

Opy

FY 2024 update

September 2024

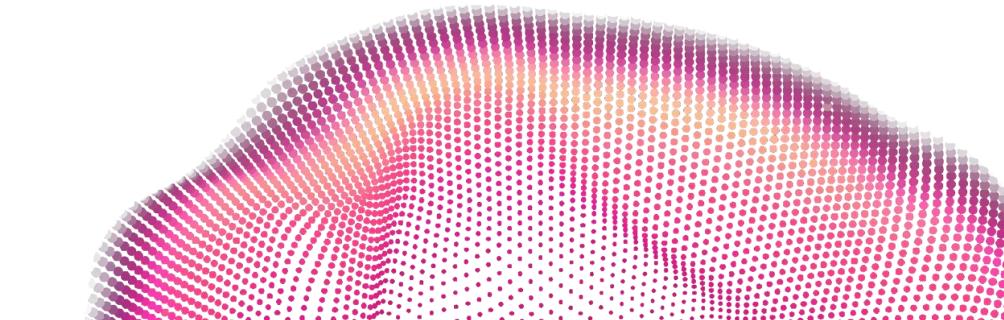
www.opyl.ai



We apply proprietary AI to improve clinical trial design efficency and resource allocation







Our vision

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

Overview



Create Optimal Trials Designs

Our platform provides precise recommendations for various trial elements, including study type, sponsor, start and end dates, number of arms and groups, primary and secondary purposes, intervention models, masking types, allocations, enrollment numbers, inclusion/exclusion criteria, hard trial status, number and location of sites, and outcome measures.



Optimise Existing Trials

TrialKey refines and enhances existing trial designs for better outcomes. Our platform applies the same rigorous AI-driven analysis to optimise and compare with past and current trials. By comparing your trial with competitors and identifying areas for improvement, TrialKey reduces the need for costly amendments and maximises success rates.



Predict Outcomes

TrialKey offers unparalleled predictive power with over 90% accuracy in forecasting trial success. Our AI models analyse vast amounts of data to deliver reliable success probabilities and competitor insights, enabling informed decision making and strategic planning for clinical research and development.

Today's speakers



Saurabh Jain
Executive Chairman



Damon RasheedCTO



Financial Performance

OPL's recent loans totalling \$700k post FY24 have increased runway, allowing the investment into further leads driving marketing initiatives, with a focus on international expansion

	Total Revenue	Total EBITDA	Net op. cashflow
FY23	\$1.2M	-\$1.8M	-\$1.4M
FY24	\$0.93m	-\$3.13M	-\$2.0M
Change	-22.5%	-73.89%	-42.86%

- Revenue Drop: Reflects the strategic divestment of Opin.ai to focus on growing the Al-driven TrialKey platform.
- Increased Costs: Higher consulting and executive costs contributed to the EBITDA decline driven by leadership changes and R&D investments in TrialKey.
- Cash Burn: Significant cash outflows were focused on R&D, leadership incentives, and development of TrialKey's new features, positioning Opl for future growth.





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
Market capitalisation	A\$2.9M
Cash (30-06-24)	A\$0.37
Debt (30-06-24)	Nil
Enterprise Value ((06-Sep-24)	A\$2.53m

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%

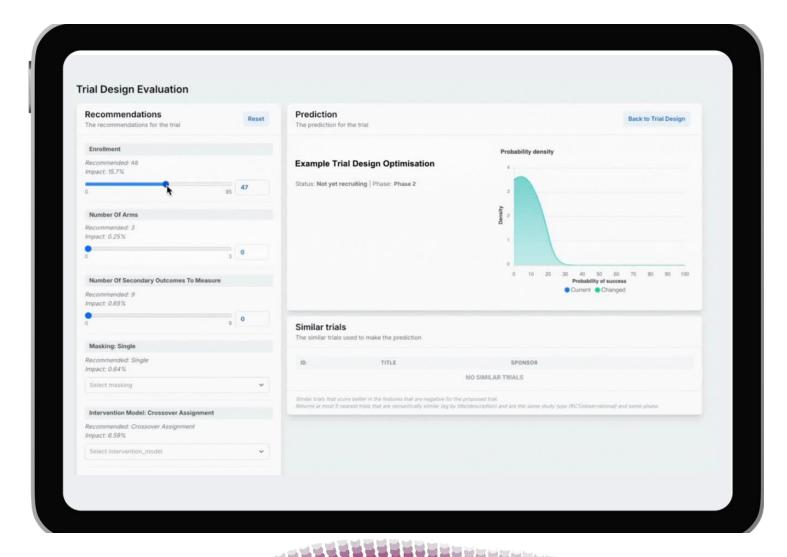
Note: Ownership holding as at 6 September 2024 Source: ASX public disclosures and CapIQ





