Lumineyes™ Laser Iris Depigmentation Clinical Practice Standard

An SSMM-Informed Clinical Framework | Public Reference Edition | Version 1.1

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A clinical governance reference for patient selection, ocular assessment, staged-treatment decisions, safety monitoring, longitudinal documentation, and quality assurance.

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Scope	Public clinical governance and scientific terminology; operational training forms and proprietary methods are supplied separately.

Publication status: Public reference edition v1.1, issued 16 November 2026 by the document owner. This author-controlled clinical governance reference is not an externally endorsed clinical guideline. Institution-specific operating procedures, implementation approvals and restricted technical controls are managed separately.

How to use this standard

This public version-controlled reference defines a framework for accountable delivery and documentation of the Lumineyes™ LID method. It consolidates the clinical program's practice principles and related conceptual systems. Local implementation of normative requirements depends on the responsible clinician's and institution's approved operating procedures.

Normative terminology

Term	Meaning in a released version
Shall	Required component of the approved institutional protocol.
Should	Preferred practice unless an appropriate reason for deviation is documented.
May	Optional or context-dependent action.
Research-only	Not a necessary criterion for routine clinical eligibility, treatment continuation, or safety status.

Boundary with the restricted operating manual

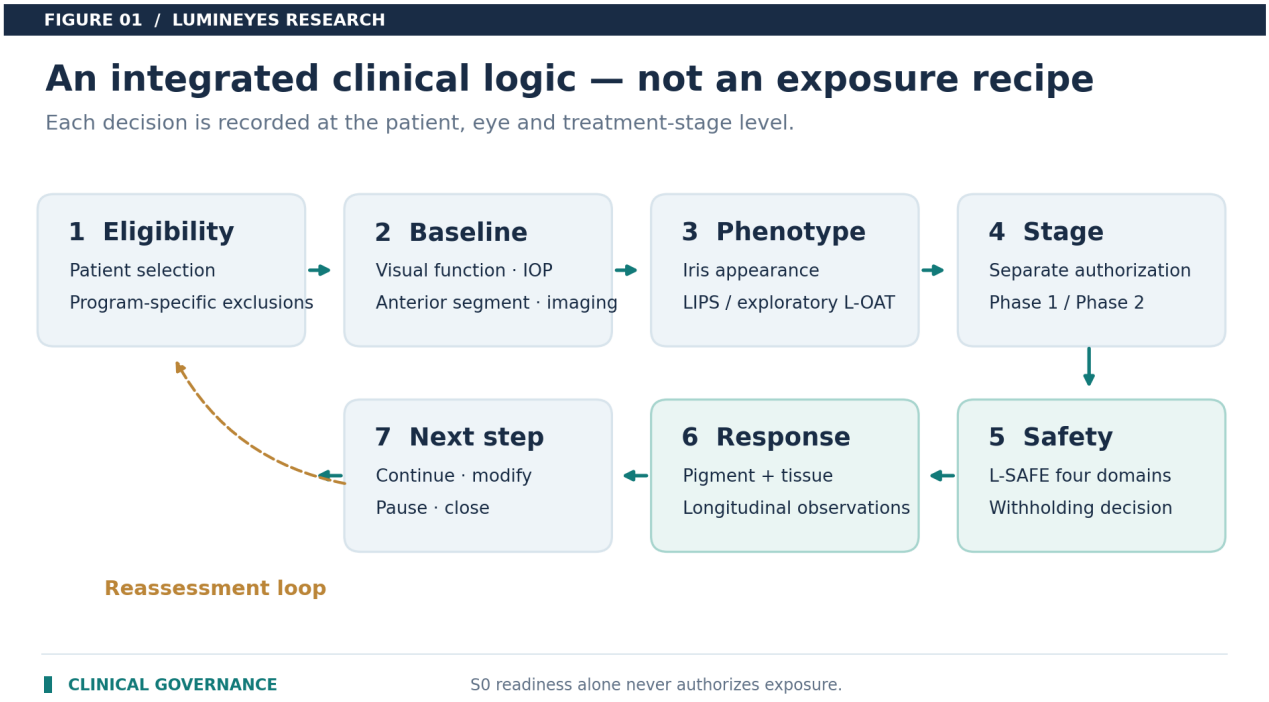
Device-specific settings, beam delivery configurations, Phase-1/Phase-2 technical distinctions, proprietary sequencing, parameter limits, and troubleshooting belong in a separately version-controlled Restricted Clinical Operating Manual. This public document does not reveal, infer, or prescribe those details. The prospective Phase-3 / 8G Dock project is excluded from the present clinical standard.

1. Purpose and scope

The purpose of the standard is to make clinical decision points traceable at the patient, eye, visit, and treatment-stage levels. A treatment visit is not defined only by the number of laser sessions delivered: each exposure is preceded by a documented eligibility and readiness decision and followed by an appropriate observation and reassessment plan.

- Applies to selection, baseline evaluation, staged-treatment consideration, recovery assessment, longitudinal follow-up, and documentation within the Lumineyes™ LID program.
- Uses eye-specific assessments while retaining the patient as the unit of consent, expectations, systemic assessment, and follow-up planning.
- Does not create a universal laser protocol or establish safety, efficacy, superiority, predictability, or permanent tissue stability.
- Local legal requirements, device approvals, the clinician's scope of practice, and independent clinical judgment are handled through the operating institution's governance process.

Figure 1. Integrated clinical logic



Interpretation. The diagram separates initial program eligibility, eye-specific baseline assessment, stage-specific authorization, four-domain monitoring, and longitudinal treatment decisions. A planned sequence does not authorize an individual exposure. S0 readiness is a necessary but insufficient condition for consideration of another stage.

Source. Basis: Clinical Standard Sections 3–8; author-designed workflow.

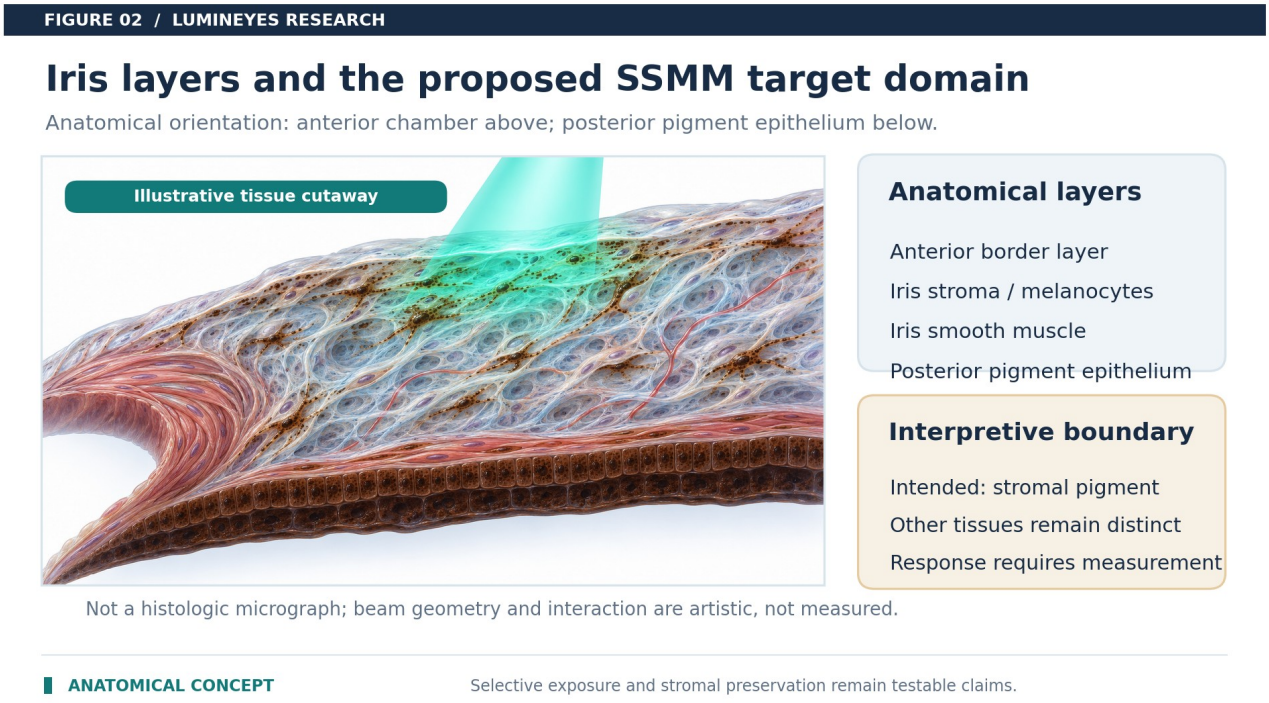
Boundary. Clinical framework; not validated against an independent cohort.

