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# TrialKey

Powered by **Opyl**

## Data-Driven Biostatistical Validation for Biotech Investments



Saurabh Jain  
Executive Chairman



ASX: OPL



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**FREE DEMO**

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# The Opportunity



Annually US\$80B is invested in **65,000+ trials** across an average **5,500 companies** annually with 90% failing, mainly due to poor trial design.



In Australia, there are over 1,200 pharmaceutical and medtech companies, 55 medical research institutes, 40 universities focused on clinical research, and 50 clinical trial networks offering Phase I – IV so **lots of opportunities for TrialKey**.



TrialKey's AI-driven analysis of 1,300+ variables, combined with biostatistical validation, predicts trial success with **92%+ accuracy** and delivers better trial designs.



If TrialKey were to provide a report for each pharmaceutical and biopharma company at \$5,000 AUD per report, the **total addressable market is \$328.745M**.

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# Challenges of Human-Led Trial Design and Systematic Reviews



**Finite number**



**Factors overlooked**

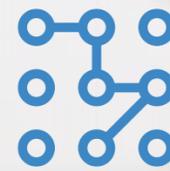


**Time-consuming and prone to bias**

# Optimising Trial Design with Large Data Sets



**AI processes thousands of clinical studies**



**Uncovers underlying patterns**



**Optimises critical elements**

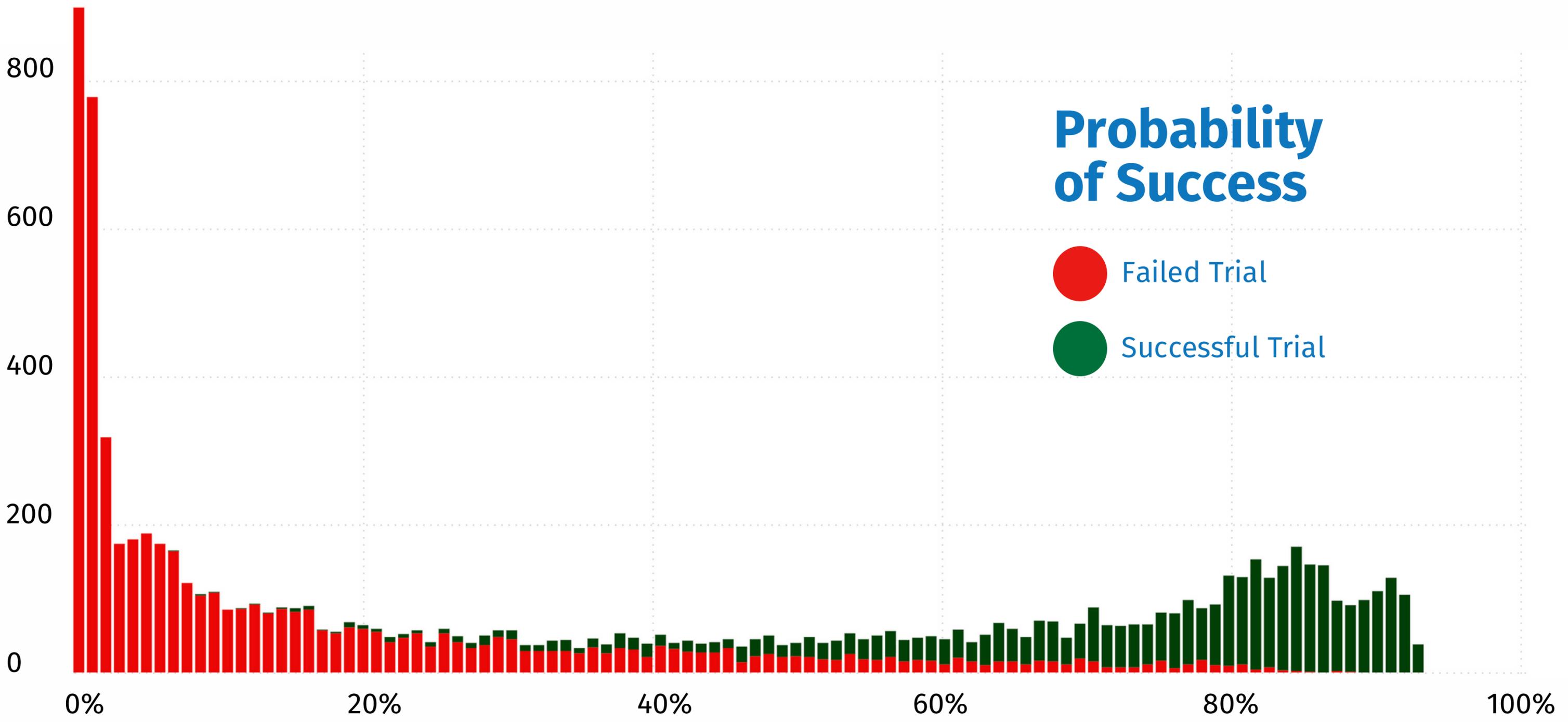


**Law of averages**



**Marginal impact of each variable**

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TrialKey's **biostatistical validation** and advanced simulator **designs, simulates and optimise** clinical trial designs.



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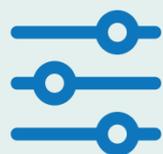
# Our vision

To be the gold standard platform for clinical trial design optimisation and prediction worldwide.

## TrialKey Services



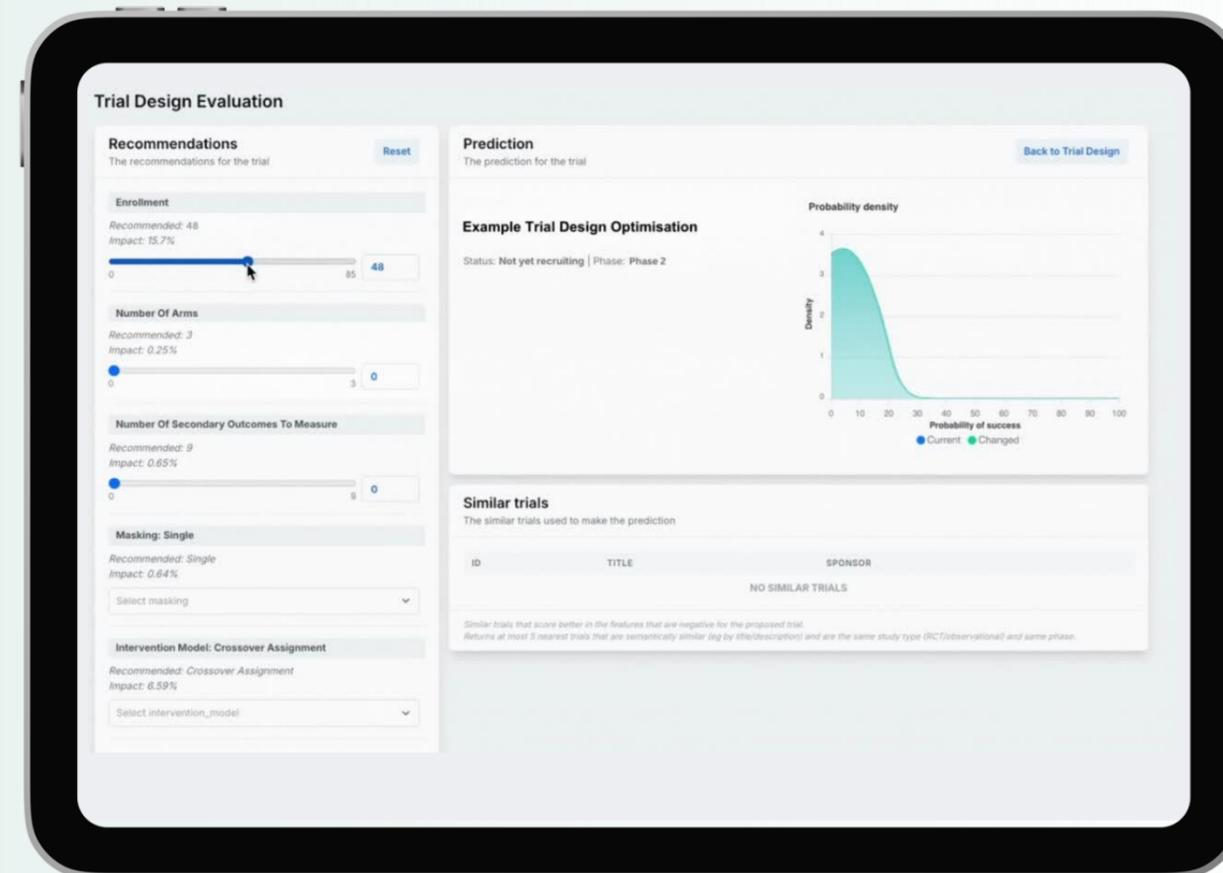
**Create Optimal Trials Designs**



**Validate and Optimise Existing Trials**



**Predict Outcomes**



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# Our Customers



## Clinical Research Organisations

Biostatistical validation to simulate trials, and optimise designs.



