EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic Health Record: Access, Share, Expand Project

Overview of stakeholder feedback received

Joint PCWP and HCPWP virtual meeting, 2 June 2020

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

Initial Stakeholder Input

- BEUC - The European Consumer Organisation
- CPME - Standing Committee of European Doctors
- EHN – European Heart Network
- EPF – European Patient Forum
- EULAR- European League Against Rheumatism
- EURODIS – Rare Disease Europe
- PGEU – Pharmaceutical Group of the European Union

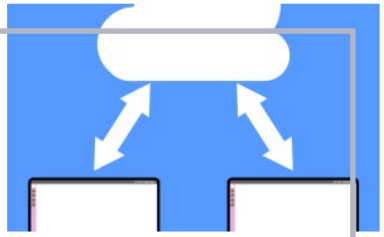
Initial Stakeholder Input

Input provided based on shared

- Position papers
- Publications in scientific literature
- Guiding principles
- Comments on GDPR consultation
- Comments on strategic reflection to the EMA Regulatory Science to 2025
- Points to consider documents
- Working documents

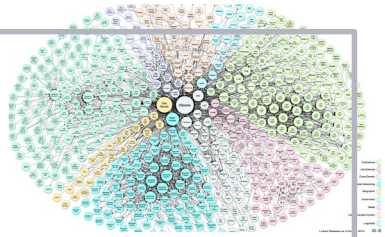
Key Topics raised in the context of health data

Data Protection



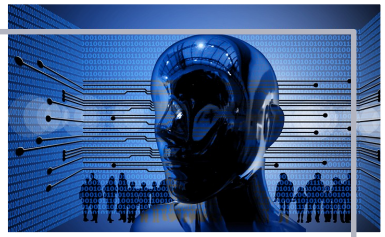
Data Sharing

Ethical Principles



Data Linkage

Cyber Security



Artificial Intelligence

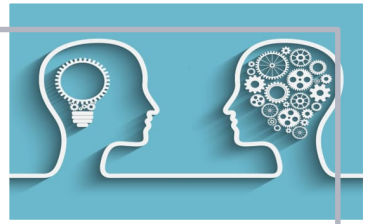
Key Topics raised in the context of health data =>

Translates into:

Policy & Rules

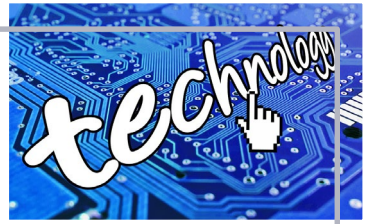
Governance

Process



Methodology

Standards



Technology

Guidance

Ongoing initiatives

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European strategy for data
- Commission Experts' Workshops Assessment of the Member States' rules on health data in the light of the GDPR 2019/2020
- Joint Action addressing differences in national General Data Protection Regulation (GDPR) implementation in the health sector, including the European Health Data Space and the health data use/eHealthAction – Innovative use of Health Data
- Commission White Paper on 'Artificial Intelligence - A European approach to excellence and trust
- European Parliament Report on a Framework of ethical aspects of artificial intelligence, robotics and related technologies
- European Parliament Study The ethics of artificial intelligence: Issues and initiatives

Next Steps

- Your input is important to determine the content of the "*Q&As on the GDPR and the Secondary Use of Data for Medicines and Public Health Purposes*".
- Please submit ***specific data protection questions*** (possibly with examples) by ***10 July 2020*** to ***dpconsultation@ema.europa.eu***
- EMA will consolidate your input and will aim to put your questions in context of operational scenarios such as medicine development, marketing authorisation approvals and post-authorisation safety monitoring.

Any questions?

Further information

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