2. Scientific and terminology framework

2.1 SSMM as the organizing model

Selective Stromal Melanin Modulation (SSMM) is the proposed biophysical and clinical framework used to distinguish optical pigment targeting, tissue-level response, and functional outcome. Its organizational dimensions are biophysical, anatomical, and functional selectivity. The term does not itself establish that a particular clinical exposure is selective or tissue-preserving.

Figure 2. Iris microanatomy and the intended target domain



Interpretation. An artistic cross-sectional cutaway depicts the anterior iris border region, stromal pigment-bearing tissue, muscular components and posterior pigment epithelium. The conceptual overlay asks where an intended interaction and separate tissue responses would need to be measured. It is not a histological photograph or evidence of compartment-selective exposure.

Source. Basis: AAO EyeWiki (Basic Histology of the Eye and Accessory Structures), Uvea (PMC7149650), and the SSMM conceptual framework.

Boundary. Illustration only; tissue selectivity and treatment-induced preservation are unverified.

2.2 Other descriptive and investigative frameworks

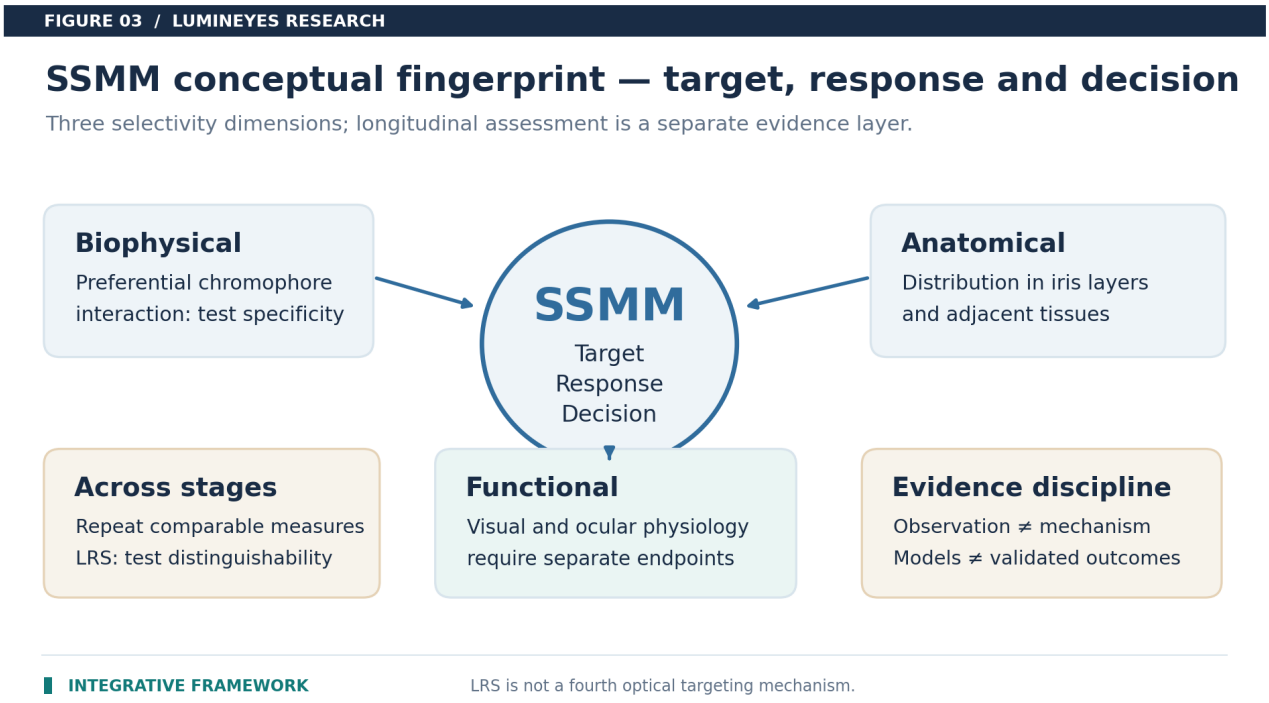
Framework	Role	Clinical use in this standard
LIPS	Proposed iris pigmentation phenotype grading.	Optional descriptive field; not a dose selector or validated outcome predictor.
L-OAT	Proposed iris optical/architectural phenotype framework.	Optional research or standardized imaging descriptor; not a prerequisite.
L-SAFE	Proposed four-state anterior-segment safety checkpoint.	Structured documentation and exposure-withholding architecture; see Section 6.
TRA	Temporal response architecture.	Supports description of the timing of response domains.

Framework	Role	Clinical use in this standard
P-CLEAR	Pigment release/clearance conceptual framework.	Supports interpretive research and longitudinal recording, not an independently validated clearance test.
LRS	Longitudinal Response Selectivity.	Research construct comparing intended pigmentary change with accompanying tissue responses over successive observations.

2.3 LIPS phenotype notation

When LIPS is recorded, Grades I–IV describe an ordered spectrum of predominantly diffuse pigmentation: I (light hazel/amber/light brown), II (medium chestnut brown), III (deep/dark chocolate brown), and IV (very dark compact black-brown). Grade V describes a qualitatively different spatially heterogeneous phenotype (e.g., sectoral/focal/asymmetric/patchy), not a fifth step of increasing darkness. Conventional color descriptors and image-acquisition conditions are recorded separately. LIPS has not yet been validated as a quantitative melanin measure.

Figure 3. The scientific fingerprint of SSMM



Interpretation. Biophysical selectivity concerns preferential chromophore interaction; anatomical selectivity asks where a response occurs; functional selectivity requires independent ocular endpoints. Longitudinal Response Selectivity (LRS) is a research concept for distinguishing those trajectories across treatment stages, not a fourth optical interaction mechanism.

Source. Basis: SSMM v2.9 / 13 Nov 2026 candidate and proposed LRS definition.

Boundary. Conceptual organization; not clinical validation.

3. Patient selection and candidacy

3.1 Two-level candidacy decision

Selection is documented at two connected levels: patient-level suitability (history, understanding, adherence and follow-up) and eye-level suitability (ocular anatomy, current findings and previous interventions). A clinically suitable fellow eye does not establish suitability of the other eye. Initial candidacy is distinct from an L-SAFE checkpoint performed before a later staged exposure.

Decision entry	Meaning for the candidacy record
Accepted for planning	Initial suitability documented; each later exposure still requires its own clinical checkpoint.
Deferred	Further evaluation, clinical stabilization, clarification or follow-up arrangements needed before a new decision.
Excluded	Clinical owner-approved program exclusion applies; specific criterion and clinical reason recorded.
Individual review	Decision cannot be generalized; responsible clinician records findings, required review and final disposition.

3.2 Eligibility policy and screening sources

Screening covers the patient's request, ocular and systemic history, current medicines, prior procedures, expectations and the feasibility of follow-up. The program-specific classification below consolidates the most recent owner decisions and the current Patient Eligibility criteria. Unresolved categories remain review-dependent until clinical approval; an eligible prior procedure does not override another active exclusion.

3.2.1 Consolidated eligibility matrix

Clinical factor	Program classification	Application note
Age below 18 years	Exclude	Eligibility page: elective cosmetic LID restricted to adults aged 18 years or older.
Prior LASIK, PRK, SMILE, cataract surgery	Eligible	These histories are suitable and not contraindications in themselves. Assess unrelated disease independently.
Prior corneal keratopigmentation	Relative contraindication	Relative contraindication; individual clinical decision; technical details withheld.
Vision-affecting retinal/macular/optic-nerve/neuro-ophthalmic or other ocular disease	Exclude	Any existing ocular disease affecting visual function is a program exclusion.
Systemic inflammatory or autoimmune disease	Relative contraindication	Broad immune-mediated disease category; individualized assessment of current activity, organ involvement, treatment and ocular findings.
Uncontrolled glaucoma / unstable IOP	Exclude while uncontrolled / unstable	The eligibility page identifies these as conditions for deferral/refusal; program rule excludes uncontrolled disease.

