GBM Precision

The case for a scalable tissue-to-decision pathway

Evidence brief for investors, philanthropic funders and technology partners

Evidence reviewed through 9 November 2026. Proposed pilot parameters remain subject to clinical, institutional and budget approval.

Executive summary

The opportunity is to make existing precision-oncology capabilities usable for more patients with glioblastoma (GBM). Surgery, diagnostic pathology, molecular profiling, live-tumor testing, expert interpretation and access to treatment are distinct steps. A coordinated pathway can be tested at each handoff, with clear measures of timeliness, quality, access and cost.

Published evidence supports the need for this implementation work. In selected molecularly profiled cohorts, matched treatment reached 15 of 483 Danish grade-4 brain-tumor patients, predominantly GBM (3.1%); 36 of 417 Italian IDH-wildtype GBM patients (8.6%); and 42 of 409 Spanish GBM patients (10.2%, as reported). These are study-specific implementation rates, not a pooled estimate or a Florida population baseline. [1–3]

The technical foundation is credible: specialist groups have demonstrated living GBM models, cryopreservation and rapid functional screening. One small randomized trial also supports clinical utility for a specific assay in recurrent GBM. Transfer to a different platform, newly diagnosed patients or a multisite implementation program still requires validation. [8–10,12]

What a proposed US$2 million pilot can establish

- Whether patients, viable tissue and usable evidence reach physician-led review reliably and within the clinical decision window.
- Which losses are operationally addressable, which reflect tumor biology or patient fitness, and which arise from unavailable treatments or trials.
- The actual cost per enrolled patient, usable result and timely decision, including failures, repeats, staff and access support.
- A reproducible operating model and consent-governed dataset that can support further trials and responsible expansion.

Investor message

GBM Precision is building a measurable connection between patients and the capabilities that already exist. We propose to fund a pathology-first pathway that preserves suitable tissue, coordinates molecular and functional evidence, supports clinician review and records what patients can actually access. The immediate return is a tested operating model and better evidence about execution. Wider clinical benefit and sustainable economics are the next questions to prove.

This is an implementation and research funding case. Clinical benefit, savings and investment returns require separate validation.

1. Define the opportunity correctly

The investable gap lies between clinical contact and usable, accessible evidence. Resection creates one tissue opportunity; it does not by itself establish suitable research tissue, successful testing, a supported treatment or patient benefit.

Step	What must be counted
Clinical opportunity	Unique eligible patients and clinically indicated procedures. Separate new diagnosis, recurrence, resection and biopsy.
Enrollment	All consented, enrolled patients, including those who later have insufficient tissue or assay failure.
Tissue capture	Material released after diagnostic needs, with identity, quantity, quality and time stamps.
Usable evidence	Molecular and functional attempts, QC passes, reportable results and missing/failed components, each separately.
Timely decision	A signed clinical review within the prespecified window, including a documented no-supported-option conclusion.
Supported option	An evidence-graded recommendation with clinical eligibility, brain exposure and safety considered.
Access and receipt	Whether the option is obtainable, offered, accepted and actually received; why it is not used.
Clinical outcome	Safety, quality of life and survival measured with appropriate follow-up and, for causal inference, a suitable comparator.

Build the Florida baseline from observed local data

The supplied Florida funnel labels its approximately 83% initial-resection and 3% personalized-therapy values as planning estimates. They are not observed, linked Florida patient counts. Dividing them does not estimate an achievable improvement or a market-expansion multiple.

Definitions materially change the apparent gap. Dumba's English national imaging-linked cohort included 4,307 people diagnosed in 2013–2014: 2,582 (60%) underwent debulking surgery, whereas 3,518 (82%) had surgery or biopsy. The surgical categories overlap. A newer English national study of 15,181 adults diagnosed in 2013–2018 likewise defines surgery to include biopsy. Neither is a contemporary Florida resection rate. [4,5]

Local sizing should use site-validated unique-patient counts and age-specific registry data. Multiplying a national age-adjusted incidence rate by Florida's population is not a direct estimate of observed Florida cases. Trial participation, recurrence and repeat surgery are not obligatory sequential funnel stages.

2. Real-world implementation evidence

Three independent clinical settings show that molecular characterization and matched treatment are different outcomes. The studies below should be read side by side, not pooled.

Denmark | Fougner et al., 2025 [1]

Retrospective Rigshospitalet cohort, 2016–2023: 483 profiled grade-4 primary brain tumors, including 435 IDH-wildtype GBMs, 39 IDH-mutant grade-4 astrocytomas and nine H3-altered gliomas. Alterations of interest occurred in 200 patients; 35 had tumor-board-actionable findings and 15 received targeted therapy. The population was selected for suitability for standard treatment. This is evidence of attrition within an implemented pathway, not a population-wide profiling rate.

