



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Real world evidence – what have we learned recently at EMA?

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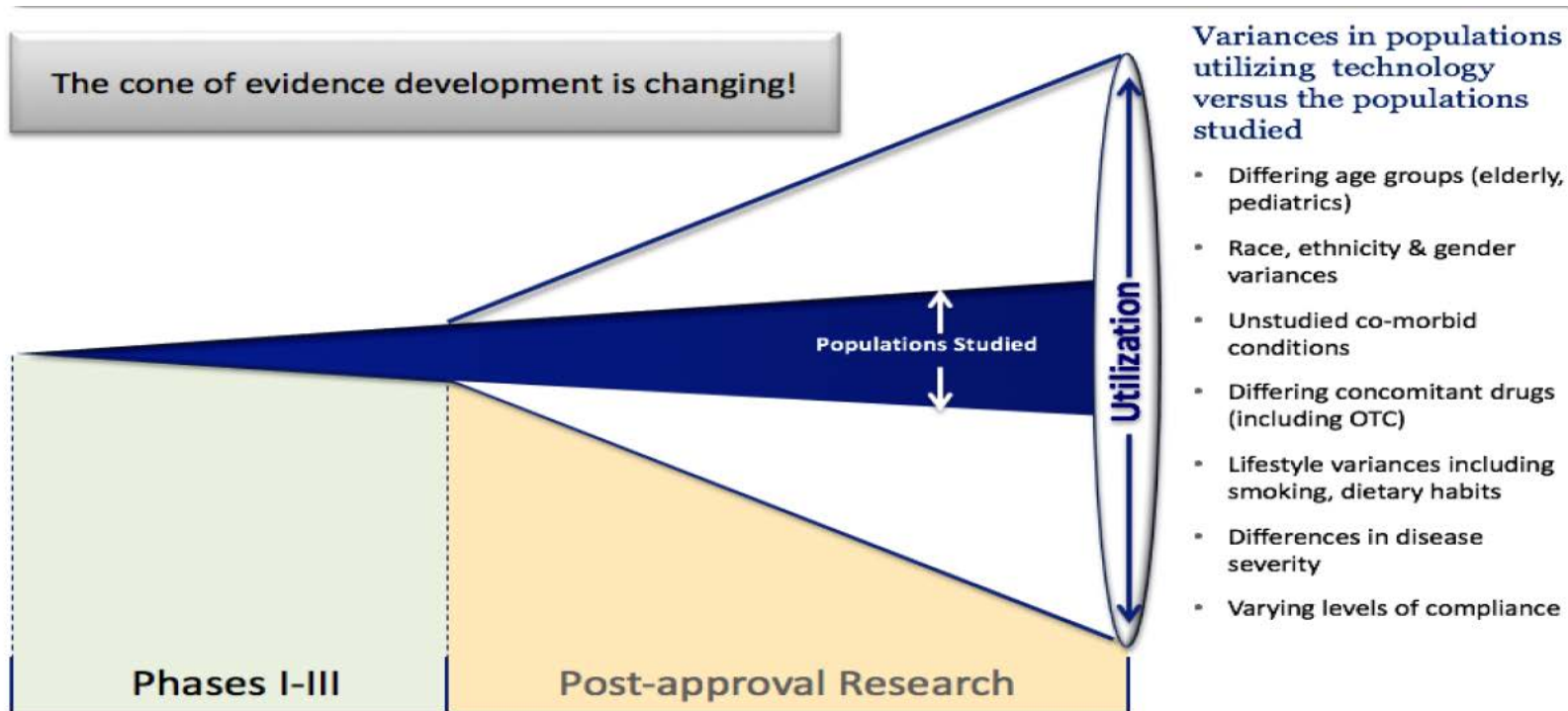




Real World Evidence – reflection points

- Identify points of concern/reflection
- Reflect on how to address the concerns
- Communication to patients and healthcare professionals in a clear and comprehensive manner

Real world evidence





Communication about RWE

- What is “evidence”?
 - How is this defined for different subgroups (patients, professionals, researchers, regulators...)
 - How should this be communicated in the appropriate stakeholders?
 - What are the key messages?
 - Who should be involved in the process and what is the role of EMA?
- What impacts access to data?
 - GDPR regulations
 - National and local guidelines
 - Role of anonymity
 - Storage and security



Establishment of RWE and registries

- Challenges of development of RWE data including provision of informed consent
 - Clear communication with appropriate stakeholder involvement at all stages
- Inclusions of outcomes relevant to patients
 - Collection and analysis of meaningful data
 - Impact on willingness to take part
- Data acquisition
 - Motivation/reward (patient and clinician)
 - Accuracy, quality and point of entry
 - Collected in a “real world” setting (e.g. community or primary care)
- Data protection and custodianship



Use of data for post-marketing follow up

- Identify adverse effects in a larger (non-trial) population
 - Population sub-groups (e.g. compulsive behaviour disorders with Dopamine agonists)
- Links with other data sources to gain a broader overview including cause and long-term follow up
 - Assessment of co-morbidities
 - Use of other anonymised non-disease/treatment specific registries and public data
- Seasonal variations (e.g. allergies)
- Prediction of adverse effects
 - Potential use in future clinical trials



Real World Evidence – reflection points

- What are the key points of concern/reflection for patients and healthcare professionals?
- How can these concerns be addressed?
- How can we communicate about the collection and use of Real World Evidence to patients and healthcare professionals in a clear and comprehensive manner