EMA WORKSHOP ON SECONDARY USE 29TH SEPTEMBER 2020

Perspectives of Medicine Developers

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- **EFPIA**
- **EuropaBio**
- **EUCOPE**
- **AESGP**

EUROPEAN COMMISSION

Brussels, 19.2.2020
COM(2020) 66 final

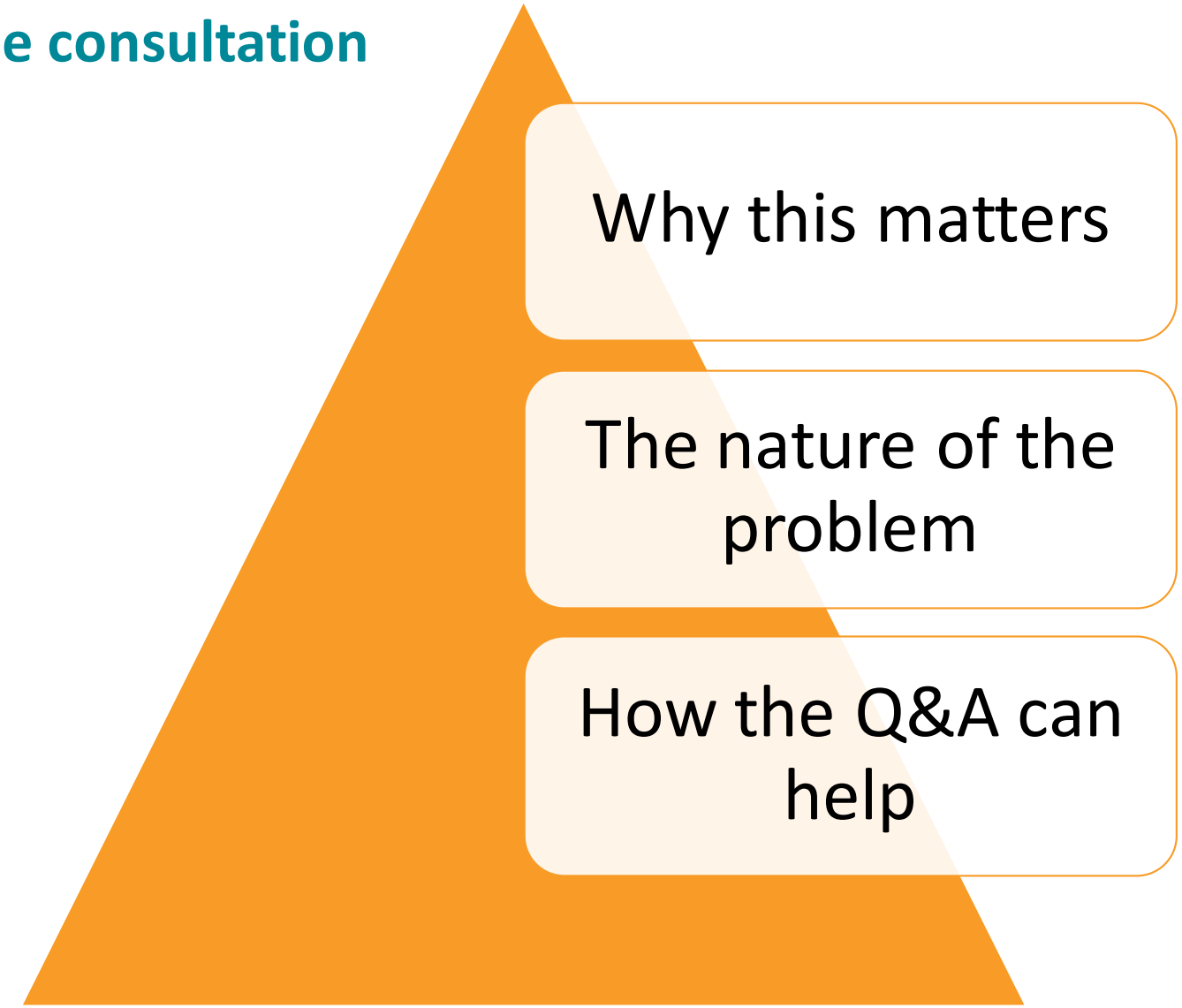
COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

