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Safe, Effective Use of AI-Powered Instruments in Optometry Education (Philippines, 2025): A Policy/Practice Analysis Aligned with Philippine Privacy and Medical Device Software Regulation

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Abstract
Background: Artificial intelligence (AI)-powered instruments are entering optometry teaching clinics faster than local governance frameworks can keep up. In the Philippines, recent issuances such as the National Privacy Commission (NPC) Advisory 2024-04 and the draft Food and Drug Administration (FDA) circular on medical device software (MDSW) create new obligations for educators who deploy AI tools in student-facing clinical settings. However, there is little guidance on how to translate these regulatory signals into concrete procurement terms, classroom controls, and assessment frameworks. Methods: We conducted a targeted policy synthesis (1 January–26 October 2025, Asia/Manila) focused on (1) Philippine primary instruments (NPC Advisory 2024-04, draft FDA-PH MDSW circular, DTI NAISR 2.0, NEDA AI policy note); (2) professional guidance from the Royal College of Ophthalmologists and the College of Optometrists; (3) global AI governance frameworks (WHO guidance on large multimodal models, FUTURE-AI consensus); and (4) peer-reviewed Philippine evidence on diabetic retinopathy (DR) AI and tele-ophthalmology. We used site-restricted searches for government and professional domains, PubMed/Scopus database searches, two-stage screening, and a simple 0–2 quality appraisal rubric. We mapped legal and regulatory requirements (lawful basis, DPIA, post-market monitoring, change control) to operational classroom controls, procurement clauses, and key performance indicators (KPIs) for termly validation. Findings: The synthesis yielded a hierarchy of obligations with Philippine law and regulation at the apex, supplemented by professional and global frameworks. We developed an educator-led governance model comprising: (1) contract language for AI-powered instruments; (2) a KPI set covering safety, performance stability, subgroup fairness, human-in-the-loop overrides, and data governance; and (3) OSCE-style assessment stations for AI literacy and safe use. We illustrate application through a worked change-control case for an updated AI-assisted retinal imaging device. Conclusions: AI-enabled instruments can be safely integrated into optometry education when educators assert explicit control over procurement, validation, and ongoing monitoring. This framework offers a practical, regulator-aligned blueprint for Philippine optometry schools and may be adapted to other health-profession programs facing similar pressures to adopt AI tools.

Keywords: Artificial Intelligence, Medical Device Software, Optometry Education, Philippines, Post-Market Surveillance, Governance, OSCE, KPI Thresholds

1. Introduction

At the Centro Escolar University (CEU) School of Optometry, the integration of artificial intelligence (AI)–enabled instruments has moved from concept to clinic. Over the past academic terms, our teaching clinics began using AI-assisted tools in routine eye tests and in screening for ocular abnormalities. As a faculty member and clinical instructor, I have seen—at the level of the exam lane and OSCE station—how these systems can accelerate workflows, standardize image quality, and surface decision cues that would otherwise demand specialist time. When used with appropriate governance, AI does not replace clinical judgment; it sharpens it.

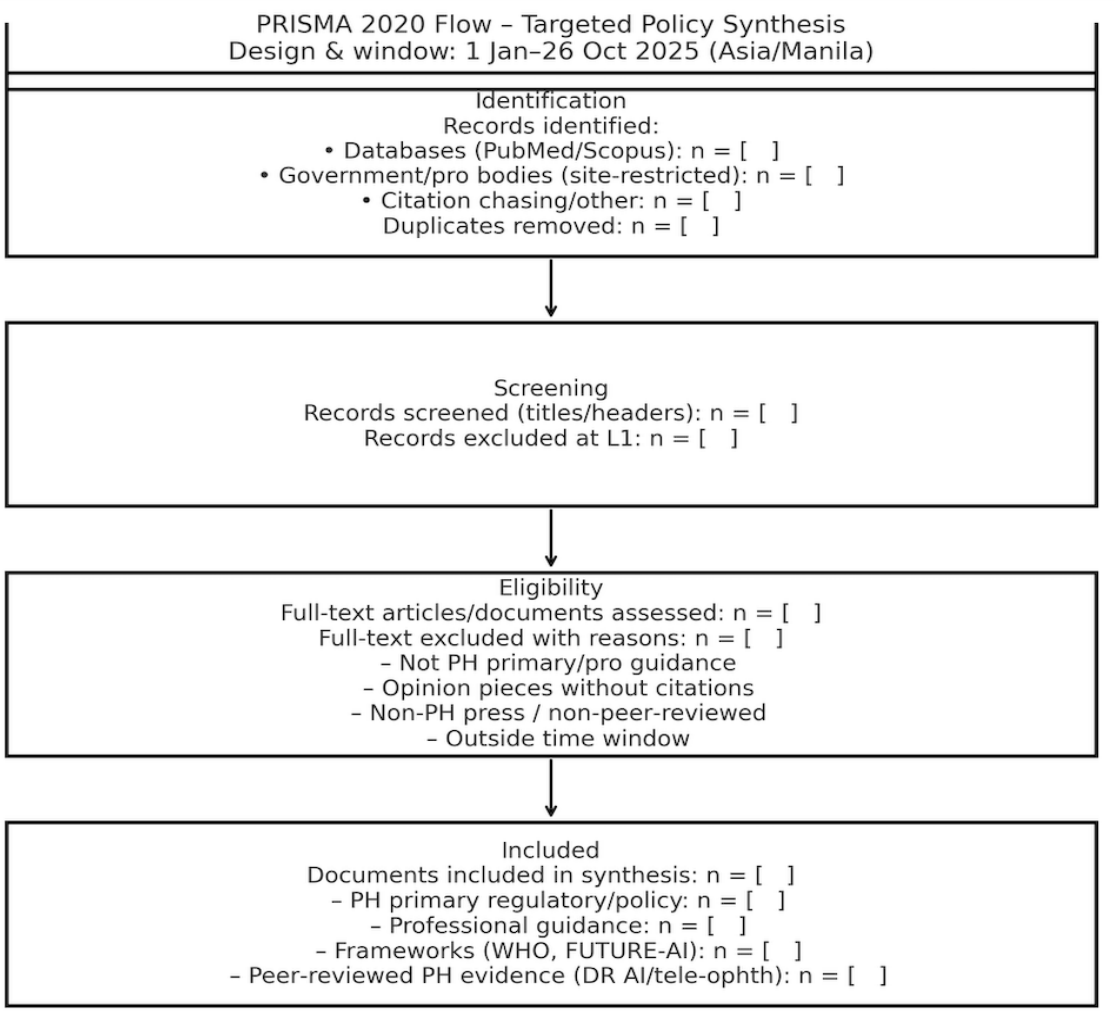
This policy-practice paper is therefore written from the vantage point of an educator responsible for patient safety, learner competency, and service efficiency. In my teaching practice, AI-generated outputs—whether an automated image-quality flag on a fundus photograph or a suggested classification on an OCT scan—have been most valuable when they produce results that are (1) accurate, (2) fast, and (3) reliable across diverse patients and devices. The promise is clear: shorter capture times, fewer repeat tests, earlier detection, and richer feedback for students. The responsibility is equally clear: we must evidence these benefits locally, monitor for drift and subgroup gaps, and retain faculty-in-control of clinical decisions.