Clinical factor	Program classification	Application note
Clinically narrow or unsafe angle / major outflow concern	Exclude or active deferral; owner verification	Former program contraindication list names narrow angles. Current state and management need to be documented.
Active uveitis, ocular inflammation or infection	Defer; no exposure during active episode	The eligibility page says not to proceed during activity. Persisting/recurrent pathology may also trigger exclusion.
Clinically significant corneal dystrophy, ectasia, endothelial compromise or severe scarring	Exclude when significant	Eligibility page and prior program criteria. Mild or uncertain corneal findings require evaluation before a decision.
Severe uncontrolled dry eye or ocular surface disease	Defer / Review	Stabilize and reassess; disease affecting vision can independently meet the EX rule.
Iris trauma or prior iris surgery with altered anatomy	Exclude under current program criteria	Distinguish from uncomplicated previous refractive or cataract surgery.
Artificial iris implantation	Exclude	Previous program exclusion; the public website currently understates the category as further review.
Uncontrolled diabetes	Exclude	Listed as unsuitable on the live Eligibility page. Controlled diabetes not automatically EX.
Immune deficiency or other immune-system disorder	Relative contraindication	Heterogeneous conditions; individualized assessment of clinical status, medications and ocular effects. Other independent exclusion criteria remain applicable.
Current or previous antipsychotic medication	Exclude	Explicit current/past exclusion in the live Eligibility page.
Uncontrolled OCD or anxiety disorder	Exclude when uncontrolled	Eligibility page identifies uncontrolled conditions; other mental-health history is not an automatic EX.
Unrealistic / inflexible outcome expectations	Exclude if incompatible with consent or medical limitations	Site: no guaranteed shade, pace or session number; inability to accept clinical stopping decisions precludes treatment.
Inability to comply with essential follow-up	Defer / exclude if not feasible	If safely correctable, defer; if monitoring cannot be secured, decline treatment.
High iris pigment density or dark iris	Individual review only	Pigment phenotype alone does not determine eligibility, final color or number of stages.
Glaucoma / ocular hypertension history without current instability	Individual review; vision-affecting pathology may be EX	History is not identical to uncontrolled state. Document actual nerve function, angle and IOP context.

Classification basis: selected categories are explicit decisions of the clinical owner; others reflect the existing program policy or eligibility-page wording and remain subject to final protocol reconciliation. These are Lumineyes™ program decisions, not universal contraindication claims.

3.3 Expectations, psychological suitability and continuity of care

- Document the desired cosmetic result and whether the patient understands that final appearance, number of stages and color uniformity cannot be specified in advance.

- Review unrealistic or fixed color demands, distress related to appearance, poorly controlled obsessive/anxiety symptoms, and other concerns that materially affect shared decision-making; document observed concerns rather than replacing them with an unsupported diagnosis.
- Confirm capacity to understand the staged plan, consent, medications, repeat examinations, travel and follow-up requirements; inability to arrange essential aftercare is a recorded deferral issue.
- Dense or unusually heterogeneous pigmentation prompts an individualized assessment of feasibility and expectations; pigment grade alone does not establish an L-SAFE state or automatically select a treatment setting.

3.4 Recording the selection decision

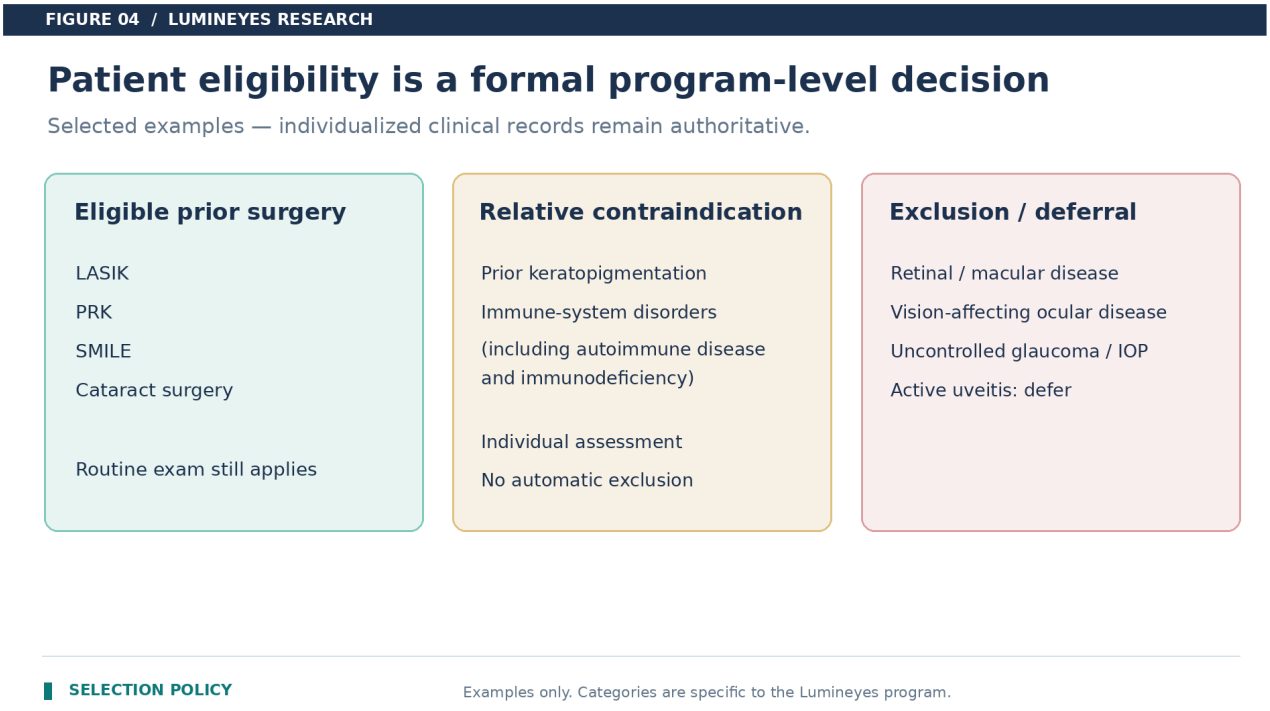
☐ Record patient-level and OD/OS eye-level decisions separately, including Accepted for planning, Deferred, Excluded or Individual review.

☐ For any flagged condition, document the specific evidence, responsible reviewer, required additional evaluation and next decision date (if relevant).

☐ If deferred, document what evidence or clinical stabilization is needed before reassessment. Do not convert a deferral into automatic eligibility merely because time has passed.

For accepted patients, retain documented expectations, consent discussion, baseline planning and the clinician responsible for follow-up. A later stage still requires a new eye-level safety checkpoint and separate authorization.

Figure 4. Program-level eligibility classification

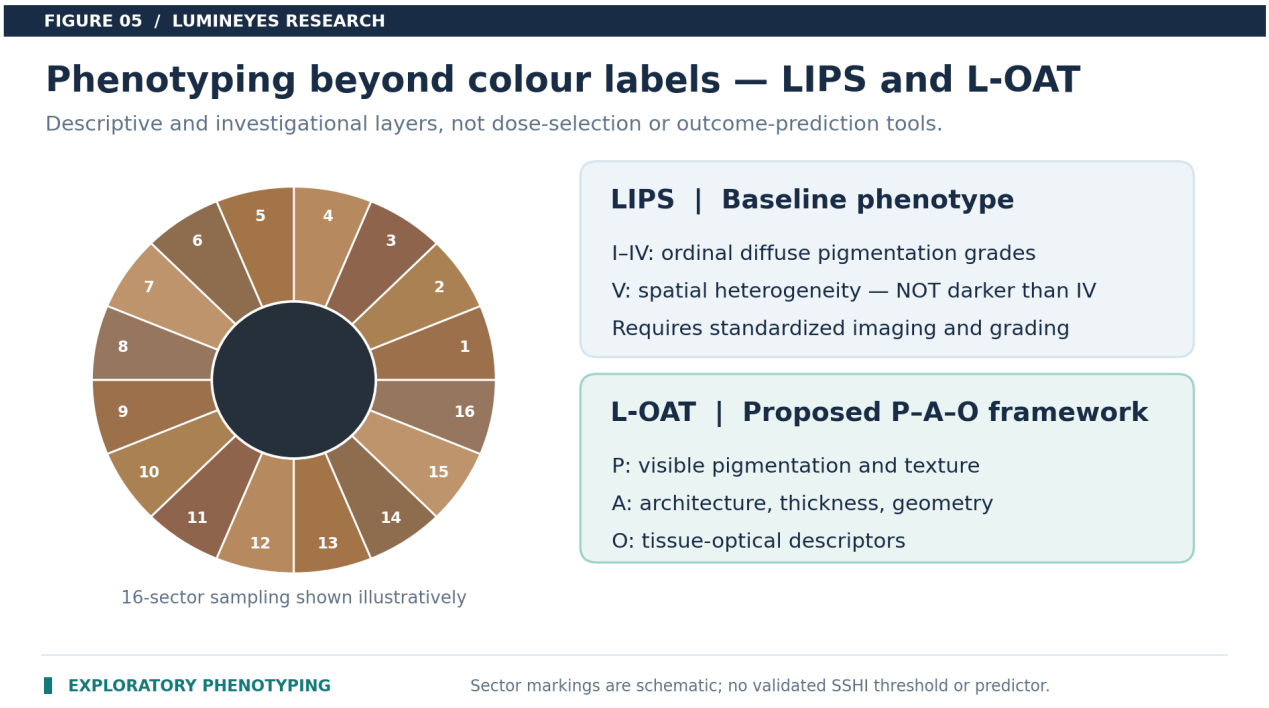


Interpretation. Selected examples from the Lumineyes clinical-selection policy distinguish suitable previous LASIK, PRK, SMILE and cataract surgery, relative contraindication for previous keratopigmentation, and program exclusions or temporary deferrals for specified ocular/systemic conditions. The full policy and individual chart control any decision.

