Ask the right questions...
... make the right choices

www.ndareg.com
Service Overview

NDA has a dedicated team of experts who understand Advanced Therapy Medicinal Products, and what is needed to get them approved and ready for market.

The NDA team has experience in a wide range of gene therapy, somatic cell therapy and tissue engineered products. The NDA team is directly involved in emerging therapeutic modalities, for example T-cells modified with Chimeric Antigen Receptors and pluripotent stem cells.

The NDA team will provide expert critical input and assessment of alternative routes for product development using a stage-gate approach resulting in:

- Increased efficiency during development
- Clear establishment of acceptable product profile and provide support to mitigate any challenges/gaps
- Consistent, clear product messages and identification of supporting data
- Early assessment of benefit/risk which is developed through life cycle
- Save time and money and increase value of product

We can guide you through the complete ATMP development programme, from non-clinical studies, through to authorisation. We can help with all or just part of the process.

Whether you are looking for targeted ATMP scientific support and advice to reach a global market, or general support, here is how we have helped other clients:

- Preparation of development plans for all types of ATMP molecules
- Definition of target product quality profile
- Manufacturing process control, characterisation studies, choice of analytical and bioanalytical methods, method validation, including bioassays
- Non-clinical and clinical study design to support a global registration strategy
- Preparation of submission documentation and responses to agency questions
- Preparation of Risk Management Plans for cell therapy products
- Development of a pharmacovigilance quality management system to meet CHMP and FDA requirements
Getting the Strategy Right

Our integrated team of specialists has hands-on understanding of how to best develop your strategy. This includes:

- Lead candidate selection stage onwards
- Regulatory and technical expertise
- Diverse range of ATMPs including gene therapies, cell therapies (autologous and allogeneic) and tissue engineered products
- Multi-disciplinary, integrated team-based approach
- Output peer-reviewed by industry experts and former regulators

How can NDA support you?

- Strategic expertise to enhance your team
- Skilfully map out development opportunities
- Assess risks during development
- Provide risk mitigation and management planning support
- Determine clear path forward to add value to your product

“Vitally important to us was NDA’s expertise and knowledge in cell therapies, which on top of their ability to deliver on time and on budget, contributed to our successful clinical trials now underway in Europe.”

Deborah Ladenheim, former VP Regulatory Affairs - Athersys Inc.

“Selecting product candidates with the highest probability of success and applying rigorous risk-based management in development maximises the value of biopharmaceutical products and increases speed to the clinic and registration.”

NDA is the ideal strategic partner in this process.
A selection of our Experts

Niamh Kinsella  
CMC and Regulatory Expert  
Specialises in CMC and regulatory aspects of the development of ATMPs.

Paula Salmikangas  
ATMP Expert  
Former chair of EMA Committee for Advanced Therapies and specialises in the development of ATMPs.

Steffen Thirstrup  
Clinical Expert  
Former member of CHMP and CAT. Specialises in clinical development and regulatory strategies.

Jenny Sims  
Non-clinical Expert  
Former Non-Clinical Assessor for MHRA, UK and specialises in non-clinical safety strategies for ATMPs.

Beatriz Silva-Lima  
Non-clinical Expert  
Former Non-Clinical Assessor for Infarmed, Portugal and specialises in non-clinical strategies for the development of ATMPs.

Paul Chamberlain  
Biopharmaceuticals and Immunogenicity Expert  
Specialises in understanding structure-activity-immunogenicity relationships for effective selection and development of ATMPs.

Josefin-Beate Holz  
Clinical Expert  
Specialises in translational medicine (First-into-Man) and accelerated development to Clinical Proof-of-Concept.

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