2025

KJO SPARKS

CURATED RESEARCH IDEAS

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KJO SPARKS

A collection of focused, actionable clinical research topics
based on the KJO Research to Reality webinar series-
Ideas organized by priority, each elaborated with the research gap,
study design suggestion, key outcomes, feasibility and brief notes.

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CATARACT & IOL

1. **Comparative outcomes of hydrophobic acrylic vs hydrophilic acrylic IOLs: posterior capsule opacification (PCO) and visual outcomes**
    - *Gap:* Local comparative PCO rates and patient outcomes across IOL materials in routine practice.
    - *Design:* Prospective cohort or randomized trial.
    - *Primary outcome:* PCO incidence/severity at 12–24 months (e.g., EPCO score) and corrected distance visual acuity (CDVA).
    - *Sample hint:* 150–300 eyes.
    - *Notes:* Readily feasible; many centres implant both types.
2. **Real-world refractive accuracy and patient satisfaction after premium IOLs (multifocal / EDOF / toric) vs monofocal IOLs in Kerala**
    - *Gap:* Local refractive outcomes, spectacle independence and satisfaction given Kerala's patient expectations.
    - *Design:* Prospective comparative cohort with validated questionnaires.
    - *Primary outcome:* Proportion within ±0.50 D spherical equivalent and patient-reported spectacle independence at 6–12 months.
    - *Sample hint:* 100–150 per arm.
    - *Notes:* Include cost/willingness-to-pay sub-study.
3. **Effect of pre-existing diabetes on cataract surgery outcomes with IOL implantation: visual, macular and complication profile**
    - *Gap:* Region-specific data on diabetic control, diabetic retinopathy progression and macular edema after surgery.
    - *Design:* Prospective cohort stratified by diabetic control (HbA1c) and retinopathy stage.
    - *Primary outcome:* Incidence of clinically significant macular edema and change in CDVA at 6 months.
    - *Sample hint:* 200–400 eyes.
    - *Notes:* Coordinate with endocrinology; OCT mandatory.
4. **Comparative study of small-incision cataract surgery (SICS) vs phacoemulsification in visual outcomes and cost-effectiveness in district hospitals of Kerala**
    - *Gap:* Practical evidence on best approach at secondary-care level balancing outcomes and resources.
    - *Design:* Non-inferiority RCT or pragmatic cohort with economic analysis.
    - *Primary outcome:* CDVA and complication rate at 3 months; incremental cost per quality-adjusted life-year.
    - *Sample hint:* 150–300 eyes.
    - *Notes:* High policy relevance for outreach programs.
5. **Incidence and microbial spectrum of post-operative endophthalmitis after cataract + IOL in Kerala and adherence to prophylaxis protocols**
    - *Gap:* Local incidence, organisms and prophylaxis effectiveness (e.g., intracameral antibiotics).
    - *Design:* Multi-centre prospective surveillance/audit.
    - *Primary outcome:* Incidence per 1,000 surgeries, organism profile and visual outcome at 3 months.
    - *Sample hint:* Surveillance of 5,000–10,000 surgeries for precise incidence; smaller audits (1,000–2,000) acceptable for dissertations.
    - *Notes:* High public health importance; requires microbiology collaboration.
6. **Posterior capsule opacification rates and Nd:YAG capsulotomy requirement: comparison by IOL edge design and optic-haptic design**

- *Gap:* Which IOL design features reduce PCO in local practice?
- *Design:* Retrospective cohort or prospective comparative study.
- *Primary outcome:* Nd:YAG capsulotomy rate at 2 years.
- *Sample hint:* 200–400 eyes.

7. **Accuracy of biometry formulas (OLCR/PCI/SS-OCT vs ultrasound) and prediction error in eyes with short/long axial lengths in Kerala population**
   - *Gap:* Local biometric distributions may affect formula performance; need validation of newer formulas.
   - *Design:* Prospective diagnostic accuracy study comparing formulas (e.g., Barrett, Kane, SRK/T).
   - *Primary outcome:* Mean absolute error and % within ±0.25/±0.50 D.
   - *Sample hint:* 200–500 eyes stratified by axial length.
   - *Notes:* Useful for improving refractive outcomes.
8. **Visual outcomes and quality-of-life after immediate sequential bilateral cataract surgery (ISBCS) vs delayed sequential surgery (DSBCS)**
   - *Gap:* Safety, patient satisfaction and efficiency data for ISBCS in Kerala context is limited.
   - *Design:* Randomized pilot or matched cohort with safety monitoring.
   - *Primary outcome:* Combined complication rate and patient-reported QoL at 1 month.
   - *Sample hint:* 80–150 bilateral patients.
   - *Notes:* Must include strict infection control protocols.
9. **Toric IOL outcomes in eyes with corneal astigmatism: rotational stability and refractive predictability in Kerala clinics**
   - *Gap:* Rotation rates, predictors of rotation and real-world refractive outcome data for toric lenses.
   - *Design:* Prospective cohort with postoperative follow-up at 1 week, 1 month, 6 months.
   - *Primary outcome:* Mean residual cylinder and % requiring re-rotation.
   - *Sample hint:* 80–150 eyes.
10. **Outcomes of cataract surgery in elderly with cognitive impairment: visual function, QoL and adherence to follow-up in Kerala**
    - *Gap:* How cognitive status affects outcomes and follow-up adherence locally.
    - *Design:* Prospective cohort using brief cognitive screen (e.g., MMSE) and QoL measures.
    - *Primary outcome:* Change in ADL-related vision scores and follow-up adherence at 3–6 months.
    - *Sample hint:* 120–200 patients.
11. **Comparison of refractive outcomes after cataract surgery in post-LASIK eyes using intraoperative aberrometry vs preoperative planning**
    - *Gap:* Best approach for accurate IOL power selection in previously refractive-operated eyes.
    - *Design:* Prospective comparative study.
    - *Primary outcome:* Refractive prediction error at 3 months.
    - *Sample hint:* 40–100 eyes (these cases less common).
    - *Notes:* Good tertiary-centre project.
12. **Evaluation of spectacles uptake and patient-reported barriers to refractive correction after cataract surgery in rural Kerala**
    - *Gap:* Post-op spectacle uptake and reasons for non-use in outreach-operated patients.
    - *Design:* Cross-sectional survey + chart review 3 months post-op.
    - *Primary outcome:* Proportion provided vs actually using spectacles; thematic barriers.

- *Sample hint:* 300–600 patients.
- *Notes:* Useful for program improvement.