Source. Basis: Lumineyes Patient Eligibility and Clinical Standard selection matrix.

Boundary. Program policy, not a universal medical contraindication scheme.

Figure 5. Iris phenotype documentation and exploratory L-OAT domains



Interpretation. The stylized 16-sector iris represents an illustrative spatial sampling geometry. LIPS grades I–IV describe an ordered diffuse phenotype whereas Grade V describes spatial heterogeneity, not a darker pigmentation grade. L-OAT's phenotype–architecture–optics (P–A–O) framework proposes complementary imaging descriptors.

Source. Basis: LIPS figure pathway, L-OAT framework and L-TIDE P–A–O–D–T architecture.

Boundary. No validated phenotype–response prediction or clinical treatment-dosing rule.

4. Baseline and pre-exposure evaluation

The baseline assessment creates a defensible reference for all later treatment-stage comparisons. The proposed assessment record captures the following items; unavailable or non-indicated findings must be explicitly distinguished from normal results.

☐ Patient ID; treating clinician; date; laterality; relevant systemic/ocular history; prior ocular treatment and active medications.

☐ Patient-specific indication and expectations, discussion/consent record, treatment-stage plan, and follow-up feasibility.

☐ Symptoms and visual function appropriate to clinical presentation, including baseline visual acuity and clinically indicated additional examination.

☐ Slit-lamp assessment of cornea, anterior chamber and iris; documented pressure measurement with method, medication, timing, and conditions.

☐ Angle/outflow evaluation including relevant gonioscopic findings; interpretation in relation to baseline and any prior ocular disease.

☐ Standardized baseline iris photographs with documented lighting, pupil and image-acquisition conditions; conventional iris color and optional LIPS phenotype.

☐ Ancillary testing where clinically indicated, such as endothelial microscopy, anterior-segment imaging, optic-nerve/retinal evaluation or other investigations.

☐ Eye-level candidacy decision, unresolved findings, and the scheduled next checkpoint.

Absence of a particular ancillary test must not be translated into a positive finding of normality. Likewise, a finding is not declared absent merely because its field is blank.

4.1 Dataset boundaries and identification

Use the institution's authorized patient identifier and consent record for direct clinical care; use a separately governed pseudonymous identifier for audit or research extracts. Record the right and left eye separately. Every observation requires the visit date/time, laterality, responsible clinician and relationship to an exposure stage. The data fields below are a proposed minimum documentation specification; locally obligatory status follows the applicable approved clinical protocol.

Record domain	Minimum information to capture
Identity and timing	Authorized clinical patient ID (pseudonymized only in separate audit/research extracts); visit ID; OD/OS; acquisition date/time; examiner; baseline vs pre-stage vs post-stage vs follow-up designation.
History and candidacy	Ocular/systemic history; prior ocular surgery; medication and allergy context; existing symptoms; patient-level and eye-level eligibility decision; unresolved exclusion flags.
Visual function	Uncorrected and best-corrected visual acuity where measurable; refractive status where applicable; symptoms affecting visual function; reason if assessment is unavailable.
Intraocular pressure	Measured IOP in mmHg, eye, date/time, tonometer method if known, relevant treatment/medication context, comparison with patient-specific baseline.
Anterior segment	Cornea clarity/edema and relevant morphology; anterior-chamber cells and flare separately from pigment/particles when distinguishable; iris findings and prior iris surgery/trauma.
Angle / outflow	Gonioscopic angle findings including pigmentation/outflow concerns as appropriate to baseline and safety-state assessment; note unobtainable examination explicitly.
Posterior segment / nerve	Macular, retinal, optic-nerve and visual-function review sufficient to apply the program vision-affecting ocular disease exclusion policy; method, result and outstanding questions recorded.
Phenotype / image	Conventional iris color, distribution/heterogeneity, optional LIPS grade, photograph ID, lens/camera and illumination/pupil conditions when available.
Outcome and decision	Eye-specific suitability, findings requiring action, consent discussion, clinician sign-off, plan for reassessment and source record links.

4.2 Baseline, ancillary and serial measurements

Core clinical examinations and conditional ancillary tests must be distinguished. A measurement is recorded as obtained, not obtained, not indicated or unavailable; blank does not mean normal. OCT, specular microscopy/endothelial cell density, anterior-segment imaging, visual field testing or other studies may be indicated by findings, technique, history or the approved local examination protocol. Where serial endothelial measurements are available, preserve the instrument, image quality and method; no unmeasured endothelial stability should be implied.

4.3 Standardized imaging and phenotype notation

For comparisons, store the original image or protected source, date, eye, camera setup if known, illumination, viewing angle, magnification and pupil conditions. Record whether images are comparable. Apparent color change must not alone be interpreted as verified pigment clearance, absence of inflammation or anatomical preservation. LIPS remains optional descriptive notation and does not decide laser dosage or safety readiness.

4.4 Checkpoint before any further staged exposure

Before considering an additional stage, capture all four L-SAFE domains for that eye: IOP, anterior-chamber response, corneal status and angle/outflow status. Document the integrated S0–S3 classification or mark the checkpoint Incomplete with reason. Only S0 permits consideration of continuing, never an automatic instruction to treat. Prior S2 and S3 events remain visible in the eye history. The detailed stage/exposure log stays within the restricted operating manual.

4.5 Minimum traceability and data-entry quality

Every record must distinguish normal, abnormal, not assessed and unknown. A clinician-signed late entry or correction should retain the original date and a reason. Follow-up records should refer to the correct patient, eye, treatment-stage ID, medication context and prior visit so that changes are not wrongly attributed to a different stage or eye.

5. Governance of staged treatment

5.1 Principle: a treatment plan is not an exposure authorization

A proposed staged course describes a possible pathway; it is not a standing order for further laser exposure. Each eye and each proposed exposure require a fresh, documented decision using the current clinical assessment, the response to previous stages, and the patient's current preferences. Time elapsed, session count, residual pigment, an earlier favorable response, or a patient request does not independently establish readiness.

5.2 Three distinct records: candidacy, checkpoint and authorization

Initial patient/eye eligibility (Section 3), the integrated L-SAFE checkpoint (Section 6), and the final clinician authorization are separate records. A completed S0 checkpoint means only that no withholding reason was identified in the four L-SAFE domains. It is not automatic permission to expose the eye. Active vision-affecting disease or another independent program exclusion remains decisive regardless of S0. An Incomplete checkpoint cannot be recorded as S0.

5.3 Structured pre-stage decision pathway

Gate	Minimum question	Record / disposition
A — Eligibility	Is the patient still eligible and is this eye still eligible under the current program selection policy?	Record newly identified diagnoses, systemic/medication changes, consent and follow-up feasibility; an exclusion overrides further planning.
B — Eye safety	Is the pre-exposure eye examination complete, and what is the current L-SAFE state?	Record IOP, anterior chamber, cornea, and angle/outflow independently. S1/S2: withhold. S3: terminate current sequence. Incomplete: do not authorize.

Gate	Minimum question	Record / disposition
C — Response and purpose	What was observed after the prior stage, and what specific purpose would another stage serve?	Describe the visible response and accompanying tissue/functional findings separately. No automatic escalation for slow or residual color change.
D — Clinical authorization	After A–C, does the responsible clinician independently authorize the proposed exposure?	Record Authorized for this stage / Deferred / Withheld / Sequence terminated, with date, reason, responsible physician, next action, and restricted log reference.

5.4 Disposition rules and L-SAFE binding

Finding or state	Rule for the current stage
S0 Ready; full eligibility and no separate concern	The next exposure may be considered but still requires an explicit stage-specific physician decision, active consent and the approved restricted technical workflow.
S1 Watch	Withhold the next exposure. Document the deviation, management/reassessment plan and new checkpoint. Improving S1 is still S1.
S2 Pause	Withhold the next exposure while the abnormality is assessed/managed. If later S0 and independent continuation are established, retain the prior S2 history and consider additional caution and surveillance.
S3 Stop	Terminate the current staged exposure sequence. Improvement or return to S0 does not by itself reopen the terminated sequence.
L-SAFE Incomplete	Do not infer S0. Record the missing mandatory domain and why it was unavailable; complete the checkpoint or defer.
Independent program exclusion or clinically material new finding	Do not authorize an exposure simply because L-SAFE is S0. Document the relevant screening rule, finding and disposition.
Patient postpones, withdraws consent, or follow-up is not feasible	Record a non-biological deferral or patient-directed stop and the agreed follow-up plan; do not falsely assign a pathological L-SAFE state.

