



# We Help RNA Therapeutics Get Into the Clinic – **Faster**

Integrated LNP formulation and sterile fill-finish  
under **one GMP system**



Faster  
timelines



Lower tech  
transfer risk



Single-site  
GMP execution

## The Execution Gap

### Why Small Clinical Supply Slips



#### Deprioritized

Small batches get pushed aside behind larger, commercial priorities.



#### Constrained

Specialised manufacturing capacity is limited and disruption-sensitive



#### Delayed

Each handoff adds time and risk to your critical path.

“

*Clinical timelines don't fail on science – they fail on execution.*

*We are built specifically, to remove this risk.*

”

# Our Identity

**Agile Operating Model** – How we deliver speed, integration, and fit in practice.

**We do what larger CDMOs are not built to do -  
execute small, complex clinical programs with **speed**, **integration**, and **precision**.**



## AGILE

Fast onboarding → faster path to clinic

- ✓ Project kickoff in weeks, not months
- ✓ Rapid decision making, dedicated teams



## INTEGRATED

One site → fewer handoffs, less risk

- ✓ LNP formulation through to sterile fill in one location location
- ✓ Small molecule drug substance through to finished dose finished dose form
- ✓ Highest quality standards



## FOCUSED

Positioned for small, complex clinical programs

- ✓ Phase I/II optimized batch sizes
- ✓ Positioned for small, complex programs
- ✓ Less manufacturing constraints



### Faster Timelines

Get to clinic faster



### Lower Risk

Fewer handoffs. Greater control



### Right-Sized Execution

Exactly what your program needs

*"You're not too small for us – you're exactly the right fit."*

# Advanced Therapies Track Record

Proven Clinical Execution in mRNA vaccines

24+

Clinical mRNA Programs Released

Proven Execution

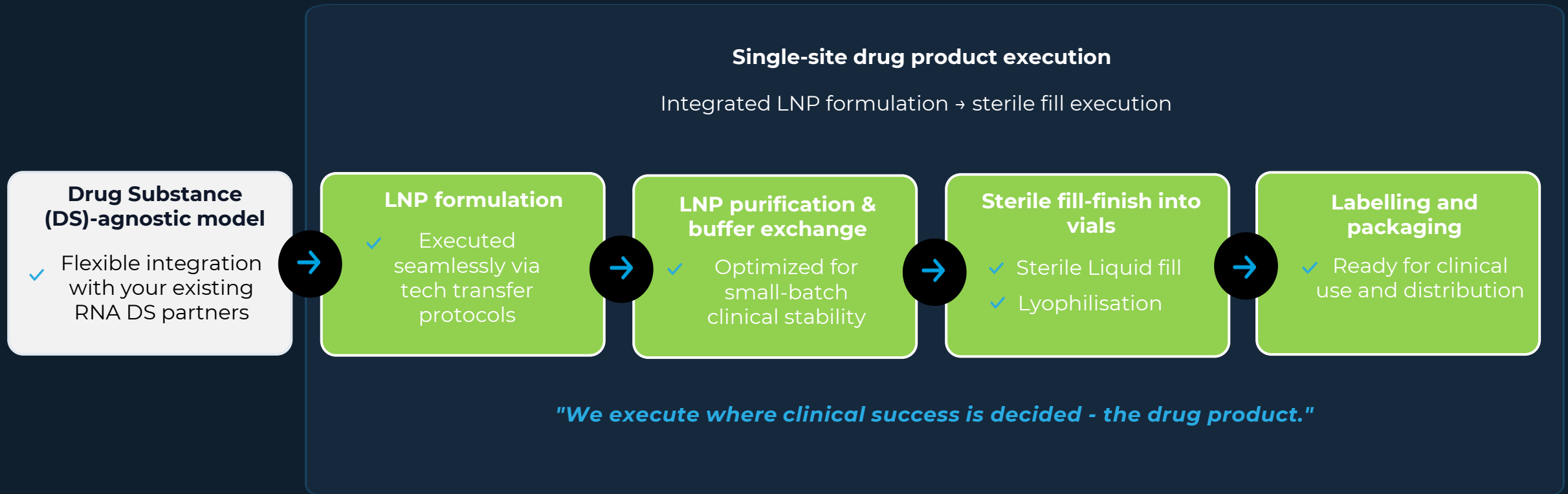
Trusted by global partners

Educational | Emerging | Global



# Where mRNA Drug Product Comes Together

Integrated mRNA LNP Formulation and Sterile Fill Finish



# Sterile Execution at Clinical Scale

## Technical Specifications



### Fill Volume

Versatile Capability

Precision sterile fill-finish operations accommodating a broad range of clinical specifications and formats.