13. **Effectiveness and safety of intracameral antibiotics (cefuroxime vs moxifloxacin) in cataract surgery in Kerala — a multicentre audit**
    - *Gap:* Comparative real-world safety and endophthalmitis prevention data.
    - *Design:* Prospective multicentre audit with large sample.
    - *Primary outcome:* Endophthalmitis rate and adverse events.
    - *Sample hint:* 3,000–10,000 surgeries for meaningful incidence estimates.
14. **Refractive surprises: factors associated with postoperative refractive error >1.0 D after cataract + IOL in Kerala**
    - *Gap:* Understanding modifiable predictors to reduce refractive surprises.
    - *Design:* Case-control study (surprises vs controls).
    - *Primary outcome:* ORs for predictors (biometry, axial length, prior surgery, formula choice).
    - *Sample hint:* 100–200 cases + matched controls.
15. **Long-term endothelial cell count changes after phacoemulsification with different viscoelastics and IOL types in elderly Kerala patients**
    - *Gap:* Endothelial safety of commonly used viscoelastics/IOLs in local elderly population.
    - *Design:* Prospective comparative cohort with specular microscopy baseline, 3, 12 months.
    - *Primary outcome:* Mean endothelial cell loss (%) at 12 months.
    - *Sample hint:* 80–150 eyes.
16. **Teleophthalmology for postoperative cataract follow-up: diagnostic concordance, patient satisfaction and cost-savings in Kerala**
    - *Gap:* Feasibility and accuracy of remote follow-up in areas with good mobile penetration like Kerala.
    - *Design:* Diagnostic concordance study (tele- vs in-person exam) plus satisfaction survey.
    - *Primary outcome:* Concordance for wound problems, infection signs, and refractive complaints; cost/time saved.
    - *Sample hint:* 150–300 postoperative visits.
    - *Notes:* Very practical after COVID-era lessons.
17. **PROMs and QOL (VFQ) stratified by different IOL types and baseline**

Quick methodological notes & tips

- **Common baseline data:** pre-op CDVA, axial length, keratometry, comorbidities (diabetes, glaucoma), medication use, biometry method, IOL model/manufacturer.
- **Follow-up windows:** early (1 day, 1 week), short-term (1–3 months) and longer-term (12–24 months) depending on endpoint.
- **Outcomes to include:** objective (CDVA, refractive error, axial length where relevant, endothelial counts, OCT macula), subjective (NEI-VFQ/other QoL, satisfaction), and safety (complications).
- **Sample sizes:** calculate exact sample sizes based on expected effect size, alpha, and power.

GEOGRAPHIC ATROPHY AND SUPPLEMENTS

1. Prospective cohort: baseline serum lutein/zeaxanthin and risk of GA progression to the fovea

- **Gap:** Little prospective data linking systemic carotenoid levels to rate/likelihood of GA centripetal progression in Indian patients.
- **Design:** Prospective cohort of eyes with established GA not yet involving the fovea; measure baseline serum lutein/zeaxanthin + dietary intake; follow every 6 months for 2–3 years with OCT + fundus autofluorescence (FAF).
- **Primary outcome:** Time to foveal involvement (fovea-involving GA).
- **Sample hint:** 150–300 eyes (depends on expected event rate).
- **Notes:** Non-interventional; easy to implement at tertiary centres with lab support.

2. Observational study: AREDS2-style supplement use and GA progression rate in Indian patients (real-world)

- **Gap:** Real-world effectiveness of AREDS2 (with lutein/zeaxanthin) on GA progression in Indian settings is unknown.
- **Design:** Prospective registry comparing users vs non-users (adjust for confounders with propensity scores). 24–36 month follow-up with structural and functional testing.
- **Primary outcome:** Annual change in GA area and proportion progressing to foveal involvement.
- **Sample hint:** 200–400 eyes.
- **Notes:** Ethical (observational) — cannot randomize to withhold recommended supplements if considered standard locally.

3. Randomized pilot: high-dose lutein/zeaxanthin supplementation + standard antioxidant vs standard antioxidant alone for delaying foveal involvement (feasibility/efficacy signal)

- **Gap:** Dose–response evidence specifically for preventing centripetal GA progression is limited.
- **Design:** Small RCT (add-on design) comparing standard antioxidant regimen ± higher-dose lutein/zeaxanthin for 24 months.
- **Primary outcome:** Change in GA area growth rate (mm^2/year) and time to foveal involvement.
- **Sample hint:** Pilot 60–120 eyes (to detect signal; power for definitive trial requires larger sample).
- **Ethics:** Compare accepted background therapy; do **not** withhold standard care.

4. Correlative study: macular pigment optical density (MPOD) and local GA growth patterns toward the fovea

- **Gap:** Relationship between local macular pigment levels and directional GA growth (centripetal vs eccentric) is unclear.
- **Design:** Cross-sectional + longitudinal MPOD by heterochromatic flicker photometry or autofluorescence-derived methods; serial FAF/OCT.
- **Primary outcome:** Association between baseline MPOD and subsequent GA centripetal growth rate.
- **Sample hint:** 80–200 eyes.
- **Notes:** Non-invasive, mechanistic.

5. Functional endpoints: do serum carotenoids / supplement use preserve central retinal sensitivity (microperimetry) as GA approaches the fovea?

- **Gap:** Structural change ≠ functional change; microperimetry data in supplement studies are limited.
- **Design:** Prospective cohort or add-on RCT with microperimetry at baseline and every 6 months.
- **Primary outcome:** Change in central retinal sensitivity and correlation with supplement exposure/serum levels.
- **Sample hint:** 80–150 eyes.
- **Notes:** Microperimetry centers required.

6. Pharmacokinetic/biomarker study: correlation between oral dose, serum/retinal carotenoid levels and GA progression

- **Gap:** How systemic levels translate to retinal deposition and clinical effect in Indian diet/genotype backgrounds is unknown.
- **Design:** Supplemented cohort with serial serum carotenoid measures and MPOD; correlate with GA growth.
- **Primary outcome:** Relationship between serum/MPOD change and GA growth rate.
- **Sample hint:** 60–120 participants.
- **Notes:** Requires lab assays and MPOD capability.

