

# Advancing oligonucleotide therapeutics with cutting-edge bioanalytics

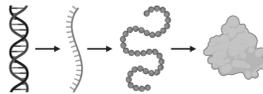
How valuable is your therapeutic development time? Our short lead times, flexible attitude and customized solutions provide you with high quality bioanalytical data in a time and cost-effective manner. Our scientists are client focused, flexible and use their extensive technical and regulatory expertise on to your advantage. We support:

## PK measurements



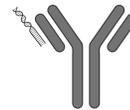
- Preclinical discovery
- Preclinical GLP compliant
- Clinical GCP compliant

## PD / biomarker



- Regulated analysis
- Exploratory analysis

## Immunogenicity assessment



- Risk based approach
- FDA & EMA guidelines

We can perform your assays on several platforms:

## PK measurements

- qPCR
- Hybr ELISA
- LC-MS/MS

## PD / biomarker

- qPCR
- ELISA
- LC-MS/MS
- Flow Cytometry

## Immunogenicity assessment

- ELISA
- Mesoscale Discovery

## Oligonucleotide Therapeutics: an Integrated Approach

In the past decade, novel oligonucleotide therapeutics have been developed and gene modulating therapies become increasingly important. Ardena has a strong track record of supporting oligonucleotide programs with bioanalytics and understands the unusual CMC regulatory situation.

In an integrated approach, Ardena's expert teams accelerate your oligonucleotide project from discovery to clinic and smoothly guide you through the complex CMC regulatory landscape.

### Nanomedicines

Wide range of nanoparticles: lipid-based nanoparticles (LNPs, liposomes and lipid micelles), polymeric nanoparticles and metal/metal oxide nanoparticles.

Synthesis of building blocks  
Process and scale up development  
Analytical method development & validation  
GMP manufacturing and release testing

Aseptic fill and finish  
ICH stability studies  
Clinical labelling and supply

### CMC Regulatory Support

Extensive experience  
Regulatory support in an unusual landscape  
IMPD/IND authoring  
Nitrosamine risk assessment  
CMC report writing

### Bioanalysis

PK measurements  
PD / biomarkers  
Immunogenicity assessment  
Pre-clinical discovery to clinical GCP  
ICH M10, FDA & EMA guidelines