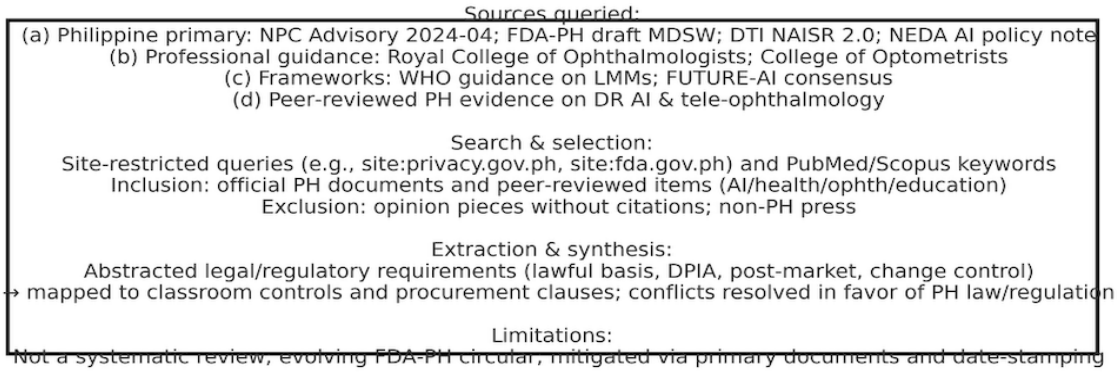
The Philippine regulatory environment is evolving quickly—anchored by the National Privacy Commission's Advisory 2024-04 on generative AI and the Food and Drug Administration–Philippines' draft circular on medical device software—while global health guidance (e.g., WHO on large multimodal models) and professional bodies provide additional guardrails. Against this backdrop, optometry schools need ***operational guidance that translates policy into classroom and clinic controls.*** What follows is a targeted policy synthesis and implementation framework tailored to CEU's teaching context but generalizable to similar programs, emphasizing lawful deployment, performance validation, equity, and change control.

Specifically, this article contributes: **(a)** a transparent, reproducible methodology prioritizing Philippine primary sources; **(b)** a comparative regulatory snapshot (PH vs regional/global anchors) to justify procurement and update requirements; **(c)** an expanded evidence base across AI-instrument classes with subgroup metrics for equity checks; and **(d)** an evaluation framework with key performance indicators (KPI), thresholds, and OSCE rubrics to embed AI-literacy behaviors into training. The goal is straightforward: to help faculty deliver patient-safe, educator-led AI adoption that measurably improves learning outcomes and clinic performance in Philippine optometry education.

2. Methodology

Design & window: Targeted policy synthesis (1 Jan–26 Oct 2025, Asia/Manila). Sources: (a) Philippine primary documents—NPC Advisory 2024-04; FDA-PH draft MDSW circular; DTI NAISR 2.0; NEDA AI policy note; (b) Professional guidance—Royal College of Ophthalmologists; College of Optometrists; (c) Frameworks—WHO guidance on large multimodal models; FUTURE-AI consensus; (d) Peer-reviewed Philippine evidence on diabetic retinopathy (DR) AI and tele-ophthalmology. Search & selection: site-restricted queries (e.g., site:privacy.gov.ph, site:fda.gov.ph) and PubMed/Scopus keywords (e.g., "diabetic retinopathy AND Philippines AND artificial intelligence"). Inclusion: official PH documents and peer-reviewed items on AI in health/ophthalmology/education. Exclusion: opinion pieces without citations, non-PH press. Extraction & synthesis: we abstracted legal/regulatory requirements (lawful basis, DPIA, post-market, change control) and mapped them to operational classroom controls and procurement clauses; conflicts were resolved in favor of Philippine law/regulation. Limitations: not a systematic review; evolving FDA-PH circular; mitigated by prioritizing primary documents and date-stamping searches.