7. Subgroup analysis: effect modification by common Indian AMD risk genotypes (CFH/ARMS2 variants) on supplement effectiveness for preventing foveal GA

- **Gap:** Genetic modifiers of supplement response are understudied in South Asian populations.
- **Design:** Case-control or cohort with genotyping; stratified analysis of supplement effect on GA progression.
- **Primary outcome:** Interaction (effect modification) between genotype and supplement-associated GA growth rate.
- **Sample hint:** 200+ subjects to have reasonable genotype subgroup numbers.
- **Notes:** Needs molecular lab; high scientific value.

8. Comparative imaging study: FAF patterns predictive of faster centripetal progression and modified by supplement use

- **Gap:** Specific FAF patterns (e.g., banded, diffuse) may predict faster approach to fovea and may interact with supplementation.
- **Design:** Prospective imaging study scoring FAF patterns, track GA growth and supplement exposure.
- **Primary outcome:** FAF pattern × supplement interaction on time-to-foveal involvement.
- **Sample hint:** 150–250 eyes.
- **Notes:** Utilizes routinely collected imaging.

9.Health-economics / implementation: cost-effectiveness of routine lutein/zeaxanthin supplementation to delay foveal involvement in Indian public health settings

- **Gap:** Is recommending supplements at scale cost-effective in India given local costs and progression rates?
- **Design:** Model-based cost-effectiveness using trial/registry effect sizes, local cost data, and quality-of-life weights.
- **Primary outcome:** ICER per quality-adjusted life-year (QALY) gained or per severe visual impairment averted.

- **Notes:** Useful for policy; uses existing clinical inputs.

10. Adherence & acceptability study: barriers to long-term oral supplement adherence among Indian AMD patients and impact on outcomes

- **Gap:** Real-world adherence to supplements is poor and understudied; non-adherence may bias effects.
- **Design:** Mixed-methods: prospective adherence monitoring (pill counts / pharmacy refill) + qualitative interviews; correlate adherence with GA progression.
- **Primary outcome:** Adherence rates and association with GA growth / foveal involvement.
- **Sample hint:** 150–250 patients for quant; 20–40 for qual.
- **Notes:** Addresses implementation gap.

11. Interaction with diet: dietary lutein/zeaxanthin intake, supplementation and GA centripetal progression in Indian diets

- **Gap:** Indian dietary patterns differ from Western cohorts; baseline intake may influence supplement effect.
- **Design:** Prospective cohort with validated food-frequency questionnaire, serum carotenoids, and GA follow-up.
- **Primary outcome:** Effect modification of dietary intake on supplement-associated GA progression.
- **Sample hint:** 150–300 eyes.
- **Notes:** Nutrition collaboration needed.

12. Imaging endpoint validation: automated quantification of GA area on OCT / FAF vs manual grading to measure supplement effects reliably in Indian images

- **Gap:** Reliable, reproducible imaging endpoints are critical for trials but need local validation.
- **Design:** Diagnostic/validation study comparing automated algorithms with expert grading; test sensitivity to detect treatment-related changes.
- **Primary outcome:** Agreement metrics (ICC, Bland-Altman) and minimal detectable change.
- **Sample hint:** 100–200 image sets.
- **Notes:** Important methodological groundwork.

13. Safety/tolerability study: adverse events and ocular/systemic safety of high-dose lutein/zeaxanthin in older Indian adults with AMD

- **Gap:** Safety profile in local elderly population with comorbidities needs documentation.
- **Design:** Prospective safety monitoring of supplemented cohort (liver function, interactions, GI effects).
- **Primary outcome:** Frequency and severity of adverse events; discontinuation rates.
- **Sample hint:** 200+ participants.
- **Notes:** Complements efficacy studies.

14 Combined outcome study: Does early initiation of lutein/zeaxanthin after non-foveal GA diagnosis preserve reading speed and vision-related quality of life when compared to late/no initiation?

- **Gap:** Functional preservation (reading, QoL) as an endpoint is patient-centred and under-studied.

- **Design:** Prospective cohort or quasi-experimental (early vs late starters) with reading speed tests, VF, and NEI-VFQ at baseline and follow-up.
- **Primary outcome:** Change in reading speed and vision-specific QoL at 12–24 months and relation to foveal involvement.
- **Sample hint:** 120–200 patients.
- **Notes:** Strong patient-centred focus.

15- PROMs and QOL (VFQ) – pre and post interventions and trends

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Common methodological notes & recommendations

- **Imaging:** Use spectral-domain OCT (for GA area and foveal involvement), fundus autofluorescence (FAF) for growth patterns, and standardized imaging protocols. Document grader masking.
- **Functional tests:** Microperimetry, contrast sensitivity, reading speed and validated QoL instruments strengthen clinical relevance.
- **Biomarkers:** Serum lutein/zeaxanthin assays + MPOD measurements give mechanistic and exposure data.
- **Follow-up:** GA progression is slow — **minimum 24 months** is recommended; 36 months preferred for robust time-to-fovea analyses.
- **Ethical note:** Don't withhold established standard supplements. Design RCTs as add-on or compare doses/formulations; observational designs are often more feasible and ethical. Obtain coordination with treating physicians for medication/supplement decisions.
- **Sample size:** compute exact numbers based on expected event rates or effect sizes.
- **Feasibility in India:** Tertiary retina centres with imaging, lab and microperimetry capability are ideal. Multi-centre collaboration improves power and generalizability.

PRIMARY ANGLE-CLOSURE GLAUCOMA (PACG)

1. Comparative effectiveness: Early clear-lens extraction vs laser peripheral iridotomy (LPI) in PAC suspect / early PACG

- Gap: Uncertainty about long-term IOP control, visual outcomes and progression when lens extraction is used earlier vs standard LPI.
- Design: Multicentre randomized controlled trial (RCT), stratified by baseline angle status.
- Primary outcome: Progression to established PACG or need for additional glaucoma surgery at 3–5 years.
- Secondary outcomes: IOP, medication burden, angle opening on AS-OCT, quality of life, complications.
- Notes: Feasible in tertiary centres; high clinical relevance.

2. Predictors of progression from primary angle-closure suspect (PACS) / primary angle closure (PAC) to PACG using multimodal imaging (AS-OCT + UBM + gonioscopy)

- Gap: Lack of validated objective imaging thresholds predicting progression.
- Design: Prospective cohort with standardized imaging and masked graders, 3–5 year follow-up.
- Primary outcome: Development of glaucomatous optic neuropathy or visual field loss.
- Predictors to test: Lens vault, angle opening distance, iris curvature, anterior chamber depth, dynamic changes (light/dark).
- Notes: Enables risk stratification and targeted intervention trials.