5.5 Session and treatment-sequence identification

Record patient ID, OD/OS, sequence ID, stage/session ID, proposed date, actual date, clinician, and links to the previous stage and relevant prior checkpoint. Record cancellations and no-exposure visits as encounters rather than creating fictitious delivered-session records. Right and left eyes are assessed and authorized separately; same-day bilateral decisions, if any, must each have their own eye-specific record.

5.6 Response-guided continuation, without an invented numerical rule

A repeat stage is considered only after adequate review of the preceding pigmentary response, symptoms, IOP course, anterior-segment findings, other visual-function concerns and patient goals. Clinical documentation distinguishes observed color/appearance, pigment/particulate findings, inflammation, corneal status, outflow status and visual function. LIPS and L-OAT may be used descriptively; neither assigns a device setting, number of shots, future session count or safe waiting period. LRS remains a research concept rather than an operational numerical score.

5.7 Phase-1 / Phase-2 confidential operational boundary

Lumineyes™ uses Phase 1 and Phase 2 as recognized names for the staged clinical workflow. Their proprietary technical functions, settings, combinations and operating decisions remain in the restricted manual. The responsible physician records the controlled operating-manual version and a restricted technical-log reference. Actual settings and device checks must be documented where legally and clinically required in the authorized clinical record, not omitted from care merely because this public document excludes them. Prospective Phase-3 / 8G Dock development is not part of current clinical delivery.

5.8 Treatment intervals and stage counts

No new interval, fixed stage count, dose, energy, shot-count, completion endpoint or automatic repetition rule is created by this public reference edition. The responsible clinical authority separately approves the locally used minimum interval policy and any circumstances requiring a longer period of recovery; the approved numerical values belong in the controlled operating protocol. A calendar date cannot replace an eye-specific reassessment and treatment authorization.

5.9 Before and after the authorized exposure

Before exposure, the responsible clinician confirms patient/eye identity, current authorization, consent, relevant clinical changes, equipment/operator eligibility and the approved restricted technical protocol. After an exposure, the record links the delivered treatment to actual examination findings, new or evolving symptoms, post-stage instructions, early reassessment responsibilities and the next planned checkpoint. Any adverse event follows the Section 8 incident-management pathway; a planned next visit is not a preauthorization for the next laser session.

5.10 Deviations, incomplete records and quality review

A protocol deviation must specify what differed from the current approved SOP, whether an exposure occurred, the immediate response, corrective action, responsible reviewer and closure date. An urgent clinical need takes precedence over form completion, with contemporaneous or appropriately identified late documentation. Missing checkpoint values, overdue follow-up, or an inaccessible restricted log trigger a documentation/quality exception and must not be silently normalized. Clinical findings and operational deviations remain separately identifiable.

5.11 Closure and re-entry are different decisions

The current sequence may end because the patient stops, the clinician determines further treatment is not indicated, the agreed clinical goal is not pursued further, a program exclusion emerges, or S3 terminates the sequence. Record eye, reason, date, final clinical state, outstanding management and follow-up arrangement. Any later request is a new candidacy and governance review rather than automatic continuation; a prior S3 termination retains its meaning and cannot be erased by an improved examination.

6. L-SAFE anterior-segment monitoring

6.1 Mandatory assessment domains

For the proposed integrated L-SAFE checkpoint, the following four domains are assessed per eye: (1) intraocular pressure, (2) anterior-chamber response, (3) corneal status, and (4) angle/outflow status. Clinical findings and medication context remain visible; the integrated state does not replace them.

State	Interpretation	Exposure-control consequence
S0 – Ready	No finding within the four mandatory domains constitutes an L-SAFE reason to withhold consideration of the next stage.	No L-SAFE withholding signal; separate candidacy and readiness checks still apply.
S1 – Watch	Mild deviation from expected recovery without an abnormality requiring S2-level management or surveillance.	Withhold further exposure; continue appropriate management and reassess. Return to S0 is required before consideration of another stage.
S2 – Pause	Clinically significant abnormality requiring active management/review and/or intensified surveillance.	Withhold exposure; manage and reassess until S0. Prior S2 response must remain in the longitudinal record.
S3 – Stop	Severe, persistent, refractory, or clinically consequential safety abnormality.	Terminate the current staged exposure sequence. Later recovery to S0 does not automatically reopen that sequence.

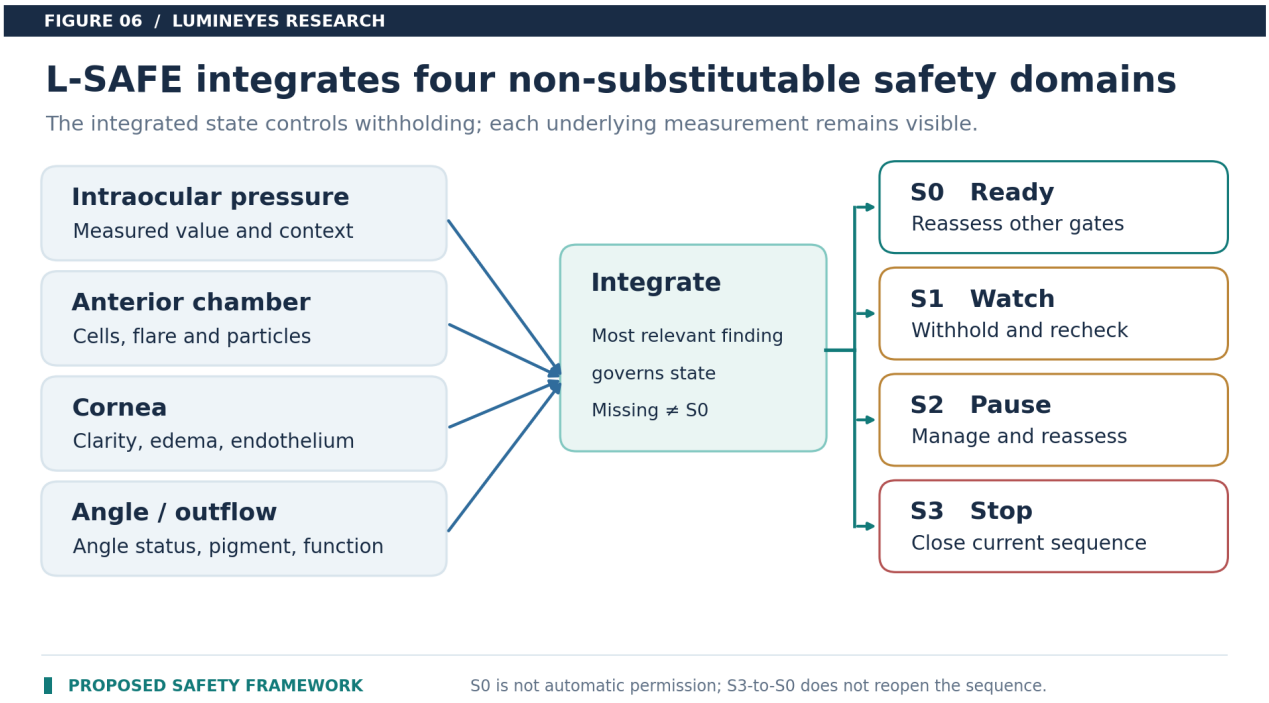
6.2 Integration and longitudinal modifiers

L-SAFE is not an additive score: a reassuring finding in one domain cannot cancel a clinically significant finding elsewhere. The most safety-relevant abnormality drives the integrated state, and the clinical reason must be recorded. Optional trajectory descriptors R (resolving), S (stable), and P (progressive) apply only to S1 and S2 when a meaningful comparison is available. An improving S1 or S2 checkpoint remains a withholding state unless reassessment supports S0.

6.3 Incomplete evaluation

If one mandatory L-SAFE domain is missing, mark the checkpoint as Incomplete with the reason. Do not label it S0 by assumption and do not create an artificial fifth biological state. Other concerning ocular findings may independently preclude exposure regardless of the L-SAFE classification.

Figure 6. Integrated L-SAFE architecture



Interpretation. Intraocular pressure, anterior-chamber response, corneal status and angle/outflow are independently documented before determining the integrated state. Incomplete mandatory observations cannot establish S0. S1 and S2 withhold subsequent exposure; S3 terminates the current staged sequence.

Source. Basis: L-SAFE methodological manuscript and Clinical Standard Section 6.

Boundary. Proposed documentation and withholding architecture; performance is unvalidated.

7. Pigmentary response and longitudinal assessment

7.1 Distinct response domains

Visible pigmentary change and accompanying ocular responses should be documented separately. Proposed observational domains include iris appearance, relevant symptoms, anterior-chamber findings, corneal findings, IOP and angle/outflow findings. Their different time courses must not be collapsed into a single “improved” or “safe” outcome.

