



Company Update



Damon Rasheed
CTO

 **ASX: OPL**

The Opportunity



Annually US\$80B¹ is invested in **65,000+ trials**² annually with 90% failing³, mainly due to poor trial design.⁴



Globally, there are over 6,000+ pharmaceutical and medtech companies, 10,000+ medical research institutes, and 120+ clinical trial networks so lots of opportunities for TrialKey.



TrialKey's AI-driven analysis of 1,300+ variables, combined with biostatistical validation, predicts trial success with **92%+ precision**⁵ and delivers better trial designs.



Taking into account phase failure rates⁶, if TrialKey was to provide a report for Phase I - IV for all 65,000 trials that would be **126,007 reports or \$1.89 billion.**

1. <https://www.grandviewresearch.com/industry-analysis/global-clinical-trials-market>

2. <https://www.statista.com/statistics/732998/number-of-registered-clinical-studies-with-posted-results-worldwide/>

3. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9293739/>

4. <https://prevailinfoworks.com/news/understanding-the-top-reasons-why-clinical-trials-fail/>

5. <https://www.nature.com/articles/nrd.2016.136>

6. <https://trialkey.ai/methodology/>

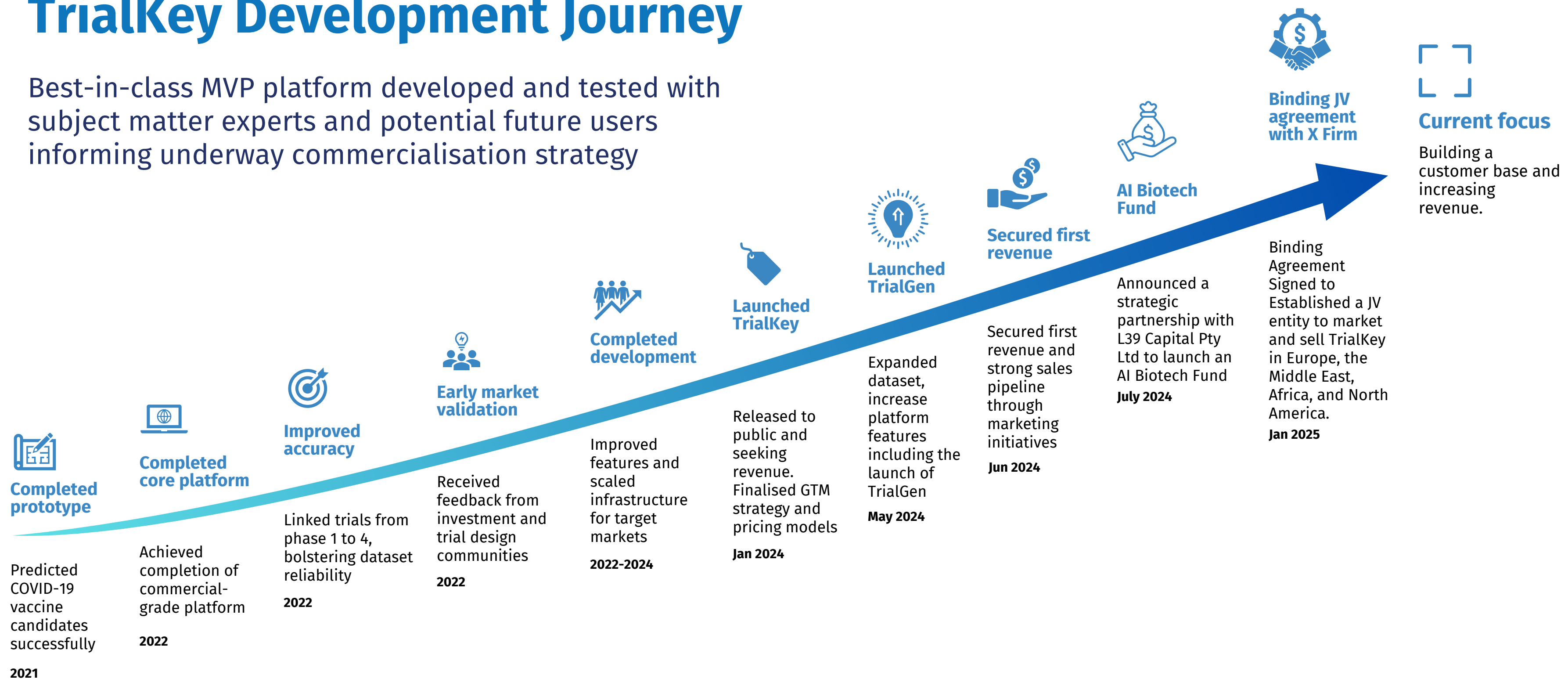


ASX: OPL



TrialKey Development Journey

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



Trusted by



Commercial Eyes, a ProductLife Group Company



Biointellect



Alithia Life Sciences



NeuOrphan



L39 Capital



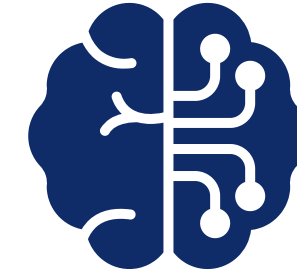
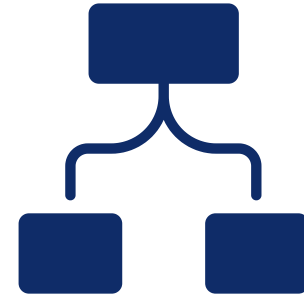
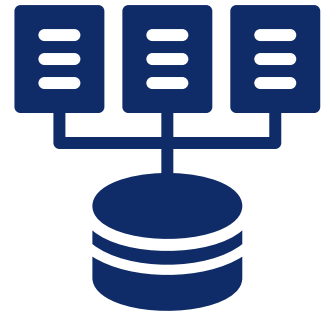
Southern Clinical Development Consulting