3. Role of anterior segment OCT quantitative metrics + machine learning models for automated screening of angle closure (community screening)

- Gap: Need for scalable, objective screening with high sensitivity/specificity in population settings.
- Design: Diagnostic accuracy study (index = AS-OCT + ML model; reference = gonioscopy by glaucoma specialist).
- Primary outcome: Sensitivity/specificity for detecting occludable angles / PACS.
- Notes: Could tie into telemedicine programs; evaluate cost-effectiveness.

4. Ethnic, regional, and sex differences in PACG — biometric and genetic correlates in Kerala

- Gap: Most large genomic/biometric datasets are East Asian or mixed; India/other South Asian populations underrepresented.

- Design: Cross-sectional biometric study plus case-control genetic sub cohort (GWAS or targeted sequencing).

- Outcomes: Prevalence of biometric risk factors, identification of population-specific genetic loci.

- Notes: Requires collaboration with genetics labs and biobanking.

5. Long-term outcomes and complications of minimally invasive glaucoma surgery (MIGS) vs trabeculectomy vs glaucoma drainage devices in PACG with coexisting cataract

- Gap: Limited randomized data comparing MIGS in angle-closure eyes; uncertain efficacy where synechial closure exists.

- Design: Pragmatic RCT or well-matched cohort study with 2–3 year follow-up.

- Primary outcome: IOP reduction and surgical failure rates.

- Secondary: Visual acuity, complications (bleb leak, hypotony), need for reoperation.

6. Impact of the extent and duration of peripheral anterior synechiae (PAS) on outcomes after lens extraction or LPI

- Gap: How much PAS (degrees/time) predicts poor response to posterior chamber lens procedures is unclear.

- Design: Prospective cohort tracking PAS extent, PAS chronicity (imaging/historical), and postoperative outcomes.

- Outcome: IOP, medication-free survival, visual field progression.

7. Cost-effectiveness and implementation research of community screening strategies for PACG in high-risk regions

- Gap: Best approach to reduce blindness from PACG in resource-limited settings is unknown.

- Design: Cluster randomized or stepped-wedge implementation trial comparing screening algorithms (questionnaire → AS-OCT → referral).

- Primary outcome: Cases detected/treated per cost; reduction in blindness rate over defined period.

8. Medical management trials for angle-closure glaucoma — prostaglandins and newer agents' effects on angle anatomy and long-term outcomes

- Gap: Most glaucoma drug trials focus on primary open-angle glaucoma; their effect on angle anatomy or progression in PACG is not well characterized.

- Design: RCT or mechanistic clinical trial measuring IOP and angle metrics longitudinally.

9. Dynamic (dark/light, pharmacologic) angle behaviour and its relationship to acute angle-closure attack risk

- Gap: Predictive markers for acute attack are poorly quantified.
- Design: Case-control and prospective cohort using dynamic imaging protocols to simulate physiologic provocation.
- Outcome: Ability of dynamic changes to predict acute episodes.

10. Quality of life, vision-related function, and psychosocial impact in PACG vs POAG and cataract — patient-reported outcomes development and validation

- Gap: Little disease-specific PRO data for PACG; existing glaucoma PROs may not capture angle-closure–specific issues.
- Design: Mixed methods (qualitative interviews to develop items) then psychometric validation cohort.
- Outcome: Validated PRO instrument to use in trials and health-economic studies.

OTHER VALUABLE / NICHE TOPICS

1. Role of platelet/vascular biomarkers and endothelial dysfunction in PACG progression (translational).
2. Impact of prior LPI on subsequent cataract surgery outcomes and angle anatomy (retrospective + prospective).
3. Effectiveness of peripheral iridoplasty in plateau iris vs lens-related closure.
4. Paediatric and secondary angle closure variants — clinical phenotype descriptions and management pathways.
5. Adherence barriers to topical therapy in PACG (particularly post-surgery) and interventions to improve adherence.
6. Tele-gonioscopy feasibility and diagnostic concordance with in-person gonioscopy.
7. Use of swept-source AS-OCT versus standard AS-OCT for better imaging of lens/angle relationships.
8. Pharmacogenomics of response to IOP-lowering drugs in PACG.

STUDY DESIGN CHECKLIST & COMMON OUTCOME MEASURES (QUICK REFERENCE)

- Key baseline measures: Gonioscopy grade, AS-OCT metrics (AOD500/750, TIA, angle recess area), lens vault, axial length, ACD, central corneal thickness, optic nerve OCT, visual fields.

- Primary clinical endpoints: Development of glaucomatous optic neuropathy (structural/functional), IOP control (mean IOP, % reduction), surgical failure, need for glaucoma medications, acute attack incidence.

- Safety endpoints: Visual acuity loss, corneal decompensation, endophthalmitis, hypotony, cataract progression (if applicable).

- Analysis notes: Time-to-event analyses (Kaplan-Meier/Cox), mixed models for repeated measures for IOP/angle metrics, diagnostic accuracy stats (ROC/AUC) for screening studies.

- Sample size hint: Depends strongly on endpoint — progression endpoints often need several hundred eyes for RCTs/cohort studies; diagnostic accuracy studies may need 200–500 eyes to achieve narrow CIs, but these are ballpark estimates.

