

HMA EMA Big Data Forum

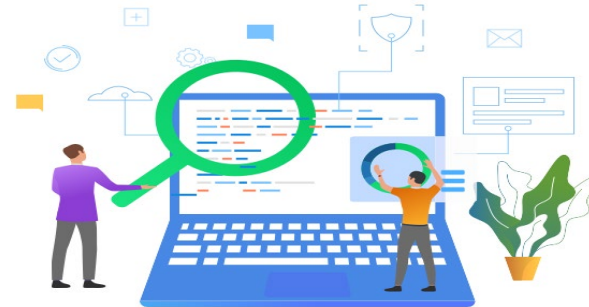
Session 3

Panel Discussion

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General Comments



Limitations to use real world data for generating evidence, include:

- **data quality** (*suitability and validity*), **selection criteria and bias**, so they should be assessed primarily for their informative value and then included in any relevant research project.
- The importance of **protecting patient data is a key consideration** and regulatory mechanisms, should ensure that they are adequately protected and used with a positive impact.
- **Proper training of healthcare professionals** is crucial, to cross check authentic patient experience data (PED) with existing literature resources and guidelines, to achieve optimal use of real world data.
- The fact that **patient-generated digital data are available** in objective and reliable formats, **thanks to novel technologies**, improves **transparency** in collecting procedures, thus increasing the validity and scientific value of PED.

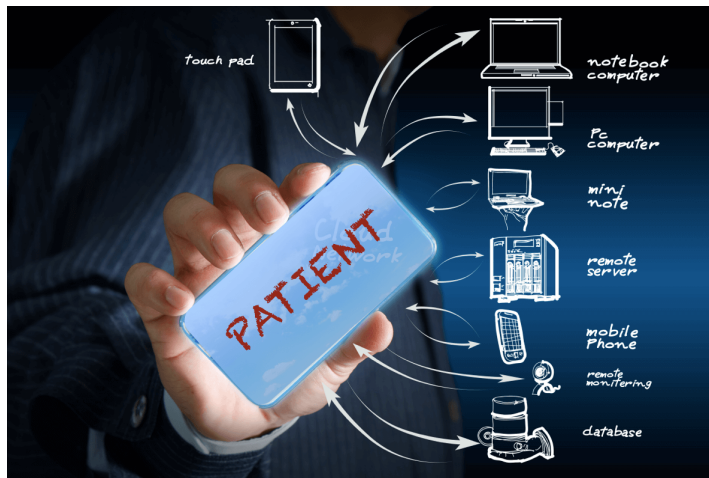


The Role of Healthcare Professionals



- It is a challenge to use **PED from vulnerable populations with minimum inclusion in clinical studies**,
e.g. pediatric patients, pregnant or lactating women
- PED from **Decentralized Clinical Trials and Personalized Medicine Clinical Trials**
- Emerging need to implement an **improved moral code** regarding data sharing, both as stakeholders and as patients' advocates -> **common commitment** can ensure **continued engagement and collaboration** with patients.
- **Education and Training** of patients and their representatives
- **Strong engagement of EAHP** in advancement of patient care with the help of digitalization
- Position Paper
- Continuous professional education and awareness
- Active participation in relative public consultations

Thank you for your attention!



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