ASX ANNOUNCEMENT

10 November 2026

TrialKey secures Paradigm contract and expands clinical trial capabilities

Highlights

- **TrialKey has signed a services agreement with Paradigm to provide an independent evaluation of its PARA_OA_012 Phase 3 osteoarthritis study.**
- **TrialKey will independently assess whether changes to study design, conduct or analysis could have affected the interim result of Paradigm's Phase 3 trial.**
- **TrialKey's 14 live services help identify study risks, compare alternative designs and assess model benefits and costs. Recent internal testing demonstrated improved predictions across nine clinical trial outcomes.**
- **The Paradigm appointment converts TrialKey's broader offering into contracted project work. Further priorities include delivery, additional biotech engagements and clinical research organisation (CRO) pilot licensing.**

Pathkey.AI Ltd (ASX: PKY) (Pathkey or the Company) announces that its subsidiary TrialKey Pty Ltd (TrialKey) has signed a services agreement with Paradigm Biopharmaceuticals Ltd (Administrators Appointed) (Paradigm) to provide an independent evaluation of its Phase 3 osteoarthritis study. The agreement has a total value of A$25,000 plus GST.

TrialKey will evaluate the trial's design, conduct and analysis to identify potential reasons for Paradigm's interim findings from its Phase 3 trial and assess whether alternative approaches could have affected the results. The findings will inform TrialKey's recommendations for Paradigm's consideration.

The agreement accompanies progress across TrialKey's broader business, including expanded clinical trial design and assessment capabilities, improved internal model performance and additional statistical functions undergoing testing or client validation. TrialKey combines historical trial evidence with information from study documents to assess risks and compare potential changes to trial design, with expert review of its outputs.

TrialKey uses machine-learning models trained on historical clinical trial data to generate predictive insights, risk assessments and recommendations. The reported performance results are based on internal retrospective testing.

Paradigm Phase 3 evaluation and trial optimisation

Paradigm's PARA_OA_012 trial evaluated injectable pentosan polysulfate sodium (iPPS) for knee osteoarthritis. On 23 September 2026, Paradigm announced that the independent Data Safety Monitoring Board had confirmed that the interim efficacy result did not reach the pre-specified threshold required for continuation of the study. In subsequent updates, including on 15 October 2026, Paradigm reported differences between United States (US) and rest of world (ROW) results and identified missing assessments and dosing interruptions as matters requiring further analysis. The overall interim futility outcome remained unchanged[1].

TrialKey will examine the protocol, statistical analysis plan (SAP) and de-identified study data to assess potential reasons for the outcome and identify areas where a different approach to trial design, conduct or analysis might have affected the findings. The work will assess regional differences, treatment exposure and missing data, including scientifically justified alternative approaches to handling missing assessments.

[1] Refer https://paradigmbiopharma.com/announcements/QbRqW9-pps-shows-significant-pain-benefit-in-rest-of-world-analysis

TrialKey deliverables include an integrated technical report and recommendations on study design, endpoints, sample size, missing-data management and trial conduct generated utilising TrialKey's platform.

The engagement demonstrates a commercial application of TrialKey's assessment and planning offering to an existing late-stage clinical programme. The current work does not establish treatment efficacy or guarantee future trial success, regulatory acceptance or funding.

Paradigm is in voluntary administration. Christopher Pattinson and Hayden White of FTI Consulting were appointed as joint and several voluntary administrators of Paradigm on 29 September 2026. Neither Paradigm nor its administrators has reviewed or endorses TrialKey's platform, model results or the other statements in this announcement.

Paradigm's de-identified data will be used solely to perform the engagement and has not been, and will not be, used to train, develop or validate TrialKey's models. The internal model results reported in this announcement do not use Paradigm data.

Trialkey platform capabilities and commercial significance

Following further platform development, Trialkey's current core capabilities and their potential commercial applications are summarised below.

