EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report from the breakout session 2: Platform for stakeholders' consultation

Learnings Initiative webinar for Optimal Use of Big Data for Regulatory Purpose

30 November 2021

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General remarks

- Stakeholders engagement is critical to allow progress in the area of Real-world data
- Scope of stakeholders to be involved should be broadened, f.e. data providers, health care systems and policy makers
- Need to ensure data is FAIR at source
- Need to reinforce the link between health care systems to facilitate use of data
  - To promote awareness at regional, national and European level "in the context of European data space"
  - Patient organisations have a key role in conveying a message that patients trust and support the use of data
  - When promoting the use of data, there is a need to strike a balance between public health needs and commercial interests

General remarks

- A strong support for policy makers to be involved in the discussion
- Need to resonate beyond the EU regulatory network and to reach society "awareness and communication campaign"
  - Make use of COVID-19 and the increased public awareness of regulatory authorities
  - Position papers could be developed to promote the use of data
  - Need to involve patient organisations and citizens in supporting the use of data

What is experience with existing platforms, are there any gaps?

- Available platforms and mechanism engaging with patients, industry and health care professionals are working well
- However, we need to make them more agile and allow broader and more flexible participation of other stakeholders
  - F.e. the link is missing with routine clinical practice
  - Facilitate interoperability between different European initiatives
  - Ensure that we are able to share learning
  - Platforms to be complemented with stakeholders fora and workshops
  - Need to consider additional channels/tools for regular communication with specific stakeholder groups, e.g. industry
- In addition to high-level guidance, work in a specific disease areas (e.g. pilots, research collaborations)

For which aspects of use of RWE is it critical to consult stakeholders?

- Patient should be consulted about the relevance of the Real-world data
- Any policy development on submission of individual patient level data, including data privacy aspects
- Consideration of all patient relevant outcomes
- The collection of hospital medical data
- More clarity about the appraisal of RWE in the pre- and post-authorisation phase
- Optimization of the ENCePP framework