2-100ml vials, cartridges, and syringes



### Lyophilisation

Freeze-Drying Capacity

Robust lyophilisation execution

Lyophiliser shelf area: 2.7m<sup>2</sup>

3,000-4,000 vials per cycle depending on format

Optimised for clinical-scale lyophilisation



### Throughput

Agile Turnaround

Clinical scale throughput explicitly designed to eliminate roadblocks and accelerate your path to FIH.



### Experience

Proven Track Record

**20+ Years**

**6+ Years in RNA**

Deep operational expertise in navigating complex sterile fill-finish and lyophilisation processes.

# More than RNA - Built for Complex Therapies

Integrated Small Molecule Manufacture



## Small Molecule API

Complex, potent compounds with specialized handling handling

- ✓ Complex synthesis and purification
- ✓ High containment for potent compounds
- ✓ Schedule 8/9 licensure



## Specialty Orals

Custom formulation development

- ✓ Capsules, tablets, non-sterile liquids
- ✓ Phase appropriate formulations
- ✓ Custom formulation development



## Sterile Injectables

Clinical-scale sterile fill-finish

- ✓ Aseptic vial filling
- ✓ Cartridges and syringes
- ✓ Lyophilisation



## Radiopharmaceuticals

Specialized handling for clinical radiopharmaceuticals

- ✓ Specialized handling
- ✓ Regulatory compliance
- ✓ Clinical-scale capability



## Analytical Services

Integrated QC, microbiology, and release testing

- ✓ Integrated QC testing
- ✓ Microbiology services
- ✓ ICH stability testing



## Additional Services

Supporting services for complex therapies





- ✓ Regulatory support
- ✓ Project management

# Partnership Model

## Where We Fit in Your Model







### Corporate Partner GLOBAL PHARMA


-  Extend capacity & reduce bottlenecks
-  Overflow when internal capacity is constrained
-  Faster execution for early clinical programs
-  Regional sterile fill-finish capability



### Innovator Partner BIOTECH

-  Get to First-In-Human (FIH) faster - with less risk
-  Right-sized batches precisely for Phase I/II
-  Integrated sequence: LNP formulation → Sterile Fill
-  Reduced tech transfer complexity and friction

Every month saved = capital preserved

"We integrate into your model - **we don't compete with it** 



# Get to FIH Faster - from Australia



## SPEED

### Start your trial months earlier

Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) pathways enable fast clinical trial start



## COST

### R&D Tax Rebate **43.5%**

Significant financial incentive dramatically lowering the total cost of clinical development.



## SECURITY

### Trusted **Jurisdiction**

Secure operational environment protecting your IP and clinical supply chain to entirely de-risk your program.