Core Capability	Current functionality	Commercial significance
ML-guided AI optimisation agent	Uses machine-learning (ML) insights to propose study improvements, then scores alternative designs within agreed budget and study constraints.	Supports higher-value study-design engagements, with quantified benefits and trade-offs for expert review.
Confidential protocol assessment	Analyses draft protocols before public registration, identifying design weaknesses and potential delivery risks.	Enables earlier engagement with sponsors while study designs can still be changed.
SAP assessment and integrated modelling	Reviews statistical analysis plans and incorporates supported statistical features into assessment and optimisation, with testing and client validation continuing.	Extends the offering into statistical planning and review, alongside protocol assessment.
Document-enhanced predictive models	**Internal validation: primary-endpoint AUC[2] increased from 0.745 to 0.807**, demonstrating improved ability to distinguish successful from unsuccessful outcomes.	Strengthens the evidence supporting predictive performance and customer evaluation.
Clinical trial cost modelling	Estimates trial budgets, potential cost overruns and expenditure over time; compares costs across proposed study designs.	Supports budget planning, funding decisions and evaluation of whether design improvements justify their cost.
Expert review and tracked-change study plans	Allows users to check extracted information and review proposed protocol changes against the original plan.	Provides a practical handover to clinical and statistical experts, with changes clearly documented.
Competitor and trial similarity analysis	Identifies comparable trials and benchmarks study designs, treatments, endpoints and development timelines.	Supports competitive positioning and differentiation of a sponsor's development programme.

[2] AUC: area under the receiver operating characteristic curve

Current product offering

TrialKey supports clinical trial development from an early idea through to review of an existing study plan. Customers can upload a confidential draft protocol or start with an indication and treatment-type idea. Neither requires a public registry entry or trial identifier.

The platform uses historical trial evidence and machine-learning models to assess recruitment risks, likely amendments, early termination and the estimated probability of meeting the primary endpoint. An AI optimisation agent uses these insights to propose alternative study designs and compare their predicted benefits and trade-offs within agreed budget and study constraints.

Competitor analysis benchmarks comparable trials, while cost modelling estimates trial budgets, potential overruns and the financial implications of proposed changes. Customers can inspect and correct extracted information, compare original and proposed designs, and review changes in a tracked-change study plan.

SAP assessment reviews statistical choices and incorporates supported statistical features into modelling and optimisation, with testing and client validation continuing. Protocol and SAP preparation combines TrialKey's analytical inputs and proposed changes with drafting and review by subject matter experts.

Commercial model and route to market

TrialKey's routes to revenue are scoped assessment, design-support and document-review engagements for biotech sponsors, and pilot licensing with potential repeat assessments through CROs. The Paradigm agreement is a contracted project engagement under the biotech services model. CRO use has the ability to extend the platform across multiple sponsor studies.

The customer proposition is to identify modifiable design and execution risks, assess existing study evidence and support planning as customer requirements change. Delivery of the Paradigm work, additional paid engagements and repeat use will be practical measures of commercial progress. The Paradigm appointment is not a recurring licence arrangement; CRO pilot licensing remains a separate commercial priority.

Internal model results supporting customer evaluation

TrialKey's models now incorporate information extracted from trial documents alongside public registry data. The additional document information provides more detail on study design and statistical methods for assessment and expert review.

Internal retrospective testing recorded improvements across all nine outcomes assessed. The largest gain was in predicting whether a trial met its primary endpoint. Improvements were also recorded for recruitment failure, early termination, enrolment shortfall and heavy amendments.

Outcome	Registry-only AUC	With documents AUC
Met primary endpoint	0.745	0.807
Accrual failure	0.736	0.777
Stopped early	0.758	0.801
Enrolment shortfall	0.757	0.793
Heavy amendments	0.746	0.749

AUC measures a model's ability to distinguish between trials with and without a specified outcome. The primary-endpoint result represents an 8.3% relative improvement in AUC, not an 8.3% increase in actual trial success rates. The results are internal historical findings and have not been independently validated. Full results and methodology are in the appendix.

Next milestones for investors

The next phase is to deliver the Paradigm engagement, establish product credibility through further validation and expand commercial use. Feedback from customers, CROs and industry participants will help guide future development, including enhanced document analysis and more comprehensive clinical trial protocol and SAP generation, supported by expert oversight. Regulatory and reimbursement assessment remain longer-term directions. Delivery depends on technical results, validation, customer requirements and resources. No platform release dates or revenue forecasts are provided.

