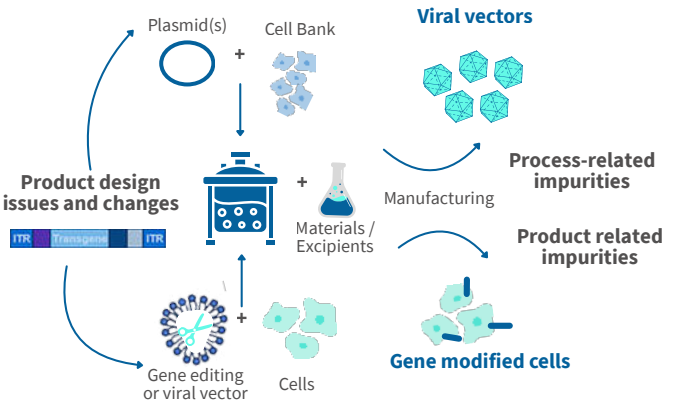
ASPHALION
Knowledge from experience
25 Years

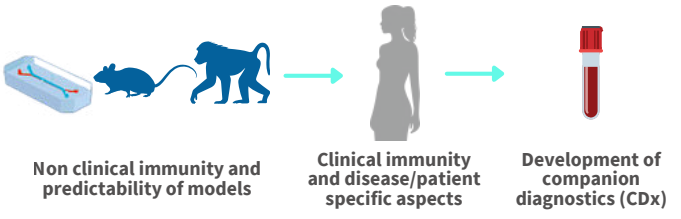
Accelerating Research and Development for Advanced Therapies (ARDAT)

ARDAT

The ARDAT consortium is a collaboration between academia, industry, small/medium enterprises and European Federation of Pharmaceutical Industries and Associations (EFPIA) members whose aim is to develop and provide tools that will advance knowledge in the field of ATMPs and so accelerate the development of new treatments for rare diseases.

As part of ARDAT, Asphalion has worked with partners to evaluate current regulatory requirements for immunogenicity assessment and the use of immunomodulation relevant for the harmonised global development of Gene Therapy Medicinal Products (GTMPs), as featured in a recent article from Cell Reports Medicine entitled "***Current regulatory requirements for assessment of immunogenicity for gene therapy medicinal products***"





Source: Mann, C.J. et al., Current regulatory requirements for assessment of …, Cell Reports Medicine (2025), DOI: 10.1016/j.xcrm.2025.102422, https://doi.org/10.1016/j.xcrm.2025.102422

Highlights of the article include:

- **Product design considerations, and the impact on immunogenicity**
- **Manufacturing processes and their link to potential immunogenicity**
- **Overview of new technologies to predict immune responses to GTMPs**
- **Review of pre-existing and treatment-induced immunity to GTMPs**
- **Recommendations for future regulatory guidance on evaluation of immunogenicity and immunomodulation of ATMPs**

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 945473