, Data Protection Coordinator Clinical Studies and Manufacturing Task Force (TCS)

Overview

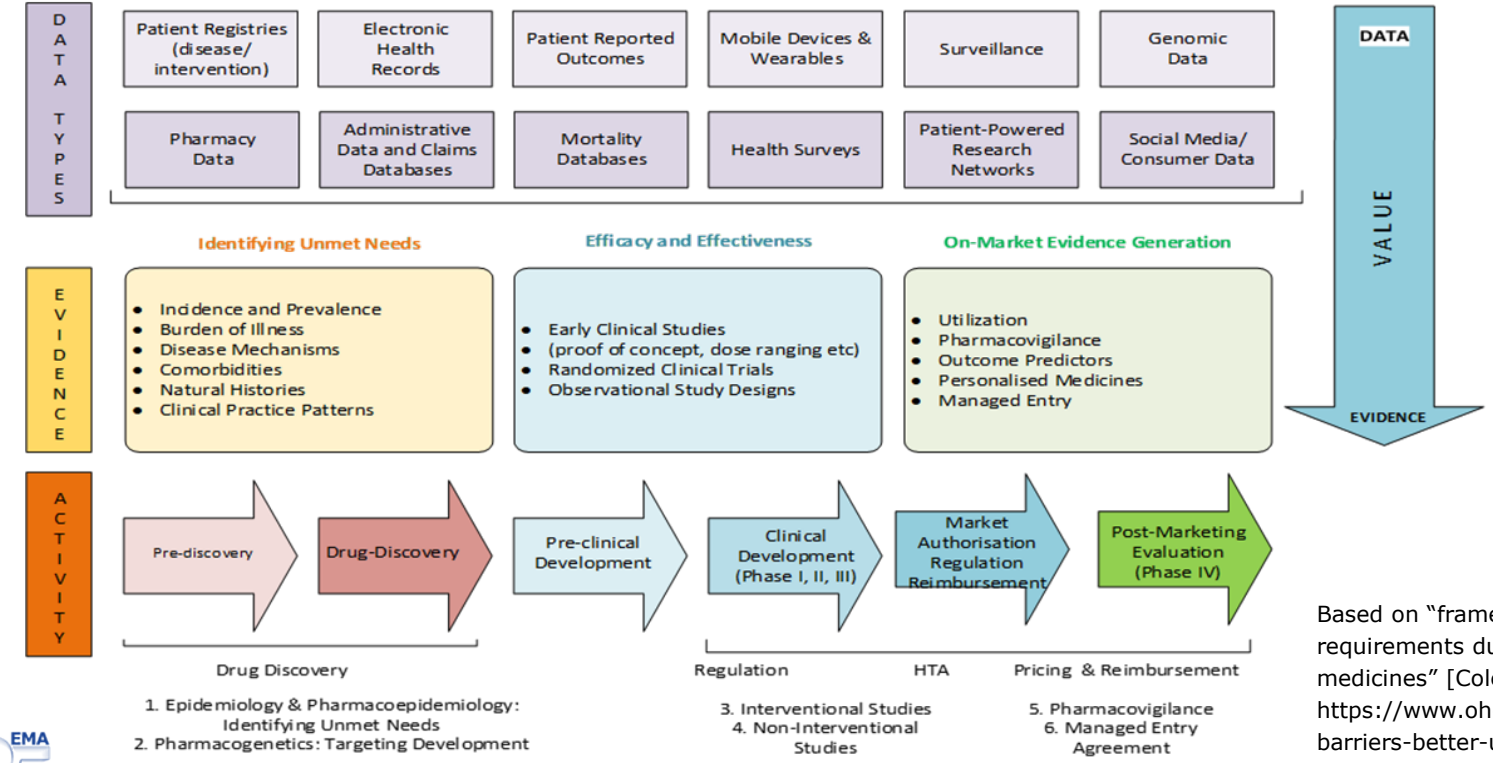
- Background
- Project need
- Project objective & deliverable
- Methodology
- Questions

Background

Health data support pharmaceutical research, development and innovation in various areas:

- Drug utilisation studies such as use in different age groups (children) and off-label use
- Relevance of clinical trial data versus clinical practice
- Safety monitoring and evaluation
- Planning and conduct of observational safety and effectiveness studies
- (Comparative) effectiveness
- Extrapolation of adult data to children or elderly
- Conduct of pragmatic clinical trials
- Identification of unmet medical need
- Monitoring the natural course of the disease following standard of care
- Assessing disease incidence/prevalence
- Measuring background rates of events (for assessment of drug safety)
- Characterising the representativeness of patients in disease registries

Background



Based on "framework for evidence requirements during the lifecycle of a medicines" [Cole, A. and Towse, A] https://www.ohe.org/publications/legal-barriers-better-use-health-data-deliver-pharmaceutical-innovation

Project Need

Potential for a strengthened evidence base for decision-making is currently perceived as being hindered by uncertainties about the correct interpretation of the General Data Protection Regulation (GDPR) in the area of the "secondary use" of health and medical data for medicines and public health purposes.

- "***Primary***" purposes are defined as those explicitly stated at the time of data collection, such as patient care, health system administration or research projects named at the time of data collection.
- "***Secondary***" (or further) purposes are those compatible with the primary purpose, that however were not explicitly stated at the time of data collection.

Project Objective and Deliverables

- Address data protection matters on the secondary use of health and medical data for medicines and public health purposes
- Develop a set of Question & Answers (Q&As) that can facilitate compliance with data protection rules including the rights of patients, consumers and healthcare professionals
  - *No formal legal status but practical and technical guidance on how to comply with the law*
  - *Collaboration with other EU Agencies*
  - *European Commission (EC) and European Data Protection Supervisor (EDPS) to be consulted on draft Q&As*
  - *Contribution to development of code of conduct – European Health Data Space (EHDS)*

Methodology

a. *Identification of data protection questions*
with input from interested stakeholders based on *discussion papers*

b. *Consolidation of data protection questions* grouped by key topic areas and *drafting of operational scenarios* e.g., studies performed to obtain marketing authorisation, mandated/voluntary post-authorisation safety studies, clinical studies during pandemic, exploratory studies

c. *Detailed analysis of arising data protection matters*

d. *Drafting of Q&As* based on the performed analysis

e. *Targeted consultation of interested stakeholders* -> update of draft Q&As

f. *Consultation of EC & EDPS* -> update of draft Q&As based on comments

g. *Publication of final Q&As and stakeholder communication* -> ***Q2 2021***

Any questions?

Further information

Sabine.Brosch@ema.europa.eu; Orsolya.Eotvos@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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