3. Eligibility criteria

Inclusion: (a) primary Philippine legal/regulatory/government artifacts (advisory, circular/guideline, strategy note) on AI/automated decision systems, medical device software, health data, or educational/clinical use; (b) professional guidance from recognized authorities (RCOphth; College of Optometrists); (c) peer-reviewed empirical studies conducted in the Philippines (preferred) or ASEAN when PH data absent; (d) main window 1 Jan 2025–26 Oct 2025 with seminal pre-2025 documents retained if in force.

Exclusion: non-documented opinions, news/blog posts, unreferenced commentary; vendor marketing without independent evaluation; non-PH government documents unless used for explicitly labeled comparative policy benchmarking.

4. Screening & selection

Level 1 (titles/headers): one reviewer screened all hits. **Level 2 (full text):** two reviewers assessed eligibility; disagreements resolved by consensus, applying a "Philippine law/regulator primacy" rule. A selection log captured full-text exclusion reasons.

5. Data extraction

Regulatory/policy: authority, legal force (law/advisory/draft), scope, obligations (lawful basis, DPIA, consent, post-market surveillance, change control), enforcement/remedy, and currency.

Empirical studies: setting, instrument/task, dataset provenance (local vs external), reference standard, sample size, primary outcomes with CIs, subgroup performance, regulatory status, post-deployment monitoring.
Operational mapping: each requirement was mapped to classroom/clinic controls and procurement clauses (configuration logging, override audit, acceptance testing, termly validation).

Table 1: Quality appraisal rubric (0–2 scale: No/Partial/Yes; critical items ★)

Domain	Item	Critical	Score (0–2)
Regulatory/government	Authority & legal force	★	
Regulatory/government	Currency (in force; draft status disclosed)	★	
Regulatory/government	Clarity & operational specificity		
Regulatory/government	Scope alignment (health/device/education)		
Regulatory/government	Enforcement/oversight		
Professional guidance	Issuing body credentials	★	
Professional guidance	Evidence basis & citations		
Professional guidance	Applicability to PH context		
Professional guidance	Implementation detail (workflows/audit)		
Empirical studies	Risk of bias (QUADAS-2 adapted)	★	
Empirical studies	Dataset provenance & spectrum		
Empirical studies	Performance reporting (AUC/Sn/Sp with CIs)		
Empirical studies	Deployment realism (prospective/quality controls)		
Empirical studies	Post-market/monitoring (drift/incidents)		
Global frameworks	Alignment with safety/ethics pillars		
Global frameworks	Translational guidance		
Global frameworks	Consistency with PH obligations		

6. Synthesis approach

Directed content analysis: obligations/safeguards from primary sources were coded to a taxonomy (lawful basis, DPIA, consent/assent, validation, update control, post-market surveillance, logging/auditability, RBAC, pedagogy/assessment). Codes were mapped to operational controls and procurement clauses. Conflicts favored Philippine requirements; gaps bridged with WHO LMM and FUTURE-AI principles as international best-practice.

7. Limitations

This study has several limitations. First, it is a targeted policy synthesis rather than a full systematic review, and we may have missed relevant international or regional documents outside our predefined domains. Second, the KPI thresholds and governance processes, while informed by existing evidence and local operational experience,

are still partly normative and require further empirical validation. Third, the worked change-control case is drawn from a single teaching clinic context and may not fully reflect the constraints of under-resourced or differently structured institutions. Finally, Philippine regulatory instruments cited here, particularly the draft FDA-PH circular on medical device software, are subject to change; institutions adopting this framework will need to monitor regulatory updates and adjust accordingly.

8. Conclusions

AI-powered instruments are no longer optional novelties but emerging infrastructure in optometry education and practice. In the Philippine context, educators cannot outsource governance of these tools to vendors or generic institutional policies alone. By aligning with national law and regulation, professional guidance, and global frameworks, and by embedding clear KPIs, change-control processes, and OSCE-based assessment into routine operations, optometry teaching clinics can integrate AI in ways that are safe, transparent, and educationally meaningful. The framework presented here offers a practical starting point that can be adapted, stress-tested, and progressively strengthened as the regulatory and technological landscape evolves.

9. Findings: Issue Overview

Governance in teaching clinics is under-specified: classroom use requires explicit role definitions (AI assistive only; faculty accountable), AI-specific DPIA, and logging (NPC, 2024). Regulatory expectations for MDSW are evolving, creating procurement risk if tools are not regulatory-ready (FDA-PH, 2025). Philippine studies demonstrate feasibility of handheld/point-of-care imaging and tele-ophthalmology but underscore the need for local validation and performance monitoring (Salongcay et al., 2024; Arcena et al., 2024; Azarcon et al., 2021; Daza et al., 2022).

10. Policy Recommendations

10.1. Governance and Accountability

1) Faculty-in-control rule: AI outputs (quality flags, structured observation prompts) are suggestive only; supervising faculty make and communicate all clinical judgments. Document faculty sign-off in the learning record (RCOphth, 2024; College of Optometrists, 2025).
2) DPIA + transparency: Complete an AI-specific DPIA and publish a patient/learner-facing notice describing tools, data flows, oversight, and rights; apply data minimization and PETs (NPC, 2024).
3) Configuration control & logging: Maintain a configuration register (features on/off, model version, faculty) and log AI–human disagreements/overrides; export logs monthly for QA (WHO, 2025; FUTURE-AI, 2025).
4) Bias & performance monitoring: Run a mini local validation each term (image-quality pass rate, failure modes, subgroup review) and document corrective actions (FUTURE-AI, 2025).
5) Assessment integrity: For non-AI OSCEs, lock diagnostic suggestions; for AI-literacy OSCEs, evaluate safe-use behaviors (recognizing drift, appropriate override, privacy compliance).

