



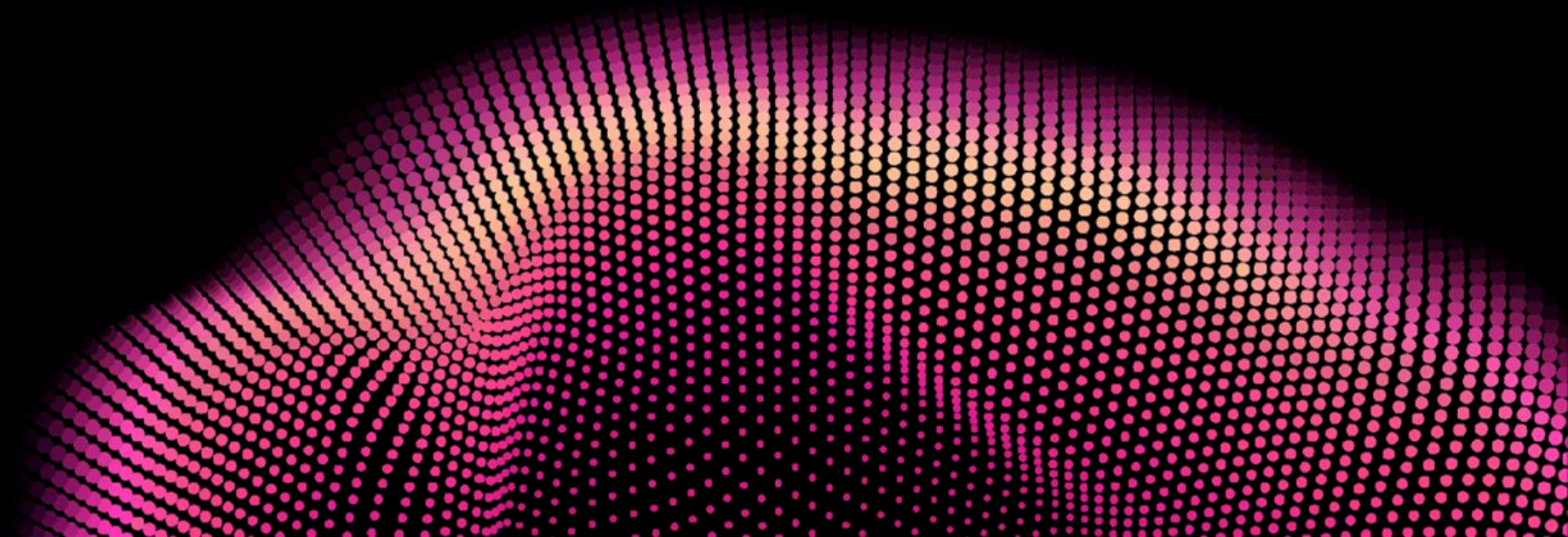
# Strategy Update & TrialKey Demonstration

September 2023

(ASX:OPL)  
[www.opyl.ai](http://www.opyl.ai)



**We apply proprietary AI to improve  
clinical trial recruitment, predict  
outcomes and design smarter trials**



# Our vision

Our vision is to enhance global health and wellbeing – empowering global biopharma and healthcare institutions with transformative AI-enabled technologies

## Overview:



OPL uses leading AI and novel methodologies to analyse health data, and recruit highly targeted candidates for clinical trials via its **Opin** platform



OPL has recently developed a second technology platform, **TrialKey** that accurately predicts clinical trial phase outcomes and provides insights and recommendations on smarter trial design – **commercialisation underway**



Moving forward, OPL is focused on driving highly scalable recurring revenues from its **Opin** and **TrialKey** platforms, moving away from bespoke one-off project and consulting revenues