This announcement has been released with support of the board.

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About Pathkey.AI Ltd

Pathkey.AI Ltd (ASX: PKY) is an Australian technology company focused on developing proprietary AI powered large language model solutions for data intensive industries. TrialKey is focused on clinical trial design and optimisation. Chipforge is developing an AI-powered chip design platform for semiconductor engineering. Both TrialKey and Chipforge platforms are built around an agent-based AI architecture combining large-language-model functionality with neuro-symbolic reasoning to solve complex design optimisation problems. In each platform, AI agents generate candidate solutions, evaluate them against defined objectives and iteratively refine them through a structured reflection loop using reinforcement driven optimisation.

About TrialKey

TrialKey uses machine-learning models trained on historical clinical trial data to generate predictive insights, risk assessments and recommendations. The reported performance results are based on internal retrospective testing; independent validation remains planned. Outputs are probabilistic and subject to limitations including data quality, completeness, historical bias and differences between individual trials. Predictions and recommendations support decision-making and do not guarantee clinical, regulatory or commercial outcomes. Actual results may differ materially from model predictions. TrialKey outputs should be considered alongside clinical expertise, scientific evidence and independent professional judgement. Predictive performance does not itself establish that using the platform improves clinical outcomes.

Appendix: internal model results and validation

TrialKey compared registry-only models with models incorporating document-derived features. The registry-only baseline was recalculated on the same dataset as the updated models, so the reported uplift measures the additional document information rather than an expanded trial population.

Outcome	Registry-only AUC	With documents AUC	Relative uplift
Met primary endpoint	0.745	0.807	8.33%
Accrual failure	0.736	0.777	5.53%
Stopped early	0.758	0.801	5.72%
Enrolment shortfall	0.757	0.793	4.78%
Eligibility section*	0.747	0.753	0.78%
Outcomes section*	0.715	0.718	0.51%
Arms section*	0.748	0.752	0.49%
Heavy amendment	0.746	0.749	0.40%
Design section*	0.716	0.718	0.29%

Relative uplift = (AUC with documents − registry-only AUC) ÷ registry-only AUC. Percentages are calculated from unrounded AUC values; displayed AUCs are rounded to three decimal places. Section outcomes relate to amendments in the named protocol sections. Source: TrialKey Validation Report 1.2 and its saved validation metrics, October 2026. Heavy amendments means four or more substantive amendments within three years.

Interpreting the results

AUC (area under the receiver operating characteristic curve) measures discrimination. A value of 0.5 indicates chance-level discrimination and 1.0 indicates perfect discrimination. An AUC of 0.807 does not mean 80.7% prediction accuracy. These are retrospective internal results, not prospective or independently validated evidence of improved clinical outcomes.

Restricting document-derived inputs to variables recorded in at least half of training trials changed primary-endpoint AUC from 0.807 to 0.809. Results varied by outcome. Further validation is required to establish performance across customer documents and trial populations.

A sensitivity analysis excluding trials whose earliest filed document fell after the relevant three-year observation window changed AUC by no more than 0.010 across the outcomes tested. This does not establish that every document version used was available before its relevant outcome. Document timing remains a validation consideration.

Independent validation and prospective assessment, with predictions recorded before outcomes are known, are planned priorities.

Other capabilities have different evidence bases

Cost modelling is intended to support relative comparisons rather than reliable absolute trial budgets. Budget forecasting currently covers drug and biological trials, not devices. Statistical review benchmarks plans against observed practice; it is not a validated prediction model.

Forward-looking statements

This announcement contains forward-looking statements about product development and releases, recruitment, commercial launch, additional tool chains, secure development, model development, custom silicon, customer delivery, validation and commercialisation. These statements reflect current intentions, assumptions and expectations, are subject to technical, commercial, staffing and funding risks and uncertainties. Actual results and timing may differ materially. Development priorities and potential commercial opportunities do not guarantee product releases, customer acceptance and agreements, recurring revenue or cash receipts. The independent evaluation assessed the product against agreed designs and criteria and is not certification of the whole platform. Pathkey does not undertake to update forward-looking statements except as required by law.