10.2. Procurement and Regulatory Readiness

1) Evidence dossier (bid requirement): intended use (education/assistive), regulatory roadmap for FDA-PH MDSW, validation summaries with subgroup metrics, post-market plan, security/privacy whitepaper, and change-management policy.
2) Contract clauses: (a) Regulatory-ready warranty—vendor to comply with FDA-PH MDSW; (b) Model update control—advance notice, change log, deferred update and rollback, local re-verification; (c) Post-market—incident portal, 72-hour safety notice, patch SLAs; (d) Data protection—PH residency where feasible, de-identification for teaching, no secondary use without consent; (e) Audit & exit—export and verified deletion.
3) Acceptance testing: Sandbox dry-run (lockouts, logging, audit trails) and pilot with a local sample before classroom scale-up.

4) Security & privacy controls: SSO with RBAC, per-user audit trails, encryption, anonymization pipeline, retention timer (NPC, 2024).
5) Costing & sustainability: include training, DPIA, validation, log storage, and post-market support in total cost of ownership; negotiate education pricing and an exit ramp.

10.3. Comparative Regulation Snapshot: Philippines vs. Regional/Global Anchors

Purpose: to justify procurement clauses, update/change-control requirements, and post-market monitoring by benchmarking the Philippines against at least two mature jurisdictions. Where conflicts exist, institutional policy defaults to Philippine law/regulator requirements. Entries below reference primary, canonical publications (list provided after the table).

Table 2: Regulation Snapshot of Philippines vs. Singapore, Malaysia & EU

Regulatory dimension	Philippines (FDA-PH / NPC) (status: MDSW circular – draft; NPC Advisory 2024-04)	Singapore (HSA)	Malaysia (MDA)	European Union (EU MDR / GDPR)
Legal basis & scope	Medical Device Act + FDA-PH draft circular for Medical Device Software (MDSW/SaMD); privacy governed by Data Privacy Act (DPA) and NPC advisories.	Health Sciences Authority regulates SaMD under medical device regulations; PDPA governs personal data; sectoral notices for health data.	Medical Device Authority regulates SaMD under Malaysian medical device regulations; PDPA 2010 governs personal data; health data guidance via MOH/MDA circulars.	EU MDR 2017/745 classifies medical device software; GDPR governs personal data including special-category health data.
Software classification	Draft circular aligns with risk-based classification; clinical purpose determines class; accessories and standalone software covered.	Risk-based classification aligned to IMDRF; standalone software covered; intended use drives class.	Risk-based classification aligned to IMDRF; standalone software covered; intended use drives class.	MDR classification rules (esp. Rule 11) for software; many diagnostic/decision-support apps fall into higher risk classes.
Pre-market route	Conformity to essential principles; registration/notification route per risk class (details to be finalized in final circular).	Conformity assessment per risk class; documentation includes clinical/performance evidence and cybersecurity/Usability files.	Conformity assessment per risk class; technical documentation and clinical/performance evidence required.	CE marking via conformity assessment with notified bodies for higher classes; clinical evaluation and post-market plans required.
Post-market surveillance (PMS) & vigilance	PMS, incident reporting, and field safety corrective actions expected; specifics to be finalized; NPC requires breach notification under DPA.	Mandatory PMS and vigilance reporting; cybersecurity incident handling expected; PDPA data breach notification requirements apply.	Mandatory PMS and vigilance reporting; PDPA 2010 breach handling requirements; MOH guidance may specify timelines.	PMS and vigilance per MDR/IVDR; periodic safety update reports (PSUR) for certain classes; GDPR breach notification timelines apply.

Change control & model updates (AI/ML)	Draft circular anticipates change-management obligations; institutions should require vendor change logs, versioning, and re-validation; DPIA updates per NPC 2024-04.	HSA recognizes algorithm change control consistent with IMDRF; significant changes may require prior assessment; institutions should maintain update/rollback plans.	MDA follows IMDRF principles; significant software changes may trigger re-assessment; institutional acceptance testing recommended.	EU MDR + MDCG guidance: significant software changes can alter conformity; PCCP-like approaches emerging; re-assessment and documentation required; DPIA per GDPR for high-risk processing.
Real-world performance / drift monitoring	Termly (or defined interval) validation recommended; incident & override logs; data-minimization and role-based access per DPA/NPC.	Post-market performance follow-up recommended; capture quality metrics; maintain audit trails.	Post-market performance follow-up recommended; maintain audit trails and incident logs.	Post-market clinical follow-up (as applicable); PSUR; field performance metrics; logging and auditability emphasized.
Data protection & cross-border transfer	DPA lawful basis + DPIA for high-risk processing; cross-border transfer subject to adequate safeguards and contracts; student data treated as sensitive.	PDPA lawful purpose/consent exceptions; cross-border transfer allowed with comparable protection measures/contractual clauses.	PDPA 2010 governs processing; cross-border transfer principles apply; contractual safeguards required.	GDPR legal bases; special-category data rules; cross-border transfers require adequacy/appropriate safeguards (SCCs etc.).
Education/teaching-clinic use	Explicitly align deployments with DPA/NPC; designate faculty-in-control; restrict automated decisions; privacy notices to students/patients.	Institutional governance expected; align with PDPA and HSA guidance; document educational use and supervision.	Institutional governance expected; align with PDPA 2010 and MDA guidance; document supervision and scope.	Institutional governance expected; GDPR transparency; ensure MDR compliance for clinical use even in training settings.