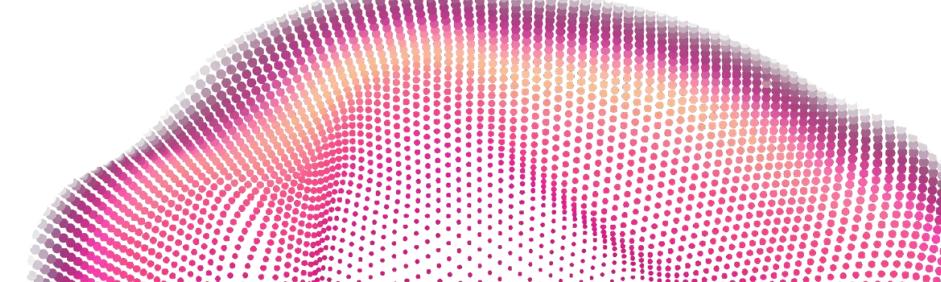
TrialKey, powered by Opyl

TrialKey leverages real-world data to design, simulate and optimise trial designs for pharmaceuticals, medical devices, alternative therapies, rare and novel conditions, significantly boosting success probabilities across all phases. With its comprehensive global capabilities, TrialKey ensures efficient resource allocation, reduces costly amendments, and accelerates market entry for groundbreaking medical advancements.









Global market opportunity | TrialKey

TrialKey supports life science investors globally by providing comprehensive global data intelligence, optimising investment decisions and enhancing clinical trial success.

Market Challenges

- Rising Volume, High Failure Rates: The increasing number of clinical trials launched each year faces high failure rates due to poor trial design.
- Significant Investment, Limited Approvals: With over US\$80bn invested annually in more than 54k trials, only an average 53 new drugs are approved by the FDA each year, highlighting the need for trial design optimisation and better investment new drugs are approved by the FDA each year, highlighting the need for trial design optimisation and better investment decisions, decisions.
- Complex Protocols, Elusive Failure Sources: The growing complexity of trial protocols makes it challenging to pinpoint the sources of trial failures.
- Focus on Minimising Failures: Financial sponsors are intent on reducing failure rates of their invester trials, aiming to intervene earlier in the trial design process.
- Demand for Accurate Data: Clinical trial stakeholders seek greater access to accurate and transparent global trial data to enhance decision-making.

 1. Clinical trial costs go under the microscope. May.M. Nature Medicine. March 2019



Including expenditures on failed trials¹

Over 490,000 trials total registered globally





TrialKey Development Journey

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





Expanded

dataset,

strategic partnership with Secured first L39 Capital Pty Ltd revenue and to launch an Al strong sales Biotech Fund pipeline through marketing

(\$)

revenue

initiatives

Jun 2024

Secured first

Announced a and sell TrialKey in Europe, the Middle East, Africa, and

Al Biotech

Fund



MOU signed with Xco Consortium



Current

customer

Build

base using case studies MOU Signed to Established a JV entity to market

July 2024

Completed prototype

Completed core platform

(1)

completion of platform

Linked trials from phase 1 to 4, bolstering dataset reliability

2022



Improved

accuracy

Early market validation

Received feedback from investment and trial design communities

2022

Improved features and scaled infrastructure for target markets

Completed

development

2022-2024

increase Released to platform features seeking revenue. including the Finalised GTM launch of strategy and TrialGen pricing models

May 2024

July 2024

North America.

Predicted COVID-19 vaccine candidates successfully

2021

Achieved commercial-grade

2022



Jan 2024

public and





3

FY24 at a glance



Revenue: \$397,637, down 35.6% from FY23

Net Loss: \$3,130,374, up 81.3% from FY23

Cash Position: \$374,645 as of 30 June 2024

First Contract: TrialKey secured its first contract with Brain Vector for trial optimisation services,

valued at up to A\$30,000

Strategic Partnerships: Establishment of the Biotech Fund with L39 Capital, targeting \$100 million

in assets under management within 36 months

Strategic Milestones



TrialKey & TrialGen Launch

On 3 June 2024, the introduction of 'TrialGen,' an AI-powered clinical trial design simulator, marked a new era in trial optimisation. Alongside this launch, ongoing development of TrialKey introduced key features like grading for inclusion/exclusion criteria and endpoints.