## Today's speakers



**Mark Ziirsen**  
Executive Chairman



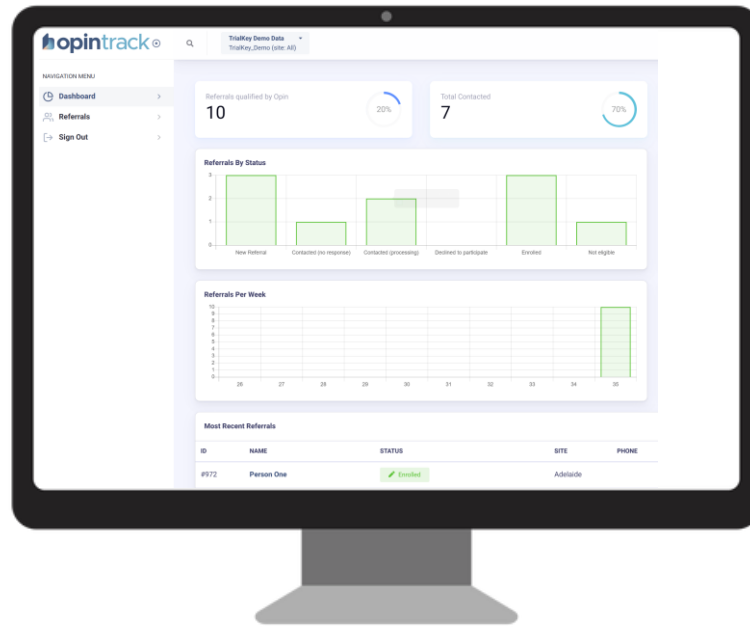
**Dr Hugo Stephenson**  
Head of Opin



**Damon Rasheed**  
CTO

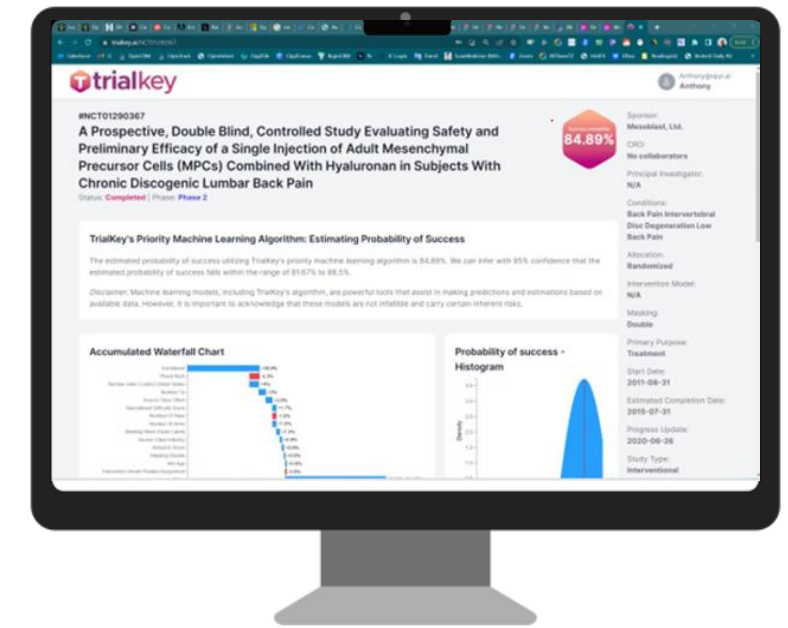
# Technology platforms

Two scalable platforms designed to disrupt and transform support services for global clinical trials



Opin:

- 🔍 Identifies high quality, targeted candidate populations
- 👥 Uses real-time data to attract and match patients to trials
- 📅 Targeted outreach promotes high candidate-to-trial conversion



TrialKey:

- Analyses >500 trial factors to predict success outcomes 📊
- Global data intelligence offering insights on trial optimisation 📈
- Trained on proprietary datasets, leveraging best-in-class AI / ML 🗄️

# FY23 Group Snapshot

Major milestones achieved across OPL’s core platforms – Opin and TrialKey – supported by strategic corporate initiatives

|                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div>Opin</div> <div>Commercialised, revenue-generating platform</div> <div>40% growth (FY23 Rev: \$352k)</div> | <div><div>✓</div>Signed new MSAs with strategic partners, including GlaxoSmithKline (GSK) and Bristol Myers Squibb (BMS)</div> <div><div>✓</div>Signed 6 new contracts, including Murdoch Children’s Research Institute and BMS</div> <div><div>✓</div>Technology developments made to drive refocused product positioning, scale and recurring revenue</div> <div><div>✓</div>New Head of Opin, Dr. Hugo Stephenson, appointed to accelerate recruitment for ANZ-based clinical trials and health programs, and unlock new business opportunities in community management</div> |
| <div>TrialKey</div> <div>Platform developed, commercialisation strategy commenced</div>                         | <div><div>✓</div>Core platform development (MVP<sup>1</sup>) complete – commercialisation strategy underway</div> <div><div>✓</div>Milestone clinical trial recall accuracy rating of 88% AUC<sup>2</sup> achieved</div> <div><div>✓</div>External platform feedback received validating platform value and market opportunity</div> <div><div>✓</div>Initial target markets identified, primary customers / pilot project partners in discussion</div>                                                                                                                          |
| <div>Corporate</div>                                                                                            | <div><div>✓</div>Cash management and cost optimisation strategy ongoing</div> <div><div>✓</div>Completed internal review, resulting in strategic shift to focus on recurring recurring revenues from Opin and TrialKey offerings versus historical bespoke, one-off project revenue</div> <div><div>✓</div>Realignment of leadership to support strategy: Dr. Hugo Stephenson appointed Head of Opin and Mark Ziirsén appointed Executive Chairman</div> <div><div>✓</div>Appointed Mark Simari and Tony Guoga as Non-Executive Directors to Opyl Board</div>                    |



1. MVP refers to Minimum Viable Product. 2. AUC is a statistical metric used to assess the performance of predictive models by quantifying their ability to distinguish between trial successes and failures. Recall measures the proportion of actual successes that the model/test correctly identifies as positive when using the 30% threshold





Update



## Introduction – Dr. Hugo Stephenson

“ I am excited by the strong platforms that exist in Opin and the opportunity to build on these foundations to transform the way patients are selected, matched and onboarded into clinical trials and health management programs.

Since joining OPL, I have focused on consolidating the existing technology assets, which are at the leading edge of the sector, and developing our operations team in specialised areas of excellence.

Given the underlying technology, the quality of our team and recent market feedback, I believe we are uniquely placed to be a key disruptor in clinical trial recruitment throughout Australia and New Zealand, and then internationally over the long-term. ”

**Dr. Hugo Stephenson**

Head of Opin

# Global market opportunity: Trial recruitment

Significant and unchanged market opportunity for Opin, with traditional methods increasingly requiring digital disruption

## Traditional clinical trial recruitment:

- **Inefficiencies:** Clinical trial patient recruitment is time consuming, costly and inefficient
- **Conversion:** Dated outreach methods / poor data result in low candidate conversion
- **Retention:** In-trial patient retention is increasingly difficult, with significant drop-out rates

~80%

Of trials fail to recruit  
on time / on budget

Up to ~60%

Of trial cost is related  
to recruitment

## Opportunity growth drivers:

- Global trend in acceptance of digital health technologies vs. traditional methods
- Increasing demand for decentralised, real-time data-centric recruitment
- Significant AI and ML advancements driving recurring revenue opportunities
- Persistent and significant barriers in accessing volunteer populations

Total Addressable Market

US\$5.7bn

Global Clinical Trial Recruitment Market<sup>1,2</sup>



Initial focus on Australia and New Zealand markets as priority



# Opin FY23 snapshot

FY23 focused on consolidating go-to-market (GTM) position and other strategic initiatives to underpin long-term, scalable growth

