

Immunogenicity testing for advanced therapy medicinal products



Non-animal models can be of paramount importance in providing the necessary data for safety assessment of new substances.



Advanced therapy medicinal products (ATMPs) hold the key for new treatments and personalised medicine for rare diseases.



Testing the immunogenicity of ATMPs in animals exposes many limitations of this type of *in vivo* model.



Fundamental biological differences between animal and human immune systems limit the translation of animal immunogenicity testing results to humans.



In vitro and *in silico* immunogenicity assessment assays can positively impact the development of ATMPs and bring more ATMPs to the market and the clinic.



Human-based models for immunogenicity testing of ATMPs offer a wide range of opportunities for innovation.

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FUTURE DEVELOPMENTS AND CHALLENGES TO BE OVERCOME



The development and acceptance of sophisticated non-animal methods will pave the way for the broader use of ATMPs in the clinic.



A more reliable and scalable supply of human immune cells is indispensable to generate human-based immunogenicity testing models.



Further research should be directed towards increasing the number of samples that can be tested in an immunogenicity experiment.



The implementation of more advanced technologies such as 'omics' could generate more information from a test.



Innovative *in silico* models of the immune system should be further developed to drive progress in the field of immunogenicity testing.



A better understanding of the regulatory and scientific challenges that hinder the use of non-animal models in this field is essential to accelerate their implementation.



The development of support platforms with ATMP expertise needs to be strengthened to better advance novel models for specific preclinical safety assessment applications.



Future progress in this area requires defining relevant non-animal models for answering specific scientific questions and pushing for their standardisation.



A continuous dialogue between test developers and relevant stakeholders can help to better define needs and opportunities and accelerate development and application.