PAEDIATRIC MYOPIA

HIGH-PRIORITY / HIGH-IMPACT STUDIES

1. **Randomized trial: aspherical myopia-control spectacle lens vs standard single-vision spectacles — effect on axial length and refractive progression (2 years)**
    - *Gap:* RCT data comparing aspherical/peripheral-defocus spectacle designs with standard spectacles in Indian children is limited.
    - *Design:* Parallel-group RCT, age 6–12, cycloplegic refraction and axial length at baseline, 12 and 24 months.
    - *Primary outcome:* Mean axial length change (mm) at 24 months; secondary: change in spherical equivalent refraction (SER).
    - *Sample hint:* 80–150 children per arm for moderate effect (pilot trials may use 50/arm).
    - *Notes:* School/clinic recruitment feasible; mask outcome assessors.
2. **Non-inferiority RCT: aspherical lenses vs multifocal/defocus-incorporated spectacle lenses for myopia control**
    - *Gap:* Head-to-head comparisons of different spectacle technologies in Indian population are scarce.
    - *Design:* Non-inferiority RCT with 1–2 year follow-up.
    - *Primary outcome:* Difference in axial elongation between groups; non-inferiority margin pre-specified (e.g., 0.10–0.15 mm/year).
    - *Sample hint:* 100–200 per arm depending on margin.
    - *Notes:* Useful to compare cost-effective Indian-manufactured aspherical lenses vs branded lenses.
3. **Effect of aspherical spectacle lens wear on peripheral refraction and accommodative response — mechanistic cohort study**
    - *Gap:* Mechanistic data linking optical changes (peripheral refraction, accommodative lag) to treatment effect in Indian children is limited.
    - *Design:* Prospective cohort with baseline and repeated peripheral refraction maps and accommodation testing (dynamic retinoscopy/auto-refractor).
    - *Primary outcomes:* Change in peripheral refraction profile; correlation with axial elongation over 12 months.
    - *Sample hint:* 40–80 children.
    - *Notes:* Provides mechanistic justification for clinical effects.
4. **School-based cluster randomized trial of aspherical spectacle distribution vs usual care for community-level myopia progression**
    - *Gap:* Real-world effectiveness and implementation at scale (school programs) is under-studied.
    - *Design:* Cluster RCT (schools randomized), 1–2 year follow-up, pragmatic outcomes.
    - *Primary outcome:* Mean change in axial length/SER at cluster level; uptake and adherence.
    - *Sample hint:* 10–20 schools per arm with 20–50 eligible children each (power depends on ICC).
    - *Notes:* High policy relevance; requires logistics with schools and parental consent.

DIAGNOSTIC / OPTIMIZATION / COMPARATIVE TOPICS

5. **Dose-response: Does degree of peripheral myopic defocus (different aspherical lens profiles) correlate with myopia control efficacy?**
    - *Gap:* Optimal peripheral add/defocus magnitude for spectacle lenses is unclear.
    - *Design:* Randomized multiple-arm trial comparing different aspherical prescriptions/profiles.
    - *Primary outcome:* Axial length change over 12–24 months.
    - *Sample hint:* 50–100 per arm.
    - *Notes:* Needs collaboration with lens manufacturer or custom surfacing lab.
6. **Comparison of single vision aspherical lenses vs progressive addition lenses (PALs) for myopia control in Indian children with near-work demand**
    - *Gap:* PAL efficacy shows mixed results; role of aspherical designs vs PALs in Indian children (many with high near work) is unclear.
    - *Design:* RCT, stratify by baseline near-work hours.
    - *Primary outcome:* SER and axial length progression at 12–24 months.
    - *Sample hint:* 70–120 per arm.
    - *Notes:* Include measurements of near-work and outdoor time.
7. **Short-term visual performance, contrast sensitivity and glare with aspherical myopia-control spectacles in Indian schoolchildren**
    - *Gap:* Safety and acceptability data (visual comfort, classroom performance, sports) is needed locally.
    - *Design:* Cross-over trial or prospective cohort with questionnaires and objective visual tests.
    - *Primary outcomes:* Contrast sensitivity, glare disability tests, school performance/reading speed, and subject-reported comfort.
    - *Sample hint:* 50–100 children.
    - *Notes:* Important for uptake/adherence.

IMPLEMENTATION, ADHERENCE & HEALTH-ECONOMICS

8. **Adherence, wear time, and barriers to effective use of aspherical myopia-control spectacles in urban vs rural Indian children**
    - *Gap:* Real-world wear adherence is critical but understudied in India.
    - *Design:* Prospective mixed-method study using parental logs, wear-time sensors (if available), and qualitative interviews.
    - *Primary outcome:* Mean daily wear hours and association with myopia progression over 12 months.
    - *Sample hint:* 150–300 children for quantitative; 20–40 for qualitative interviews.
    - *Notes:* Sensor use adds objective adherence data.
9. **Cost-effectiveness analysis of providing aspherical myopia-control spectacles through school eye programs in India**
    - *Gap:* Economic evidence to support scale-up is missing.
    - *Design:* Model-based cost-effectiveness using trial inputs (effect size, adherence) and local cost data.
    - *Primary outcome:* ICER per case of high myopia prevented or per quality-adjusted life-year (QALY) gained.
    - *Sample hint:* Uses trial/registry inputs rather than primary enrolment.
    - *Notes:* Useful for public health decision-making.
10. **Parental and teacher perceptions, acceptability and willingness-to-pay for myopia-control spectacle lenses**

- *Gap:* Socio-cultural drivers of uptake are not well quantified.
- *Design:* Cross-sectional survey and discrete choice experiment.
- *Primary outcomes:* Acceptability, WTP thresholds, influencing factors.
- *Sample hint:* 300–600 respondents across socio-economic strata.
- *Notes:* Informs pricing and uptake strategies.

SAFETY, SPECIAL POPULATIONS & ADJUNCTS

11. **Safety and ocular surface effects of prolonged aspherical spectacle wear in Indian children — tear film & dry-eye parameters**
    - *Gap:* Long-term ocular surface impact is unknown.
    - *Design:* Prospective cohort with OSDI, TBUT, Schirmer and corneal staining at baseline and 12 months.
    - *Primary outcome:* Change in tear film metrics and symptom scores.
    - *Sample hint:* 80–150 children.
    - *Notes:* Important for safety monitoring.
12. **Efficacy of aspherical lenses in children with high near work (tuition/after-school study load) vs low near work**
    - *Gap:* Treatment effect modifiers like near-work exposure may alter efficacy.
    - *Design:* RCT with pre-specified subgroup analysis by near-work hours.
    - *Primary outcome:* Interaction effect on axial elongation/SER.
    - *Sample hint:* Overall 150–300 children to power subgroup comparisons.
    - *Notes:* Collect objective near-work (apps/logs) where possible.
13. **Use of aspherical spectacle lenses as adjunct to low-dose atropine: additive, synergistic or redundant?**
    - *Gap:* Combination therapy is promising but not well-studied for spectacles + atropine in India.
    - *Design:* 2×2 factorial RCT (spectacle type × atropine 0.01% vs placebo) or comparative cohort.
    - *Primary outcome:* Axial length progression at 12–24 months.
    - *Sample hint:* 60–120 per cell for pilot; larger for definitive trial.
    - *Notes:* Must follow safety/regulatory norms for atropine use.
14. **Effectiveness of lower-cost Indian-manufactured aspherical lenses compared to imported myopia-control spectacle lenses**
    - *Gap:* Cost-effective local solutions need validation versus established (often expensive) products.
    - *Design:* Non-inferiority trial or matched cohort.
    - *Primary outcome:* Axial length change and SER progression at 12–24 months.
    - *Sample hint:* 100–200 per arm depending on non-inferiority margin.
    - *Notes:* Collaboration with local manufacturers helpful.
15. **Predictors of good responders to aspherical spectacle interventions — baseline biometric and behavioural factors**
    - *Gap:* Identifying which children benefit most enables targeted therapy.
    - *Design:* Secondary analysis of RCT/cohort data; multivariable modelling.
    - *Primary outcome:* Clinical & demographic predictors of >50% reduction in axial elongation.
    - *Sample hint:* Use pooled dataset; 200+ children preferred for stable models.
    - *Notes:* Useful for personalized myopia management algorithms.
16. **PROMs and QOL (Pre and Post spectacle correction plus trends over time)**

