ARDAT

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ACCELERATING RESEARCH & DEVELOPMENT FOR ADVANCED THERAPIES

Working towards safe and effective Advanced Therapy Medicinal Products

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Who and what is ARDAT?

The **"Accelerating Research and Development for Advanced Therapies"** or **ARDAT consortium** is a collaboration between academic institutions, micro, small and mediumsized enterprises (SMEs), and European Federation of Pharmaceutical Industries and Association (EFPIA) members. The project started in November 2020 and is due to run until November 2025 and is funded by the Innovative Medicines Initiative (IMI)[1] and EFPIA in kind contributions.

Why was ARDAT created?

Advanced therapy medicinal products (ATMPs) including gene therapy, cell therapy and tissue engineered products represent a major paradigm shift in modern medicine and are currently a field of intense scientific and financial interest. Despite the potential benefits for ATMPs, there are also a number of issues surrounding their use that may limit their potential or slow development and access to patients. Some issues include potential immunogenicity, insertional mutagenesis and oncogenicity, duration of efficacy and long-term follow-up (LTFU), amongst others.

The overall objective of ARDAT is to develop and provide the data and tools to fill gaps in our knowledge-base in the areas of immunology and vector metabolism and to identify areas for regulatory harmonisation in order to accelerate the research and development of ATMPs.

What are the specific objectives of ARDAT?

To meet the challenges slowing development of ATMPs, the ARDAT consortium intends to:

- Develop improved and sustainable model systems, bioanalytical methods and novel reagents for predicting immunogenicity in humans.
- Establish a central and sustainable biobanking infrastructure for patients receiving approved or experimental ATMPs for supporting immunogenicity assessments.
- Explore the clinical factors around pre-existing immunity that can limitsing patient access to advanced therapies.
- Enhance our understanding of AAV gene therapy metabolism inside a range of cell types and explore strategies to mitigate this loss.
- Engage with regulatory authorities and stakeholders, including patient advocacy groups, charities and sponsors to identify areas for regulatory harmonisation.

How to get in touch?

For more information on ARDAT go to:
www.ardat.org
www.twitter.com/AAtmps
www.linkedin.com/company/ardat

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[1] The Innovative Medicines Initiative is a publicprivate partnership funded by taxpayers in the European Union and the pharmaceutical industry. For more information, please visit https://www.imi.europa.eu/about-imi

imi innovative medicines initiative

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