\$352k

FY23 revenue

\$75-100k

Average contract value

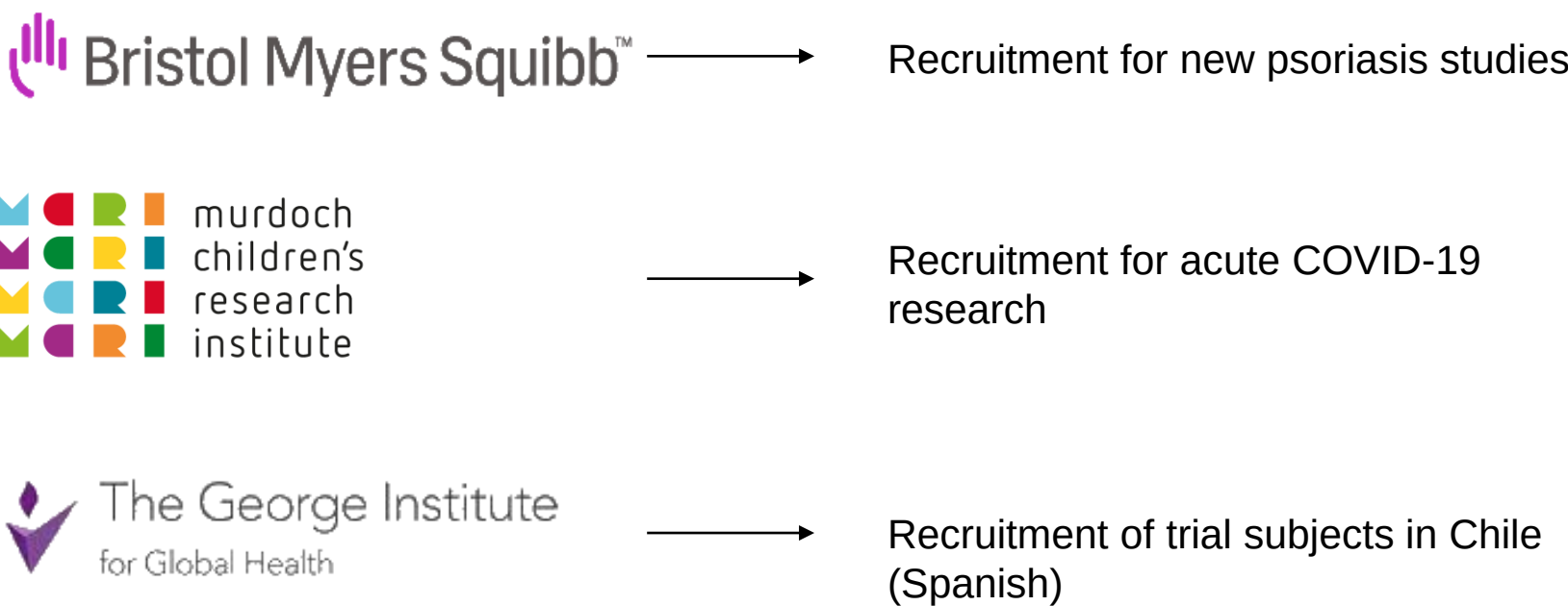
27,000

Patients in Opin platform

## Milestone achievements

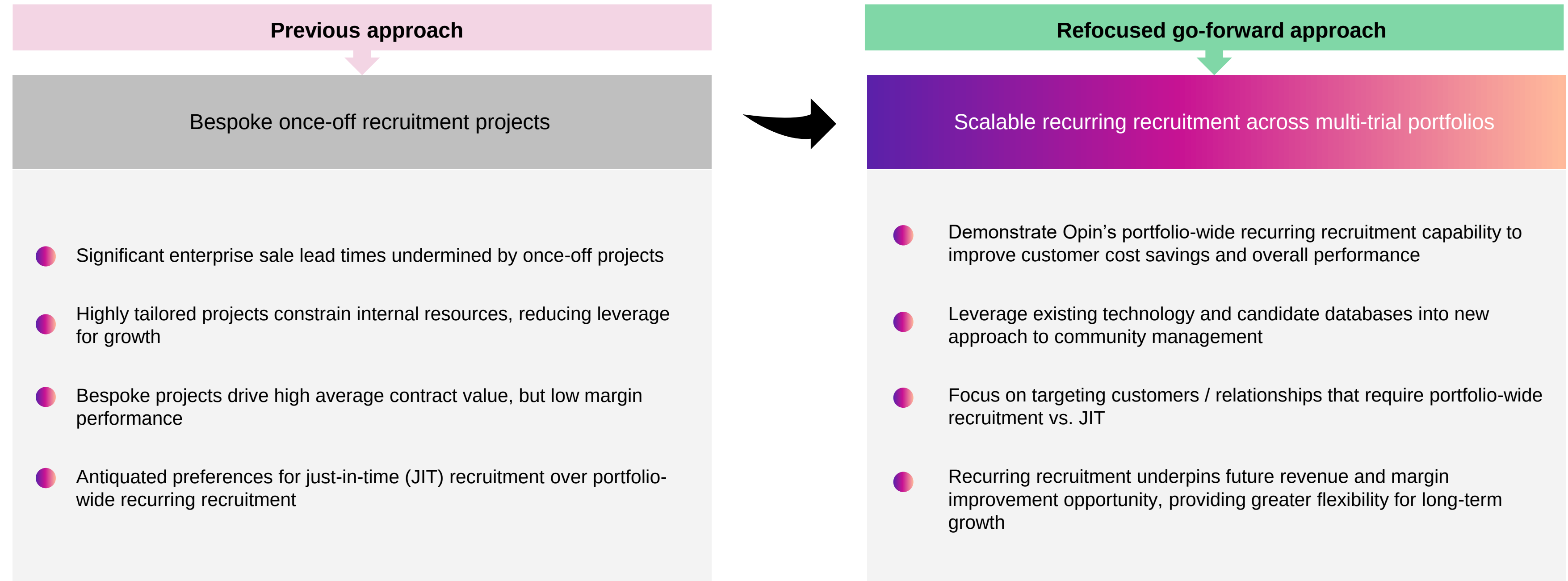
- 6 new customers signed in FY23, including Murdoch Children’s Research Institute
- Master Services Agreements (MSAs) signed with strategic partners, including BMS and GSK - key to securing biopharma and CRO trial and patient data
- Technology improvements made to unlock scale and recurring revenue opportunity
- New leadership appointed to develop ANZ presence and drive global growth over the long-term