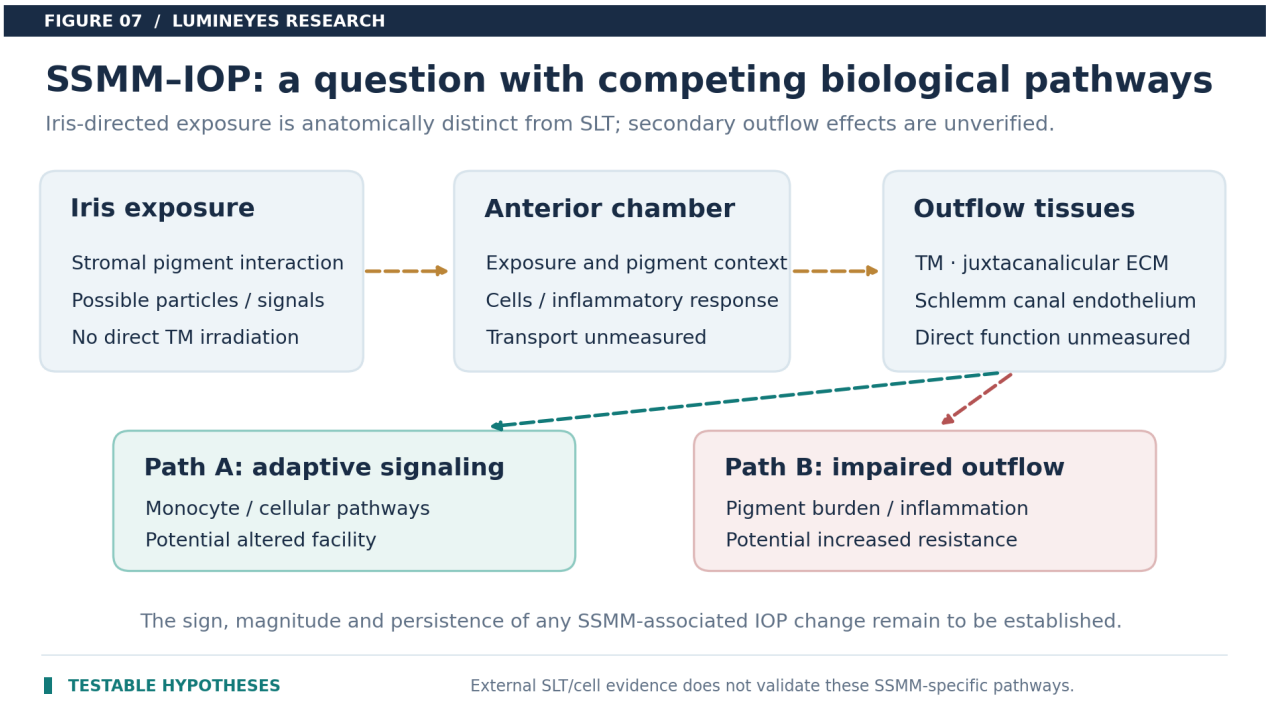
7.2 Standardized appearance comparisons

For longitudinal photographs, preserve laterality, capture conditions, and date. Where technically feasible, use comparable illumination, magnification, pupil condition, and camera settings. Report changes in appearance as observed findings rather than inferred cellular clearance or definite stromal preservation.

7.3 Position of LRS

LRS is the proposed extent to which intended stromal pigment modification can be distinguished from accompanying tissue responses across successive observation periods and treatment stages. It is a research assessment concept, not another laser-treatment phase, a validated score, or a biological safety guarantee.

Figure 7. Competing SSMM–IOP hypotheses

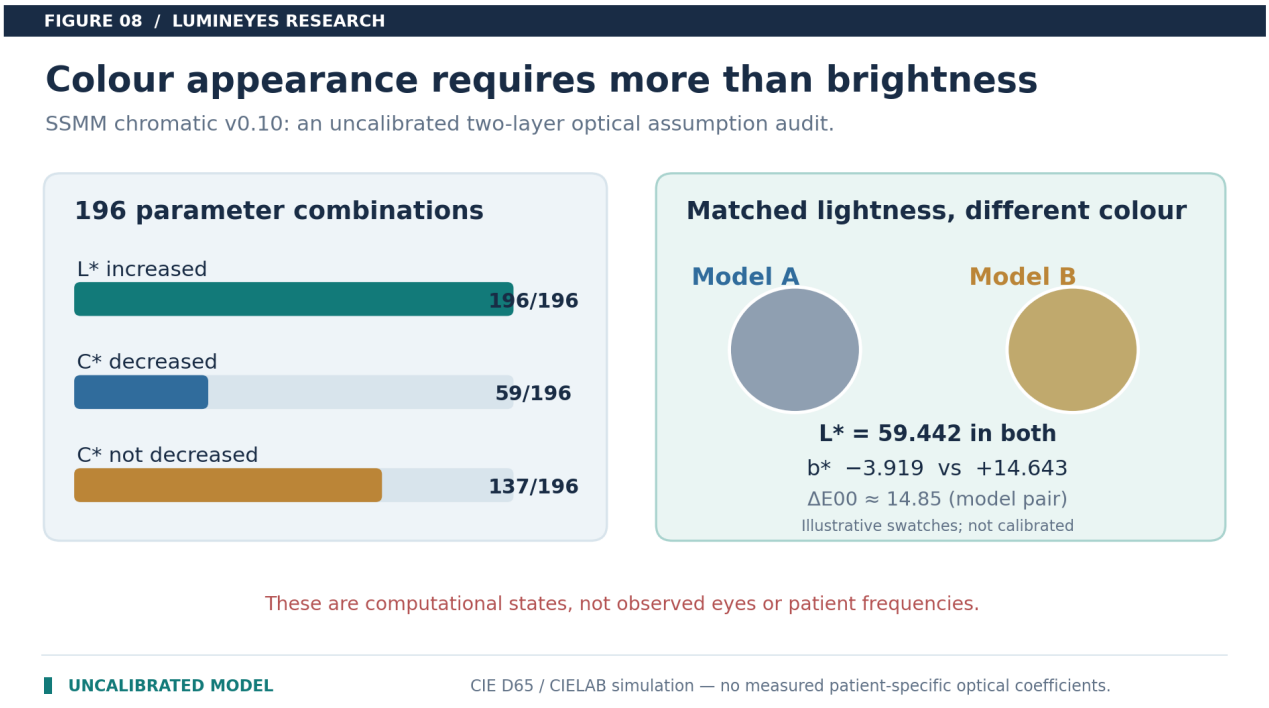


Interpretation. The figure distinguishes iris-directed treatment from SLT and traces the *proposed*, indirect connection between iris-associated responses and aqueous outflow. Cellular adaptation and outflow obstruction are competing pathways; neither a durable pressure-lowering mechanism nor a favorable direction has been demonstrated for SSMM.

Source. Basis: Mete, 2026 SSMM–IOP preprint; Alvarado et al., 2010 SLT monocyte findings.

Boundary. Mechanistic hypothesis, not evidence that SSMM lowers IOP or treats glaucoma.

Figure 8. What a chromatic toy model can and cannot establish



Interpretation. A two-layer, uncalibrated optical model showed higher CIELAB L* in 196/196 parameter configurations after an illustrative scattering increase, but lower chroma C* in only 59/196. A computationally matched-lightness pair had L*=59.442 in both states but markedly different b* and ΔE00≈14.85. The circles are schematic colour swatches, not calibrated reflectance renderings.

Source. Basis: SSMM Chromatic Research v0.10 technical result, 8 Nov 2026.

Boundary. Toy-model outputs; not patient frequencies, treatment success rates or predicted eye colours.

8. Follow-up, incident management and sequence closure

8.1 Follow-up plan

Each treated eye receives documented post-stage instructions, a clinically appropriate reassessment schedule, the route for unscheduled evaluation, and a record of medication changes where applicable. The frequency and examination content are individualized and aligned with local operating procedures; this public reference edition specifies no universal visit-calendar cutoff.

8.2 Events and deviations

Unexpected symptoms or examination changes are recorded with onset, laterality, severity/clinical significance, investigations, treatment and recovery status. The treating clinician determines whether urgent assessment or referral is required. Protocol deviations are recorded with an explanation and corrective action; omissions are not silently treated as normal findings.

8.3 Stopping and closure

Closure of a staged sequence is recorded distinctly from a completed desired appearance or from a recovered abnormal safety state. A previous S3 termination remains traceable after any improvement. The patient receives a final documented assessment and an appropriate ongoing-care plan.

8.4 Proposed encounter framework (without a fixed calendar)

The table distinguishes encounter purposes rather than assigning universal visit days. Timing is set by the treating clinician and the controlled local SOP, based on the eye-specific response, access to clinical care and documented instructions. This public reference edition neither creates a routine 24-hour/7-day threshold nor replaces prompt assessment of an acute concern.

