

“VAC2VAC” – contribution of the Paul-Ehrlich-Institut

Project manager

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Project team

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Project summary

VAC2VAC is a wide-ranging collaborative research project funded by IMI2 which aims to develop and validate quality testing approaches for both human and veterinary vaccines using non-animal methods. The Paul-Ehrlich-Institut is a partner in this project.

Current vaccines are mostly complex preparations of biological origin and natural inherent variability. This poses high demands on the control systems used since they should assess the most critical determinants of vaccine quality, safety and efficacy. Due to their respective relevance, in vivo tests are still essential during vaccine development. Likewise, batch testing of licensed vaccines often still relies on animal experiments.

In the context of the ‘consistency approach’, batch testing is based on a set of analytical, animal free methods to generate a product profile. Similarity with a reference batch of proven clinical efficacy and safety justifies batch release.

Test related research at the Paul-Ehrlich-Institut helps to elaborate reproducible and precise in vitro assays to assess and to monitor product quality, efficacy, safety and consistency of production to ensure a favourable benefit-risk balance. It further contributes to a better insight in the quality determining components of medicinal products within the responsibility of the Paul-Ehrlich-Institut.

In the VAC2VAC cooperative project funded by the European Commission within the Innovative Medicines Initiative 2 (IMI2) and launched in 2016, our research focuses on Diphtheria-, Pertussis-, Tetanus- and Leptospira vaccines. The project is performed in close cooperation between Divisions of Microbiology, Veterinary Medicine, and Allergology, the latter providing the Proteomics Core Facility of the Paul-Ehrlich-Institut. Within this alliance of laboratory scientists and experts from the regulatory field PEI takes a leading role within one of the different project consortia.

It is anticipated that the coordinated research within the consortium of 24 international partners will yield additional understanding of vaccine quality, safety and efficacy. This is expected to be beneficial for future vaccine development.

Further information

[IMI](#) – Innovative Medicines Initiative