Phenix Health

 **ASX: OPL**





Data Collection

Data Processing

Variable Categorisation

Data Targeting

AI Model

Automated Designs and Reports

+468,429 trials
+114,925 conditions
+2.69 billion patients

+1300 variables
Structured and unstructured data

Trial execution variables:
These include details about the trial's execution

Technology variables:
These encompass information related to the drug or device being studied

Predict whether a trial successfully meets a major endpoint

Explainable AI - allows us to optimise each variable to improve success rates

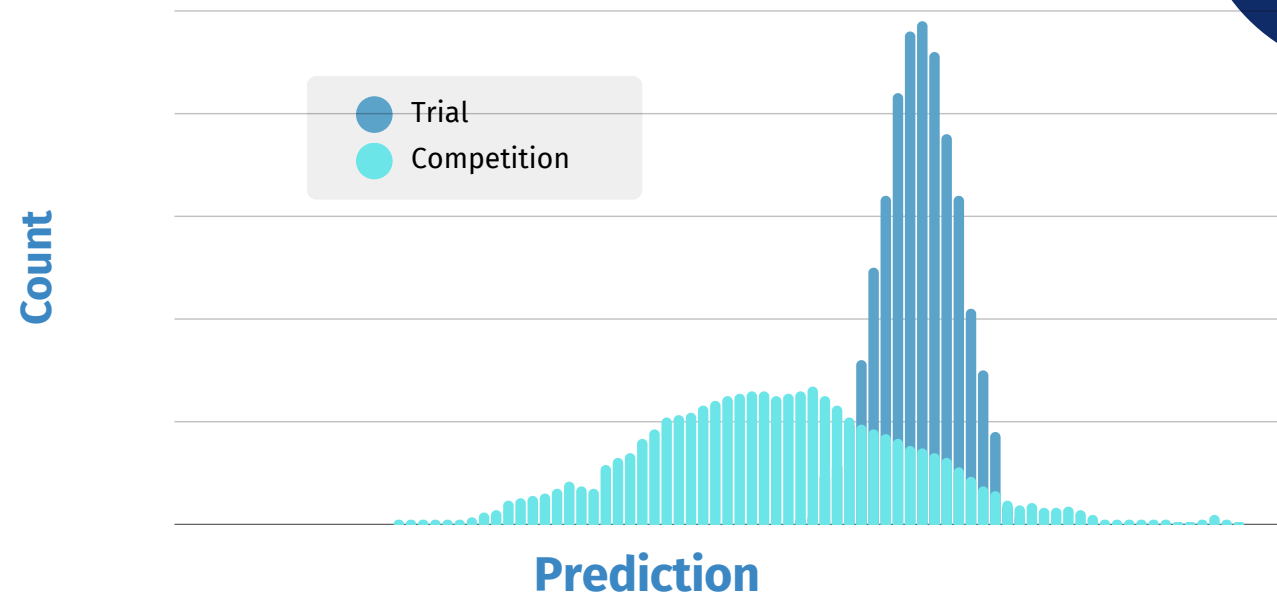
Advanced AI modelling using XGBoost and other cutting edge AI models

Probability Density

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

Trial scores in the top 17% based on 100,000 simulations

**Top
17%**

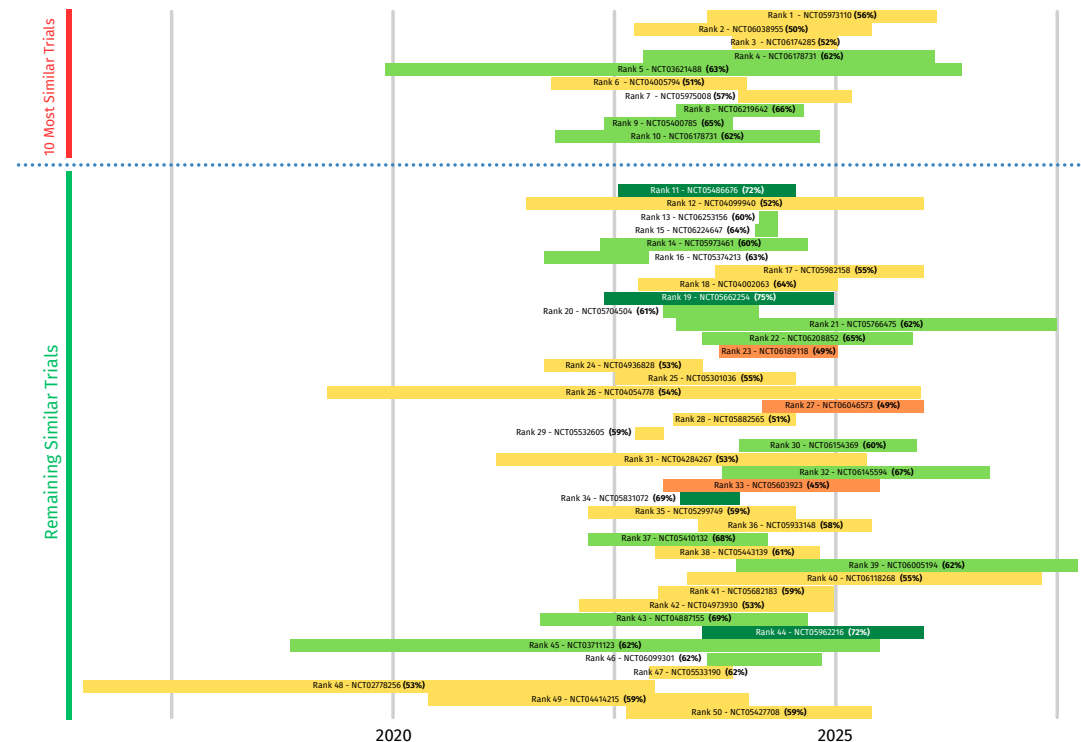


About TrialKey's AI Model

- Market-leading +92% accuracy in predicting clinical trial completion
- Our platform is trained using data from over 460,000 clinical trials and 1300+ variables
- Each trial is simulated up to 100,000 times providing robust, reliable predictions, ensuring data-driven biostatistical validation for optimised trial designs

Competitor Benchmarking

The trial, analysed through the TrialKey model, has an estimated probability of success between 62.4-75.1%, representing a 95% confidence interval and currently placing it in the 44th percentile. This assessment is based on a 100,000-machine learning simulation by TrialKey, with competitor analysis limited to currently active Phase II/III and Phase III trials. TrialKey has identified actionable insights and key recommendations that could significantly elevate this trial's success rate into the 79th percentile.



