

# Scientific & Regulatory Affairs Support during development of ATMPs & Biologics

We are your scientific and regulatory partner for the development of your innovative products

## Experts in :

Gene therapy, Cell therapy,  
Therapeutic vaccines,  
Antibodies, Tissue  
engineered products,  
Nanoparticles, Biomaterials  
and Biosimilars



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Early discovery



Non-clinical



Clinical



Approval

CMC - Manufacturing

## Regulatory Roadmaps

- Strategic regulatory and scientific assessment by providing CMC, non-clinical and clinical development plans, to bring your product to the patient in the most efficient way
- Feasibility assessment, including overview of development timelines and costs

## Scientific Advice

- Preparation of briefing packages and attendance to the meetings with authorities
- National Competent Authorities (NCAs) in Europe
- EMA: Scientific Advice, Protocol Assistance, Innovation Task Force (ITF)
- FDA: INTERACT, Pre- BLA/NDA, PRE-IND, EOP2

## Orphan Drug Designation

- Management of Orphan Drug Designation (ODD) procedure including presubmission
- Preparation of ODD applications including significant benefit, prevalence calculation and medical plausibility
- Experience with both EMA and FDA

## Clinical Trials

- Preparation of Investigational Medicinal Product Design (IMPD) and Investigator's Brochure (IB)
- Clinical Trial Application (CTA) submission in EU
- Adhoc support during Clinical Trial conduction
- IND Preparation and Submission

## ATMP Specific Services

- CMC consultancy
- Preclinical and clinical regulatory advice
- GMO Submissions
- ATMP classification and certification
- Long-term project management and consulting with investigator groups and biotech companies

## Regulatory Tools

- Classification of your company as SME (Small Medium Enterprise)
- Priority Medicines (PRIME) and accelerated assessment
- Qualification of novel methodologies
- Paediatric Investigation Plan (PIP) and Pediatric Study Plans (PSPs)

## ATMP and biologic product expertise

Oncolytic viruses · Adeno-associated virus (AAV) · Modified Vaccinia Virus (MVA) · Plasmids · Lentivirus · Adenovirus (AdV) · CAR-T · Mesenchymal stem cells · Bone marrow-derived hematopoietic stem cells · Adipose-derived stem cells · Aptamers · Antibodies · Biologics · Vaccines · Personalised medicine · Tissue engineered products · Dendritic Cells (DCs)