## Trial Sponsors

Accelerate therapy development with TrialKey's tailored recommendations



## Biotech Investors

Predict clinical trial successes and identify high-potential stocks



## Sites

Enhance recruitment, retention, and operational efficiency

**\$5K AUD per report**

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# Total addressable market is \$328.745M



# Existing Clients and Partners

Opyl is projected to generate substantial revenue across its partnerships.

Partnership/Client	Target	Opyl's Fees
Phenix Health	900 products	\$5000 per report for 900 products
AI Biotech Fund	AUD 100M AUM within 24 months	25% of performance fees, 19.9% equity stake, \$25,000 upfront payment
Joint Venture (Xco Consortium)	USD 1M (2025), USD 2M (2026), USD 4M (2027)	20% of first \$1.25M, 40% after
Other Partnerships*	175 reports/year	\$5000 per report

\* Averaged 175 reports annually from partners and clients who do not publicly disclose project numbers

# Corporate Overview

Strong ownership holding among OPL insiders and associated parties

Financial information	
Share price (06-Sep-24)	\$0.017
52-week trading range (low / high)	\$0.015/\$0.049
Shares on issue (m)	170.7
<b>Market capitalisation</b>	<b>A\$2.9M</b>
Cash (30-06-24)	A\$0.37
Debt (30-06-24)	Nil
<b>Enterprise Value ((06-Sep-24)</b>	<b>A\$2.53m</b>

Substantial shareholders	% interest
Antanas Guoga (Non-Executive Director)	13.84%
Niv Dagan	13.12%
Irwin Biotech	12.74%
Balmain Resources	7.50%
Scintilla Capital	4.10%
L39 Capital	3.95%

- **Note:** Ownership holding as at 6 September 2024
- **Source:** ASX public disclosures and CapIQ

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# TrialKey Development Journey

Best-in-class MVP platform developed and tested with subject matter experts and potential future users informing underway commercialisation strategy





# Joint Venture for EMEA and North US Expansion: XCO Consortium

- ✓ **Due Diligence:** Completion by EOD September
- ✓ **Cash Payment:** AUD 1.5 million for license rights and R&D
- ✓ **Capital Raise:** Between USD 3 million and USD 5 million within nine months
- ✓ **Opyl Equity Stake:** 20% equity stake
- ✓ **Revenue Sharing:** 20% of initial USD 1.25 million of revenue, 40% of revenues exceeding this initial amount
- ✓ **Structure of New Entity:** Opyl will initially hold 20% and appoint 1 director
- ✓ **1-3 Years Sales Targets (USD):** \$1M, \$2M, \$4M
- ✓ **Regions:** JV to sell in EMEA & North US



# Partnerships

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**Alithia Life Sciences**



**Phenix Health**



**Biointelect**

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# Client Case Study: Brain Vector

TrialKey partnered with Brain Vector to optimize a clinical trial for a neuro device treating mild to moderate depression. Using advanced AI, TrialKey refined the study plan, including enrolment, study arms, duration, and endpoint selection. The platform also analyzed competitor trials, providing valuable benchmarking and ensuring strategic trial positioning.