Probability Score



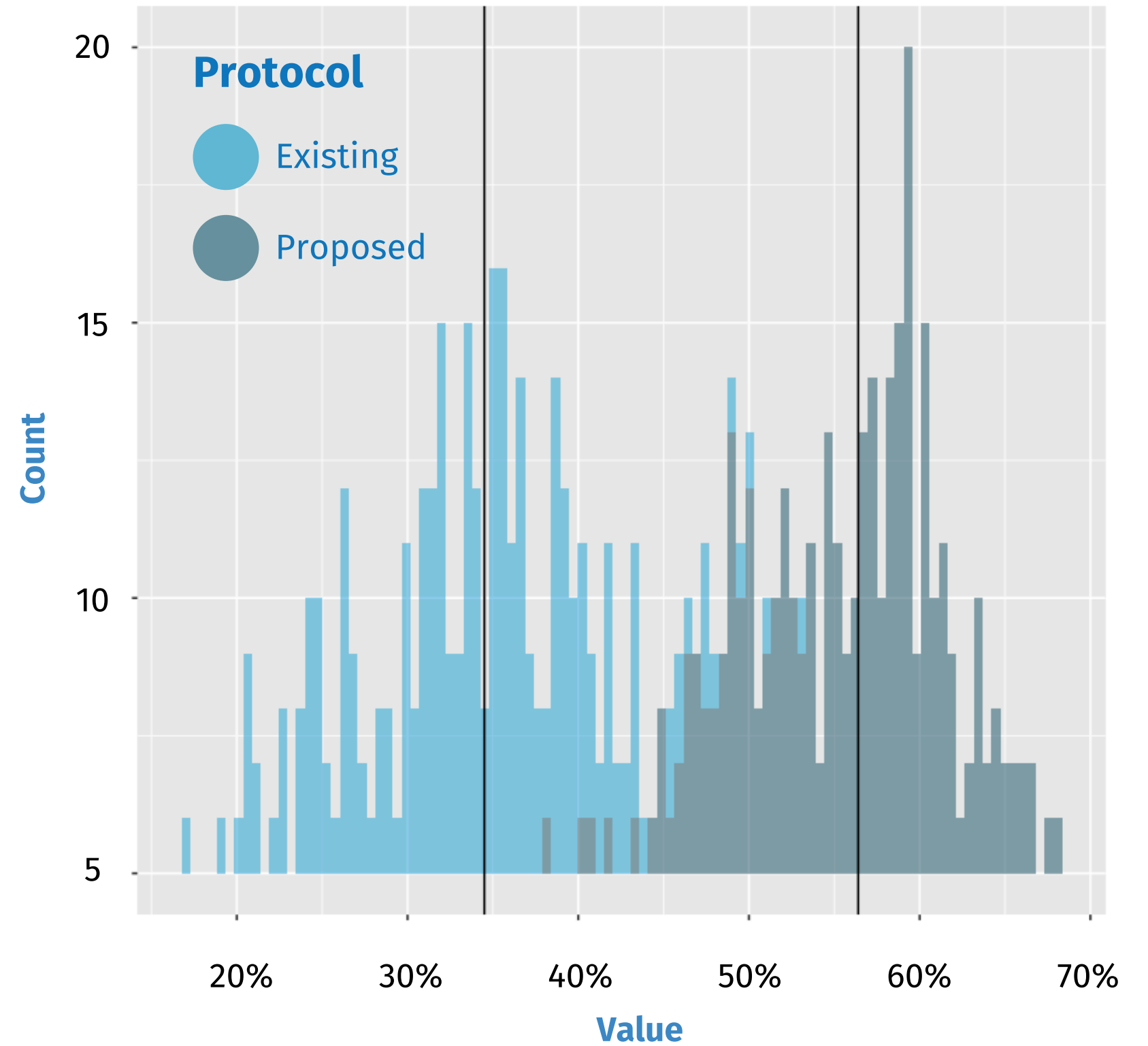
TrialKey's AI model can predict with 95% confidence that the probability of success lies between 62.4 and 75.1%.

Example Simulation

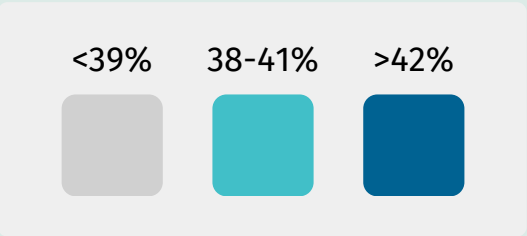
- ✔ Increases success rates from **34.5%** to **56.4%**
- ✔ Potential client saving **\$7M**