Italy | Padovan et al., 2023 [3]

In 417 IDH-wildtype GBM patients screened at a single center, 343 had at least one potentially actionable alteration. Thirty-six received personalized treatment through trials, off-label or compassionate access: 10.5% of the molecular candidates, or 8.6% of the screened cohort. Treatment began at second line or later, with median line three. The broad “potentially actionable” category must not be confused with a validated, available therapy.

Spain | Mirallas et al., 2026 [2]

A retrospective study across seven hospitals included 541 NGS-tested glioma patients, 409 with GBM. Forty-two GBM patients received matched treatment. The paper reports 36 GBMs with ESCAT I/II alterations and 303 with ESCAT III/IV alterations. Lower tiers reflect weaker or investigational actionability. Referral and testing selection, changing assays and treatment access limit generalization. The final publication is January 2026, despite “2025” in the DOI.

United States | Byron et al., 2018 [11]

This prospective recurrent/progressive GBM feasibility study enrolled 20 patients. Sixteen had sufficient tissue; 15 of those 16 received genomics-informed recommendations within 35 days, and seven received a recommended treatment. Thus, the 94% timeliness figure applies to tissue-sufficient patients. From all 20 enrollees, 15 timely recommendations represent 75%, and seven treated represent 35%. The small, selected surgical cohort supports feasibility, not a survival-effect estimate.

What this evidence supports

A shared pathway can be evaluated against real losses in tissue availability, interpretation and implementation. Better coordination may recover some opportunities, but the recoverable fraction is unknown: insufficient evidence, lack of a brain-penetrant drug, toxicity, eligibility, progression and patient preference may remain limiting factors. The pilot should identify these reasons rather than assume every non-treatment is a process failure.

3. Preserve fit-for-purpose tissue

Initial clinically indicated tissue acquisition is an important planning point. Once material has been fixed or consumed, it may no longer support a living model. Planning ahead can preserve additional analytical options when adequate tissue exists, while diagnosis and clinical care always take priority.

A clinically grounded operating standard

The joint RANO recommendations distinguish diagnostic FFPE material, deep-frozen samples and additional live tissue for cell lines or organoids. They recommend timely processing, separate collection and processing time stamps, appropriate consent and protection of diagnostic reserves. NCI's 2026 Best Practices provide a complementary framework for governance, quality management, tracking, data linkage and sustainability. These are operational standards, not evidence that tissue banking improves survival. [6,7]

Material	Useful role	Important distinction
FFPE	Routine histology and many molecular assays	Formalin-fixed material is not a viable-cell reserve.
Snap-frozen tissue	DNA/RNA, proteins and other analytes, depending on validated methods	Preserving analytes does not establish recoverable living cells.
Fresh live tissue	Immediate functional assays, culture or model establishment	Requires pathology release and assay-specific transport and timing.
Viably cryopreserved tissue or models	Potential later recovery and testing	Requires validated freezing, storage, thawing and post-thaw QC; not interchangeable with snap-freezing.

Biological feasibility, with clear limits

Jacob and colleagues reported a biobank of 70 GBM organoids from 53 patient cases, including different tumor regions, and a reported establishment success of 91.4%. Cultured organoids could be cryopreserved and recovered. The work supports model feasibility, not a 91.4% all-patient clinical service yield. [8]

The related protocol describes approximately 2–4 weeks for organoid generation before a further experimental step such as CAR-T co-culture. Early model formation is not the same as a final, clinically interpretable report. Each laboratory must define its full acquisition-to-report clock. [9]

Preserved initial tissue also has a temporal limit. The GLASS study analyzed paired longitudinal samples from 222 adults with diffuse glioma and found individualized post-treatment evolution. A baseline model is a time-stamped biological resource, not a guarantee that later recurrent disease has identical sensitivities. [17]

No research-only operation or delay to standard care is justified by this proposal. The pilot must report failed preservation and inadequate residual tissue, not only successfully banked samples.

4. Functional testing: evidence and limits

Randomized clinical proof of concept, specific to one assay [12]

Ranjan et al. randomized 78 patients with recurrent GBM to ChemoID-guided chemotherapy (43) or physician choice (35), after screening 123. In the intention-to-treat analysis, median overall survival was 12.0 versus 7.5 months (log-rank p=0.009), and median progression-free survival was 6.5 versus 3.3 months. This is the strongest direct clinical evidence in this brief for a functional treatment-selection strategy.

It was a small, selected, operable recurrent-disease population with good performance status, used the older WHO definition including IDH-mutant cases, and stopped recruitment after a planned interim efficacy analysis. The assay company supplied funding/resources and two authors held platform intellectual property. Independent larger confirmation and platform-specific validation are important. This trial does not establish efficacy of GBM Precision, organoids in general or first-line testing.

