Journal of Pharmacokinetics & Experimental Therapeutics

Principles of causality assessment and sender's comment: everyday challenges and possible solutions

Daniela Di Cosmo
Ferring Pharmaceuticals A/S, Denmark

Assessing the causal relationship between a drug (or IMP) and the adverse event occurred plays a crucial role in the safety reporting flow, and it can be seen sometimes as challenging as it depends on multiple key factors (such as: temporal relationship, pharmaceutical properties of the drug/IMP, knowledge of the event, just to mention some). Counfounding risk factors can be present as well as lack of important information that make more difficult such assessment. What to do in these cases? How our choice impact the results? And what are the challenges in making a decision which should always be be risk-based, reliable and considering what it is already known about the company's products, but also, what is possibly unknown yet.

Daniela Di Cosmo has been working in the Pharmacovigilance field since 2013, firstly in Hospitals in Italy, and then abroad (Czech Republic, UK, Ireland and Denmark), handling all possible tasks in both clinical (all clinical trials' phases) and post-marketing. She has always operated on a global level, yet facing the possible new changes given by local legislations

Pharmacovigilance and regulatory affairs
MedDRA Safety data analysis
SMQs for physician

14th Global Pharmacovigilance And Clinical Trials Summit ,March 16-17,2020 ,Sydney, Australia

Daniela Di Cosmo , principles of causality assessment and sender's comment : everyday challenge and possible solution, Global Pharmacovigilance 2020,March 16-17,2020, Sydney, Australia