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Opyl delivers world-first in mapping and linking global clinical trial outcome data

- TrialKey achieves key development milestone by tracing global clinical trials to their outcomes, with 92% accuracy, reducing bias in the predictive model
- TrialKey is a world first approach using AI to design and optimise clinical trial protocols
- to overcome the trial outcome data gap using Artificial Intelligence (AI)
- Only ~13% of trials report results¹ via international registries, and no trials linked as they progress thereby reducing the value of the data set
- The outcomes data gap is a key reason for high reported clinical trial failure rates
- TrialKey is Opyl's 2nd clinical trial efficiency solution following successful launch of Opin

Melbourne, Australia – Opyl Limited (ASX:OPL) is pleased to announce that its clinical trial prediction and protocol design software solution, TrialKey, has successfully achieved a key development milestone, reducing bias to improve predictive accuracy in the model, by accurately tracing a random subset of clinical trials reported to global registries through to their outcomes, with 92% accuracy.

This is significant as only around 13% of the circa 431,000 clinical trials¹ registered on the US government website, ClinicalTrials.gov, have posted their results to the site and no trials are linked over time as they progress between clinical phases.

The huge information gap is a major problem for the medical research sector as no one benefits from past learnings and often repeat protocol (trial plan) design mistakes made in previous trials. This information asymmetry contributes to high trial failure rates and the unnecessary waste of time and money on research destined to fail.

The scalable TrialKey Software-as-a-Service (SaaS) solution overcomes this issue by using machine learning/AI and natural language processing (NLP) to link trials across multiple global databases and sources, reducing failure bias and thereby improving predictive and protocol design accuracy and value of the software.

"This is the first-time clinical trials have been extensively linked on a global scale using artificial intelligence (AI) and our collaboration with RMIT University was instrumental in helping us achieve this critical development milestone," said Michelle Gallaher, Chief Executive Officer of Opyl. "Together we have addressed a major barrier in being able to use public datasets in global trial registries to develop a software solution."

"TrialKey can accurately trace and link a clinical trial across phases in minutes when it would typically take five manhours to complete the same task manually. I am confident that we are close to developing a powerful and valuable offering that can greatly improve the design and outcomes of clinical trials."

¹ <https://www.clinicaltrials.gov/ct2/resources/trends>

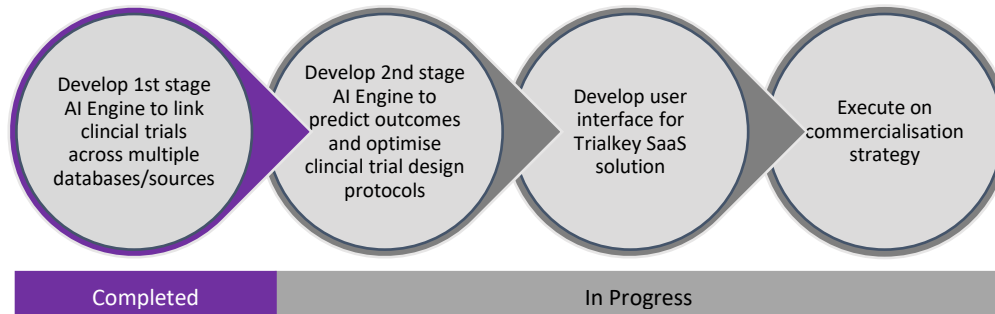


Fig 1: Milestones to Commercialisation of TrialKey

Next Steps

The completion of the first major development milestone was funded under the federal government's Innovation Connections grant and was done in partnership with RMIT University's School of Computational Sciences. The linking of clinical trial outcomes across phases leading into an accurate software trial design solution will prove to be an invaluable tool for researchers around the world from big pharma to emerging biotech and medtech.

With the rising costs of medical research and clinical trials that translates into the higher cost of new drugs and devices, TrialKey aims to reduce failure rates and therefore waste of valuable financial and clinical resources which it is hoped, will deliver more affordable healthcare.

"The clinical trials literature is an incredibly rich source of information, not only about the efficacy of new treatments, but also of the factors that contribute to the success of the trials themselves," said Prof Karin Vespoor, Dean, School of Computing Technologies, RMIT University.

"We are excited to work closely with Opyl to help drive innovation and digital transformation in clinical trial design and efficiencies."

TrialKey is Opyl's second clinical trial efficiency SaaS solution, following the successful launch in May 2022 of OpIn (www.opin.ai) – a global clinical trial recruitment platform. OpIn is gaining strong market traction with global biopharma, contract research organisations (CRO) publicly funded researchers and SME biotechs successfully recruiting to trials and studies using the platform and service.

The two platforms, OpIn and TrialKey present independent but linked revenue generation and partnering opportunities for the company.

Details on TrialKey model validation

Using a sub-set of 17,661 phase 1, 2 and 3 trials sourced from a public registry, the Opyl team, working with Dr Antonio Jimeno Yepes and Prof Karin Vespoor from RMIT University, was able to estimate linkages to future phases for the same trial 45% of the time. For example, table 1 shows that of the 6,847 phase 2 trials conducted, Opyl was able to find 3,800 phase 3 trials that link to a phase 2 study (55%).



The sub-set of trials was based on trials conducted by a selection of publicly listed companies world-wide since 1990. For a linkage to exist a trial must have met one of the stated primary objectives in the previous phase. Although data on the percentage of trials that pass each phase is hard to come by, Opyl considers an overall linkage rate of 45% to be a high match rate based on available estimates of trial success rates by phase².

After incorporating our linkage estimates, our data shows that just 46% of successful trials have reported outcomes, highlighting the lack of overall reporting and poor quality of global datasets. That is, more than 50% of trial outcomes were not reported.

Table 1: Trial linkages by phase and reported outcomes

Phase	Number of trials	Trial matches to future phases	% of outcomes	Reported outcomes from linked trials	% of reported outcomes
Phase 3	5,099	2,018	39.6%	1,215	60.2%
Phase 2	6,847	3,800	55.5%	1,962	51.6%
Phase 1	5,715	2,088	36.5%	458	21.9%
Total	17,661	7,906	45.0%	3,635	46.0%

The Board has authorised this announcement for release to the ASX.

-ENDS-

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Opyl is a new generation Australian digital health company that applies artificial intelligence to improving clinical trials. Our platforms make clinical trials more efficient and easier to access, giving patients more options and saving medical researchers time and money.

Our key offering for biopharma, medtech, government and healthcare organisations:

- clinical trial recruitment solutions – Opin.ai
- clinical trial predictive analytics and protocol design – TrialKey
- deep social media insights and analysis – Social Insights

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1. Opyl analysis of clinicaltrials.gov and WHO International Clinical Trial Registry. September 2022

2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6609997/>

3. Fogel, D.B. Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review. Contemp Clin Trials Commun.2018, September; 11: 156-164