A European strategy for data

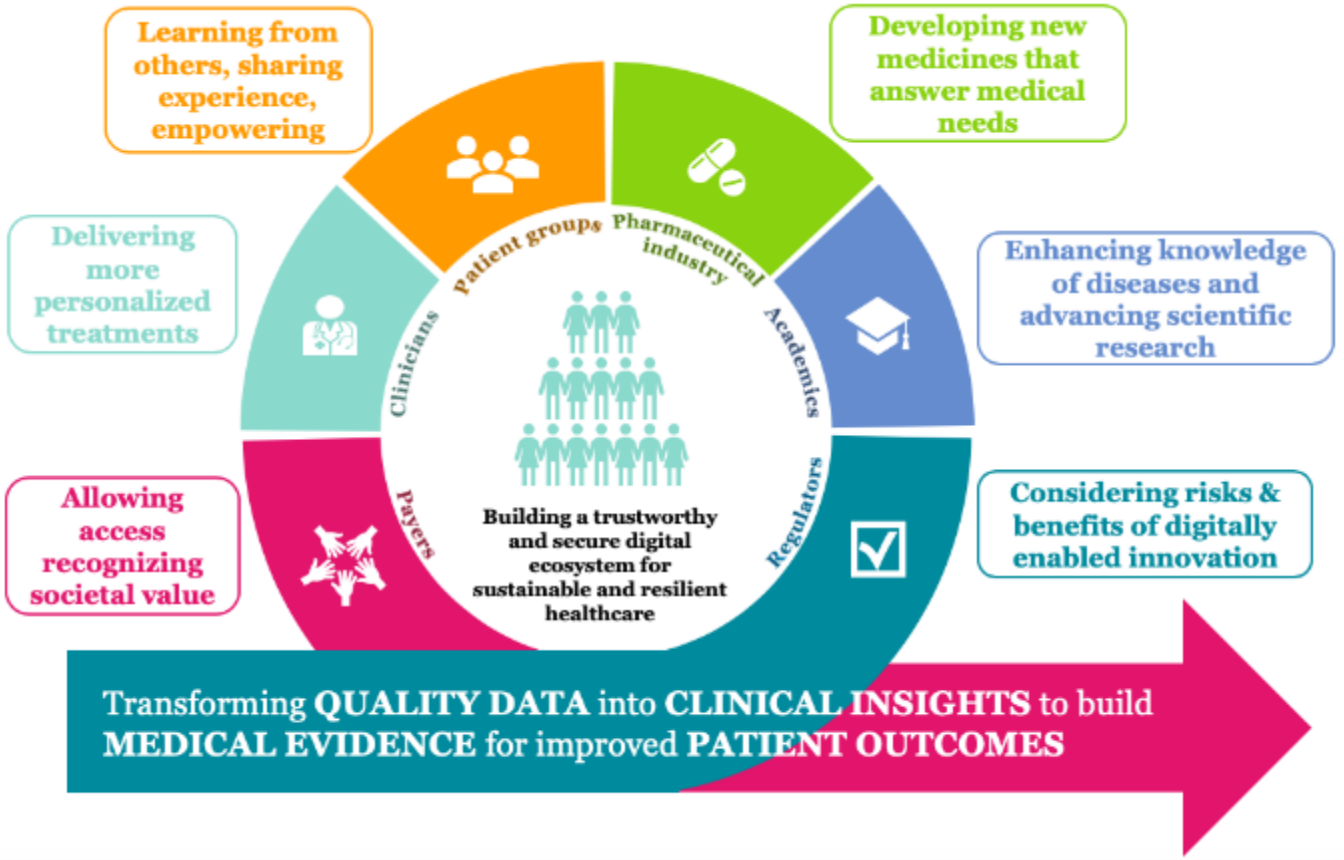
The current regulatory and research models rely on access to health data, including individual level data from patients. ***Strengthening and extending the use and re-use of health data is critical for innovation in the healthcare sector. …It also contributes to the competitiveness of the EU's industry.***

Health is an area where the EU can benefit from the data revolution, increasing the quality of healthcare, while decreasing costs. **Progress will often depend on the willingness of Member States and healthcare providers to join forces and find ways to use and combine data, in a manner compliant with the GDPR,** under which health data merit specific protection. While the GDPR has created a level playing field for the use of health personal data, fragmentation remains within and between Member States and the governance models for accessing data are diverse. The landscape of digital health services remains fragmented, especially when provided cross-border

Responses to the consultation



The GDPR provides one of the key regulatory elements that will govern the use of the world of health data for secondary scientific research purposes, and ultimately patient benefit.