Current vs Proposed protocol distribution of probability of success

Current: 34.5% (20.7%-47.8%) 95% CI
Proposed: 56.4% (44.5%-65.8%) 95% CI



Major Technologies Used In X Research



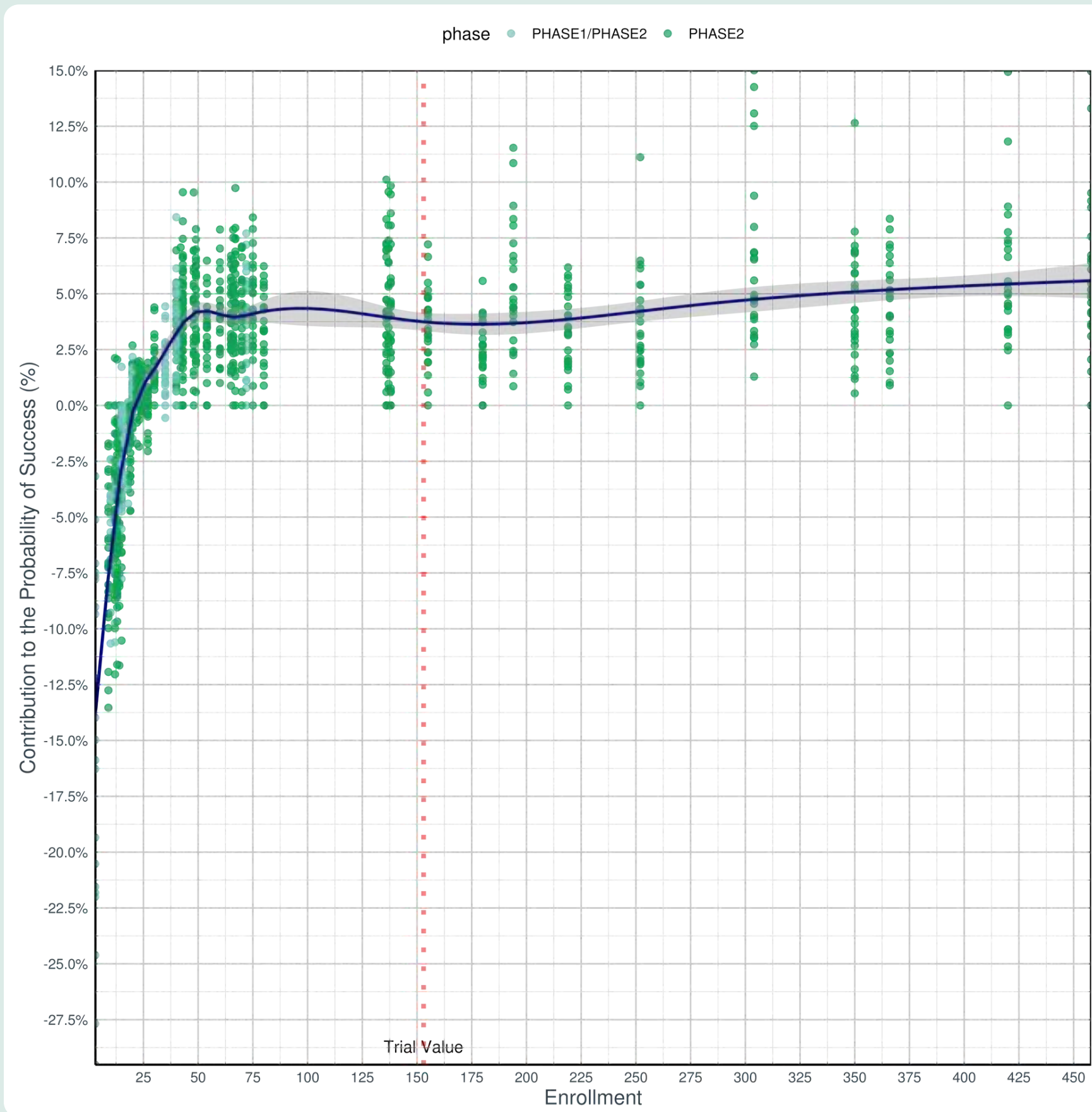
Sponsors

Key

- No reported Success
- Success



Enrollment Effect on Success Rate

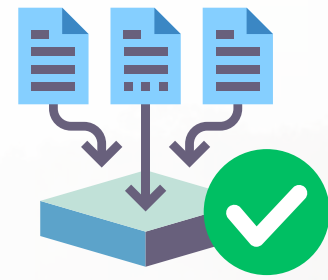


Our Competitive Moat



Proprietary Dataset

We've spent over two years curating a unique and extensive dataset, a complex task that required significant effort and expertise, tailored specifically to solve this market problem.



Trial Analysis

+1300 variables
While Clinicaltrials.gov reports outcomes for less than 20% of trials, we've expanded this by incorporating data from press releases and peer-reviewed journal articles.