Faster experimental workflows are becoming practical [10]

Jungwirth et al. studied tumors from 11 IDH-wildtype GBM patients, nine newly diagnosed and two recurrent. An automated 166-drug screen with dose-response follow-up was completed within eight days after surgery. Selection of adequate high-quality tissue and a specialist workflow limit generalization. The study demonstrates experimental speed, not multisite all-comer performance, drug access or improved patient outcomes.

Molecular tailoring still faces therapeutic constraints [13,14]

In Chen et al.'s 2026 phase I study, 30 adults with recurrent grade-4 tumors received genomically tailored multiagent regimens. Overall efficacy was not significantly improved versus a contemporary nonexperimental cohort, and toxicity often constrained dosing. EANO similarly distinguishes target detection from actual treatment and demonstrated benefit. Frequent GBM alterations are not automatically effective therapeutic targets.

Emerging operational evidence: clearly provisional [18]

The SLiCE prospective feasibility preprint, not peer reviewed, reports viable tissue from 35 of 60 consented patients with mixed CNS tumors. One repeat procedure produced 36 specimens; 35 met a 28-day reporting endpoint. Seventeen collections were missed because surgery fell outside research hours, four because tissue went to other trials and four because residual tissue was insufficient. Its specimen-level result must not be presented as patient-level access. The observation directly motivates testing coverage and handoffs.

Functional response must be interpreted with model composition, clinically achievable concentrations, brain penetration and safety. Assays that measure different biology are not interchangeable. A positive laboratory result is not a treatment recommendation by itself.

5. A pilot that answers the next questions

The proposed Florida design targets 100 enrolled adults across two to three sites, with 60–80 analysis-ready records as a planning assumption. Newly diagnosed and recurrent disease should be reported separately. One prespecified index tissue procedure per person anchors the primary denominator; subsequent procedures are linked events, not new participants.

Question / hypothesis	Measurement	Proposed criterion or interpretation
Can capture be reliable?	All screened, eligible, consented and collected cases; reasons for losses; tissue and assay disposition.	At least 95% disposition documentation. Report capture and viability separately; targets for yield require local validation.
Can evidence reach review in time?	Signed board decision within 35 calendar days of acquisition / all index enrolled procedures.	At least 70%; preliminary review around day 14 is separate. Report medians only alongside failures and full-cohort rates.
Was the evidence usable?	QC-passed molecular and functional results; complete versus qualified packets.	Minimum evidence content locked before enrollment. A timely no-option review is not a successful assay.
Does integration inform decisions?	Molecular-only interpretation compared with integrated review where feasible; added, confirmed, contradicted or unchanged.	Descriptive contribution, not a causal benefit estimate. Include missing assays and selection into optional protein studies.
Can patients access an option?	Evidence grade, clinical eligibility, availability, clinician consideration, actual receipt and reasons for non-use.	Use all enrollees and eligible recommendation subsets with clearly labeled denominators.
Can follow-up be complete?	90-day treatment-access and clinical-status capture.	At least 80% of all enrolled patients; report missingness and mature the final follow-up window.
Is expansion sustainable?	Invoices, staff effort, failures/repeats, patient burden, throughput and full versus incremental costs.	Prespecify affordability and capacity gates after validated local quotes; no literature-derived ROI target.

Make the result interpretable

Enroll consecutive eligible cases where feasible; retain unsuccessful cases; prespecify outcomes and missing-data rules; stratify by site, disease setting and procedure. Track after-hours cases, rural/underserved access and patient burden under approved privacy safeguards. Record trial and drug availability when recommendations are made, not retrospectively inferred from eventual receipt.

If 70 of 100 participants meet the day-35 endpoint, the exact two-sided 95% binomial interval is approximately 60.0%–78.8%. Meeting the observed target does not prove that the true population rate exceeds 70%, or that survival improved. These are proposed operational targets, not published GBM Precision results.

6. Economics: measure the whole pathway

The economic rationale is to reduce avoidable loss and create a reusable capability. Whether this saves healthcare spending, generates commercial revenue or is cost-effective remains unproven.

What the cost literature contributes

Christopher et al.'s 2026 systematic review included 21 studies and 15,547 real-world GBM patients. Costs varied markedly across countries, treatment pathways and study horizons. Its upper-end US cumulative-cost estimate is not a universal cost per patient or an avoidable-cost pool. The review supports local economic evaluation, not a savings forecast for this pilot. [15]

Henkel et al.'s Norwegian microcosting study models genomic profiling together with molecular-tumor-board integration by workflow step and resource category. Consumables and personnel were major drivers. That method is useful for the pilot; its local panel costs are neither a US commercial price nor a quote for combined molecular and functional testing. [16]

Transparent illustration at a rounded US$2 million total

Illustrative denominator	Arithmetic	What it means
100 enrolled patients	$2,000,000 ÷ 100 = $20,000	Average total program cost per enrollee.
60–80 analysis-ready records	$2,000,000 ÷ 60–80 = $25,000–$33,333	Average program cost per usable longitudinal record, depending on yield.
70 timely decisions	$2,000,000 ÷ 70 = $28,571	Average program cost per timely review, including no-supported-option decisions.