## Select customers:



# Refocused positioning to unlock scale

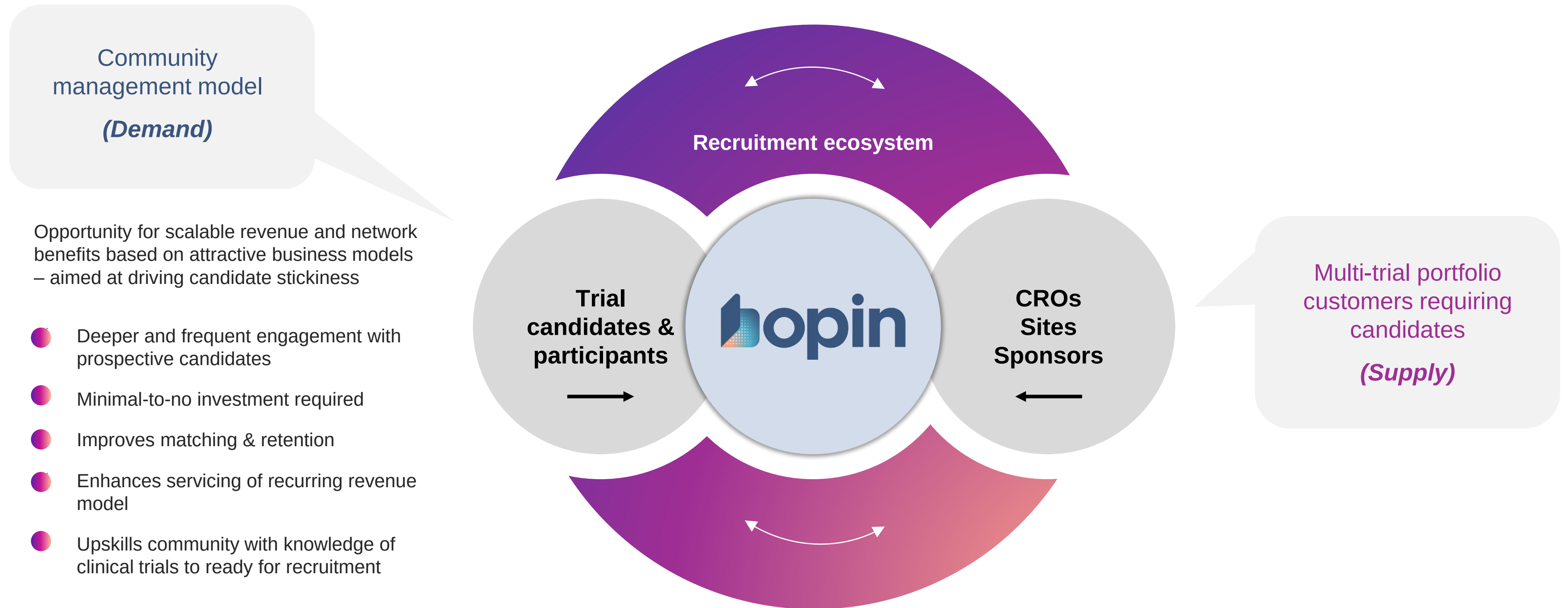
Leveraging learnings through FY23, Opin is focused on driving recurring revenues versus historical once-off, low margin project revenue





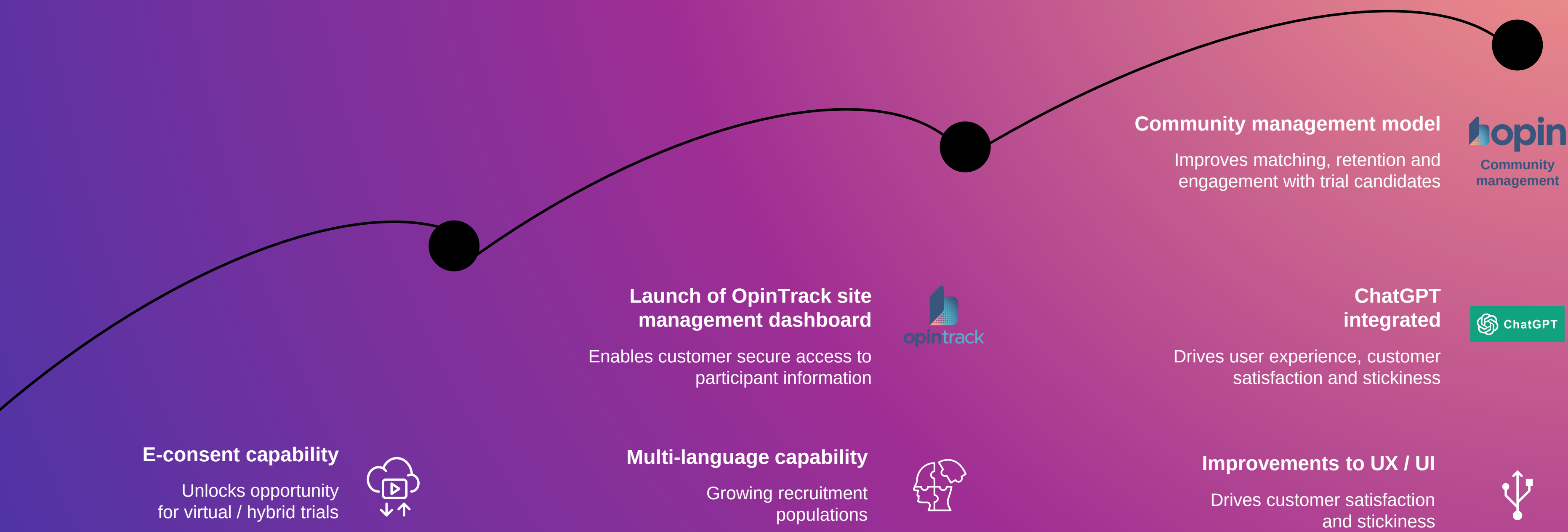
# Community management

Strong technology foundations enabling new community management models – opportunity to manage virtual private communities on behalf of research institutions, patient advocacy groups and sponsors to drive early recruitment into trials



# Technology foundations

Significant progress in the development of OpIn to-date, with strategic investment enhancing long-term recurring revenue proposition