Using a scalable LM approach able to categorize success/failure



Proprietary Feature Set

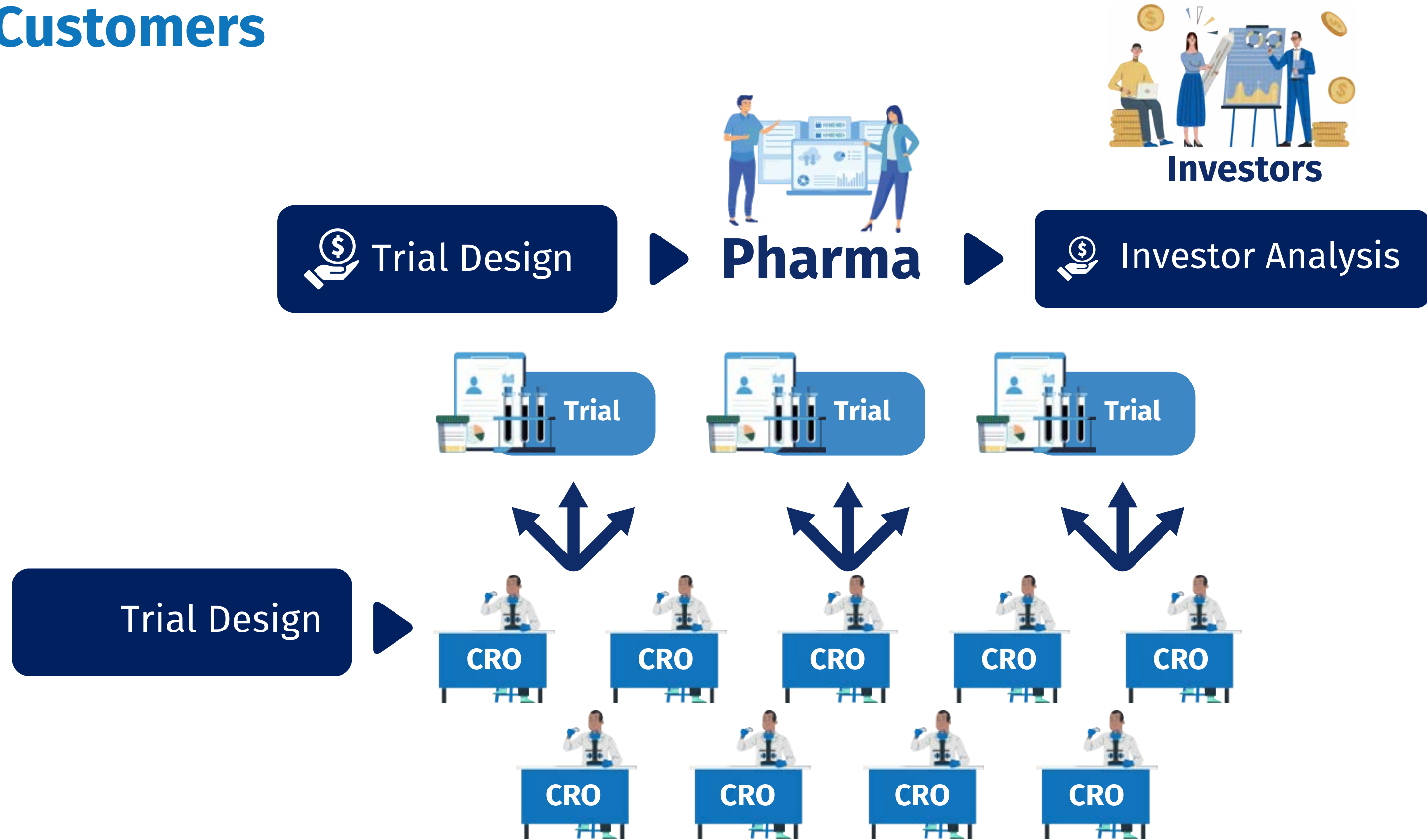
Our feature set combines both structured and unstructured data, enabling us to answer highly specific questions, such as determining the level of disease progression in motor neuron disease that gives the best chance of clinical success — a task only possible through advanced language models.



Subject Matter Expertise in Modeling

With deep expertise in data modeling, we've achieved higher accuracy compared to competitors, delivering more reliable insights.

Our Customers



Scaling Our CRO Network



Current Trajectory

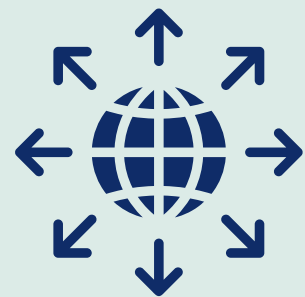
Signing 2 new CROs per month in AU

Target of 30+ new APAC CRO partnerships within 2 years



\$170K In Bids

Based on 35 Preliminary Reports provided to partners



Market Expansion

JV to sell in Europe, the Middle East, Africa and North America

Target of 100+ CROs over 2 years

Joint Venture for EMEA and North US Expansion with X Firm

- ✓ **Cash Payment:** AUD 1.5 million paid to Opyl for license rights and R&D
- ✓ **Capital Raise:** Between USD 3 million and USD 5 million within nine months
- ✓ **Opyl Equity Stake:** X Firm receives 19.9% stake in Opyl
- ✓ **Revenue Sharing:** 20% of initial USD 1.25 million of revenue, 40% of revenues exceeding this initial amount
- ✓ **Structure of New Entity:** Opyl receives 19.99% of X Firm and appoint 1 director
- ✓ **1-3 Years Sales Targets (USD):** \$1M, \$2M, \$4M
- ✓ **Regions:** JV to sell in EMEA (Europe, Middle East, and Africa) & the USA.



Joint Venture CRO Network Targets



The Opportunity

There are **4232+**¹ CROs in US and **1100+**² in UK



Pilot Pricing

Premium pricing for pilot clients, exceeding AU rates, with scope for future increases.



Revenue Targets

Year 1: USD \$1 million, Opyl earns **AUD \$320,000 + \$1.5m licensing fee.**

Year 3: USD \$4 million, Opyl earns **AUD \$1.98 million.**

Total projected revenue share by Year 3 = **AUD \$3.19 million**

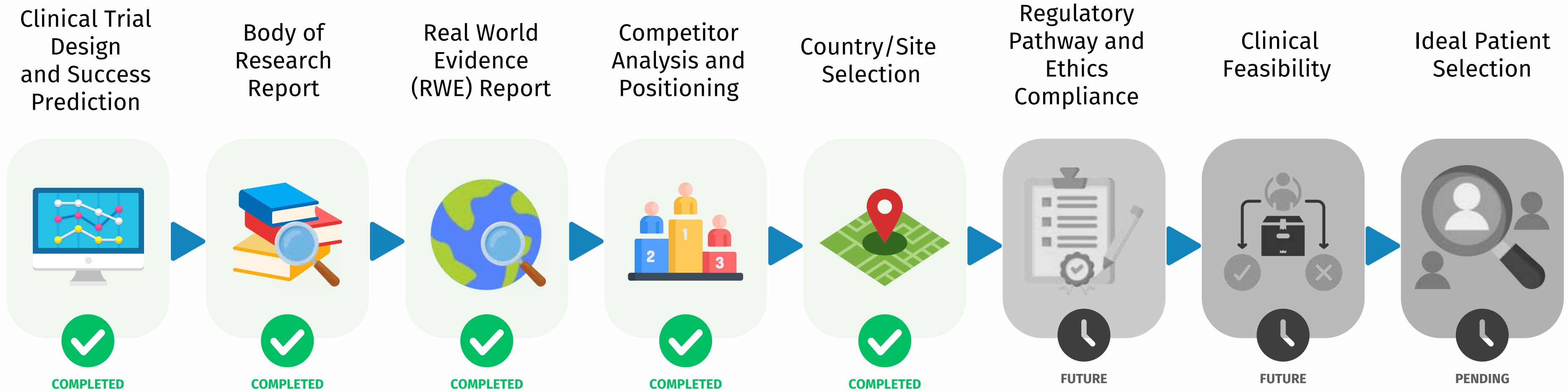
Note: Revenue estimates are based on internal modeling. The licensing fee is conditional upon Firm X successfully raising capital and is not guaranteed.

