



OLIGONUCLEOTIDE THERAPEUTICS APPROVALS & QPS MILESTONES

CELEBRATING
QPS 
 CUSTOM-BUILT RESEARCH™
30 YEARS OF EXCELLENCE

QPS

2003

Oligonucleotides PK via LC-MS/MS

2006

CLIA Assay - Inclusion/Exclusion Criteria

Biomarkers - Primary End-point

2007

Oligonucleotides PK via Hybridization-ELISA

1998

ASO Vitravene™ (fomivirsen)

2004

Aptamer Macugen® (pegaptanib)

KEY

BIOANALYSIS

ADME

OLIGONUCLEOTIDE THERAPEUTICS APPROVALS



2009

Oligonucleotides PK via Hybridization-LC-FLD

Oligonucleotides PK via LC-UV

2010

LNP *in vitro* Protein Binding

LNP *in vitro* Metabolic Stability

LNP Reaction Phenotyping

LNP Metabolite Identification

LNP *in vitro* CYP Inhibition

2010

LNP *in vitro* CYP Induction

Oligonucleotides Biodistribution via Autoradiography

Oligonucleotides *in vitro* Metabolic Stability

Oligonucleotides Reaction Phenotyping

Oligonucleotides Metabolite Identification

Oligonucleotides *in vitro* CYP Inhibition

2011

Oligonucleotides Biodistribution via QWBA

Oligonucleotides Mass Balance/Excretion

2012

Oligonucleotides Biodistribution via Microautoradiography

2013

Oligonucleotides (ASO, siRNA, miRNA) ADA

Oligonucleotides *in vitro* CYP Induction

2013

ASO Kynamro® (mipomersen)

2018

siRNA Onpattro® (patisiran)

ASO Tegsedi® (inotersen)

2014

Oligonucleotides PK via LC-HRMS

Oligonucleotides *in vitro* Protein Binding

2015

Oligonucleotides *in vitro* Reaction Phenotyping

2016

Oligonucleotides *in vitro* Drug Transport

2016

Polydisperse Natural Oligonucleotides Defitelio® (defibrotide)

ASO Spinraza® (nusinersen)

ASO Exondys 51® (eteplirsen)

2018

siRNA Onpattro® (patisiran)

ASO Tegsedi® (inotersen)

2019

siRNA Givlaari® (givosiran)

ASO Waylivra® (volanesorsen)

ASO Vyondys 53™ (golodirsen)

2020

ASO Viltipso® (viltolarsen)

siRNA Oxlumo® (lumasiran)

2021

ASO Amondys 45™ (casimersen)

siRNA Leqvio® (inclisiran)

2022

siRNA Amvuttra® (vutrisiran)

2021

AOC/POC PK via Immunocapture LC-MS/MS

AOC/POC PK via LBA

AOC/POC ADA via LBA

2023

ASO Qalsody™ (tofersen)

Aptamer Izervay™ (avacincaptad pegol)

siRNA Rivfloza™ (nedosiran)

ASO Wainua™ (eplontersen)

2024

ASO Tryngolza™ (olezarsen)

2025

siRNA Qfitlia™ (fitusiran)

ASO Dawnzera™ (donidalorsen)

2025

Oligonucleotides PK via Hybridization-LC-MS/MS

Downstream Protein Quantitation via Immunocapture LC-MS/MS

Immunophenotyping via Flow Cytometry

Cellular Immunogenicity via Flow Cytometry

Cellular Immunogenicity via ELISpot