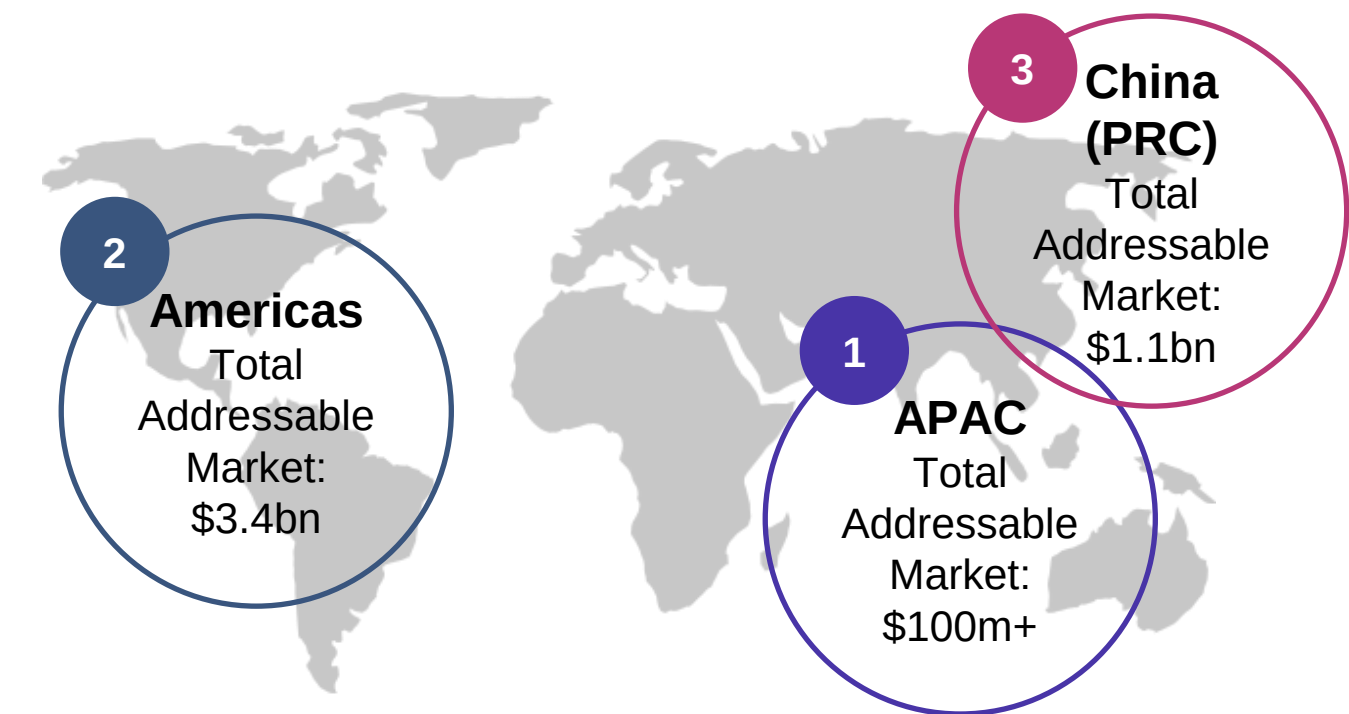
# Opin growth priorities

Leveraging Opin's core strengths to drive revenue growth in Australia and New Zealand over the short to medium-term, with global expansion plans once local track-record achieved

## Immediate growth priorities:

- 1 Continue to demonstrate recurring recruitment capability and value proposition over JIT methods
- 2 Target marquee multi-trial customers through senior accretive relationships - securing preferred vendor status across trial portfolios
- 3 Form new strategic partnerships to build leverage into existing sales and marketing efforts
- 4 Achieve full HIPAA compliance, GDPR, ISO accreditations to bolster current offerings and unlock global opportunity

## Long-term opportunity:



Pursue international expansion, focusing on broader APAC and geographies with high research activity i.e., US & China





Update

# Global market opportunity: TrialKey

Global opportunity to support lifescience investors in optimising investment decisions, and other market participants increasingly seeking global data intelligence on clinical trials

## Market challenges:

- Increasing number of clinical trials launched each year, with poor trial design driving high failure rates
- Increasing complexity of trial protocols driving difficulty in pin-pointing trial failure sources
- >US\$47bn invested into clinical trials p.a. across >35k trials, and only ~30-40 new drugs approved by the FDA p.a. – implying significant opportunity for trial design optimisation and better investment decisions
- Financial sponsors focused on minimising failure rates of investee trials, seeking to intervene earlier in the trial design process
- Clinical trial market participants seeking greater access to accurate and transparent global trial data to aid in decision-making

Investment into clinical trials p.a.

# US\$47bn

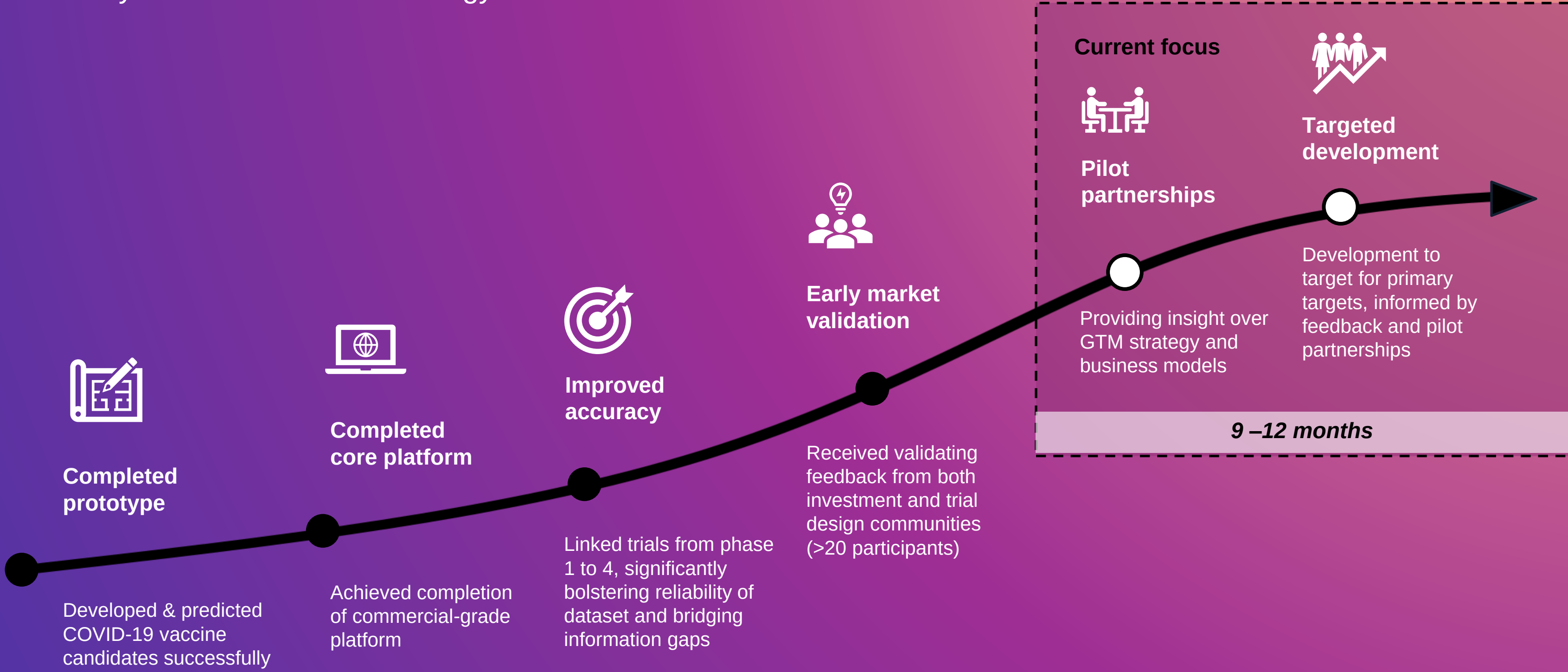
Including expenditures on failed trials<sup>1</sup>





