



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report from the breakout session 4: Training and expertise

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

30 November 2021

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An agency of the European Union





Which learning and skills gaps should be addressed in priority

1. It is clear that people don't know what they don't know. People need to be aware of the methodological skills that are necessary for analyzing Big Data. It is important to boost this basic understanding, and to have the capability to ask the right questions to experts, concerning evidence derived from Big Data.
2. Everyone agreed that we need a common understanding of terminology and definitions. The regulatory network needs to be clear on definitions.
3. Communication regarding the interpretation of the data and the evidence are important aspects here.



Which learning and skills gaps should be addressed in priority 2

1. The EMA is using a step-by-step approach, as it is currently using RWE for drug utilization, incidence, prevalence and pharmacovigilance studies. In the future, this will also include causal studies.
2. Stakeholders welcome the step-by-step approach. We need to investigate which of the methodologies are appropriate and acceptable for the regulators for the initial stages.
3. Regulators need to develop a portfolio of methodologies that would be acceptable in the different phases of the drug development and post-marketing authorization.



Do stakeholders need training from regulators following publication of guidelines published by EMA and the regulatory network?

1. Stakeholders think they need training on new guidelines, but less so on existing ones, for which more experience is available.
2. Learning by doing: It would be valuable to be able to share real cases and the methodology that was used. What worked and what didn't work? For instance, EMA could hold stakeholder meetings, such as those of the EMA Innovation Task Force.



Are you producing training material for your own audience? How could collaborations fulfill training needs?

1. There is a lot of training, but this is mostly internal training that is not openly available or that can be shared.
2. Multi-stakeholder training curricula: Regulatory networks and stakeholders need to collaborate on training in order to come to a common understanding.
3. Keep the dialog open between regulators and stakeholders.
4. Accessibility of training materials being developed is crucial.



Could the training being developed for the EU regulatory network also address the needs of other stakeholders and how?

1. Possibly yes, if there is a multi-stakeholder cooperation for the development of such training. This would include multi-stakeholder meetings on real world examples, in which feedback is generated.
2. The training materials that are being developed are currently not widely accessible.
3. An accessible repository of training materials, that focusses on real world examples would be helpful.