Encounter	Documentation emphasis	Timing status
Baseline / initial eligibility	Patient/eye selection; functional and structural baseline; medications; iris images; planned care and consent.	Before first stage; owner to define required timing and acceptable data age.
Pre-stage readiness	Intervening history and medicines; four L-SAFE domains; state / incomplete; explicit decision and physician.	Before each later stage; no numerical interval inferred.
Early post-stage review	Symptoms, IOP where clinically indicated by protocol, cornea/anterior chamber, instructions, medication and return precautions.	Owner-defined early checkpoint and any clinically indicated urgent recheck.
Recovery / interim review	Clinical evolution relative to prior visit; unexpected findings; L-SAFE checkpoint when subsequent stage is being considered.	Response-driven; date/time entered in individual plan.
Long-term review	Visual function, IOP method/context, ocular examination, iris appearance, relevant corneal/endothelial data, events and treatment history.	Proposed periodic follow-up; specific windows await owner decision.
Unscheduled concern	Onset/time of symptom or finding, measurements, triage, contact, management, escalation and outcome.	At clinical need; not deferred to a routine appointment.

8.5 Measured IOP and visual-function series

Preserve the raw eye-specific IOP values, units, instrument method, measurement date/time, relevant medication status and whether the visit preceded or followed a treatment stage. Record visual acuity as actually measured, not merely “stable,” including correction status when relevant. Trends can then be reviewed without assigning causality. The occurrence of a lower or higher IOP in an individual chart is not proof of a treatment effect or absence of injury.

8.6 Post-treatment symptoms and clinically important events

Record photophobia, discomfort/pain, reduced vision, redness and other relevant concerns using onset, duration, laterality, progression and management. New or worsening loss of vision, severe pain, pronounced inflammatory signs or other potentially consequential findings require clinician-directed urgent evaluation under the local care pathway; no symptom should be dismissed solely because a prior checkpoint was S0. Adverse events, suspected events, incidental diagnoses and protocol deviations are recorded as distinguishable categories.

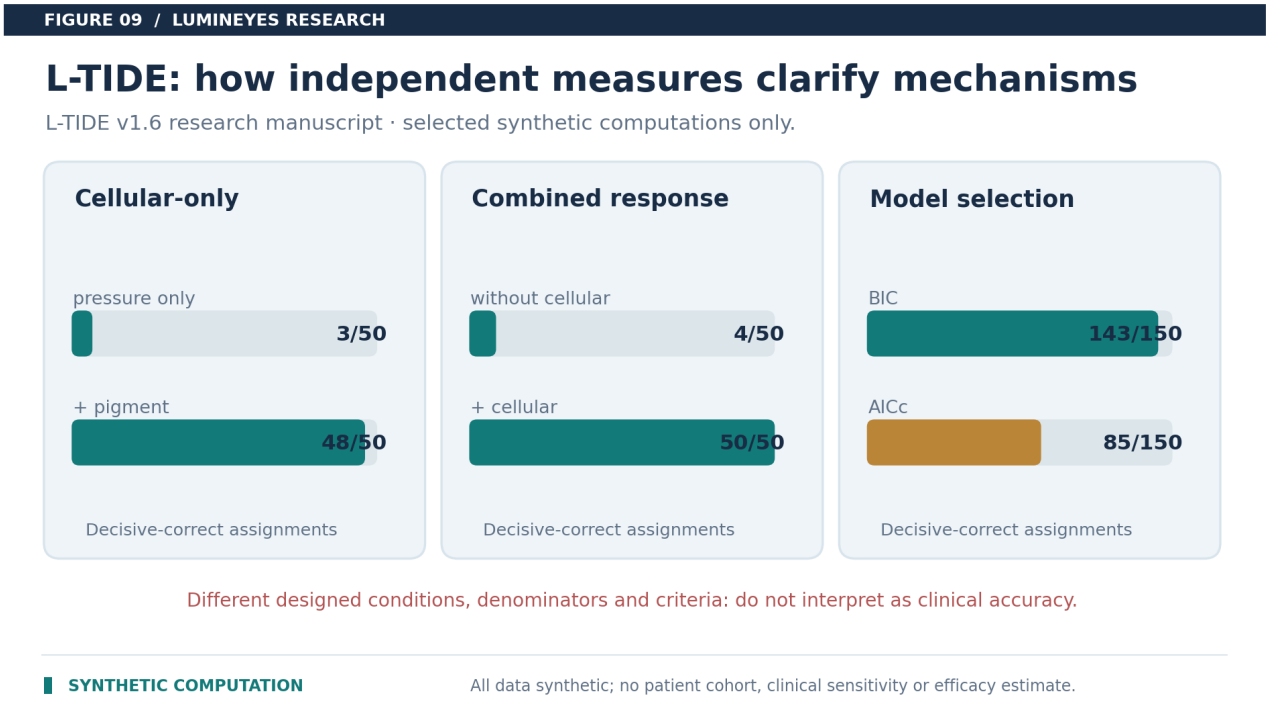
8.7 Missed visits, remote follow-up and closure

Record scheduled date, actual attendance, missed/rescheduled appointments and outreach or referral attempts. Remote symptom reports are attributed to their source and are not presented as equivalent to an examination. At end of care or transfer, document the latest eye-specific assessment, unresolved concerns, responsible follow-up clinician, emergency instructions and whether the treatment sequence was completed, voluntarily stopped or terminated for safety.

8.8 Longitudinal dataset versus clinical chart

Routine care records are primarily clinical records. Any later retrospective or prospective research dataset requires its own definition of eligibility, denominator, time windows, missingness and applicable governance. This Clinical Standard does not itself announce a retrospective study, analyze previously treated patients or validate a mechanistic effect.

Figure 9. L-TIDE computational observability results



Interpretation. In selected fully synthetic experiments, decisive-correct cellular-only classification increased from 3/50 to 48/50 with pigment observations; combined-response classification increased from 4/50 to 50/50 with a cellular observation. In a different 150-dataset experiment, decisive-correct active assignments were 143 using BIC and 85 using AICc. These are distinct study conditions and criterion-dependent numerical findings.

Source. Basis: L-TIDE v1.6 working manuscript, 2026; all observations synthetic.

Boundary. Not patient results, procedure outcomes, or clinical sensitivity/specificity.

9. Documentation and quality assurance

9.1 Traceability and record quality

Records should link patient ID, individual eye, visit ID, treatment-stage ID, device/exposure log reference, pre-stage checkpoint, post-stage findings and the accountable clinician. Outcomes and complications must be assigned to the correct denominator (patient, eye, visit or exposure) before any quantitative reporting.

9.2 Quality review

The operating program should periodically review record completeness, missed checkpoints, appropriateness of L-SAFE state documentation, patient follow-up status, deviations from approved practice, and closed/terminated sequences. Audit outputs should distinguish “not measured,” “not recorded,” and “measured and normal.”

Formal training, supervised practical assessment, competency review, renewal and authorization to act under the Lumineyes name are separate steps. Completion of an educational course is not automatically equivalent to demonstrated competence or authorization to use the method. Detailed training and licensing rules belong in controlled program documents.

10. Controlled documents and release

The public clinical-governance reference and the separately maintained restricted operating layer are distinct controlled documents. Publication of this public edition does not disclose or authorize technical device settings. The responsible clinical authority separately approves applicable local SOPs, implementation permissions, their effective dates and the restricted version register.

10.1 Integrated clinical workflow

Step	Decision / evidence	Next record
1 · Patient candidacy	Patient-level health and suitability, program exclusions, expectations, consent discussion and aftercare feasibility.	Patient selection outcome; outstanding issues.
2 · Eye eligibility	Independent OD/OS examination; visual function and relevant anterior/posterior structures; known program exclusions.	Eye-specific eligibility; baseline reference.
3 · Baseline dataset	Capture observed measures, photographic provenance, IOP context, ocular findings and outstanding investigations.	Visit ID; source clinical chart; relevant baseline items.
4 · Pre-stage checkpoint	Four L-SAFE domains recorded independently; S0/S1/S2/S3 or explicit Incomplete designation.	Checkpoint ID, objective findings, rationale and trajectory if appropriate.
5 · Stage decision	Candidacy + checkpoint + response/purpose + independent physician authorization.	Authorized for this stage / Deferred / Withheld / Sequence terminated.
6 · Exposure or no exposure	If authorized and carried out, link the actual restricted procedural record. A cancelled visit must not be counted as treatment.	Exposure event ID or no-exposure disposition.
7 · Follow-up and sequence status	Record symptoms, eye function, IOP, cornea, anterior chamber, angle/outflow and events as indicated.	Follow-up visit, next reassessment, closure or new candidacy if appropriate.