## QUALITY

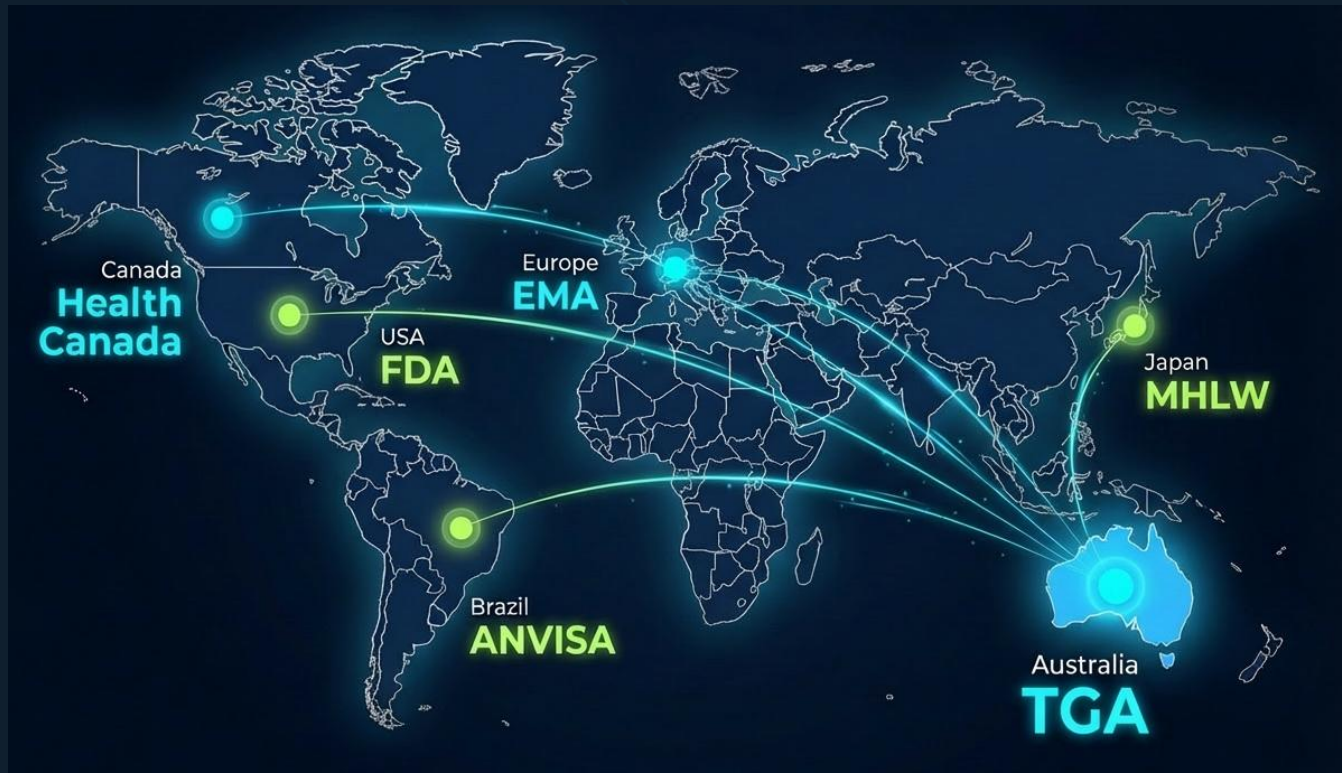
### Regulatory Accreditations: TGA FDA EMA MHLW ANVISA **GMP Compliant**

Stringent regulatory standards recognised seamlessly across major global markets - zero compromise.

Faster Start | Lower Cost | Reduced Risk

# Global Regulatory Accreditation

Quality you can trust



And APVMA for Veterinary  
(Australia)



TGA GMP certified



Globally recognised standards



Trusted by international partners



Full analytical/microbiology/ICH stability support



One quality system

# Strategic **Timing** - Why IDT Australia, Why Now

🕒 The convergence of three critical factors makes this the optimal time for your clinical program



## Post-Pandemic mRNA Infrastructure

Leverage globally proven, clinical-ready, and highly agile capabilities expressly built for advanced modalities.



## Complex Therapy Pipeline Growing

As novel therapies expand, Phase I/II supply needs are surging well beyond legacy CDMO capacities.



## Speed is Capital

In today's environment, every month saved equals a lower burn rate and a faster path to critical milestones.

For early-stage biotechs featured in [Fierce Biotech's ecosystem](#), IDT Australia offers a clinical manufacturing partner built for your stage.

 Ready to partner



# Get Your Program Into Clinic - **Faster.**

 Your Agile Clinical GMP CDMO



## **mRNA LNP Formulation**

Integrated mRNA LNP  
formulation (tech transfer  
ready)



## **Sterile Fill-Finish**

Aseptic vial filling and sterile  
manufacturing capabilities



## **Complex Small Molecules**

Complex synthesis and  
purification for potent  
compounds



## **Capsules, Tablets & Non-Sterile**

Custom formulation  
development for oral delivery



## **Radiopharmaceuticals**

Specialized handling for  
clinical radiopharmaceuticals

 **Faster Timelines | Lower Risk | Right-Sized Execution**

# Let's Talk



 Trusted by global partners. Ready for your next program.



## Website

Visit our website for more information about our services and capabilities.

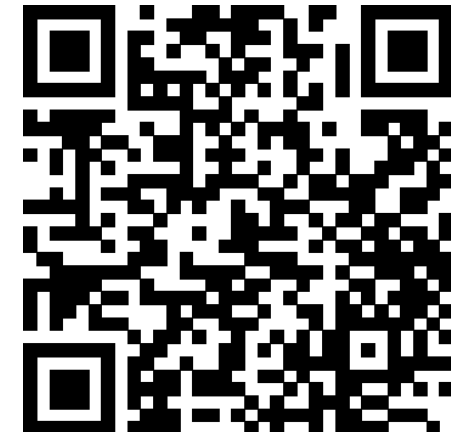
<https://idtaus.com.au> 



## Contact

Reach out to **Mike Thompson** for inquiries and partnership discussions.

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## Pitch Deck



Ready to **accelerate** your clinical program?

[Get Started →](#)