Growth Strategy

Expanding client offerings through advanced reports that address critical trial needs from regulatory compliance to market commercialisation.



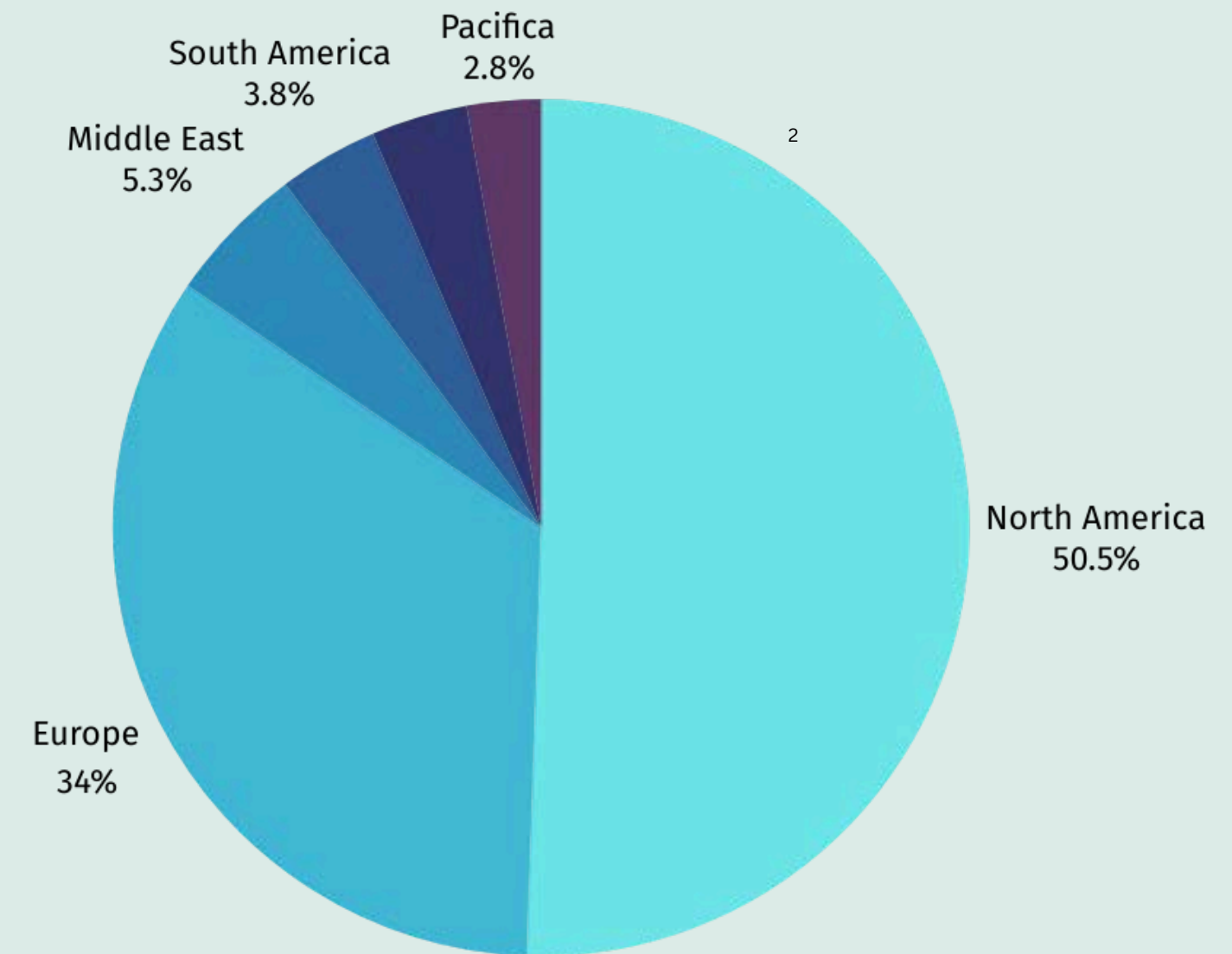
Customisable Upsell Opportunities



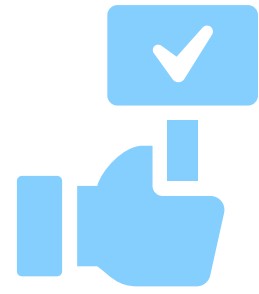
Capturing a \$1.9B+ Market Opportunity

65,000+¹ Clinical trials registered annually

Phase	Failure Rate	Reports Sold
Phase I	37% fail	65,000
Phase II	69% fail	40,950
Phase III	42% fail	12,694.5
Phase IV/Regulatory	9.6% fail	7,362.81
	Total contestable market	\$1.89 Billion



1. <https://www.statista.com/statistics/732998/number-of-registered-clinical-studies-with-posted-results-worldwide/>
 2. <https://credevo.com/articles/2023/03/05/north-america-clinical-trials-sites-clinical-investigators-in-usa-canada-mexico/>
 3. <https://www.nature.com/articles/nrd.2016.136>



\$170K
currently in bids



130+
new CRO
partnerships
target over 2 years

11M
Revenue 2025-2027

70%¹

of trials
use a
CRO



45,500
annual registered trials
TrialKey can be part of
the bidding process with
a CRO partner

Competitive Landscape

TrialKey stands out as the market leader in AI-driven clinical trial design with the highest prediction accuracy, operating in a less competitive space, presenting a significant growth opportunity for investors.