Divestment of Opin

Sale of its Opin business to Dr. Hugo Stephenson on 31 May 2024, now rebranded as Trial Screen, following shareholder approval at the General Meeting (GM). This divestment has significantly improved Opyl's cash flow by approximately \$700k per annum, based on the previous cash burn rate, effectively extending the company's operational runway and facilitating intensified efforts to accelerate the growth of TrialKey.ai

Strategic Milestones



Signing of MOU

Opyl signed a strategic MOU with the Xco Consortium to establish a joint venture for the expansion of TrialKey across EMEA, and North America. The JV will market and sell TrialKey products, with a three-month due diligence period, a \$1 million cash payment to Opyl, and a planned capital raise of \$3-5 million. Opyl will hold a 20% equity stake, receiving 20% of the first \$1.25 million in revenue and 40% thereafter, with revenue targets of \$1 million in the first year, \$2 million in the second, and \$4 million in the third.

Establishment of an Al Biotech Fund

Opyl has partnered with L39 Capital to launch a Biotech Fund utilising TrialKey technology, aiming to significantly enhance revenue streams and market positioning while demonstrating the transformative potential of

Al in biotech investments. Opyl will receive 25% of the funds fees.

TrialKey Development



+92%
Accuracy in predicting trials passing primary outcome



Platform Development and Enhancements: Core platform technology development launched with several significant feature improvements completed.

Expanded Database: Database extended from 65,000 trials to over 350,000 trials, enhancing data depth and accuracy.

First Revenue Milestone: Secured first customer and revenue with Brain Vector, validating the platform's market potential.

Launch of TrialGen: Opyl has introduced TrialGen, the world's first AI-powered trial simulator, enhancing clinical trial design with high accuracy, process automation, and scalable solutions, driving efficiency and success in the clinical research industry.

Global Applicability: Through a strategic joint venture with the Xco Consortium, TrialKey is poised for global expansion, supporting clinical trials across Europe, the Middle East, Africa, and North America.





TrialKey Development



+1300

of variables reviewed to drive predictive insights per trial



Commercialisation Focus: TrialKey is focused on commercialisation and go-to-market strategy, with primary use cases identified for life science investors and clinical trial designers/operators. Discussions with pilot project partners are in progress.

Robust Sales Pipeline: Established a strong sales pipeline through targeted marketing initiatives and industry event sponsorships.

Industry Presence: Expanded industry presence by speaking and exhibiting at key events like Australian Healthcare Week, Digital Health Fest, Pharma and Device Forum, Global Clinical Trials Connect, and ARCS. Upcoming sponsorships include Bio Asia-Taiwan, BioConnections, and Victorian Healthcare Week. Featured on podcasts such as Eye on AI, Everyday AI, and Think Future.

Scalability: The platform's scalable model caters to both small firms conducting a few trials annually and large companies managing thousands of trials, offering flexible solutions for diverse needs.

New Feature Updates: Recent updates to TrialKey.ai include Al advancements for conditions, sponsors, site trials, and principal investigators. These enhancements improve user experience with comprehensive data on trial numbers, success rates, site performance metrics, and an innovative rating system for investigators.



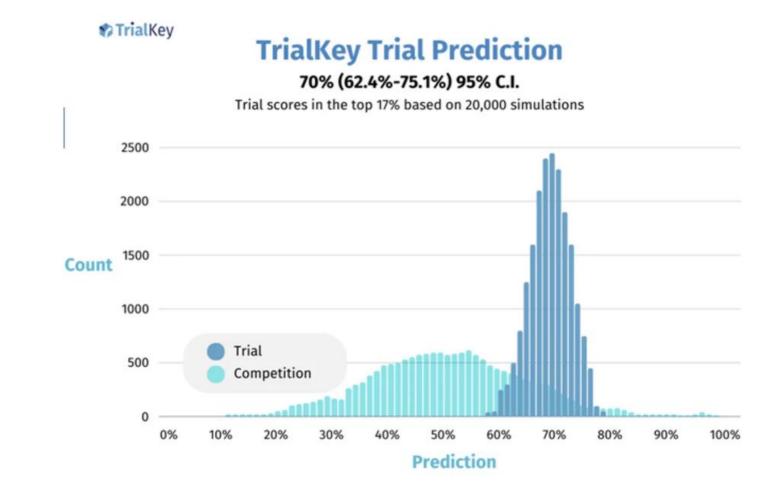


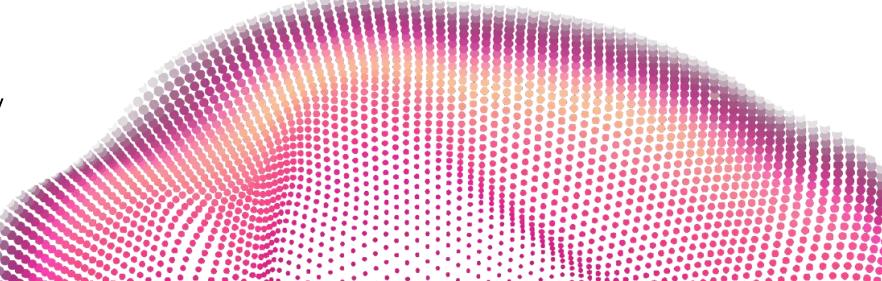
Customer Case Study

TrialKey partnered with Brain Vector to optimise 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 analysed competitor trials, providing valuable benchmarking and ensuring strategic trial positioning.

