



The Retinal Intelligence Platform

Retina IQ installs the network. The evidence engine proves the signal. FDA-authorized biomarkers validate the platform.

Executive read-ahead deck · v5.0

The investment thesis

A platform, not a single test and not a reading service.

1. Install the network

Retina IQ gives independent optometry practices an immediate clinical reason to connect with SpectOcular: specialist interpretation, structured workflow and patient trust.

2. Manufacture evidence

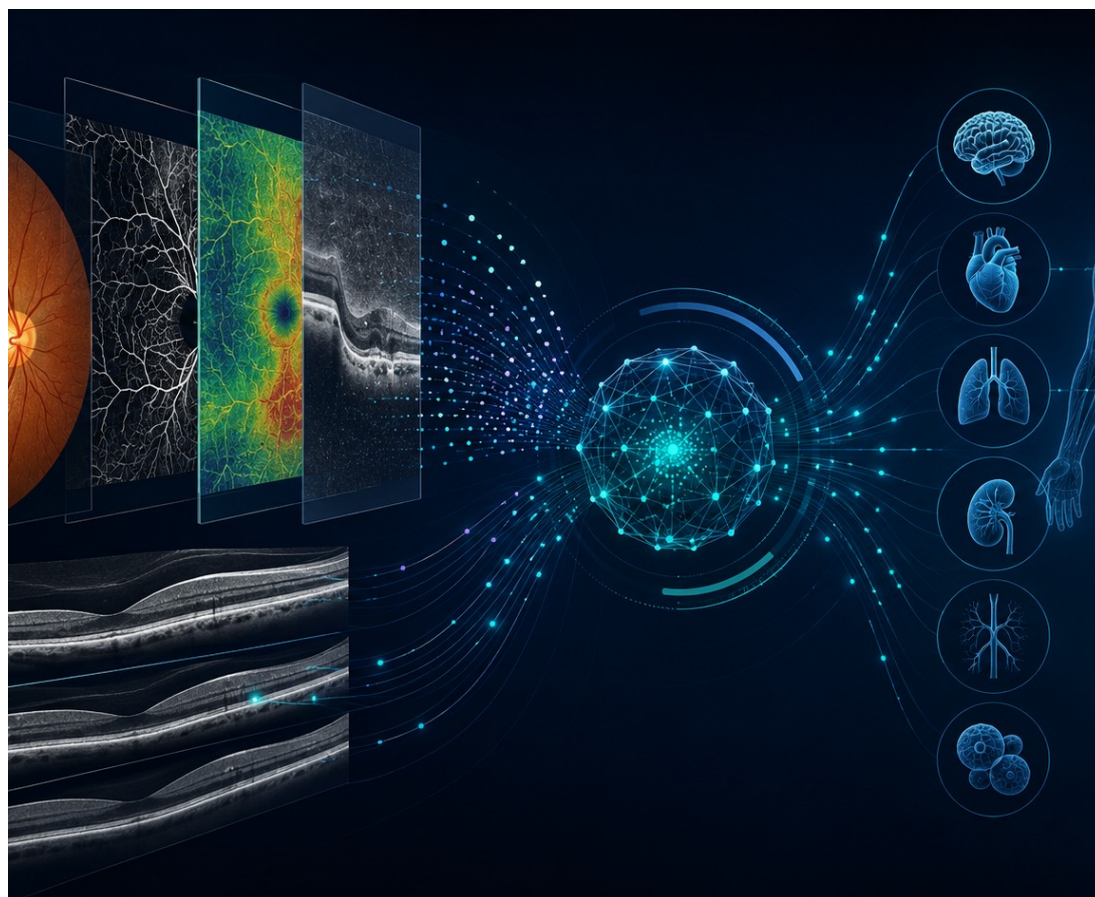
Routine imaging becomes prospective, consented, re-contactable, multimodal evidence linked to labs, records, pharmacy and outcomes.

3. Produce biomarkers

The first FDA authorization proves the engine. The platform value comes from repeating the process across kidney, metabolic, vascular, neuro and ocular indications.