## Key Outcomes

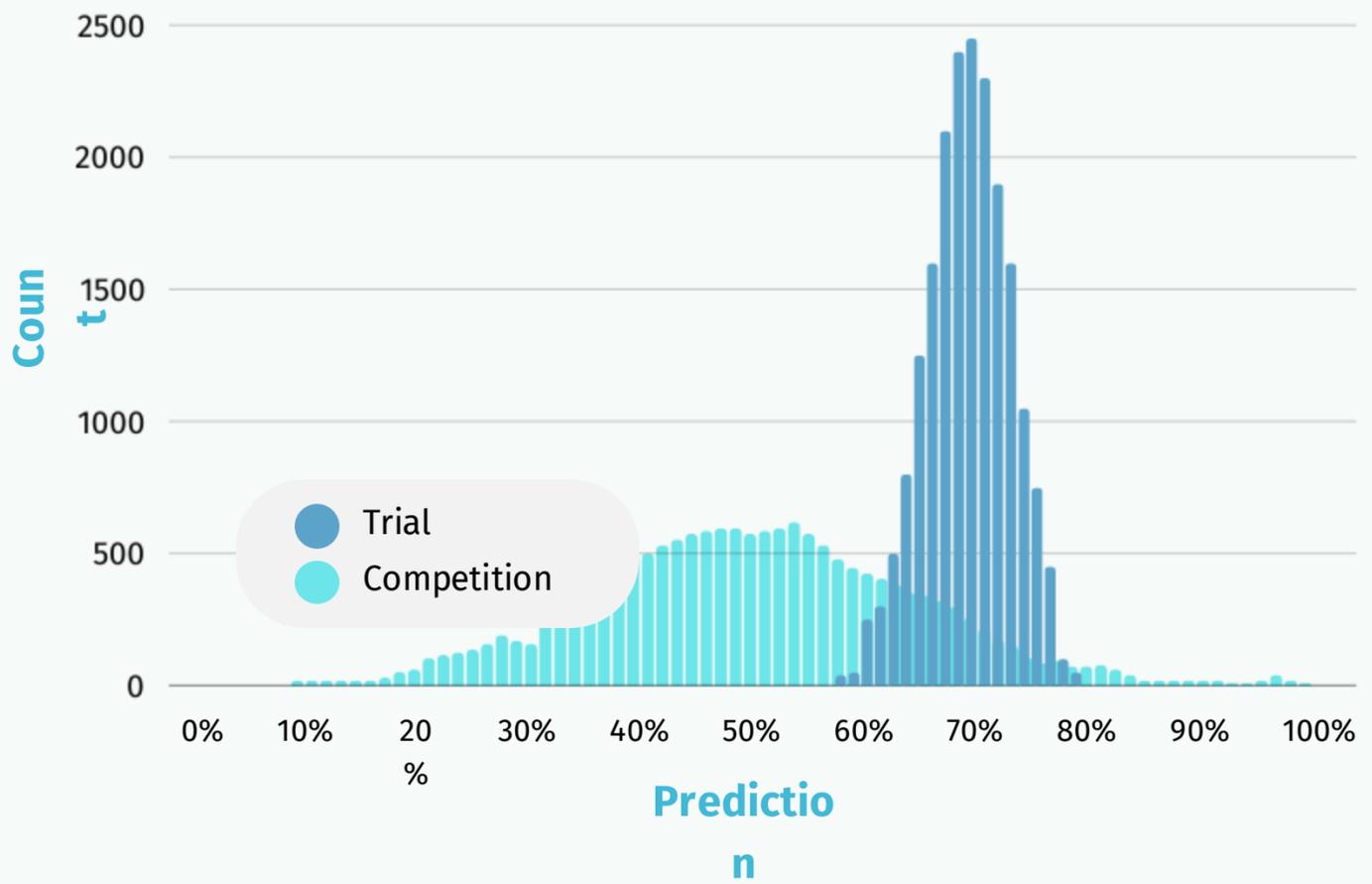
- Optimized trial design with a 70% predicted success rate.
- Single-group, open-label study targeting 150-200 patients over 12-26 weeks.
- Enhanced market positioning through a cobranded campaign targeting neurologists in Australia and New Zealand.

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## TrialKey Trial Prediction

**70% (62.4%-75.1%) 95% C.I.**

Trial scores in the top 17% based on 20,000 simulations



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# TrialKey

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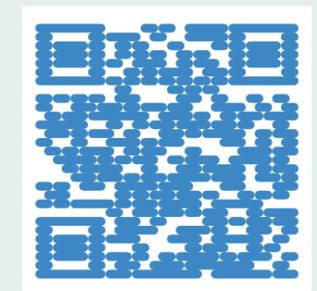


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**Book a meeting**



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the AI Biotech Fund**