# TrialKey development journey

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





# TrialKey status

TrialKey platform now developed, with best-in-class recall accuracy, significant training datasets and high impact trial intelligence reporting capability

88.8%

Accuracy in predicting trials passing primary outcome<sup>1</sup>

>40,000

# of clinical trials used to train AI model<sup>2</sup>

>500

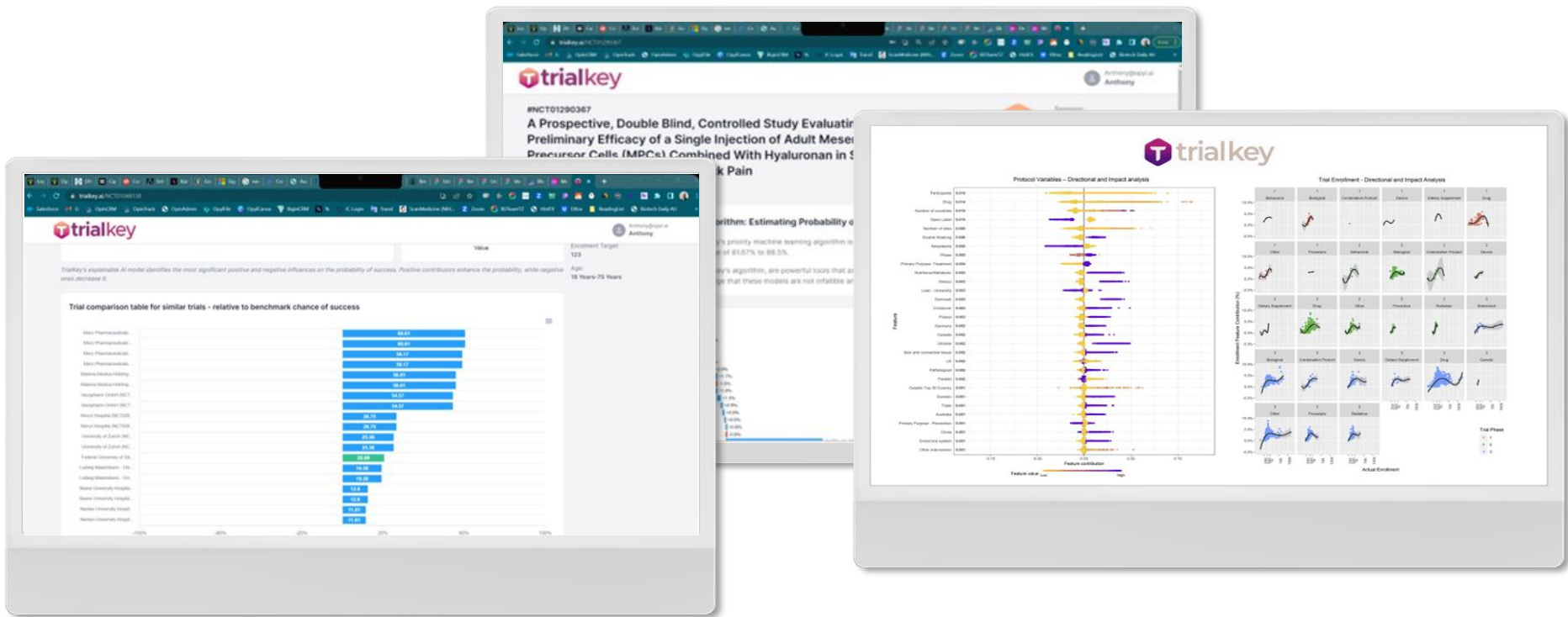
# of variables reviewed to drive predictive insights per trial

0.89

Area Under the Curve<sup>3,4</sup>

## TrialKey commercialisation progress:

- Completed core platform technology development to minimum viable product (MVP) stage
- TrialKey team focused on commercialisation and GTM strategy – internal review of business and revenue models informed by recent market feedback
- Primary use cases identified – lifescience investors and clinical trial designers operators. Discussions with pilot project partners in progress



1. Accuracy in predicting outcomes of Phase 2 and Phase 3 trials at 30% recall. Recall defined as the number of successful trials a model is able to rank in a specified percentile.  
2. Trained on registered clinical trials via clinicaltrials.gov registered before 2018  
3. Based on a sample dataset of 2,469 trials with 373 known successes and 2,095 known failures  
4. Area Under the Curve (AUC) interpreted as the ability for a model to rank positive cases higher than negative cases with x% probability