The retina is becoming a systemic-health sensor

The same routine scan can capture eye disease, microvasculature, structure and systemic signal.



What is different now

AI models can extract signal from retinal patterns that clinicians do not consciously score.

Why multimodal matters

Fundus is scalable; OCT adds structure; OCT-A adds microvascular discovery signal. SpectOcular tests which layer actually improves prediction.

Why longitudinal matters

Routine eye care creates repeat observations over years. Re-contact rights allow targeted follow-up, re-imaging and biospecimens.

Why this can become a platform

Each product creates evidence, infrastructure and regulatory learning that reduces the cost of the next product.

The gap: millions of retinal images, no retinal biomarker platform

Existing datasets are large. They are not built for repeated, prospective systemic-health product development.



Large retrospective datasets are useful for discovery, but they cannot reliably call participants back, collect missing labs, add biospecimens, standardize future imaging, or deliberately enrich underrepresented cohorts.

SpectOcular's opportunity is to pair existing archives for speed with a prospective optometry network that can fill exactly those gaps.

Why now

The category has moved from academic signal to commercial competition.

FDA pathway

AI-enabled diagnostics and De Novo / 510(k) pathways are established enough to plan around.

OEM validation

Strategic imaging companies are buying or partnering around systemic retinal AI.

Multimodal installed base

Fundus + OCT workflows are already routine in optometry and retina care.

Foundation models

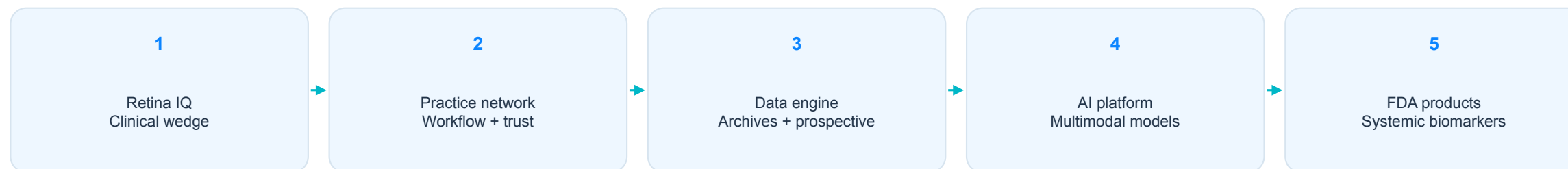
Self-supervised retinal models make broad biomarker discovery more practical.

Data rights matter

The next bottleneck is not images alone; it is consent, linkage, re-contact and clinical-grade labels.

The SpectOcular architecture

One engine, two evidence systems, many products.



Clinical engine

Immediate value for practices and patients; installs transfer, reading and consent workflows.

Evidence engine

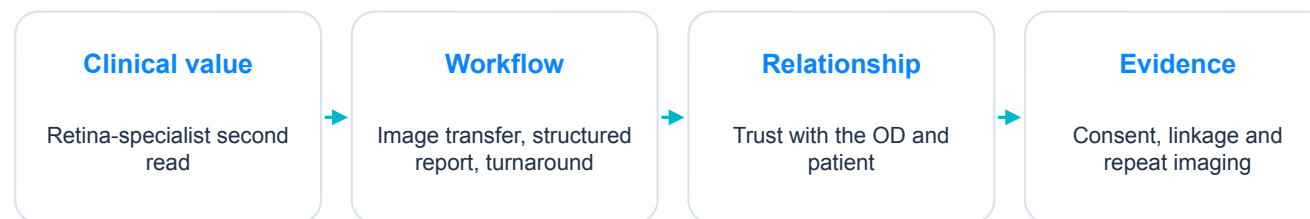
Retrospective archives for speed; prospective cohort for quality, diversity, re-contact and follow-up.

Product engine

CKD first; additional biomarkers follow the same infrastructure.

Retina IQ is the installation wedge

It is not the company; it is the reason practices adopt the platform.



Primary metric

CRLP

Cost per Regulatory-Grade Longitudinal Patient

The goal is not to maximize read margin. The goal is to lower the net cost and time required to create each submission-grade patient and each future biomarker.