Drug Discovery



Trial Discovery



Trial Management



The Most Comprehensive Dataset for Precision Trial Optimisation

TrialKey's dataset covers 468,429 Trials, 114,925 Conditions, 2.69 Billion Patients and 608 Million Data Points

- **QuantHealth:** Focuses on drug interactions
- **Lokavant:** Primarily operational data, don't optimise endpoints or inclusion/exclusion criteria
- **Phesi:** Mainly focus on patient centric trial design. Don't seem to use AI to optimise all aspects of trial design.
- **ConcertAI:** Undisclosed real-world oncology data, but less comprehensive in non-oncology trials
- **Saama:** Clinical and operational data integration, TrialKey has wider range of actionable insights offered

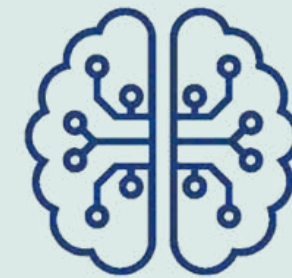


Partnership: **AI Biotech Fund**



Targets

- ✓ **Objective:** Leverage Opyl's TrialKey AI technology to drive significant capital appreciation by identifying successful biotech and pharmaceutical stocks
- ✓ **Target Annual Return:** 20%
- ✓ **Target AUM:** AUD 100 million in assets under management within 36 months.
- ✓ **Opyl Revenue Share:** Opyl will receive a 25% share of the fees earned by the fund, sourced from the 2% management fees and 20% upside fees.



AI BIOTECH
— **FUND** —

 **ASX: OPL**

 **TrialKey**



Marketing Update:
Initiatives driving growth,
securing contracts, and
global reputation-building



Bernice Averion

Head of Marketing and Communications



Marketing and brand awareness



Conferences



Socials



Networks



Networking



Emails



Webinars

Strategic Event Participation

- ✓ Every contract and sale tied to event attendance and strategic connections
- ✓ Focus on building relationships with decision-makers



In 2024,
each event secured an average of
100+ leads and 40+ meetings
with a **+7x ROI**

Driving Growth Through Marketing

- ✓ Attending industry-leading events: CROs, pharma, biotechs
- ✓ Demonstrating TrialKey and optimising clinical trials
- ✓ Part of the Australian delegation: cost-effective support from the government



Creating a Global Presence

- ✓ Building awareness about TrialKey as an AI solution
- ✓ Connecting with industry leaders to meet their needs
- ✓ Fostering long-term relationships for sustained success