Illustrative arithmetic only, using planning volumes, not a forecast, vendor price, marginal test cost or cost per benefited patient. The Florida proposal's provisional ceiling is $1,999,000. Funding, local recruitment capacity, quotes, scope and approvals must be reconciled before commitment.

What the ledger must include

- Fixed costs: activation, validation, training, data systems, governance and study closeout.
- Variable costs: collection, transport, processing, testing, QC, repeats, storage, interpretation, navigation and follow-up.
- Capacity costs: after-hours coverage, failed batches, downtime, minimum volumes and staffing at each new site.
- Separate payer views: research-program costs, routine clinical care, subsequent treatment and patient/caregiver burden. Avoid double counting bundled services.

The scaling model should distinguish fixed startup expenditure from incremental cost per additional completed pathway. Higher throughput can spread fixed costs, but may also require more staff and equipment or create batching delays. Efficiency gains count as cash savings only when expenditure actually falls after integration, review and error-correction costs.

7. Scale through measured performance

A staged funding proposition

Gate	Evidence required before expansion
Activate	Named accountable clinical and pathology teams; eligible site volumes; approvals, consent and contracts; validated transport; assay QC and reporting scope; complete budget.
First 20 index procedures	Review capture, reportable yield, day-35 decisions, failures, patient burden and actual spending. Repair weak handoffs before adding sites.
Complete the funded cohort	Reconcile every enrolled case, mature follow-up, publish denominator-complete process and cost results, and document clinician use and access.
Replicate, then test benefit	Show reproducibility at additional sites with stable quality and timeliness. Use a suitably designed comparative study to evaluate clinical outcomes and cost-effectiveness.

Where partners can create and capture value

Hospitals and patients may gain a more reliable referral and evidence-review process. Laboratories may gain better characterized samples and clearer specifications. Technology partners may support secure data integration, auditability, workflow automation and responsible analytics. Research partners may gain access to consent-governed, quality-controlled longitudinal resources through appropriate agreements. These are testable sources of shared value, not guaranteed revenue, exclusive data rights or endorsed partnerships.

Risk management that strengthens the case

- Biological: insufficient viable tumor, heterogeneity, treatment-induced evolution and limited predictive validity. Preserve QC failures and validate each assay's intended use.
- Clinical: no supported option, toxicity, rapid progression or poor brain exposure. Keep treating-clinician authority and never delay standard care.
- Operational: after-hours collection, transport delays, competing tissue demands and staff capacity. Use named handoffs and timestamped failure codes.
- Access and finance: unavailable trials/drugs, eligibility, insurance, travel and uncertain reimbursement. Record actual access and cost instead of assuming that recommendations convert to treatment.
- Governance: consent, specimen custody, data access, vendor conflicts and post-pilot sustainability. No sponsor obtains automatic rights to patient data or tissue.

The decision for funders

Fund a disciplined demonstration of the pathway: more complete tissue and data capture, reliable physician-led review, transparent access outcomes and a costed plan for replication. The literature provides a credible reason to test this model. The pilot's job is to establish how much of the opportunity can be delivered locally, for whom, at what cost and under which conditions.

Method: focused evidence review of primary clinical cohorts, prospective trials, experimental platforms, authoritative guidance and economic studies. This is not a preregistered systematic review or meta-analysis. Study-level limitations are summarized; formal risk-of-bias adjudication and medical review should precede claims of clinical effectiveness. Institutional affiliation or publication authorship does not establish participation in this pilot.

References

Numbered citations correspond to the text. Links open the original publication or official guidance. No patient-level personal information is included in this brief.

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Publication / source

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Publication / source

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Publication / source

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Publication / source

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Publication / source

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Rapid Functional Drug Screening of Passage-Zero Patient Brain Tumor Tissues Ex Vivo: Results from a Clinical Feasibility Study. Research Square. 4 November 2025. Version 1. PREPRINT.

Publication / source

Not peer reviewed. Mixed CNS tumors; patient-level capture versus specimen-level success.

Project assumptions: the supplied Florida pilot proposal dated 28 October 2026 and its planning funnel inform the proposed targets, not the scientific evidence grades. Prices, site participation, institutional approvals and funding remain to be confirmed. No private correspondence or clinical records are reproduced.