Evidence strategy: archive + prospective network

The fastest cohort is the one already sitting in practice archives — but the prospective network makes it regulatory-grade.

Archive engine

Use existing fundus and OCT archives to test linkage, reproduce baseline CKD detection, evaluate retina + EHR + pharmacy fusion, and identify the fastest viable claim.

Purpose: speed and discovery.

Prospective engine

Collect same-visit labs, standardized imaging, demographic targets, medication reconciliation, re-contact rights and optional biospecimens.

Purpose: regulatory-grade evidence and label expansion.

Do not spend five years building a giant cohort before reaching a product milestone. Build the prospective registry in parallel with the first regulatory program.

Multimodal retina is the key technical hypothesis

SpectOcular must prove that fundus + OCT $\pm$ OCT-A adds clinically meaningful signal beyond cheap conventional variables.

Fundus

Scalable deployment modality

OCT

Structural phenotype: retina, choroid, nerve, vasculature-adjacent layers

OCT-A

High-information microvascular discovery layer

Clinical + pharmacy

Benchmark and fuse; do not confuse correlation with product value

The honest kill criterion

If multimodal retina does not outperform fundus alone and clinical baselines in a reproducible way, SpectOcular should narrow the product strategy instead of selling a false multimodal story.

The AI platform: shared representation, many products

Each indication should reuse the same data-quality, feature, validation and governance backbone.

1

Self-supervised retinal encoder

2

Multimodal fusion: fundus + OCT + OCT-A

3

Clinical / lab / pharmacy feature layer

4

Locked train / tune / test partitions

5

Subgroup performance + calibration

6

Drift monitoring + model governance

The platform matters only if the next biomarker is faster, cheaper and more defensible than the first.

First product: CKD detection

CKD is first because it is the fastest proof, not because it is the final destination.

Lead development hypothesis

Detection of prevalent, previously unrecognized CKD stage 3+ from routine retinal imaging in adults presenting for eye care.

Why CKD first

Same-day eGFR/uACR reference standard; enriched enrollment; no outcome waiting; strong clinical need; clear pathway to test with Q-Sub.

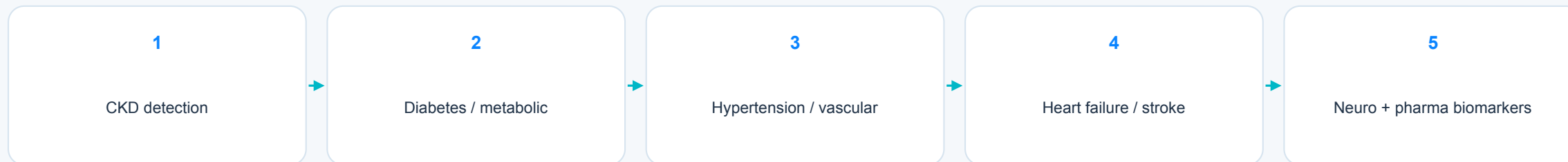
Co-claim leverage

Draw HbA1c on the same subjects and evaluate undiagnosed diabetes/prediabetes as a second output from one evidence program.

Cardiovascular is sequenced, not abandoned. It remains a later program if SpectOcular can show additive value beyond cheap, established clinical risk models.

From first product to portfolio

One imaging workflow. A shared evidence engine. Multiple potential biomarker products.



Development logic

Start with claims where the reference standard exists today.

Expansion logic

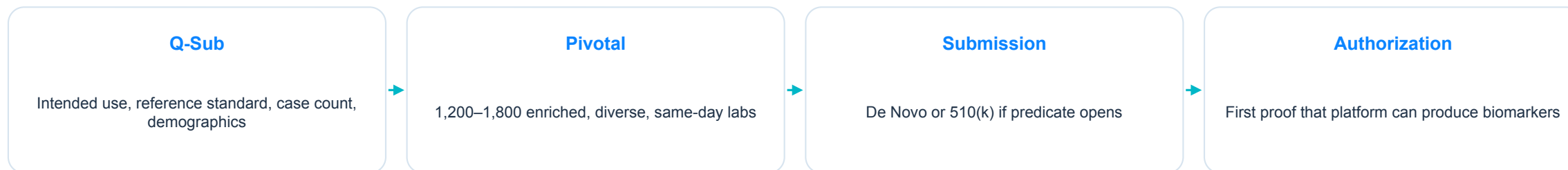
Move to progression and response claims once longitudinal data matures.

