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## Can the usage of apps support risk minimisation communication and provide real-time feedback on the effectiveness?

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The complete risk profile of a medicinal product can never be known at the beginning at the time of authorization. Therefore, the health authorities in the US and Europe established risk management of the products with the specific goal to mitigate risks associated with the use of a drug. Successful risk mitigation requires adequate communication which might be done via medication guide or patient package insert, patient alert cards or educational material, direct health care professional letters or even videos. Besides a good communication it is also necessary to check if the risk minimization was successful. The current approach of sending out such risk communication via letters or emails or just making it available on websites has the problem that especially health care professionals might mix up such letters with advertisements or are not aware that they need to actively search for this additional information. Also, patients are normally only aware of such information when their physicians informed them about it. To check the successful, timely implementation is even more difficult as market research and questionnaires are not collected on time after distribution with only a limited amount of replies. A possible aid for risk mitigation would be the usage of simple software applications (apps) on mobile devices. The usage of such app can include information management, reference and information gathering and medical education and training and even videos. And in addition, apps can collect and feedback about implementation success and encourage people in active risk management.

### Biography

Anika Staack has completed her Master of Science (Biology) from Marburg University. She is currently working as EU-QPPV for a pharmaceutical company. In total, more than 14 years of experience in drug safety/pharmacovigilance she collected experience with the EU Clinical Trial Directive, introduction of EudraVigilance and GVP modules, especially risk management.

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