EU Big Data Stakeholder Forum 2024

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Leveraging data through technology & digitalisation

Social media

- **Easy platform to exchange information/experiences/opinions (e.g.patients groups)**;
  - SM may hold potentially valuable **safety information** in several contexts (e.g detecting undisclosed signals, capturing less frequently reported AE, or detect AE earlier than traditional methods). WEB-RADR IMI project, etc.
  - SM could also detect the **potential for abuse or misuse of certain medications**, **off-label**, evaluate **acceptability and risk perception by patients** (…).

- The **use of SM data in medicines evaluation is not standard practice yet in EU medicines regulation and remains very limited**.
  - The **validity of information** posted requires careful analysis and interpretation (unstructured text, images or videos); **selection bias/representativeness** (DUS)
  - **Volume and complexity of the data**: the development and standardization of more effective and robust mining and processing methods is necessary and is yet to be established.

Need for focused initiatives / proof of concept studies to assess SM's utility across various regulatory applications (e.g. safety/misuse)

M-health

- **Important source of patient health generated data**: capture data that is not available on healthcare databases (claims, emHR, registries, etc.)

  - Potential **advantages of mobile endpoints** : real-time data capture and analytics, less frequent visits (in trials), ability to capture day-to-day variability by collecting data continuously, complement PRO/CRO, more likely to reflect habitual/daily experiences, etc.

- **The role of digital, specifically mobile devices in drug development and regulation, is only expected to grow (product related submissions, interactions with the regulators have been identified regarding discussion on mHealth tools or data) – but not without challenges.**

  - (unknown) **validity** of information and interpretation | substantial **variability** in terms of reporting **completeness**, **terminology**, **variability**, **interoperability** | choice of **relevant and fit-for-purpose digital endpoints**

1) technical expertise requirements/capacity building (building on use cases examples /learnings on the use of mHealth data in EU Medicine Regulation); 2) early dialogue with regulators/qualification procedures (e.g. SAWP) and 3) roadmap/guidance is needed.

Genomic data

- The **Pharmacogenomics and the Real-World Data Specialised Interest Areas (SIA)** of the **Methodology ESEC are now established and will help to share learnings** and **build knowledge amongst regulators**. **Efforts should continue in that direction**.
- **DARWIN EU studies** are being run, this should continue in the future, **by expanding the network's access to more genomic data**. **Learnings should be shared for continuous improvements and acceptance of generated data to support regulatory decision-making**.
- **European Health Data Space (EHDS) will help to access and share more and more data**. **The EHDS should be leveraged to harness the increasing amount of pharmacogenomic information and integrate** it with other sources of data, such as electronic health records.