A selection of our Experts

Niamh Kinsella
CMC and Regulatory Expert

Specialises in CMC and regulatory aspects of the development of biological products, including recombinant proteins, monoclonal antibodies, vaccines and advanced therapy medicinal products.

Paula Salmikangos
ATMP Expert

Former chair of EMA Committee for Advanced Therapies and specialises in the development of ATMPs.

Paul Chamberlain
Biopharmaceuticals and Immunogenicity Expert

Specialises in understanding structure-activity-immunogenicity relationships for effective selection and development of therapeutic proteins and advanced therapy medicinal products.

Jenny Sims
Non-clinical Expert

Specialises in non-clinical safety strategies for chemical, biological & advanced therapies, mechanistic safety, juvenile animal study design and interpretation.

Josefin-Beate Holz
Clinical Expert

Specialises in translational medicine (First-into-Man) and accelerated development to Clinical Proof-of-Concept of NBEs and NCEs.

Translational Science

Translation is the process of turning observations in the laboratory into products that improve the health of individuals and the public. Researchers across the globe face common barriers in translational research that can delay the development of new interventions for patients in need.

We can help you save time and money and increase the value of your product by using a stage-gate approach:

- Opportunity Analysis
- Lead candidate selection
- Developability
- Translational Strategy
- IND-enabling Safety Studies
- First-Time-in-Human
- Clinical Proof-of-Concept

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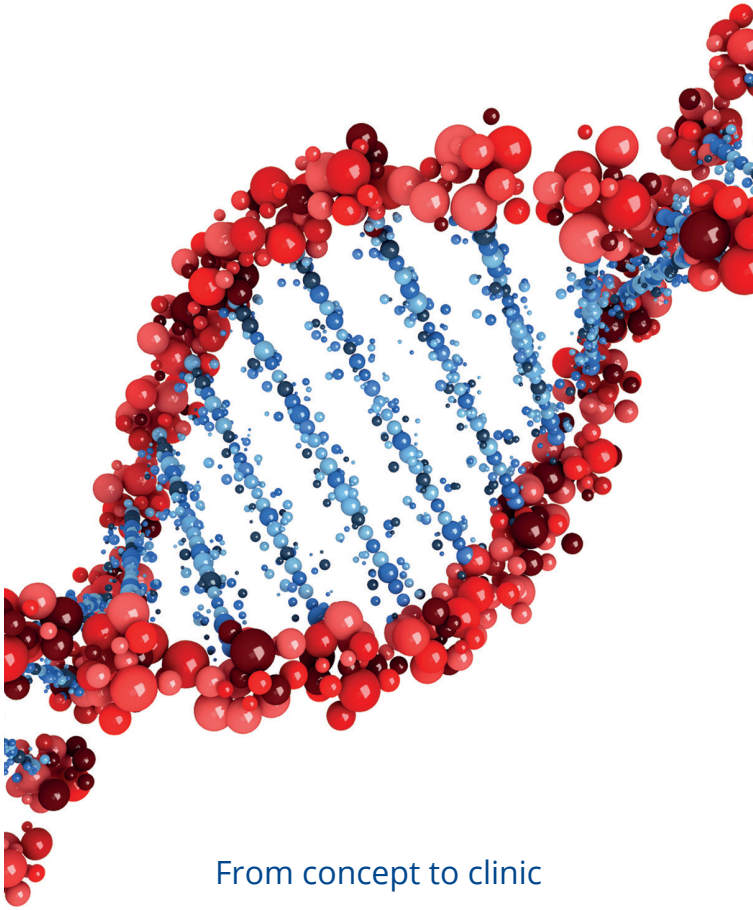
NDA

Translational Science



From concept to clinic

Translational Science

Our experts will provide tailored drug development advice to meet the regulatory requirements and expectations for both the EU and the US, thus ensuring speed to the clinic and increasing the value of the product.

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

- Increased efficiency due to the identification of common (core) requirements, resulting in a core dossier for the EU and US
- Clear establishment of acceptable product profile and 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

The Stage-Gate Approach

Opportunity Analysis	Commercial viability of proposed target & indication?
Lead candidate selection	Which molecular format is optimal?
Developability	Adequate quality and productivity achieved?
Translational Strategy	Dose- and concentration-response relationships?
IND-enabling Safety Studies	All pertinent risks evaluated in relevant models?
First-Time-in-Human	Positive benefit-to-risk for administration to humans?
Clinical Proof-of-Concept	Evidence of therapeutic effect in target population?

NDA Takes You from Idea to Value

Our expert team can help you develop your business plan and can support you by evaluating your financing requirements (scenarios, costs, etc).

We can be your strategic partner and can help you:

- Lay out your product development road-map
- Examine assets, resources and perform gap analysis
- Map competencies
- Plan development from value proposition to end-customer
- Chart work-packages (discovery, development, commercial)
- Define resource requirements
- Save time and money and increase value of product

We will help you to define input data to inform decisions at critical stages to prioritise your development activities in order to add commercial value and minimise regulatory risk, to stratify the incremental investment in adaptable pathways and to define multi-disciplinary inter-dependencies in order to coordinate project management and inform decision making.

"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.

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 biopharmaceuticals and vaccines, from peptides through proteins to cell therapies
- 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

"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.

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