Platform logic

Each validated product improves distribution, data quality and regulatory credibility.

Regulatory strategy: learn early, spend after feedback

The Q-Submission is the highest-information milestone in the first nine months.



\$25–75K

Regulatory consulting budget to file and obtain pre-submission feedback

12–18 mo

Initial planning range for enriched pivotal enrollment

Y4

Planning target for first authorization if the archive/pivotal path works

Commercial architecture: operating P&L funds product creation

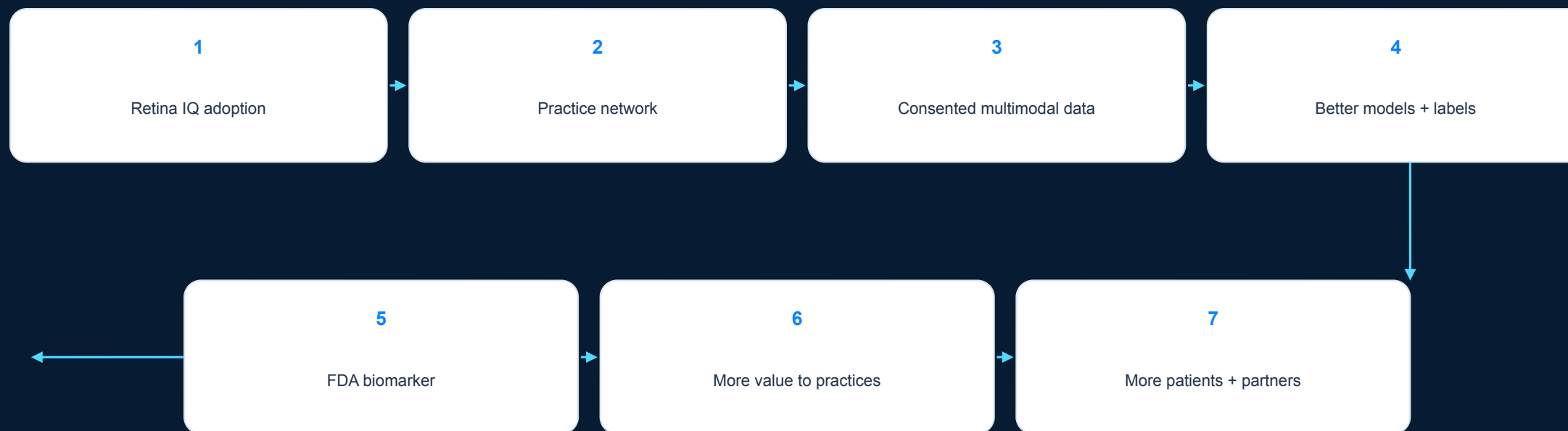
Judge every revenue line by whether it reduces time and cost to regulatory-grade evidence.

Revenue line	Buyer	Strategic role
Retina IQ	Patient via practice	Install and sustain network
Wellness	Patient via practice	Acquire consent + re-contact
Sponsor studies	Pharma / CRO	Non-dilutive evidence funding
Authorized diagnostic	Payers / partners	Terminal product revenue engine

The read business is the downside case. The platform upside is created when that business manufactures reusable, submission-grade evidence.

The flywheel

The first authorization should make every subsequent product easier to create and sell.



Every loop lowers the cost of the next biomarker.

Why SpectOcular can win

The company sits at the intersection of clinical credibility, consent architecture and reusable evidence generation.

Retina-specialist credibility

Founder and governance anchor clinical trust and quality.

OD network wedge

Retina IQ gives practices immediate usefulness before systemic biomarkers exist.

Prospective consent

Re-contact, re-imaging and biospecimen options large datasets cannot add retroactively.