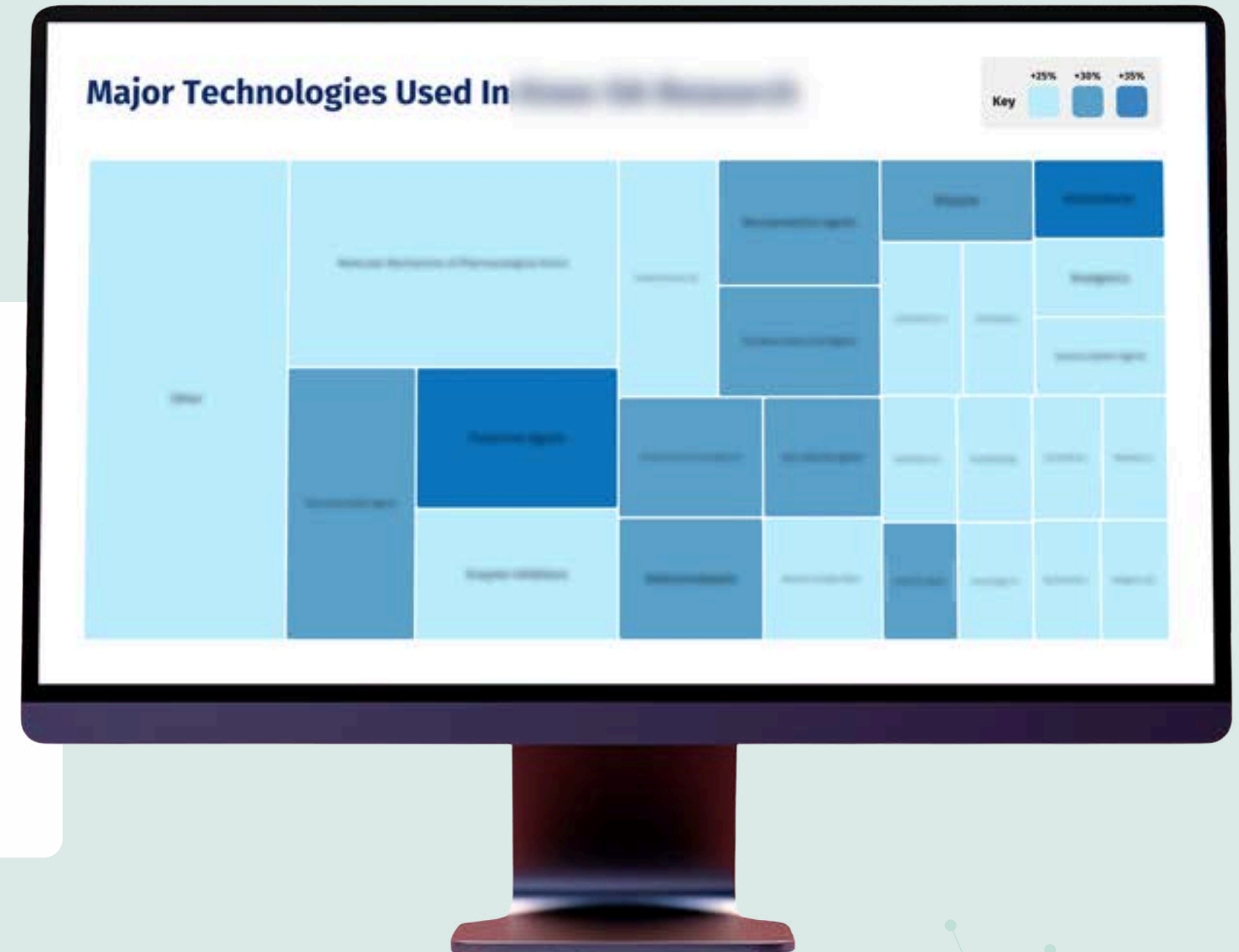
Nurturing Leads



Tailored retargeting for leads from events

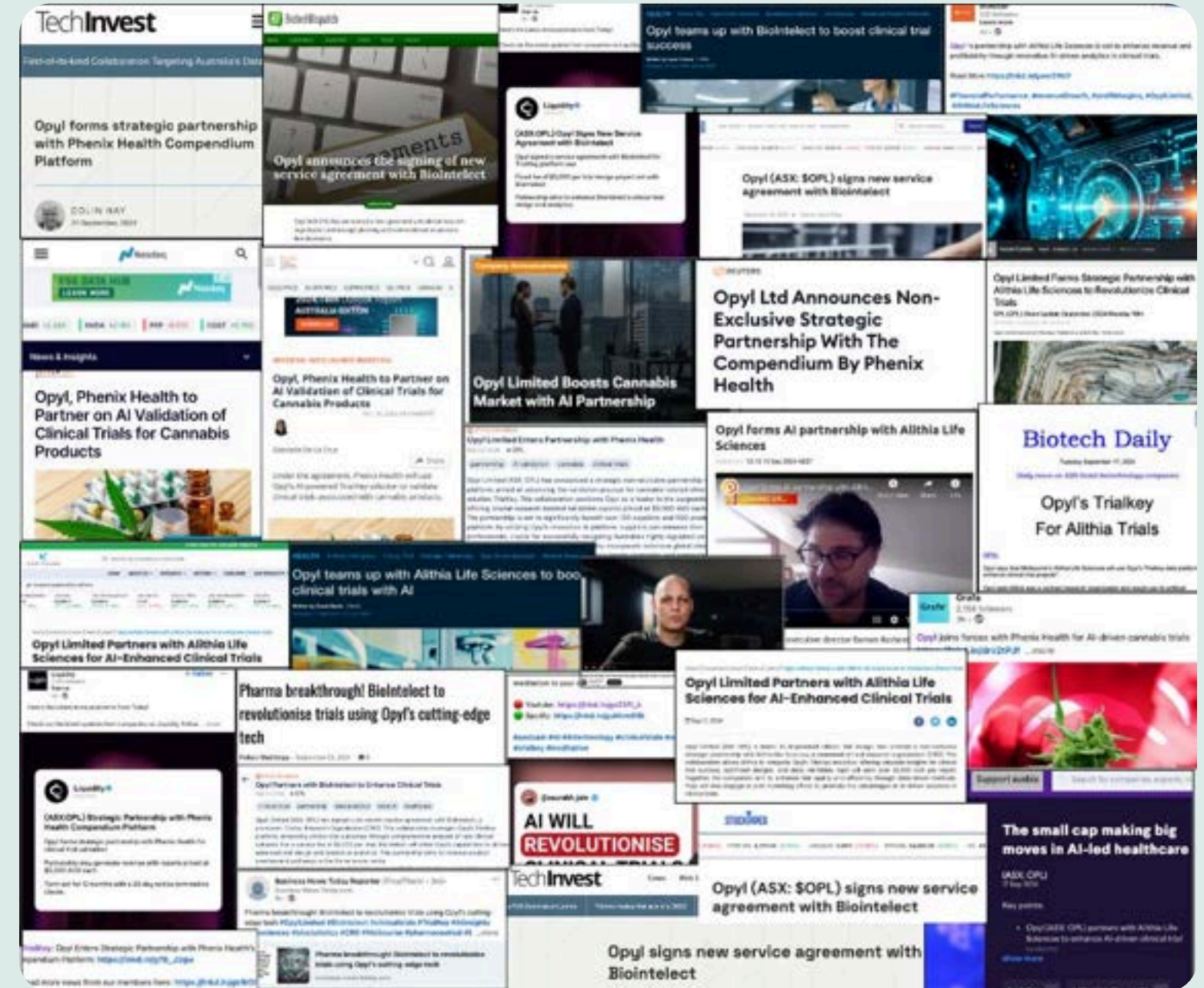
Includes:

- Competitor analysis, personalised messaging
- Free Preliminary Report so they can see firsthand the insights available and quality of the reports



Personalised outreach to 150+ journalists/editors

News articles, podcasts, TV interviews, Social media mentions, demo requests, speaker invites and more



Key Growth Drivers

Expansion into Global Markets

- Leveraging partnerships to drive adoption of TrialKey
- New joint venture with X Firm Ltd. to target high-growth regions including Europe, Middle East, and Africa.
- Projected revenue share from JV to exceed USD \$4M by Year 3, with Opyl receiving \$1.5M AUD in licensing fees and up to 40% revenue share on future deals.

AI Biotech Investment Fund Success

- The AI Biotech Fund, launched in partnership with L39 Capital, aims to reach \$100M AUD in Funds Under Management (FUM) within three years.
- TrialKey's predictive analytics will identify 200+ critical market inflection points annually, driving precision investments in high-potential clinical trials.
- Opyl to receive a 25% revenue share from fund management fees and performance-based earnings.

Expansion of Report Offerings

- Newly Launched Reports: Clinical Trial Design and Success Prediction Report, Body of Research Report, Real World Evidence (RWE) Report, Competitor Analysis and Positioning Report, Site Selection Report
- Upcoming Reports: Regulatory Pathway and Ethics Compliance Report, Clinical Feasibility Report, Ideal Patient Selection Report



Any questions?



Book a meeting



**Learn more about
the AI Biotech Fund**

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