Key Outcomes

- Optimised 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.









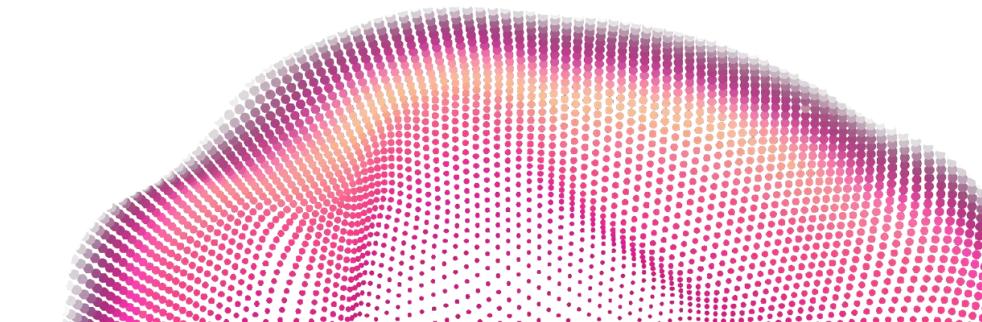
Customer Testimonial

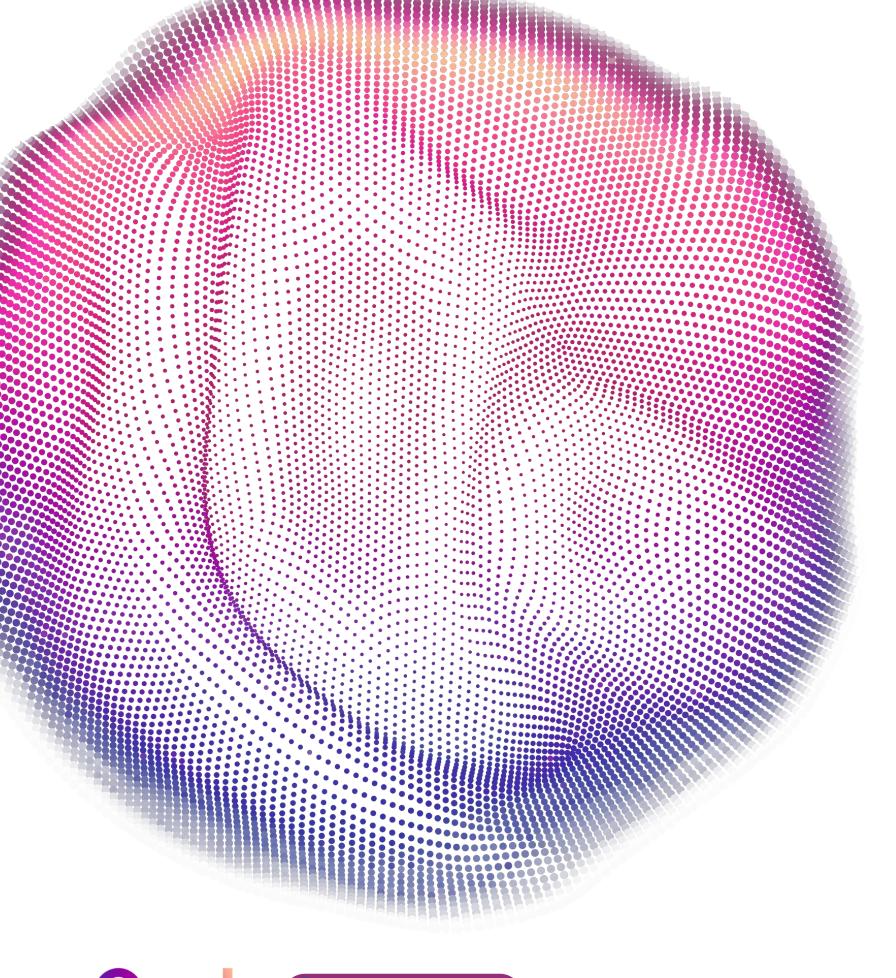
"Working with TrialKey has been transformative for Brain Vector. The insights from their comprehensive report have significantly reduced costs and time while providing invaluable data that sharpened our focus on the most impactful areas. This collaboration has laid a strong foundation for our clinical trial and our broader mission to enhance mental health care."

Dr. Stephane Verhaeghe, CEO of Brain Vector









Opyl

Q&A





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Thanks!