** **Notes:** The Philippines MDSW circular is currently a DRAFT; final text will supersede placeholders here. Singapore HSA and Malaysia MDA align closely with IMDRF SaMD principles. EU MDR Rule 11 commonly elevates the class of diagnostic/decision-support software. Institutions should default to the most stringent applicable requirement when procuring multi-site or cross-border systems.*

10.4. Evaluation Framework: KPIs, Thresholds, and OSCE Rubrics

This framework specifies institution-level key performance indicators (KPIs) with explicit thresholds, monitoring cadence, and ownership; and a competency-based OSCE rubric to evaluate AI-literacy behaviors in teaching clinics. KPIs align with the Methodology's operational mapping (validation, update control, post-market surveillance, privacy compliance, equity).

Table 3: KPI Catalog (institutional monitoring)

Domain	Metric (definition)	Target / Threshold	Frequency	Owner	Data source / collection	Trigger & corrective action
Safety & quality	Image-quality pass rate (% encounters passing automated/standard QC on first attempt)	≥ 90% pass; alert if < 85% for 2 consecutive weeks	Weekly dashboard; termly review	Clinic Lead; Imaging Supervisor	Device logs; QC exports; random audit 5% cases	Targeted re-training for operators; adjust capture protocols; vendor ticket if systemic
Safety & quality	Override rate (% AI outputs overruled by clinician with documented rationale)	2–10% expected; alert if <1% (over-reliance) or >15% (poor model fit)	Weekly; termly trend	Service Head; QA Committee	EHR decision log; AI middleware audit logs	Case review; threshold tuning; local re-validation
Safety & quality	Incident rate (AI-related near misses/adverse events per 1,000 encounters)	< 1 / 1,000; zero high-severity without immediate containment	Immediate notification; monthly roll-up	Risk Manager; DPO (for privacy incidents)	Incident system; root-cause analysis forms	CAPA within 14 days; report to regulator if required
Performance validation	Local AUC/Sn/Sp (or MAE for biometry) vs. baseline	Within 2 pp (AUC/Sn/Sp) of baseline; MAE ≤ baseline + 0.05 D	Termly (or post-update)	Model Steward; Faculty-in-control	Validation set; stratified by device/vendor/site	If breached: freeze updates; rollback; re-tune/collect local data
Equity & generalizability	Subgroup gap (max Δ vs. overall)	Gap < 10 pp (Sn/Sp/AUC) or < 0.10 D (MAE)	Termly; post-update	Equity Lead; QA Committee	Subgroup table; confidence intervals	Mitigate: data enrichment; threshold per subgroup; vendor escalation
Privacy & compliance	DPIA currency and control execution (%)	100% of required controls executed; DPIA updated per major change	Quarterly; on change	Data Protection Officer (DPO)	DPIA register; change-control log	Block deployment until DPIA updated; retrain staff
Change control	Update acknowledgement latency (days from vendor release to institution sign-off or deferral)	≤ 7 days for security patches; ≤ 30 days for functional updates	Per release	IT/Clinical Engineering; Model Steward	Vendor change log; ticketing system	Escalate to Steering Committee; risk acceptance record

Operations & training	OSCE pass rate on AI-literacy stations (%)	≥ 85% overall; no critical fail on any station	Per OSCE cycle	Course Director; Clinical Preceptors	OSCE sheets; inter-rater reliability (κ)	Remediation plan for candidates; calibrate raters if κ < 0.7

Threshold logic: *KPI breaches trigger documented corrective actions (CAPA). Equity and performance breaches require immediate local re-validation; privacy/compliance breaches halt deployment until resolved. All termly validations are archived with version hashes of models/configs.*

Table 4: OSCE Rubrics for AI-literacy Behaviors

Scoring scale: 1–5 (1 = Unsafe/Absent, 3 = Competent, 5 = Exemplary). Candidates must score ≥3 on all critical items (★) and ≥85% aggregate. Stations simulate real clinic workflows with AI-assisted instruments. Inter-rater reliability target κ ≥ 0.7.

Station 1 — Image Quality Triage & Capture (critical: QC; privacy)

Behavior	1–2 (Below safe)	3–4 (Competent)	5 (Exemplary)
Applies QC protocol ★	Skips QC; proceeds with poor signal/noise	Runs QC; repeats capture until pass; documents failures	Anticipates artifacts; coaches patient/operator to optimize first-pass success
Handles privacy/consent ★	No consent or generic statements	Explains AI-assist; obtains consent/assent; anonymizes per SOP	Tailors consent to scenario; verifies minimal data capture; logs any deviations
Logs capture context	No logs	Enters device, camera type, field protocol	Adds vendor/firmware; flags atypical conditions for validation

Station 2 — AI Output Appraisal & Override (critical: clinical reasoning; override rationale)

Behavior	1–2 (Below safe)	3–4 (Competent)	5 (Exemplary)
Interprets AI output ★	Accepts output at face value	Cross-checks with clinical signs; considers pretest probability	Explains limitations/calibration; integrates uncertainty and context
Override decision ★	Overrides without rationale or never overrides	Overrides when discordant; documents structured rationale	Anticipates failure modes; proposes follow-up testing
Communicates to patient	Jargon; no shared decision	Plain-language explanation; shares next steps	Uses teach-back; provides written after-care notes