MEASUREMENT & METHODOLOGICAL CHECKLIST (RECOMMENDED FOR MOST TOPICS)

- **Key tests:** Cycloplegic autorefraction (or retinoscopy), axial length (optical biometer), peripheral refraction mapping, accommodative lag (dynamic retinoscopy or autorefractor), best-corrected VA, contrast sensitivity, binocular vision assessment.
- **Definitions:** Progression often reported as annual change in SER (D/year) and axial length (mm/year); pre-specify responder definitions.
- **Follow-up:** Minimum 12 months for pilot studies; 24 months preferred for definitive myopia control outcomes.
- **Masking:** Mask outcome assessors to spectacle type when possible.
- **Sample-size planning:** For a moderate treatment effect (e.g., 0.20–0.25 mm/year AL difference), expect ~80–150 per arm; smaller pilot studies (40–60/arm) acceptable to estimate effect sizes and feasibility.

RECURRENT CORNEAL EROSIONS

EPIDEMIOLOGY & RISK-FACTOR STUDIES

1. **Prevalence and risk factors of recurrent corneal epithelial erosion in a tertiary eye hospital population in India**
    - *Gap:* Lack of region-specific prevalence and risk profile (trauma, diabetes, dry eye, epithelial basement membrane dystrophy).
    - *Design:* Cross-sectional study of consecutive cornea clinic attendees.
    - *Primary outcome:* Prevalence of RCE; multivariable odds ratios for risk factors.
    - *Sample hint:* 400–800 patients (depending on expected prevalence).
    - *Notes:* Useful baseline data for referral/education programs.
2. **Association between diabetes control (HbA1c) and frequency/severity of RCE episodes**
    - *Gap:* Relationship between glycaemic control and epithelial healing in Indian diabetic population not well quantified.
    - *Design:* Case-control or prospective cohort (RCE patients stratified by HbA1c).
    - *Primary outcome:* Rate of recurrences over 6–12 months.
    - *Sample hint:* 100–200 patients.
    - *Notes:* Adds important systemic management implications.

DIAGNOSTIC / IMAGING / OBJECTIVE MEASURES

3. **Role of anterior segment OCT (AS-OCT) and in vivo confocal microscopy in detecting epithelial basement membrane dystrophy (EBMD) in Indian patients with RCE**
    - *Gap:* Diagnostic yield of imaging vs slit-lamp in suspected EBMD-related RCE.
    - *Design:* Diagnostic accuracy study (index = AS-OCT/confocal; reference = expert slit-lamp ± histopathology when available).
    - *Primary outcome:* Sensitivity/specificity for EBMD detection.
    - *Sample hint:* 100–200 eyes.
    - *Notes:* Valuable where confocal is available in tertiary centres.
4. **Tear film osmolarity / inflammatory cytokine profile in RCE patients vs controls**
    - *Gap:* Local tear biomarkers predicting recurrence are understudied in Indian cohorts.
    - *Design:* Case-control biochemical study (ELISA multiplex).
    - *Primary outcome:* Differences in selected cytokines (IL-1β, MMP-9) and association with recurrences.
    - *Sample hint:* 50–100 per group.
    - *Notes:* Requires lab collaboration; translational value.

MEDICAL MANAGEMENT TRIALS

5. **Randomized trial: topical hypertonic saline 5% ointment vs nocturnal bandage contact lens for prevention of recurrences after an acute RCE**
    - *Gap:* Comparative effectiveness data in Indian practice settings is limited.
    - *Design:* RCT, follow-up 6 months.
    - *Primary outcome:* Recurrence rate at 6 months.
    - *Sample hint:* 120–200 eyes (power to detect moderate effect).
    - *Notes:* High clinical applicability; consider cost/adherence endpoints.
6. **Efficacy of topical matrix metalloproteinase inhibitor (e.g., doxycycline oral vs topical MMP inhibitor) as adjunct to conventional therapy**
    - *Gap:* Role of MMP modulation in RCE recurrence prevention needs clinical validation.
    - *Design:* Randomized open-label trial (standard therapy ± doxycycline).
    - *Primary outcome:* Time to recurrence over 12 months.
    - *Sample hint:* 100–150 patients.
    - *Notes:* Monitor adverse effects; ensure clear inclusion criteria.

PROCEDURAL / SURGICAL INTERVENTIONS

7. **Long-term outcomes of anterior stromal puncture (ASP) vs epithelial debridement + diamond burr polishing in RCE due to EBMD**
    - *Gap:* Comparative long-term efficacy and complication profiles in Indian eyes are not well-documented.
    - *Design:* Prospective randomized or well-matched cohort study, 1–2 year follow-up.
    - *Primary outcome:* Recurrence-free survival at 12 months; secondary: pain scores and visual acuity.
    - *Sample hint:* 80–150 eyes.
    - *Notes:* Feasible in most cornea units.
8. **Efficacy and safety of phototherapeutic keratectomy (PTK) for refractory RCE in Indian patients**
    - *Gap:* Limited local data on outcomes, refractive change, and recurrence rates post-PTK.
    - *Design:* Prospective interventional case series with 1–2 year follow-up.
    - *Primary outcome:* Recurrence rate; secondary: refractive stability, corneal haze.
    - *Sample hint:* 30–80 eyes (smaller series acceptable for dissertation).
    - *Notes:* Requires access to excimer laser.

MICROBIOLOGY, WOUND HEALING & COMPLICATIONS

9. **Microbial colonization of RCE lesions and risk of infectious keratitis in Indian settings**

- *Gap:* Spectrum of organisms and risk factors for secondary infection in RCE not well characterized locally.
- *Design:* Prospective observational study with culture/PCR of lesions during acute episodes.
- *Primary outcome:* Frequency and type of pathogens; rate of progression to infectious keratitis.
- *Sample hint:* 100–200 episodes.
- *Notes:* Useful for guiding empirical antibiotic choices.

