

# 4<sup>th</sup> International Conference and Exhibition on Pharmacovigilance & Clinical Trials

August 10-12, 2015 London, UK



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## Intentional medication errors: Off-label use?

To obtain a marketing authorisation (MA), companies are expected to evaluate the safe use of their medicinal product. In the risk management plan, dedicated sections address medication errors and off-label use; two sides of the same coin: the authorized product information guidance is not followed, either inadvertently (in error) or intentionally. Several initiatives are currently taking place to monitor medication errors, e.g. to develop a medication error SMQ; and the EMA has published good practice guides on coding and reporting, and on risk minimization and prevention. The balancing line between product usages that categorizes as medication errors versus off-label use is thin, and may be drawn differently by different MAHs, also depending on the authorized indications for their specific products. How often is it clear from the reported information that the “off-label” administration indeed occurred intentionally? How to code reports where a patient intentionally takes a product for longer than is written in the product information? Also, the same active substance, usually the level on which signal detection activities occur, can be authorised for multiple indications. This means that if signalling activities occur by different stakeholders, different results will be obtained. Finally, where the concept of medication errors includes an unintended error or failure in the drug treatment process, the concept of off-label refers to an intention to not use the product according to the authorised indication. How should this be managed?

## Biography

Angela van der Salm specializes in providing tailor made pharmacovigilance support, including QPPV provision and responsibility for the clients' pharmacovigilance systems. She creates safety data exchange agreements on behalf of her clients, offers database management of patient reports on adverse events related to medicinal product use, gives training on basic and advanced pharmacovigilance, writes periodic reports on the risk-benefit balance of pharmaceutical products by evaluating literature, case reports and all other relevant sources. She also monitors the department for quality and compliance. Her research interests lie with benefit/risk evaluation and risk management, off-label use and medication errors.

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