Station 3 — Change Control & Validation Review (critical: update risk; documentation)

Behavior	1–2 (Below safe)	3–4 (Competent)	5 (Exemplary)
Reads vendor change log ★	Ignores/skim read; misses significant change	Identifies change scope; checks for required re-validation	Maps change to local risk profile; proposes rollback plan
Validates post-update ★	Uses old validation; no stratification	Runs termly/local validation; reviews subgroup table	Expands validation to new edge cases; coordinates cross-site comparison
Records decisions	No record	Signs off or defers with justification	Links decision to KPI dashboard; schedules follow-up audit

Station 4 — Incident Reporting & CAPA (critical: safety; timeliness)

Behavior	1–2 (Below safe)	3–4 (Competent)	5 (Exemplary)

Identifies incident severity ★	Misclassifies; delays containment	Classifies severity; contains; informs lead	Preempts escalation; initiates interim safeguards
Completes report ★	Incomplete/inaccurate	Complete with timestamps and context	Includes preliminary root-cause; proposes CAPA
Implements CAPA	No follow-through	Executes assigned CAPA within SLA	Verifies effectiveness; updates SOPs/training

Station 5 — Privacy, DPIA & Data Governance (critical: DPA/NPC compliance)

Behavior	1–2 (Below safe)	3–4 (Competent)	5 (Exemplary)
Identifies lawful basis ★	Incorrect/none	Correctly identifies basis; links to notice/consent	Addresses special cases (minors/teaching); ensures minimal data
Executes DPIA controls ★	Misses required controls	Checks controls executed; logs residual risk	Proposes control enhancements; aligns with update/change
Manages cross-border transfer	Unprotected transfer	Uses approved clauses; documents purpose	Adds encryption at rest/in transit; verifies vendor adequacy

Passing criteria: *aggregate ≥ 85% AND no critical (★) item below 3 on any station. Rater calibration: conduct a 10-case calibration; compute κ; if κ < 0.7, retrain and re-assess before summative OSCE. Archive OSCE sheets and link to the KPI dashboard.*

Abbreviations

1. AI – Artificial Intelligence
2. DPIA – (Data) Privacy Impact Assessment
3. DTI – Department of Trade and Industry
4. FDA-PH – Food and Drug Administration Philippines
5. FUTURE-AI – International consensus guideline for trustworthy medical AI
6. LMM – Large Multimodal Model
7. MDSW – Medical Device Software
8. NEDA – National Economic and Development Authority
9. NPC – National Privacy Commission
10. OSCE – Objective Structured Clinical Examination
11. PETs – Privacy-Enhancing Technologies
12. REACH-DR – Remote Retinal Evaluation Collaboration in Health – Diabetic Retinopathy
13. WHO – World Health Organization.

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Conflicts of Interest: The author declares no competing interests.

Ethics: This synthesis used publicly available documents and published studies and did not involve individual-level data collection. Institutional research ethics approval was therefore not required. For the worked change-control example, all operational details were de-identified and presented as an illustrative case.

Declaration of Generative AI and AI-assisted Technologies: This study has not used any generative AI tools or technologies in the preparation of this manuscript.

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Annex A – Methods and PRISMA-Style Flow (Targeted Policy Synthesis)

A1. Search strategy

- **Government/Regulatory documents**
  - Site-restricted searches: site:privacy.gov.ph "artificial intelligence", site:fda.gov.ph "medical device software", site:dti.gov.ph "AI Strategy", site:depdev.gov.ph "artificial intelligence".
  - Filters: 2021–2025; preference for official advisories, circulars, strategy notes.
- **Professional and global frameworks**
  - Targeted search for "Royal College Ophthalmologists AI statement", "College of Optometrists AI interim position", "WHO large multimodal models guidance", "FUTURE-AI guideline".
- **Empirical evidence**
  - Databases: PubMed, Scopus.
  - Keywords: "diabetic retinopathy AND Philippines AND artificial intelligence"; "tele-ophthalmology AND Philippines"; "telemedicine ophthalmology Philippines".
  - Filters: articles in English; priority to 2021–2025; earlier seminal studies retained where relevant.

A2. PRISMA-style flow (narrative)

1. **Identification**
   - Government/Regulatory: ~30 documents initially identified from NPC, FDA-PH, DTI, NEDA and related domains.
   - Professional/Frameworks: ~10 items (statements, guidance documents, consensus guidelines).
   - Empirical studies: ~25 records retrieved from database searches and reference lists.
2. **Screening (titles/headers and abstracts)**
   - Excluded: press releases, news items without substantive policy content, vendor marketing material, global documents with no clear relevance to PH context, and duplicates.
   - Retained: documents with explicit regulatory or policy relevance and empirical studies on DR screening, tele-ophthalmology, or telemedicine in the Philippine setting.
3. **Eligibility (full-text review)**
   - Applied inclusion criteria:
     - Philippine legal/regulatory artifacts on AI, MDSW, data privacy, or educational/clinical use.
     - Recognized professional guidance and global frameworks.
     - Peer-reviewed empirical studies with clearly reported methods and outcomes.
   - Excluded at this stage: commentaries without citations, opinion pieces, and non-PH government documents unless used purely for comparative benchmarking.
4. **Included in synthesis**
   - Core corpus:
     - NPC Advisory 2024-04, FDA-PH MDSW draft circular, DTI NAISR 2.0, NEDA AI policy note.
     - WHO LMM guidance, FUTURE-AI consensus, RCOphth and College of Optometrists statements.
     - Key PH empirical studies (Salongcay et al., Arcena et al., Azarcon et al., Vega et al., Daza et al.) and related evidence.