# Target markets

Focused on two distinct and significant sectors with feedback already received from >20 test enterprise participants in both markets validating TrialKey's value



## Lifesciences investment community

E.g. Investors, analysts, fund managers, senior clinical trial decision-makers informing investment decisions

- Investment community focused on analysing clinical trials that represent a key value inflection point
- Opportunity to support investors in understanding success likelihood, providing tools to evaluate trial opportunities
- Supports investors in making data-driven investment decisions leading to better allocation of capital / optimised returns
- Opportunity to work with portfolio trial investee companies through consultation with trial designers and clinical trial intelligence reporting



## Clinical trial designers / operators

E.g. Global biopharma, MedTechs, Contract Research Organisations (CROs), site networks, hospitals, research institutes

- Biopharma and MedTech groups focused on designing clinical trials to maximise success outcomes
- Growing number of trial protocol factors driving difficulty in pinpointing source of poor outcomes
- TrialKey identifies / mitigates design risk, enhances trial parameters, and selects appropriate vendors (CROs, sites, sponsors)
- Supports biopharma and medtech groups to reduce costs of clinical trials, improve efficiencies and improve overall probability of success

Significant positive feedback received from both target markets to-date  
Recurring revenue model highlighted to future-proof OPL financial profile and underpin scale

# Attractive and scalable business models available

Commercialisation plans informed by recent platform feedback supports delivery of TrialKey via two high-margin and scalable business models

## Licensing model

- Tiered annual subscription model
- Subscription tiers unlock additional features i.e. region, protocol modelling, number of trial analysis requests per month
- Optimises and provides predictive modelling of protocol designs
- Supports vendor selection with CROs and sites
- Maintains a watchlist view of companies, therapeutic areas or technology asset classes
- Delivers ongoing analysis of technology asset types or therapeutic areas

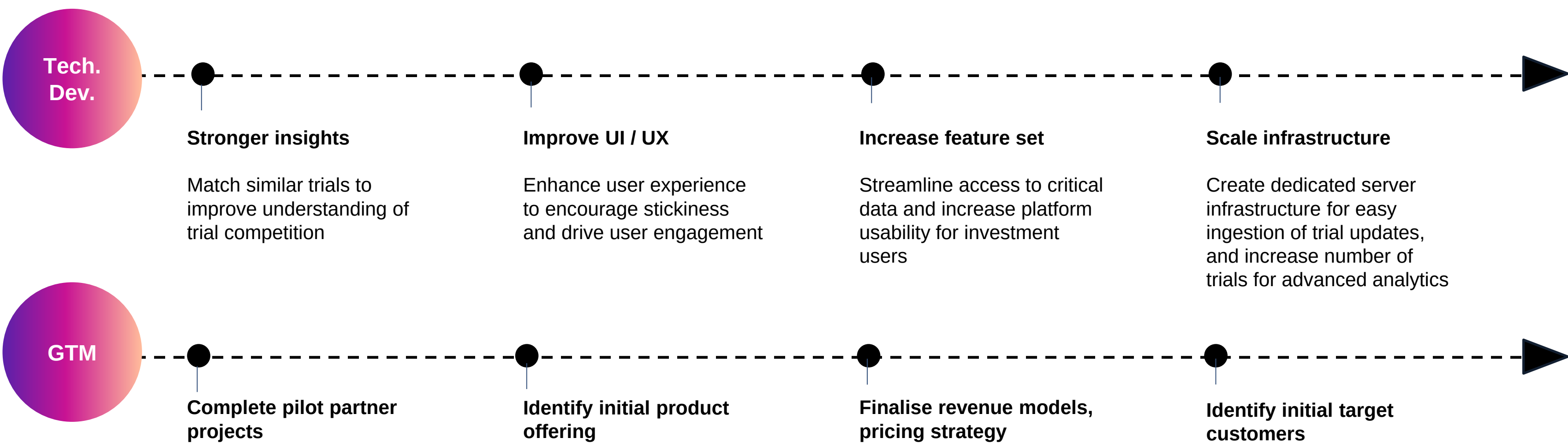
## Global clinical trial data intelligence reports

- Provides discrete analysis reports on trial protocols for lifescience investors and clinical trial market participants
- Revenue model under development with optionality to provide under subscription models or tiered report pricing.
- Capability to assess feasibility of trial for investment, recruitment, success outcomes and other trial intelligence factors
- Provides data and intelligence on single company clinical programs (Phase 1 to Phase 4)
- Analyses diverse types of medical technology assets and therapeutic areas



# Priorities to commercial launch

Two parallel workstreams underway to commercially launch platform in-market: (1) technology development to future-proof underlying technology, and (2) GTM strategy, including business model finalisation



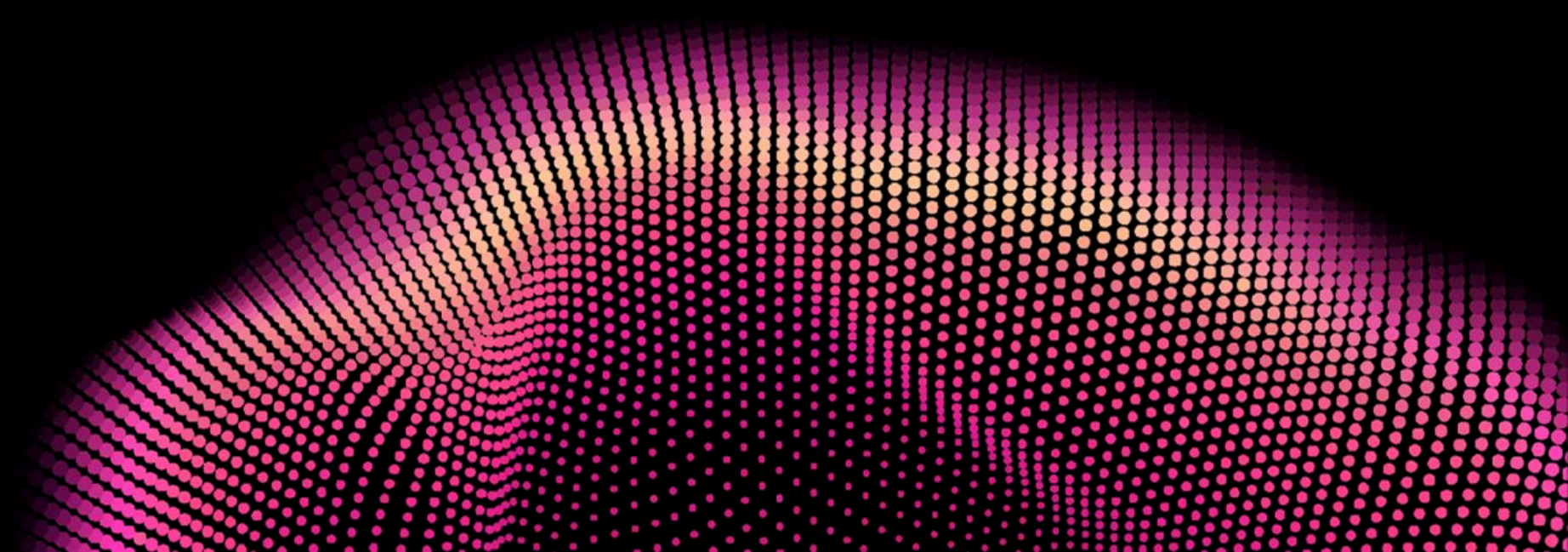
Note the TrialKey platform is revenue-ready, however ongoing focus will be on technology development and GTM work to ready the platform for scale.