Multimodal strategy

Fundus for scale; OCT/OCT-A for differentiation if incremental value is proven.

Authorization-first discipline

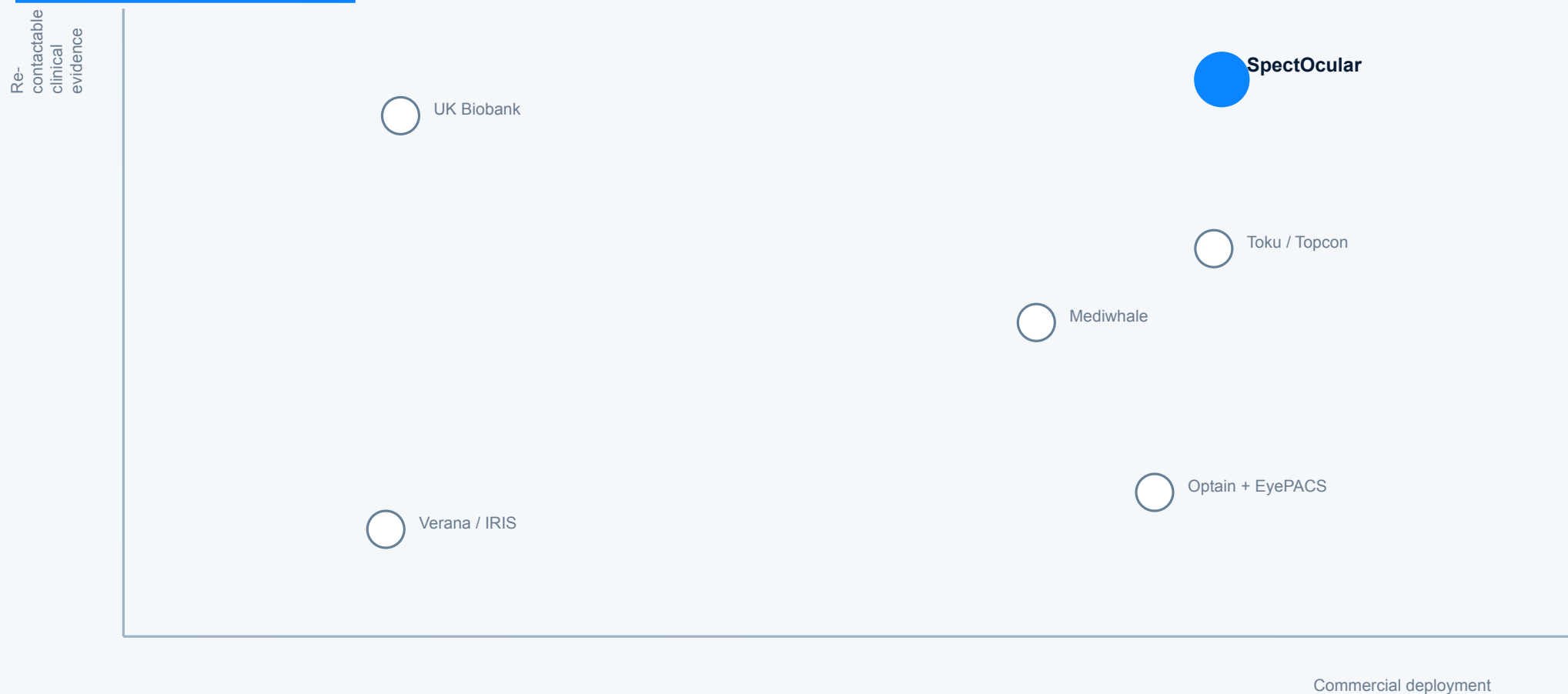
First product chosen for speed of proof, not vanity market size.

Strategic optionality

OEMs, pharma, payers and RWE buyers all become potential counterparties.

Competitive position

SpectOcular should not claim to be first at everything. It should claim the narrow wedge it can own.



Positioning: build the US multi-ethnic, re-contactable, multimodal cohort and use competitors' regulatory progress as a potential predicate rather than a reason to wait.