(Institutions may convert this narrative into a full PRISMA 2020 diagram if needed.)

A3. Quality appraisal

A **0–2 mixed-source appraisal rubric** was used:

- **Regulatory/government sources:** authority & legal force (★), currency, scope alignment, clarity, enforcement/oversight.
- **Professional guidance:** issuing body credentials (★), evidence basis, PH applicability, implementation detail.
- **Empirical studies:** adapted QUADAS-2 items (risk of bias ★), dataset provenance, performance reporting (AUC/Sn/Sp with CIs), deployment realism, post-market monitoring.

- **Global frameworks:** alignment with safety/ethics pillars, translational guidance, consistency with PH obligations.

Annex B – Evidence Table (Philippine AI and Tele-Ophthalmology)

Table B1. Summary of Key Empirical Studies

(Textual summary; you can convert to a formal table in Word.)

1. **Salongcay et al. (2024)** – *Ophthalmology Science*
    - **Setting:** Community diabetic eye screening program in the Philippines using handheld retinal cameras with integrated AI grading.
    - **Instrument/Task:** Automated grading for referable diabetic retinopathy.
    - **Key outcomes:** Good accuracy (AUC, sensitivity, specificity) for referable DR; demonstrated feasibility of handheld + AI in community settings.
    - **Governance implications:**
        - Need for **local validation** across clinics and populations.
        - Importance of monitoring image-quality pipelines and operator performance.
2. **Arcena et al. (2024)** – *Philippine Journal of Ophthalmology*
    - **Setting:** Community-based screening program.
    - **Instrument/Task:** Automated machine learning model using handheld retinal images.
    - **Key outcomes:** Demonstrated that models trained with local data can achieve clinically useful performance.
    - **Governance implications:**
        - Highlights benefits of **local dataset development**.
        - Reinforces the need for **subgroup performance checks** and update governance.
3. **Azarcon et al. (2021)** – *Clinical Ophthalmology*
    - **Setting:** National survey on tele-ophthalmology practices and attitudes during the COVID-19 pandemic.
    - **Instrument/Task:** Tele-ophthalmology workflows (not necessarily AI powered).
    - **Key outcomes:** Identified enabling factors (convenience, reach) and barriers (infrastructure, regulation, data governance).
    - **Governance implications:**
        - Underlines the importance of **infrastructure, workflow design, and data governance** in remote eye care.
4. **Vega et al. (2021)** – *Philippine Journal of Ophthalmology*
    - **Setting:** Tertiary hospital telemedicine use.
    - **Task:** Knowledge, attitudes, practices of telemedicine in ophthalmology.
    - **Key outcomes:** Mixed familiarity and comfort with telemedicine tools; identified training and policy gaps.
    - **Governance implications:**
        - Signals the need for **structured training** and supportive policy for digital tools.
5. **Daza et al. (2022)** – *Journal of Medicine, UST*
    - **Setting:** Community type 2 diabetic population.
    - **Task:** Telemedicine-based screening for diabetic retinopathy.
    - **Key outcomes:** Telemedicine can effectively screen DR prevalence in Filipino communities.
    - **Governance implications:**
        - Reinforces the case for **remote imaging with robust workflows and follow-up pathways**.

These studies collectively justify the **AI and tele-ophthalmology trajectory** in the Philippines while highlighting the need for:

- Local validation of AI performance.
- Ongoing monitoring for drift and bias.
- Strong data governance and workflow design.

Annex C – KPI Justification Note

This annex explains **why** each KPI in the main text is chosen and how it maps to regulatory and educational requirements.

1. **Image-quality pass rate**
    - **Why:** Poor image quality undermines all downstream AI grading and clinical interpretation.
    - **Regulatory link:** Supports duty to ensure safe, effective device use and aligns with post-market performance monitoring expectations.
    - **Educational link:** Reinforces student skills in acquisition and QC.
2. **Override rate (2–10% expected)**
    - **Why:** A very low override rate suggests **over-trust of AI**, while a very high rate suggests poor model fit or misuse.
    - **Regulatory link:** Aligns with principles that humans remain accountable and that automated decision-making must be contestable.
    - **Educational link:** Encourages students to critically appraise AI outputs and practice structured override documentation.
3. **AI-related incident rate**
    - **Why:** Captures safety signals that might not be visible through performance metrics alone.
    - **Regulatory link:** Supports incident reporting and post-market surveillance duties under FDA-PH MDSW and NPC's breach reporting.
    - **Educational link:** Promotes a safety and reporting culture among trainees.
4. **Local performance vs baseline**
    - **Why:** AI tools rarely perform identically across settings and populations; local validation is critical.
    - **Regulatory link:** Required for medical device software performance claims and change control.
    - **Educational link:** Helps students understand external vs local evidence and the need for context-specific validation.
5. **Subgroup performance gaps**
    - **Why:** Undetected disparities can harm vulnerable groups and undermine trust.
    - **Regulatory link:** Supports equity and non-discrimination principles in AI use.
    - **Educational link:** Exposes students to the realities of bias and fairness in AI.
6. **DPIA control execution**
    - **Why:** DPIAs must be living documents; controls must actually be implemented and checked.
    - **Regulatory link:** Direct expectation under NPC guidance for high-risk AI processing.
    - **Educational link:** Introduces students to **data protection by design and by default**.
7. **Update acknowledgement latency**
    - **Why:** Institutions must respond quickly to security patches and carefully to functional updates.
    - **Regulatory link:** Consistent with post-market obligations and security expectations.
    - **Educational link:** Illustrates how software lifecycle management affects clinical practice.
8. **OSCE AI-literacy pass rate**
    - **Why:** Competency must be assessed, not assumed; student behavior is a critical risk control.
    - **Regulatory link:** Indirect but important—competent users reduce the likelihood of misuse and incidents.
    - **Educational link:** Directly tied to program outcomes and graduate readiness.