In the industry's view:

- *the use of big data in the regulatory dossier will increase and use of secondary data will be critical to the development process and the generation of evidence.*
- *there are important links between the EMA's purpose in developing the Q&A and both the Regulatory science strategy to 2025 and the delivery of the major outputs from the Joint Big Data Steering Group Workplan*

The EMA Q&A

The industry welcomes the EMA's initiative, which can contribute to Europe providing global leadership in the responsible use of personal health data and looks forward to further collaboration

EFPIA believes that

- *even without formal legal status, the Q&A should be developed in collaboration with the European Data Protection Board and the Commission. We also ask the EMA to continue to collaborate with the private sector*
- *One of the most important considerations of such a document is the understandability of such a complex topic by a lay person. There is also a broader consideration here which is reflected in the EMA's objective – securing public trust in the use of personal health data.*
- *The Q&A represents an opportunity to highlight good practice and also to define key concepts in a way that reflects the intent of the legislator and policymakers to facilitate responsible use of health data for research. It would be valuable to include use cases*
- *The Q&A could act as a guide to data "gate keepers", such as registries, ethics committees and data custodians*

The current situation is not consistent with Europe's policy goals and does not benefit patients. We need a system of regulation that offers high levels of protection for individuals and high-quality data access for researchers and healthcare providers

General Points

- **The industry seeks an interpretation of GDPR which is consistent, responsible and which facilitates the use of health data for scientific research purposes with appropriate safeguards for individuals. At present we see:**

  - No agreed definition of secondary use
  - Tension between the exploratory nature of research and restrictive privacy regulation
  - Privacy regulator's preference for restrictive policy over safeguards
  - Tension between EU harmonization and what works well already at local/national level
  - Lack of a holistic health data ecosystem approach
  - lack of alignment between stakeholders, such as between sponsors, hospitals and research sites and ethics committees.
  - International data transfers which are critical to research and public health are subject to legal uncertainty

THE NATURE OF THE PROBLEM

Inconsistencies in institutional practices	Inconsistencies in the interpretation of GDPR	Inconsistencies in the implementation of both EU and national laws which support GDPR implementation
No standardized role for "gatekeepers" in the process of approving research projects	Lack of consistency and much legal uncertainty in relation to the legal basis for processing health data	Conflicting legal bases for health data processing in clinical research within national legislation/regulation and existence of scientific research exemptions outside GDPR
No common understanding among competent bodies of concepts such as anonymization, pseudonymization and de-identification	Interpretation and/or use of the "research exemption" of Art. 5(1)(b) of the GDPR is inconsistent and weak	Divergences in defining (or lack of) appropriate safeguards for secondary use (Art. 5(1)(b) GDPR) or in support of article 9(2)(i) and (j) in EU or national law
Lack of harmonized supporting material (such as ICF templates and other documents) to facilitate the research process	No consistent view on how the derogations for scientific research in the GDPR can be used (e.g., under Art. 14(5)(b), Art. 17(3)(d), Art. 21(6) GDPR)	No consistency in introducing necessary derogations (under Art. 89(2) of the GDPR) in EU or national law
Differences in the interpretation of primary and secondary us		Secondary use: lack of clarity about acceptability of different methods of informing data subjects of secondary use and when transparency obligations apply

Develop a Code to sustain and provide certainty around the research process

Build public trust in the use of data in research

Progress harmonisation through consistent interpretation

What can Industry do - what about Codes of Conduct?

Build it step by step

Improve alignment between research partners

Concluding Remarks

- EFPIA believes that it is important that this is inclusive process engaging and aligning all relevant authorities and stakeholders, such as between research sites/HCOs and Ethics Committees
- It would be useful to further clarify the role, scope and ownership of the Q&A
- Will the Q&A be a living document and if so, who will be responsible for maintaining its relevance
- Could EMA consider how to integrate the work on Q&A's with industry–led activities, such as Codes of Conduct
- Would EMA consider a workshop on secondary use?
- How will the EMA connect this initiative to the EU's plans for a European Health Data Space?