Zusammenfassung der Master-Thesis
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Hurdles encountered on the way to implement meta-analytic review in vaccine safety - Development of an integrated safety database

Purpose: To develop a model for vaccine safety analysis and presentation for product registration and product-related documents over the whole life-cycle of the product.

Background: To meet the demand for new approaches in safety data analysis new analytical tools are to be implemented.
As studies usually are underpowered with regard to the detection of adverse events meta-analytic review based on combined data is suggested. However, valid statistical analysis can only be performed based on a well structured safety database, which is a very sensitive part in the whole process.

Methods: All studies with the virosomal hepatitis A vaccine sponsored by the manufacturer were identified and retrospectively entered into an integrated safety database. The risk estimates and 95% confidence intervals from random-effects meta-analysis were compared to the results from simple pooling.

Results: The main challenge for the set-up of the integrated safety database was the harmonization of the data in transferring it into the global integrated safety database. By comparing risk estimates and confidence intervals of
random-effects meta-analysis versus simple pooling it was shown, that simple pooling underestimates risks and conceals heterogeneity.

Conclusion: A standard approach in collecting, evaluating and analysing data over the whole life cycle of a product is of utmost importance to profit from a structured dataset, to have a valid basis for further statistical analysis, to
facilitate the link from pre-market to post-marketing safety data assessment. To get precise risk estimates it is useful to compare results from meta-analysis and simple pooling.