Annex D – Sample Procurement and Contract Clauses

Institutions can adapt the following **model clauses** when procuring AI-powered instruments for teaching clinics.

D1. Evidence dossier requirement

Vendors must submit an **evidence dossier** including:

- Intended use and clinical/educational context.
- Regulatory status and roadmap (including compliance plan for **FDA-PH MDSW**).
- Validation summaries including AUC/Sn/Sp, confidence intervals, and subgroup performance where available.
- Post-market surveillance plan and incident reporting process.

- Data protection, security, and privacy whitepaper (encryption, access control, logging, retention).
- Change-management policy including versioning for AI models and software.

D2. Regulatory-ready warranty

Vendor warrants that:

- The instrument and associated software are on a credible pathway to comply with **FDA-PH** requirements for MDSW.
- The vendor will cooperate with the institution to provide documentation needed for regulatory submissions or audits.

D3. Model update and change-control clause

- Vendor shall provide **advance written notice** for any update that materially affects AI performance, intended use, or data handling.
- Each update must be accompanied by a **change log** and performance summary.
- Institution has the right to **defer or roll back** updates pending local validation.
- Significant changes may require **new DPIA** and renewed faculty training.

D4. Post-market monitoring and incident reporting

- Vendor maintains a **portal or channel** for incident reporting, with a maximum **72-hour** acknowledgement for safety-related reports.
- Vendor commits to timely security and safety patches, with defined SLAs.
- Vendor will provide aggregated field performance data where feasible.

D5. Data protection and cross-border transfer

- Student and patient data remain under the control of the institution; any transfer or processing outside the Philippines requires:
    - Contractual safeguards (e.g., data processing agreements).
    - Documentation of adequate protection in the receiving jurisdiction.
- Vendor is prohibited from using data for purposes beyond the contract (e.g., model training) without explicit, documented consent and institutional approval.

D6. Audit, exit, and data deletion

- Institution may commission audits of logs, security controls, and performance claims within reasonable limits.
- Upon termination, vendor must support **export of all relevant data and configurations** in a usable format and provide **verified deletion** of stored copies.

Annex E – OSCE Framework for AI-Literacy Behaviors

This annex consolidates the OSCE framework described in the main text.

E1. General principles

- **Stations:** Five stations, each 8–10 minutes, simulating realistic teaching clinic scenarios.
- **Scoring:** 1–5 per behavior (1 = unsafe/absent; 3 = competent; 5 = exemplary).
- **Critical items (★):** Must score ≥ 3 on all critical items.
- **Pass criteria:** Aggregate score ≥ 85% and no critical item < 3 on any station.
- **Rater calibration:** Target $\kappa \geq 0.7$ using a 10-case calibration set; recalibrate if $\kappa < 0.7$.

E2. Station summaries

1. **Station 1 – Image Quality Triage & Capture**
    - Critical focus: **QC protocol (★)** and **privacy/consent (★)**.
    - Student must:
        - Apply QC steps, repeat capture when needed, and document failures.
        - Explain AI assistance to the patient, obtain consent/assent, and ensure anonymization.
        - Log capture context (device, field, unusual conditions).
2. **Station 2 – AI Output Appraisal & Override**
    - Critical focus: **clinical interpretation (★)** and **override decision (★)**.
    - Student must:
        - Interpret AI outputs using clinical signs and pretest probability.

        - Decide when to accept or override, and document a structured rationale.
        - Explain the decision to the patient in plain language.
3. **Station 3 – Change Control & Validation Review**
    - Critical focus: **reading vendor change logs (★)** and **post-update validation (★)**.
    - Student must:
        - Identify whether a change is significant and whether re-validation is needed.
        - Plan a basic local validation (including subgroup checks) for updated models.
        - Record decisions and link them to KPI monitoring.
4. **Station 4 – Incident Reporting & CAPA**
    - Critical focus: **incident severity classification (★)** and **report completion (★)**.
    - Student must:
        - Classify incident severity, contain the risk, and inform the appropriate lead.
        - Complete an incident report with timestamps and context.
        - Propose preliminary root-cause and CAPA steps, and understand follow-through.
5. **Station 5 – Privacy, DPIA & Data Governance**
    - Critical focus: **lawful basis (★)** and **DPIA control execution (★)**.
    - Student must:
        - Identify the correct lawful basis for processing (e.g., legitimate interest, consent, public health/education).
        - Check that DPIA-mandated controls (access restrictions, anonymization, retention, cross-border safeguards) are implemented.
        - Manage or flag cross-border transfers and ensure encryption and contractual safeguards when needed.

E3. Linking OSCE results to governance

- OSCE scores contribute to the **OSCE AI-literacy KPI** (Annex C).
- Repeated weaknesses on specific items trigger:
    - **Curriculum adjustments** (e.g., more teaching on DPIA or incident reporting).
    - **Targeted remediation** for individuals or cohorts.
    - Governance committee review if weaknesses suggest systemic issues in workflows or vendor tools.