10. **Corneal nerve morphology (confocal microscopy) and its correlation with pain severity and recurrence in RCE**
    - *Gap:* Role of neural recovery in symptomatic recurrences underexplored.
    - *Design:* Prospective cohort with imaging at baseline and post-treatment.
    - *Primary outcome:* Nerve density/reflectivity vs pain scores and recurrence.
    - *Sample hint:* 40–80 patients.
    - *Notes:* Needs confocal access and pain scoring tools.

PUBLIC HEALTH / ACCESS / PATIENT-CENTERED RESEARCH

11. **Adherence to preventive therapy and barriers to follow-up in patients with RCE in urban vs rural India**
    - *Gap:* Socioeconomic and system barriers affecting recurrence prevention and outcomes are poorly described.
    - *Design:* Mixed-methods study (quantitative adherence data + qualitative interviews).
    - *Primary outcome:* Proportion adherent at 6 months; thematic analysis of barriers.
    - *Sample hint:* Quant cohort 150–300 patients; qualitative n=20–40.
    - *Notes:* High policy relevance.
12. **Development and validation of a patient-reported symptom & function questionnaire specific to RCE for Indian patients**
    - *Gap:* No disease-specific, culturally validated PRO for RCE in India.
    - *Design:* Instrument development (qualitative item generation) → psychometric validation.
    - *Primary outcome:* Validated tool with good reliability and responsiveness.
    - *Sample hint:* Development n=20–30; validation n=200+.
    - *Notes:* Useful across all interventional trials.

BIOMATERIALS & THERAPEUTICS (APPLIED RESEARCH)

13. **Comparative study of different bandage contact lens materials (silicone hydrogel vs conventional hydrogel) for pain control and epithelial healing in RCE**
    - *Gap:* Material-specific outcomes in Indian climatic conditions not well-studied.

- *Design:* Randomized crossover or parallel trial.
- *Primary outcome:* Pain reduction (VAS) and epithelial healing time.
- *Sample hint:* 60–120 patients.
- *Notes:* Consider cost-effectiveness analysis.

14. **Autologous serum eye drops vs topical lubricants for refractory RCE: a randomized trial**
    - *Gap:* Evidence for autologous serum in RCE exists but limited in Indian cohorts and resource-limited setups.
    - *Design:* RCT, follow-up 6–12 months.
    - *Primary outcome:* Recurrence rate and time to re-epithelialization.
    - *Sample hint:* 80–150 patients.
    - *Notes:* Requires facility to prepare serum drops under sterile conditions.

GENETICS / MOLECULAR

15. **Association of COL17A1 and other basement membrane genes with familial or recurrent RCE in Indian patients**
    - *Gap:* Genetic contributors to EBMD/RCE underrepresented in South Asian datasets.
    - *Design:* Case-control genetic association or targeted sequencing in familial cases.
    - *Primary outcome:* Frequency of variants associated with RCE/EBMD.
    - *Sample hint:* 50–200 cases + matched controls (dependent on design).
    - *Notes:* Collaboration with molecular genetics lab needed.

QUICK METHODOLOGICAL & ETHICAL NOTES

- **Common inclusion/exclusion:** Define acute vs recurrent (e.g., ≥2 clinically documented symptomatic episodes), prior interventions (PTK, ASP), contact lens use, systemic disease.
- **Key outcome measures:** Recurrence rate, time-to-recurrence, pain (VAS), epithelial healing time, BCVA, complications (infection, scarring), patient-reported QoL.
- **Follow-up duration:** Minimum 6 months for many interventions; 12 months preferable for robust recurrence data.
- **Sample size planning:** calculate exact sample sizes once you pick a design and expected effect size.
- **Ethics & safety:** Infection risk when sampling lesions; informed consent for autologous serum/PTK; data privacy for genetic studies.
- **Feasibility:** Many topics (e.g., ASP vs burr polishing, hypertonic saline vs BCL) are highly feasible in typical Indian tertiary cornea units. Genetic/biomarker studies need lab partners and funding.

ETHAMBUTOL OPTIC NEUROPATHY

1. **Prevalence and risk factors of ethambutol-induced optic neuropathy in a tertiary Indian TB clinic**
    - *Gap:* Reliable prevalence data and locally relevant risk profile (age, renal disease, malnutrition) are limited.
    - *Design:* Cross-sectional study of consecutive TB patients on ethambutol with baseline and screening exam.
    - *Primary outcome:* Point prevalence of EON; adjusted ORs for risk factors.
    - *Sample hint:* 500–1,000 patients (depends on expected prevalence).
    - *Feasibility:* High — can be done alongside DOTS clinics.
2. **Prospective cohort: dose-duration–cumulative dose relationship and threshold for clinically significant EON**
    - *Gap:* Uncertainty about safe cumulative dose/duration in Indian patients with variable dosing and comorbidities.
    - *Design:* Prospective observational follow-up of patients initiating ethambutol, serial testing until 6–12 months.
    - *Primary outcome:* Incidence of EON by cumulative dose categories.
    - *Sample hint:* 300–500 patients.
    - *Feasibility:* Good in tertiary centres with TB caseload.
3. **Diagnostic accuracy: phone-based colour vision and visual acuity tests vs clinic-based standards for early detection**
    - *Gap:* Access limitations to formal screening in rural/primary settings — can smartphone tools triage?
    - *Design:* Diagnostic accuracy study (index = smartphone app; reference = ophthalmologist exam + Ishihara/Farnsworth/Munsell).
    - *Primary outcome:* Sensitivity/specificity for detecting early EON.
    - *Sample hint:* 200–400 eyes.
    - *Feasibility:* Excellent; scope for telemedicine.
4. **Temporal retinal nerve fibre layer (RNFL) and ganglion cell–inner plexiform layer (GCIPL) changes on OCT as early biomarkers of EON**
    - *Gap:* Need objective structural markers that precede symptomatic vision loss.
    - *Design:* Longitudinal cohort with baseline and monthly/quarterly OCT.
    - *Primary outcome:* % eyes with statistically significant RNFL/GCIPL thinning before clinical EON.
    - *Sample hint:* 100–200 patients (repeat measures).
    - *Feasibility:* Requires OCT access; ideal in tertiary centres.
5. **Pattern of visual field defects in EON: 24-2/30-2 vs 10-2 and correlation with OCT**
    - *Gap:* Optimal field protocol for early detection is debated.
    - *Design:* Cross-sectional + short prospective follow-up correlating VF defects with structural OCT changes.
    - *Primary outcome:* Sensitivity of 10-2 vs 24-2 in early detection; structure-function correlation metrics.
    - *Sample hint:* 100–150 eyes.
    - *Feasibility:* Straightforward if perimetry is available.
6. **Electrophysiology (VEP/Pattern ERG) as an objective early detection tool and prognostic marker**
    - *Gap:* Objective tests might detect subclinical optic dysfunction; prognostic value unclear.
    - *Design:* Prospective cohort measuring baseline and follow-up VEP/pERG.

