Tackling the challenge of replacing in vivo test methods for vaccine quality testing

European public and private organisations are collaborating in VAC2VAC, a new project funded by the Innovative Medicines Initiative (IMI2)

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 initiative that started on 1 March 2016 aims to provide the data to support the 'Consistency Approach' for quality control of established vaccines. The current quality control approach for final products relies on in vivo methods.

"VAC2VAC takes into account both vaccine safety and animal welfare", says Prof. Coenraad Hendriksen from Intravacc and Utrecht University, one of the key promoters of the project and the approach behind it. "It will allow us to move away from the traditional paradigm of vaccine batch release testing and to accelerate the introduction of a new paradigm based on innovative non-animal techniques".

The industry representatives on the scientific management team, Catrina Stirling from Zoetis, Sylvie Uhlrich from Sanofi Pasteur, and Denis Lambrigts from GSK, noted the importance and impact of this project. "The VAC2VAC project provides a unique platform to support the transition away from in vivo batch release testing for vaccines. It brings together both the human and veterinary pharmaceutical industry along with academia and regulators, to build a platform for the development, validation and regulatory acceptance of alternative approaches. For industry this is a very positive One Health approach to the challenge of replacement of the long established in vivo test methods and all companies involved are committed to the success of this project".

VAC2VAC is a public-private consortium of twenty partners, involving experts from veterinary and human vaccine industry in a partnership with Official Medicines Control Laboratories, academia, translational research organisations, and vaccinology alliances. To achieve their goal, the project partners will develop,

optimise and evaluate physicochemical and immunochemical methods, cell-based and other assays for routine batch quality, safety and efficacy testing of vaccines. This will be done in collaboration and consultation with regulatory agencies. The ultimate goal of the project is to develop tests and approaches that will allow acceptance of the Consistency Approach for existing vaccines by the regulatory agencies and thereby significantly reducing in the future the use of animals for batch testing in routine vaccine production.

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