EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Questions and Answers (Q&As) on data protection and the secondary use of personal data for medicines development and public health purposes

Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes, 29 September 2020

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Overview

- Background
- Project need
- Project objective
- Structure of the draft Q&As
- Drafting status of the Q&As
- Next steps

Background

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

- Relevance of clinical trial data versus clinical practice
- Safety monitoring and evaluation
- Drug utilisation studies such as use in different age groups (children) and off-label use
- Extrapolation of adult data to children or elderly
- Identification of unmet medical need
- Assessing disease incidence/prevalence

Project Need

Patients and HCPs,
Research performing or supporting infrastructures,
Medicines developers

- Union data protection legislation (GDPR)
- How to use personal data for secondary purposes

Medicines development and scientific research

Public health
Regulatory authorities

- Union data protection legislation (GDPR, EUDPR)
- How to use personal data for secondary purposes

Evidence base for decision-making, safety monitory and policy making

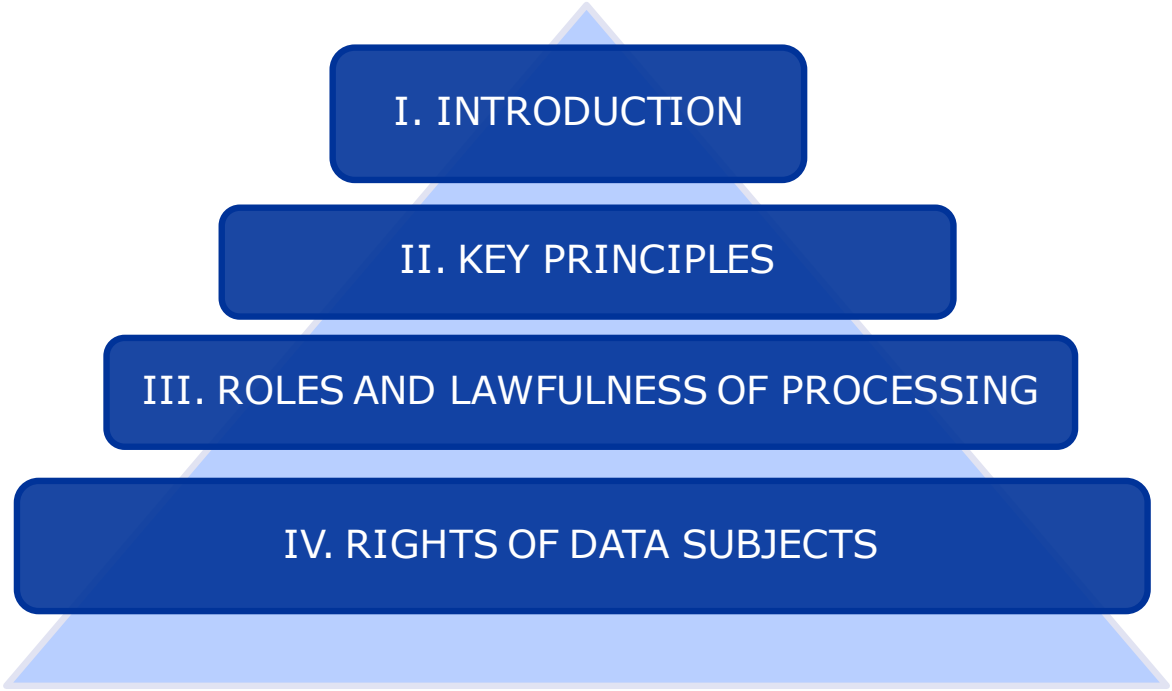
Project Objective

Develop a set of Question & Answers (Q&As)

- Clarify compliance with data protection legislation
- Ensure rights and freedoms of patients and consumers
- Facilitate the secondary use of health data for medicines and public health purposes

- Clarify the concept of **secondary use of data** within the GDPR/EUDPR
- Clarify the concept of **scientific research** within the GDPR/EUDPR
- Clarify the **specific rules** applicable to scientific research and secondary use, e.g. legal basis (consent or other), data erasure and retention period, transparency

Structure of the draft Q&As



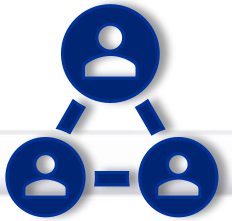
KEY PRINCIPLES

- Scope of the Q&As
- What are personal data?
- What are special categories of personal data?
- What does secondary use of data mean?
- When does the GDPR/EUDPR apply to secondary use of data?
- What are the data protection principles?
- How long personal data can be retained?

ROLES AND LAWFULNESS OF PROCESSING

- Who is the data controller in the context of secondary data use?
- Compatibility of secondary data use
- Legal bases (legal obligation, public interest, legitimate interest, consent)
- Post-Authorisation Safety Studies (PASS) or Post-Authorisation Efficacy Studies (PAES)
- Studies performed by medicines regulators

RIGHTS OF DATA SUBJECTS



- Impact of different legal bases
- Information to be provided to data subjects - exceptions
- Request to access or a copy of personal data
- Request to rectify or complete personal data
- Restriction of personal data processing, Right to object
- Withdrawal of consent
- Right to erasure

Drafting status of the Q&As

Phase 1 Drafting of Questions & Answers (Q&As)

- Initial key topics discussed with stakeholders
- Operational scenarios (PAES, PASS, regulators)

Phase 1 Draft Q&As - Informal Consultation

- EC DG SANTE - completed
- EC DG JUST - ongoing
- European Data Protection Supervisor (EDPS) - ongoing

Targeted Stakeholder Consultation

- Based on Discussion Papers (May to July) - completed
- Consolidation of feedback received - completed

Next Steps

Phase 2 Drafting of Q&As

- Analysis of input received in Targeted Stakeholder Consultation
- Review of comments from EC and EDPS in the informal consultation

» Update of Phase 1 draft Q&As based on the above

Targeted Consultation of Phase 2 draft Q&As

- EMA Stakeholder representatives » update of draft Q&As
- EMA Scientific Committees » update of draft Q&As

Formal consultation of draft final Q&As

- Consultation with EC (DG SANTE & JUST) and EDPS

Publication of final Q&As

Any questions?

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