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INPLASY

Diagnostic Accuracy of Regulatory-Approved Deep-Learning Systems for Fundus-Based Detection of Diabetic Retinopathy – A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - NR.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2025 and was last updated on 31 May 2025.

INTRODUCTION

Review question / Objective To evaluate the diagnostic accuracy and performance heterogeneity of regulatory-approved AI-based systems for diabetic retinopathy detection across global clinical settings, with pooled sensitivity/specificity and meta-regression analyses.

Condition being studied Diabetic retinopathy (DR), a vision-threatening complication of diabetes mellitus and a leading global cause of preventable blindness.

METHODS

Participant or population Adults undergoing fundus-based DR screening evaluated by a regulatory-cleared AI system.

Intervention Use of autonomous deep learning/artificial intelligence systems authorized by FDA, CE, or equivalent for diabetic retinopathy screening.

Comparator Reference standard includes human grading (retina specialists), consensus protocols (ETDRS, ICDR), or enhanced imaging tools.

Study designs to be included Diagnostic accuracy studies (prospective, retrospective, real-world validations).

Eligibility criteria Inclusion: adult studies using regulatory-cleared DL systems with 2x2 data available. Exclusion: pediatric cohorts, non-DL or non-fundus imaging systems, secondary literature.

Information sources Electronic databases (PubMed, Embase), ClinicalTrials.gov, hand-searching reference lists.

Main outcome(s) Pooled sensitivity and specificity of DL systems for detecting DR (any, referable,

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vision-threatening), stratified by patient- and eye-level.

Quality assessment / Risk of bias analysis QUADAS-2 tool applied in duplicate to assess methodological risk of bias and applicability concerns.

Strategy of data synthesis Hierarchical bivariate random-effects meta-analysis; HSROC curves plotted; univariate and multivariate meta-regressions conducted to explore heterogeneity.

Subgroup analysis By DR severity, economic status, imaging protocol, grader type, vendor involvement, and image quality (gradable vs ungradable).

Sensitivity analysis Stratified by vendor involvement, publication type, and study design; impact on pooled accuracy.

Country(ies) involved Taiwan.

Keywords diabetic retinopathy; deep learning; artificial intelligence; autonomous screening; diagnostic accuracy; regulatory-approved devices; systematic review; meta-analysisdiabetic retinopathy; deep learning; AI; systematic.

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