- *Primary outcome:* Proportion with abnormal tests preceding clinical EON; predictive value for recovery.
- *Sample hint:* 80–150 patients.
- *Feasibility:* Needs electrophysiology lab.

7. **Recovery patterns after ethambutol cessation: factors that predict visual recovery and time course**
   - *Gap:* Predictors of good vs poor recovery (age, baseline OCT/VF abnormalities, duration of exposure) are not well quantified locally.
   - *Design:* Prospective cohort of patients who develop EON; follow-up at 1,3,6,12 months.
   - *Primary outcome:* Proportion with ≥2-line VA improvement or VF improvement at 6 months; time-to-recovery analysis.
   - *Sample hint:* 100–200 EON cases (multi-centre helps).
   - *Feasibility:* High clinical relevance.
8. **Effect of renal impairment on ethambutol toxicity: should dose adjustments be standardized?**
   - *Gap:* Real-world outcomes with/without dose adjustment in CKD patients on ethambutol are unclear.
   - *Design:* Comparative cohort (CKD patients with adjusted dose vs non-adjusted) or case-control.
   - *Primary outcome:* Incidence/severity of EON.
   - *Sample hint:* 150–300 patients (pooled).
   - *Feasibility:* Requires collaboration with nephrology/TB clinics.
9. **Pharmacogenomic susceptibility to EON in Indian population (candidate genes or exome sequencing)**
   - *Gap:* Genetic predisposition poorly studied in South Asian cohorts.
   - *Design:* Case-control genetic association study (cases = EON; controls = ethambutol-exposed without EON).
   - *Primary outcome:* Association of variants with increased risk (ORs).
   - *Sample hint:* 100–300 cases + matched controls (depends on expected effect sizes).
   - *Feasibility:* Requires molecular lab/collaboration and funding.
10. **Ethambutol toxicity in children: incidence, presentation, monitoring challenges and outcomes**
    - *Gap:* Paediatric data limited; children may not report symptoms reliably.
    - *Design:* Prospective paediatric cohort with age-appropriate screening methods.
    - *Primary outcome:* Incidence and time-to-detection; sensitivity of paediatric screening tools.
    - *Sample hint:* 150–300 children (multi-centre desirable).
    - *Feasibility:* Important for paediatric TB programs.
11. **Implementation research: feasibility and yield of a screening protocol (baseline + monthly or bimonthly checks) in DOTS centres**
    - *Gap:* Best operational screening frequency and components for resource-limited settings are uncertain.
    - *Design:* Stepped-wedge or cluster implementation study comparing different screening algorithms.
    - *Primary outcome:* Cases detected per 1,000 patients screened; cost and manpower requirements.
    - *Sample hint:* Cluster size depends on DOTS centre throughput.
    - *Feasibility:* High policy relevance; potential for funding.
12. **Cost-effectiveness analysis: routine OCT-based screening vs symptom-driven referral for EON in India**

- *Gap:* Economic justification for advanced screening tools lacking for LMIC settings.
- *Design:* Model-based cost-effectiveness using local costing data and clinical cohort inputs.
- *Primary outcome:* Incremental cost-effectiveness ratio (ICER) per case of severe visual loss averted.
- *Sample hint:* Uses cohort inputs rather than primary enrolment.
- *Feasibility:* Requires health economics input.

13. **MRI optic nerve diffusion metrics and their role in severe/progressive EON — correlation with clinical severity and prognosis**
    - *Gap:* Neuroimaging biomarkers for severe EON not well characterized.
    - *Design:* Case series/diagnostic correlation study in severe EON cases undergoing MRI.
    - *Primary outcome:* Correlation of diffusion changes with visual outcomes.
    - *Sample hint:* 30–80 cases (MRI cost limits size).
    - *Feasibility:* Niche; tertiary centres with MRI access.
14. **Randomized pilot: neuroprotective therapy (e.g., citicoline or high-dose B vitamins) vs standard care after EON detection**
    - *Gap:* No proven adjunct therapy to improve recovery after ethambutol cessation.
    - *Design:* Small RCT assessing safety and signal of efficacy over 6 months.
    - *Primary outcome:* Mean change in VA/VF/OCT at 6 months.
    - *Sample hint:* 60–120 patients (pilot for larger trial).
    - *Feasibility:* Pilot-level feasible; needs regulatory/ethical oversight.
15. **Knowledge, attitudes and practices (KAP) among TB physicians and ophthalmologists regarding ethambutol monitoring, referral patterns and reporting**
    - *Gap:* Gaps in clinician awareness/practice may delay detection.
    - *Design:* Cross-sectional KAP survey with qualitative interviews and clinical audit.
    - *Primary outcome:* Proportion following recommended screening; barriers identified.
    - *Sample hint:* 200–400 clinicians/respondents.
    - *Feasibility:* High; useful for targeted education programs.
16. **PROMs and QOL in patients using ethambutol and with ethambutol toxicity (pre and post)**

Quick methodological notes (common to many of the above)

- **Key baseline tests:** Best-corrected visual acuity, colour vision (Ishihara + D-15 or CAD where possible), contrast sensitivity, automated perimetry (10-2 and 24-2/30-2), OCT (RNFL & GCIPL), VEP/pERG (if available), renal function tests, complete drug history.
- **Case definition:** Standardize EON definition (bi- or unilateral vision loss with colour/field/EON-compatible findings in the context of ethambutol and no alternative cause). Use objective endpoints where possible.
- **Follow-up duration:** Minimum 6 months for recovery studies; 6–12 months for incidence and prospective cohorts.
- **Ethics:** Early detection may require stopping anti-TB drug — coordinate with treating TB physician and national TB program guidelines; obtain informed consent, and ensure clear referral pathways.
- **Sample size:** compute exact sample sizes based on expected event rates/effect sizes.

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