10.2 Public and restricted document boundary

Public clinical standard	Restricted operating manual
Scope, terminology, program eligibility decisions, examination/record structure	Authorized equipment, confidential phase-specific operating steps and device controls
L-SAFE framework, checkpoint and stage-authorization concepts	Device-specific checklists, detailed procedural parameters and troubleshooting
Training principles and governance of completion versus program permission	Practical supervised training detail, restricted evaluation material and access logs

Public clinical standard	Restricted operating manual
Document version, public source register and limited revision summary	Access permissions, revision sign-off and reference mapping to released public version

10.3 Local implementation and document-control checkpoints

Local control	Implementation requirement	Status
I01 · Selection	Align clinic eligibility policy and public patient information before local implementation.	Local sign-off
I02 · Baseline	Approve required and indication-based examinations and measurement provenance.	Local sign-off
I03 · Staging/SOP	Approve stage intervals and controlled operating manual; technical details remain restricted.	Local sign-off
I04 · Follow-up	Authorize clinic-specific follow-up, clinician responsibility and escalation pathways.	Local sign-off
I05 · Decisions	Approve four-gate documentation, withholding, closure and re-entry workflow.	Local sign-off
I06 · Training	Authorize course competencies, completion certification, mentorship and separate practice permissions.	Local sign-off
I07 · Audit	Approve retention, audit sampling, deviation handling and access controls.	Local sign-off
I08 · Local adoption	Record institutional SOP approval, implementation effective date and local control owner.	Local sign-off

Publication of this public reference edition does not certify that every clinic-specific operational requirement has been approved. The accountable clinical institution must document separate SOP approval, training authorization, access permissions and effective dates before implementation.

Appendix A. Clinical compliance checklist

One eye-level checklist for a relevant stage. A tick confirms that a record exists; it does not independently authorize treatment.

☐ Patient, eye (OD/OS), responsible clinician and encounter date are identified.

☐ Patient- and eye-level eligibility, relevant exclusions, expectations and follow-up feasibility are recorded.

☐ Prior ocular surgery, medical conditions, medication context and unresolved screening findings are addressed.

☐ Visual acuity, measured IOP with method and medication context, anterior segment and relevant posterior-segment examination are recorded.

☐ Angle/outflow status is documented when required for the L-SAFE checkpoint.

☐ Iris appearance, optional LIPS category and image acquisition metadata are recorded where available.

☐ Four L-SAFE domains and the integrated state are recorded, or the checkpoint is explicitly incomplete.

☐ S1/S2 withholding, S3 sequence termination and any independent exclusion are applied as appropriate.

☐ The treatment-stage purpose and independent physician authorization are recorded separately from S0.

☐ The actual delivered or non-delivered stage is documented; cancelled visits are not counted as exposures.

☐ Technical-log identifier, restricted SOP revision and any relevant deviation are traceable.

☐ Post-stage observations, symptoms, event/escalation response and next follow-up responsibilities are documented.

☐ Longitudinal trends retain measured values and identify missing visits or remote reports.

☐ Previous S2/S3 events, sequence closure and any later re-entry review remain in the chart.

Appendix B. Controlled source and framework register

Source list of the scientific and program documents used in this public reference edition. Bibliographic status, links and source versions should be reconciled when a subsequent edition is prepared.

- Selective Stromal Melanin Modulation (SSMM), latest author manuscript / Zenodo candidate, 13 November 2026.
- Lumineyes Anterior-Segment Safety Staging (L-SAFE), author's methodological manuscript, four-state / four-domain specification.
- Lumineyes™ Iris Pigmentation Scale (LIPS), proposed Grade I–V clinical grading pathway / Figure 2.
- Longitudinal Response Selectivity (LRS), research definition within SSMM.
- L-OAT, TRA and P-CLEAR: companion conceptual frameworks and working research records.

Patient eligibility reference (English): https://mylumineyes.com/eye-color-change-patient-eligibility/ (reviewed for R9 on 14 November 2026).

Restricted clinical operating manual: identifier and approved revision to be entered by the clinical document owner before release.

Evidence and measurement tables

The tables distinguish literature-supported anatomy and physiology, program-specific policies, proposed frameworks and computational demonstrations. No numerical patient-outcome estimates are introduced.

Table V1. Evidence-level crosswalk

Component	Evidence position	Interpretation / constraint
Iris anatomy	General ophthalmic anatomy	Anterior border, stroma, muscle and posterior epithelium are distinct structures.
Clinical eligibility	Lumineyes program policy	Program-defined exclusions and relative contraindications; not universal contraindications.
SSMM	Proposed biophysical framework	Selectivity dimensions are investigational and require independent endpoints.
L-SAFE	Proposed clinical documentation architecture	Four-domain integrated state; the classification has not been validated as a safety-benefit predictor.
LIPS / L-OAT	Proposed phenotype descriptors	Descriptive use only pending reliability and predictive validation.
SSMM–IOP	Mechanistic hypothesis + external experimental analogies	No demonstrated SSMM-specific outflow mechanism or durable pressure lowering.
L-TIDE	Synthetic computational results	Inform measurement design; not a patient-response model.
Chromatic v0.10	Uncalibrated two-layer optical model	No patient-specific hue prediction or clinical dose selection.

Table V2. Minimum measurement and validation crosswalk

Scientific question	Candidate observations	Design safeguard
Pigment appearance	Standardized iris photography; regional colour metrics	Lighting, white balance, pupil size and registration documented.
Iris architecture	AS-OCT thickness, geometry and angle parameters	Device, reconstruction and repeatability tracked.
Tissue optics	Measured iris reflectance spectra; model comparison	Lock optical model before independent spectral validation.
Anterior-chamber response	Cells, flare and pigment material recorded separately	Avoid conflating inflammatory cells with pigment particulates.
Intraocular pressure	Repeated IOP with medication and measurement context	Analyze within-eye repeated observations and attrition.
Aqueous outflow	Direct facility / perfusion experiments where feasible	Separate transport, cellular signaling, obstruction and hydraulic parameters.
Functional safety	Vision, cornea and indicated posterior-segment endpoints	Independent outcomes, not inferred from colour or pressure alone.

These measurement proposals are research design requirements, not instructions to perform additional exposure or a substitute for clinically indicated assessment.

Table V3. Falsifiable questions and negative results

Proposition	Test capable of discriminating explanations	Meaning of a negative result
Pigment change equals selective action	Independent layer-sensitive and tissue-function endpoints	Visible change may not imply selective preservation.
SSMM alters outflow facility	Direct outflow measurement with controls / washout	A pressure trajectory alone cannot establish facility or mechanism.
Early signal causes persistent remodeling	Serial biological sampling and alternative models	Delayed persistence may not exist or may have another cause.
Iris phenotype predicts clinical response	Independent prospective validation and masked grading	Phenotype categories may not be predictive.
Optical brightness determines hue	Spectral measurements and independent colourimetry	L* alone cannot specify blue, green or gray appearance.

Scientific provenance and source notes

Links and references below support the anatomy, comparisons, and document provenance. Proposed frameworks and synthetic work are identified as such.

Anatomy. AAO EyeWiki, Basic Histology of the Eye and Accessory Structures (https://eyewiki.aao.org/Basic_Histology_of_the_Eye_and_Accessory_Structures); Uvea, PMC7149650 (https://pmc.ncbi.nlm.nih.gov/articles/PMC7149650/).

SSMM / LRS. Mete M. Selective Stromal Melanin Modulation, revised conceptual research manuscript (13 Nov 2026 candidate); SSMM Zenodo record DOI 10.5281/zenodo.23424601.

L-SAFE / LIPS / L-OAT. Mete M. L-SAFE v1.1 proposed four-state framework; LIPS proposed iris pigmentation grading; L-OAT proposed P–A–O architecture. Clinical Standard public release-candidate source register.

SSMM–IOP. Mete M. Long-Term Intraocular Pressure Dynamics After Selective Stromal Melanin Modulation: A Testable Mechanistic Framework. Preprints.org (12 Nov 2026). https://doi.org/10.20944/preprints202611.1334.v1

SLT comparison. Alvarado JA, Katz LJ, Trivedi S, Shifera AS. Monocyte modulation of aqueous outflow and recruitment to the trabecular meshwork following selective laser trabeculoplasty. Arch Ophthalmol. 2010;128(6):731–737. doi:10.1001/archophthalmol.2010.85.

L-TIDE. Mete M. L-TIDE: A Multimodal Measurement Architecture for Iris–Trabecular Dynamics and Mechanistic Identifiability. Author working manuscript v1.6 (2026). Computational / synthetic only; publication status not assumed.

Chromatic model. SSMM Chromatic Research v0.10. Separating Lightness, Hue, and Chroma in a Two-Layer Iris Optical Model. Author technical result note, 8 Nov 2026. Uncalibrated synthetic calculations.

Version history. v1.1 (16 Nov 2026): public-release status and document-control language reconciled; the eight former open release gates are now identified as separate local implementation checkpoints. Scientific sections, figures, clinical framework and training description are retained from v1.0 RC1. Publication does not establish external clinical validation or institutional authorization.