SYNGENIS
CLINICAL

A SPECIALIST CLINICAL RESEARCH CRO

The Contract Research Organisation built for RNA and DNA medicine

A NEW FRONTIER IN MEDICINE NEEDS A NEW KIND OF CRO

A CRO Purpose-built for Nucleic Acid Therapeutics and Diagnostics

We provide bespoke, end-to-end clinical research services exclusively for the development of RNA and DNA oligonucleotide therapeutics and diagnostics, namely antisense oligonucleotides (ASOs), siRNA, microRNA and antimiR constructs, guide RNA, aptamers, PMOs and other functional nucleic acid modalities.

Nucleic acid medicine is one of the fastest growing frontiers in healthcare, yet it remains one of the least well served by the clinical research industry. Most CROs are generalists that spread their expertise across every therapeutic category. Syngenis Clinical is built specifically to close that gap.

As an oligonucleotide manufacturer with decades of collective industry experience behind us, we understand these molecules from the sequence up. It makes sense that the organisation which can synthesise, validate and characterise your candidate can also run the clinical program that takes it to patients.

DEEP NUCLEIC ACID SCIENCE, NOT GENERALIST COVERAGE

Our Difference

The value a CRO brings to a nucleic acid program depends on how well it understands the modality. Oligonucleotides behave unlike small molecules and unlike biologics. A CRO that treats a nucleic acid therapeutic or diagnostic like any other introduces delay and risk. Syngenis Clinical does not.

Positioning Axis	Generalist/Large CROs	SYNGENIS CLINICAL
Modality focus	All therapeutic areas, oligonucleotides one of many	**Exclusively RNA and DNA oligonucleotide therapeutics and diagnostics**
Scientific depth	Clinical operations expertise, limited molecular insight	**Sequence-level understanding from a working oligonucleotide manufacturer**
Manufacture link	Coordinated through third-party suppliers	**In-house GLP synthesis, GMP scaling and analytical characterisation under one roof**
Trial design	Standardised across modalities	**Nucleic acid specific PK, PD, biomarker and endpoint strategy**
AI capability	Emerging, generalist	**Integrated AI and in silico methods matched to nucleic acid programs**

THE ADVANTAGE OF A SINGLE SCIENTIFIC PARTNER

Synthesis, Characterisation, Trial Design and Clinical Delivery

Because Syngenis manufactures and characterises the material it studies, sponsors avoid the fragmentation, revalidation and intellectual property exposure that arise when discovery, manufacture and clinical development sit with different providers. The same team that understands your chemistry helps design the trial, guiding it from investigational material through to a regulator-ready clinical study report.

1 Design
In silico sequence and target design

2 Synthesis
In-house GLP and GMP oligonucleotide manufacture

3 Characterisation
Analytical release and CMC

4 Trial Design
Nucleic acid PK, PD, biomarkers and endpoints

5 Clinical Delivery
Operations, safety, data and biometrics

6 Reporting
Database lock, analysis and regulator-ready CSR

INVESTIGATION → ONE SCIENTIFIC PARTNER, ONE CHAIN OF CUSTODY → CLINICAL REPORT

FROM FIRST TRIAL DESIGN TO FINAL CLINICAL STUDY REPORT

Full CRO Services

From full trial design through to complete project management, our experienced team provides end-to-end solutions across every phase of clinical development. We are conversant with TGA, FDA and EMA requirements for clinical reporting and data integrity, factors that are critical to the development of investigational medicinal products (IMP). For each study we customise a project blueprint for optimal results.

Core Clinical Services

Trial Design

From initial concept to study protocol, participant informed consent forms (PICFs), core trial documents, Investigator Site Files and initial regulatory submissions.

Safety Monitoring

SAE reporting systems, Safety Review Committee, DSMB, DMC or DMEC set-up, and support with local and regulatory authority safety reporting.

Study Start-Up

Project and operational plans, kick-off and site activation, investigator meetings, CRA and site training, and electronic trial master file (eTMF) build.

Study Team Set-Up

Vendor identification, selection and ongoing management, so the right vendor is engaged at the right price, on budget and on time.

Data and Biometrics

Data management, biostatistics and statistical analysis, EDC validation, database design through to lock, and statistical programming including SDTM, ADaM and pharmacokinetics.

Operations and Logistics

Central pharmacy management, central laboratory and imaging coordination, and site and study management from start-up through recruitment, treatment, follow-up and close-out via dedicated CRAs.

Clinical Study Report

All study findings brought together in a final report aligned with regulatory expectations, supported by tailored, ongoing client communication throughout.

AI and In-Silico Trial Capability

We are progressively incorporating AI into our CRO design and trial programs. We are building selective in silico capability, including virtual patient modelling and synthetic control arm approaches. AI supports our science; it does not replace the rigour and regulatory discipline behind it.

THE AUSTRALIAN ADVANTAGE

Why run your nucleic acid trial in Australia?

Talk to us and we will show you how your program can benefit from:

Rapid trial start-up	**An ethnically diverse population**
A world-class health system	**Onshore, sovereign IMP supply from Syngenis**
A streamlined regulatory process	**Generous R&D Tax Incentive support**

Individually, each of these advantages strengthens the case for Australia. Taken together, they make it one of the most attractive destinations in the world for nucleic acid clinical development, combining speed, scientific quality and secure onshore supply from Syngenis. Yet perhaps the most compelling advantage of all is financial, and it is one we help sponsors capture in full.

THE R&D TAX INCENTIVE ADVANTAGE

Up to 43.5% of Eligible R&D Spend, as a Refundable Cash Offset

One of the most compelling reasons to run a nucleic acid trial in Australia is the Federal Government's Research and Development Tax Incentive (R&DTI), one of the most generous innovation programs in the world. Syngenis Clinical does more than make sponsors aware of it. We help establish the eligible structure, set up the R&D activity registration, manage the program across the trial, and handle the compliance and contemporaneous documentation that a robust claim requires.

R&DTI figures are current for the 2025-26 and 2026-27 income years and are provided as general information, not tax advice. Eligibility and outcomes depend on individual circumstances.

A SPECIALIST PROPOSITION IN A GENERALIST INDUSTRY

The Specialist CRO that Unites Deep Nucleic Acid Science with Clinical-stage Trial Delivery

Syngenis Clinical offers sequence-level expertise, in-house manufacture and characterisation, and a single scientific partner from investigational material to clinical study report.

SYNGENIS LABS LTD

AN INTEGRATED LIFE SCIENCES COMPANY

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