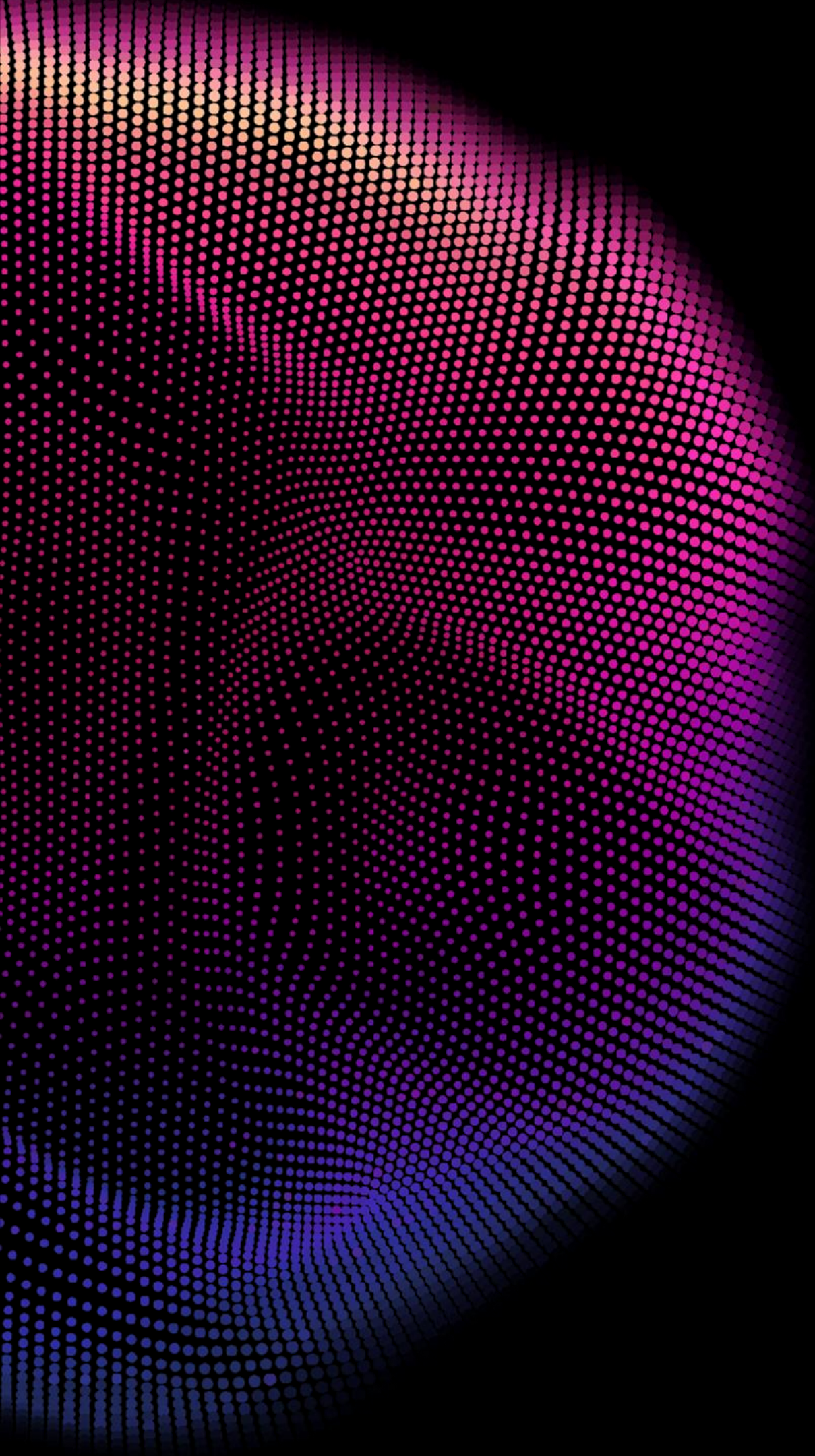
1. Note Technology Development and GTM initiatives are not sequential. Order displayed is for illustrative purposes only



Tech. Demo.







# Recap



# Recap

FY24 priorities focused on expanding Opin's ANZ presence and driving recurring revenues, commercialising TrialKey and corporate initiatives to accelerate growth



- Establish OPL as a market leader in ANZ, converting recurring revenue opportunity
- Execute on refocused approach to market and build community management
- Secure preferred vendor status with global partners
- Continue to advance discussions with patient advocacy groups and major hospitals to build early patient communities



- Finalise commercialisation and GTM strategy work
- Ongoing technology development to ready for scale

Corporate

- Pursue strategic partnerships and growth opportunities to accelerate growth
- Continue to carefully manage cashflow and costs
- Strategically invest in technology and sales and marketing to position platforms and unlock long-term revenue opportunity

# Q&A

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