The pilot tests the data engine

The first 90–120 days should answer whether the platform can be made operationally real.

Gate 1 — Network

≥50% of piloted ODs convert to paid within 60 days. Fail = revise wedge/channel before scale.

Gate 2 — Cohort

Consent, multimodal imaging and record linkage complete reliably. Fail = fix workflow before adding sites.

Gate 3 — CRLP + quality

CRLP lands inside target and data are model-ready. Fail = do not subsidize an expensive cohort.

In parallel: tokenize existing consultant archives and measure true linkage to claims, labs, pharmacy and NDI.

Four tests under ~\$250K and ~90 days

The plan is designed to create facts before committing serious capital.

0 · Mediwhale / Topcon call

Would a partner pay for US multi-ethnic enrollment + distribution?

1 · FDA Q-Sub

Reference standard, case count, demographics, De Novo vs 510(k).

2 · UK Biobank Tier 3

Does retina + records + pharmacy outperform retina alone?

3 · Archive linkage pilot

Are US practice archives retrievable and linkable?

Five-year milestone plan

Value is created by moving up the biomarker-platform milestone ladder.

Y0–Y1

Archive linkage, UK Biobank, Q-Sub, pivotal opens

Y2

Pivotal enrolled, Breakthrough / readout

Y3

Submission filed, second archive publication

Y4

First authorization granted

Y5

Authorization + first commercial revenue + cohort

Y7–8

Category I CPT / coverage

Y10+

Prognostic claims and scale

Important discipline: prognostic cardiovascular / CNS claims are not year-five products. They are long-dated options after the cohort matures.

Valuation logic: milestone position, not revenue multiples

The reading business is the operating engine. The product authorization is the value inflection.

Today

Team + thesis + pilot-ready
modest

After archive/Q-Sub

Key technical and regulatory facts known
\$10–25M planning range

After pivotal readout

US diverse evidence package
\$30–60M

Authorization

First systemic retinal biomarker validated by FDA
\$110–200M

Authorization + launch

Clarity-like position plus network
\$150–250M

Reimbursement + portfolio

Repeatable product engine
\$250M–\$1B+ option

Founder advantage

SpectOcular's first operating advantage is clinical credibility plus immediate launch capacity.



Retina surgeon

Specialist credibility behind Retina IQ and clinical QA

Existing practice platform

RONT provides initial clinical operations and reputation

OD relationships

Pilot begins in the founder's own network

Research posture

IRB, consents, and data-rights architecture already in motion

Scientific background

Comfort with biomarker, AI and clinical-validation framing

Execution constraint

Scale requires professional operator after pilot

Capital strategy: raise after facts, not before them

Keep optionality, avoid premature exclusivity, and preserve founder ownership through value inflections.

Bootstrap / practice-funded

Pilot, archive linkage feasibility, regulatory preparation, and early data infrastructure. Goal: avoid selling cheap equity before proof.

Non-dilutive / strategic

Pharma-sponsored biomarker studies, OEM pilots, and research prepayments where they do not give away platform control.

Equity after inflection

Consider venture or strategic capital only after pilot + archive/Q-Sub create a better valuation and a cleaner story.

Ownership discipline: the platform can still work with institutional capital, but major dilution should follow major de-risking.

Risks and kill criteria

The plan is ambitious, but it should not survive failed evidence.

Multimodal signal fails

Narrow to fundus/clinical or stop differentiated-multimodal narrative.

Archive not linkable

Year-five plan reverts to slower prospective path.

Clinical utility weak

Q-Sub and intended-use framing must test whether output changes decisions.

Compensation exposure

Keep FMV, time-and-effort, no volume bonuses, counsel sign-off.

Competitor opens code

Treat as 510(k) opportunity if SpectOcular evidence is ready.

Founder bottleneck

Hire operator and build reader/AI/QA system after pilot.



One retinal scan. Many biomarkers. A repeatable engine for systemic disease.

The first authorization is not the destination. It is proof that SpectOcular can repeatedly turn routine retinal imaging into validated diagnostic products.

Next: four tests, under ~\$250K and ~90 days